Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Reports of the office of Inspector General.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured depository institutions or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof:

Names of persons and names and locations of depository institutions authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Note.—Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda:

Matters relating to the liquidation of a depository institution's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 47,818 (Amendment)
Silverado Banking, Savings and Loan Association, Denver, Colorado
Case No. 47,829 (Amendment)
Various Failed Depository Institutions, Nationwide

Matters relating to the possible closing of certain insured depository institutions:

Names and locations of depository institutions authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898–6757.

Dated: October 6, 1992.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 92–24733 Filed 10–7–92; 9:21 am]

BILLING CODE 6714-0-M

LEGAL SERVICES CORPORATION BOARD OF DIRECTORS COMMITTEE MEETING

Notice

TIME AND DATE: Meetings of the Legal Services Corporation Board of Directors Provision for the Delivery of Legal Services, Office of the Inspector General Oversight, and Audit and Appropriations Committees will be held on October 18, 1992. The meetings will commence at 12:00 p.m. and will be held in the following order, with each meeting continuing until all business has been concluded:

1. Provision for the Delivery of Legal Services Committee;
2. Office of the Inspector General Oversight Committee; and
3. Audit and Appropriations Committee.

PLACE: The Legal Services Corporation, 750 1st Street, NE., The Board Room, Washington, DC 20002, (202) 336–8896.

Provision for the Delivery of Legal Services Committee Meeting

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.
2. Approval of August 8, 1992 Meeting Minutes.
3. Consideration of Status Report on the Staff Analysis of Law School Clinical Programs.
4. Consideration of Status Report on Development of Options for a Loan Repayment Program for the Recruitment and Retention of Staff Attorneys of LSC-Funded Grantees.
5. Consideration of Status Report on the Alternative Dispute Resolution Project.

Office of the Inspector General Oversight Committee Meeting

STATUS OF MEETING: Open, except that a portion of the meeting may be closed if a majority of the Board of Directors votes to hold an executive session. At the closed session, pursuant to receipt of the aforementioned vote, the Committee will consider and vote on approval of the draft minutes of the executive session held on August 10, 1992. In addition, the Committee will hear and consider the report of the Inspector General on several investigations. The closing will be authorized by the relevant sections of the Government in the Sunshine Act [5 U.S.C. Sections 552b(c)(7) (C) and (D)], and the corresponding regulation of the Legal Services Corporation [45 CFR Sections 1622.5(f)(3)].[1] The closing will be certified by the Corporation's General Counsel as authorized by the above-cited provisions of law. A copy of the General Counsel's certification will be posted for public inspection at the Corporation's headquarters, located at 750 First Street, NE., Washington, DC, 20002, in its two reception areas, and will otherwise be available upon request.

MATTERS TO BE CONSIDERED:

Open Session:

1. Approval of Agenda.
2. Approval of Minutes of August 10, 1992 Meeting.
3. Consideration of Inspector General's Report on the General Activities of the Office of the Inspector General.
4. Consideration of Inspector General's Report on the Fiscal Year 1993 Budget Request for the Office of the Inspector General.

Closed Session:

5. Approval of Minutes of August 10, 1992 Executive Session.

Open Session: (Resumed)

6. Consideration of Motion to Adjourn Meeting.

Audit and Appropriations Committee Meeting

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.
2. Approval of Minutes of September 26, 1992 Meeting.
3. Consideration of Report by the Provision for the Delivery of Legal Services Committee.
4. Consideration of Status Report on the Leasing of the Corporation's Former Headquarters Office Space.
5. Consideration of Inspector General's Report on the Fiscal Year 1993 Budget Request for the Office of the Inspector General.
6. Consideration and Review of Proposed Fiscal Year 1993 Consolidated Operating Budget.

CONTACT PERSON FOR INFORMATION: Patricia Batie (202) 336–8896.

Date issued: October 7, 1992.

Patricia D. Batie,

Corporate Secretary.

[FR Doc. 92–24826 Filed 10–7–92; 3:44 pm]

BILLING CODE 7050-01 M

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[1] As to the Board's consideration and approval of the draft minutes of the executive session held on the above-noted date, the closing is authorized as noted in the **Federal Register** notice corresponding to that Board meeting.

Corrections

Federal Register
Vol. 57, No. 197
Friday, October 9, 1992

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF ENERGY

University Research Instrumentation Program 1993

Correction

In notice document 92-23740 beginning on page 45041 in the issue of Wednesday, September 30, 1992, make the following correction:

On page 45041, in the second column, in **SUPPLEMENTARY INFORMATION**, in the first paragraph, in the tenth line from the bottom, "Instruction" should read "Instrumentation".

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing-Federal Housing Commissioner

[Docket No. N-92-3411; FR-3195-N-02]

Fund Availability (NOFA) for Supportive Housing for Persons With Disabilities-Set-aside for Persons Disabled as a Result of Infection With the Human Acquired Immunodeficiency Virus

Correction

In notice document 92-23618, beginning on page 45065 in the issue of Wednesday, September 30, 1992 make the following correction:

On page 45065, in the second column, in the **DATES** section, in the second line the date should read November 16, 1992.

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 172

[Docket Nos. HM-181, HM-181A, HM-181B, HM-181C, HM-181D, HM-142A, HM-189, and HM-204; Amdt. Nos. 106-8, 107-23, 171-111, 172-123, 173-224, 174-68, 175-47, 176-30, 177-78, 178-97, 179-45, and 180-3]

RIN 2137-AA01, 2137-AB87, 2137-AB88, 2137-AA10, 2137-AB56, and 2137-AB90

Performance-Oriented Packaging Standards; Revisions and Response to Petitions for Reconsideration

Correction

In rule document 91-28240 beginning on page 66124 in the issue of Friday, December 20, 1991, on page 66254, in the third column, in § 172.313, paragraph (a) was incorrectly printed. Paragraph (a) is revised as set forth below:

§ 172.313 Poisonous hazardous materials.

(a) For materials poisonous by inhalation (see § 171.8 of this subchapter), the package shall be marked "Inhalation Hazard" in association with the required labels or placards, as appropriate, or shipping name, when required. (See § 172.302(b) of this subpart for size of markings on bulk packages.) Bulk packagings must be marked on two opposing sides.

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Departmental Offices

Privacy Act of 1974; Publication of an Existing System of Records

Correction

In notice document 92-22718 beginning on page 43485 in the issue of Monday, September 21, 1992, make the following correction:

On page 43486, in the 1st column, in the 1st full paragraph, in the 13th line after "or" insert "settlement negotiations, in response to a court-ordered subpoena, or".

BILLING CODE 1505-01-D

federal register

Friday
October 9, 1992

Part II

Consumer Product Safety Commission

16 CFR Part 1500

Labeling Requirements for Art Materials Presenting Chronic Hazards; Guidelines for Determining Chronic Toxicity of Products Subject to the FHSA; Supplementary Definition of "Toxic" Under the Federal Hazardous Substances Act; Final Rules

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1500

Labeling Requirements for Art Materials Presenting Chronic Hazards; Guidelines for Determining Chronic Toxicity of Products Subject to the FHSA; Supplementary Definition of "Toxic" Under the Federal Hazardous Substances Act

AGENCY: Consumer Product Safety Commission.

ACTION: Final rules.

SUMMARY: This document announces three actions taken by the Consumer Product Safety Commission.[1] The Commission is finalizing the codification of ASTM standard D–4236 as a Commission rule which was mandated by the Labeling of Hazardous Art Materials Act ("LHAMA").

LHAMA also directed the Commission to issue guidelines specifying criteria for determining when any customary or reasonably foreseeable use of an art material can result in a chronic hazard. The Commission is issuing final chronic hazard guidelines as directed by LHAMA. Because the substance of the guidelines directed by LHAMA applies equally to materials other than art materials, these guidelines also may be used by the manufacturers of other products subject to the FHSA to determine whether their products present a chronic hazard and, therefore, require labeling under section 2(p) of the FHSA. The guidelines are not mandatory.

Finally, the Commission is issuing a final regulatory definition of toxic that will define chronic toxicity under the Federal Hazardous Substances Act (FHSA). This definition supplements the Commission's existing regulatory definition of toxic that concerns acute toxicity. The definition will apply to all products subject to the FHSA.

DATES: The codification of ASTM D–4236 (31500.14(b)(8)) which is effective on October 9, 1992.

FOR FURTHER INFORMATION CONTACT: Charles M. Jacobson, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400.

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[1] Copies of statements issued by each of the three Commissioners are available from the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207; (301) 504–0800.

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This document is effective on January 7, 1993.

I. Introduction

A. The Proposals

On April 17, 1991, the Commission proposed (1) a codification of ASTM D–4236 standard for labeling hazardous art materials as a Commission rule under the Labeling of Hazardous Art Materials Act ("LHAMA"); (2) guidelines for determining when an art material or other product subject to the FHSA may present a chronic health hazard; and (3) a supplemental regulatory definition of "toxic" (under the FHSA) to include chronic toxicity. 56 FR 15672 and 56 FR 15705 (1991). (The proposed guidelines and definition were together in one document.) The Commission proposed that the guidelines and the supplemental definition would apply to all products subject to the Federal Hazardous Substances Act ("FHSA").

The proposal originally provided for submission of comments until July 1, 1991. In response to numerous requests for more time to respond, the Commission extended the comment period to October 1, 1991.

LHAMA required the Commission to conduct a public hearing on guidelines issued under LHAMA. 15 U.S.C. 1277(d)(1). The Commission originally scheduled a hearing for July 18, 1991. However, when the period for written comments was extended, the Commission rescheduled the public hearing for October 17, 1991. The Commission has considered all written and oral comments on the three proposed actions.

This document summarizes the most significant public comments received and explains the Commission's responses to those comments. It attempts to clarify some points in the proposed actions that engendered confusion, and in doing so it addresses the major issues raised by comments. The preamble also explains the statutory bases for the Commission's actions and makes some changes in the proposals.

B. Overview of this Document

The Commission is finalizing three actions. Each is described in greater detail in a separate section of this preamble. First, the Commission is issuing the final codification of ASTM D–4236. LHAMA made this voluntary standard for labeling hazardous art materials a mandatory Commission rule under section 3(b) of the FHSA. Congress made some changes in provisions of ASTM D–4236, such as the definition of art material. Although LHAMA did not require the Commission to codify ASTM D–4236, the Commission decided to do so for the convenience of those subject to the LHAMA. Since the codification reflects changes by Congress, contains some editorial changes to make the standard consistent with other standards in the Code of Federal Regulations, and reflects the Commission's interpretation of the standard, the Commission determined to publish the codification as a proposed rule. 56 FR 15705. Today the Commission issues the codification in final form. The substance of the codification and the Commission's interpretation of certain provisions are explained in section III. of the preamble.

The second action taken by the Commission is the finalization of guidelines for determining chronic toxicity. LHAMA required the Commission to issue guidelines for determining when customary or reasonably foreseeable use of an art material can result in a chronic hazard. 15 U.S.C. 1277(d)(1). The guidelines proposed by the Commission on April 17, 1991, explained the principles used by the Commission staff in making this determination. The proposed guidelines specified conditions under which an art material would be considered to contain a carcinogen, neurotoxin, or a developmental or reproductive toxicant. The proposed guidelines also explained certain principles to be used in evaluating the risk resulting from exposure.

Because the principles behind the proposed guidelines apply to other products subject to the FHSA as well as to art materials, the Commission proposed that the guidelines could be used by manufacturers of all products subject to the FHSA to determine if the product presents a chronic hazard. As explained more fully in section II A. of this preamble, the FHSA requires that all products subject to that act must be properly labeled if they present a chronic hazard.

The Commission continues to believe that the principles behind the guidelines are applicable to all products subject to the FHSA. Thus, manufacturers of all such products may use the final guidelines to aid in their determination of whether their products present chronic health hazards. The Commission reiterates that the guidelines are not mandatory. Producers of art materials or any other product will not be required to follow the guidelines in determining chronic toxicity. However, as explained in section V.C. of the preamble, the Commission does expect that products subject to the FHSA will be appropriately labeled according to section 2(p) of the FHSA if they present a chronic hazard. The Commission may bring enforcement actions against such misbranded products.

Finally, the Commission is issuing a final rule under section 10 of the FHSA to supplement the current regulatory definition of "toxic." The existing

regulatory definition specifies tests to determine if a substance presents an acute toxic hazard but does not specify a similar means for defining a chronic toxicant. As explained more fully in section VII A. of this preamble, the statutory definition of "toxic" is quite broad and includes chronic as well as acute toxicity. The supplemental definition will close this gap between the statutory definition and the regulatory definition. As the definition is issued under the FHSA, it will apply to all products subject to the FHSA, not just art materials. As explained in section VII.B. of the preamble, the final definition is broader and more flexible than the one proposed.

II. Applicable Statutes

The Commission's actions are taken pursuant to two statutes: LHAMA and the FHSA. It is important to understand both statutes and how they work together.

A. The Federal Hazardous Substances Act

The FHSA, enacted in 1960, requires labeling of "hazardous substances" if they are "intended, or packaged in a form suitable, for use in the household or by children." 15 U.S.C. 1261(p). A hazardous substance that does not bear the labeling specified by section 2(p)(1) of the FHSA is misbranded and its introduction or receipt in interstate commerce is a prohibited act under the FHSA, 15 U.S.C. 1263, subjecting the violator to certain penalties, 15 U.S.C. 1264.

A hazardous substance under the FHSA includes "any substance or mixture of substances which (i) is toxic * * * if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. 1261(f)(1)(A). This definition encompasses two components: that the substance be "toxic" and that its reasonably foreseeable or customary use may cause substantial personal injury or illness.

The FHSA broadly defines the term "toxic" to apply to "any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. 1261(g).

The FHSA's labeling requirement for a hazardous substance (as defined in the act) that is intended or packaged for household use or for children is essentially self-executing. The FHSA does not establish a program of pre-marketing approval of products. Nor does it require the Commission to develop lists of hazardous substances. Rather, it is the manufacturers' responsibility to determine if their products are or contain a hazardous substance and must be labeled under the FHSA. Section 3(a)(1) of the FHSA does provide for the Commission to declare a particular substance to be a "hazardous substance" under the act in order to avoid or resolve uncertainty 15 U.S.C. 1262. But the Commission is not required to designate a substance as hazardous before enforcing the labeling requirements of section 2(p).

The Commission's regulations specify tests that can be used to determine whether a product presents a hazard of acute toxicity. 16 CFR 1500.3(c)(2). The existing regulations do not contain criteria to determine if a product presents a risk of chronic toxicity.

B. The Labeling of Hazardous Art Materials Act

The Labeling of Hazardous Art Materials Act (LHAMA), enacted November 18, 1988, amended the FHSA. 15 U.S.C. 1277. It provided that, as of November 18, 1990, the requirements for the labeling of art materials set forth in the 1988 version of ASTM D–4236 shall be deemed to be a Commission regulation issued under section 3(b) of the FHSA. Section 3(b) of the FHSA authorizes the Commission to issue labeling regulations different from or in addition to those of section 2(p)(1).

ASTM D–4236 requires producers and repackagers of art materials to submit the material's formulation to a board certified toxicologist for review. The toxicologist must determine whether the art material has the potential to produce a chronic health hazard and must recommend appropriate labeling. The requirements of ASTM D–4236 are explained in greater detail in section III. of this preamble.

LHAMA made some changes and additions to ASTM D–4236. LHAMA requires each producer or repackager of art materials to describe in writing the criteria used to determine whether the product has the potential to produce chronic adverse health effects. The producer or repackager must submit to the Commission those criteria and a list of the art materials that require chronic hazard warning labels. *Id.* sec. 1277(b)(3). Upon request of the Commission, the producer or repackager must also submit to the Commission the product formulations. *Id.* sec. 1277(b) (4).

In addition to the labeling required by ASTM D–4236, LHAMA provides that art materials that require chronic hazard labeling must include on the label the name and address of the producer or repackager, an appropriate telephone number, and a statement that the art materials are inappropriate for use by children. *Id.* sec. 1277(b)(5). LHAMA requires that 12 months after a producer or repackager has discovered significant information regarding hazards of the art material or ways to protect against the hazards, the new information must be incorporated into the chronic hazard label. *Id.* sec. 1277(b)(6).

LHAMA states that a toxicologist must "take into account opinions of various regulatory agencies and scientific bodies" in determining whether an art material has the potential to produce adverse chronic health effects. 15 U.S.C. 1277(b)(8). In a separate section, the statute requires the Commission to issue guidelines containing criteria for determining when "customary or reasonably foreseeable use of an art material can result in a chronic hazard." Congress directed the Commission to issue these guidelines within one year of enactment of LHAMA. *Id.* sec. 1277(d)(1). Due to the complexity of the scientific issues involved and the lack of a Commission quorum for a period of time, issuance of the guidelines was delayed.

III. Issues Concerning the Codification of D–4236

A. General Requirements

ASTM D–4236 requires the producer or repackager of an art material to submit the product's formulation to a toxicologist who will review the formulation to determine if the art material has the potential to produce chronic adverse health effects through customary or reasonably foreseeable use. The toxicologist will advise the producer or repackager of appropriate chronic hazard labeling and the producer or repackager must adopt suitable precautionary labeling. The labeling recommended must be in accordance with section 5 of ASTM D–4236. Such labeling includes a signal word, a list of potential chronic hazards, the name(s) of the chronically hazardous component(s), safe handling instructions, a list of sensitizing components, an identification of a source for additional health information, and, where appropriate, more detailed technical information in supplemental documents.

If the art material presents an acute hazard the labeling must also warn of it. Labeling of art materials subject to LHAMA must also conform to labeling

requirements of section 2(p) of the FHSA and regulations issued thereunder.

ASTM D–4236 states certain considerations that the reviewing toxicologist must "take into account." These include "opinions of various regulatory agencies and scientific bodies * * *on the potential for chronic adverse health effects of the various components of the formulation."

B. Statement of Conformance

ASTM D–4236 provides for a statement of conformance that informs the purchaser that the product complies to the standard. The standard specifies that the conformance statement "should appear whenever practical on the product," but it could also be placed on (1) the individual product package, (2) a display or sign at the point of purchase, (3) separate explanatory literature available on request at the point of purchase, or (4) a response to a formal request for bid or proposal.

The Commission interprets this provision of ASTM D–4236 to require that with every art material product there must be a conformance statement or, if it presents a chronic hazard, the product must have an appropriate precautionary label. Although the language of ASTM D–4236 does not clearly mandate a conformance statement for all art materials, the Commission believes that allowing use of conformance statements for some products but not others would result in confusion to purchasers. Purchasers would be in doubt whether an unmarked art material has been found not to present a chronic hazard or simply has not been reviewed at all. ASTM D–4236 expresses a preference that the conformance statement appear on the product, but the other options mentioned in the standard will also satisfy the conformance statement requirement.

C. Telephone Number

ASTM D–4236 requires that the precautionary label on an art material that has been determined to present a potential chronic health hazard must identify a source for additional health information. The ASTM D–4236 standard provides three examples of such a statement: (1) provision of a 24-hour toll free telephone number, (2) a statement to contact a physician, or (3) a statement to call the local poison control center.

The LHAMA requires, however, that "art materials that require chronic hazard labeling * * * must include on the label * * *. an appropriate telephone number." 15 U.S.C. 1277(b) (5). Thus, Congress has required that an actual telephone number appear on the label. The Commission believes that "an appropriate telephone number" is one which will enable the purchaser to obtain additional information about the product's potential chronic hazard. The number could be that of the producer or repackager or another source that could provide such information. However, the label must contain a phone number, not just a statement to contact a doctor, and it must be a United States telephone number.

D. Standard is Applicable only to Art Materials

The Commission emphasizes that the requirements of ASTM–D4236 as modified by LHAMA are applicable only to art materials. Thus, only producers and repackagers of art materials must submit product formulations to toxicologists to determine the product's chronic hazard potential and appropriate labeling. Non-art materials must be properly labeled under the FHSA if they are hazardous, but the FHSA does not impose any specific review procedure upon manufacturers of non-art materials. Rather it is the manufacturers' responsibility to determine by appropriate means whether their non-art material product is hazardous.

Congress provided a very broad definition of art material or art material product in LHAMA. The term is defined as "any substance marketed or represented by the producer or repackager as suitable for use in any phase of the creation of any work of visual or graphic art of any medium," excluding products subject to the Federal Insecticide, Fungicide, and Rodenticide Act or to the Federal Food, Drug, and Cosmetics Act. Although the Commission believes that the determination of what is or is not an art material must be made on a case by case basis, there are some general principles that the Commission believes will be helpful in enforcing the requirements for art materials.

The broad statutory definition could be interpreted to include many items not traditionally considered art materials, such as the many kinds of tools and implements used in the process of creating a work of art. The Commission does not believe that such a broad sweeping definition was intended by Congress. Statements during floor debates on the LHAMA amendment indicate a narrower interpretation. Examples noted are solvents in cements, permanent markers, and inks; lead in paints, clay, and glazes; cadmium in silver solders. 134 Cong. Rec. S16838 (Oct. 19, 1988) (statement of Sen. Gore). Similar examples also cited were solvents in oil painting and silk screening; solders for stained glass; lead in paints and ceramics; and asbestos in talcs and clays. *Id.* at S16838 (statement of Sen. McCain).

The Commission believes that under the statutory definition of "art material" three general categories can be discerned as follows:

1. Those products which actually become a component of the work of visual or graphic art, such as paint, canvas, inks, crayons, chalk, solder, brazing rods, flux, paper, clay, stone, thread, cloth, and photographic film.

2. Those products which are closely and intimately associated with the creation of the final work of art, such as brush cleaners, solvents, ceramic kilns, brushes, silk screens, molds or mold making material, and photo developing chemicals.

3. Those tools, implements, and furniture that are used in the process of the creation of a work of art, but do not become part of the work of art. Examples are drafting tables and chairs, easels, picture frames, canvas stretchers, potter's wheels, hammers, chisels, and air pumps for air brushes.

Although products falling in the third category could come within a broad interpretation of the term "art material," the Commission does not believe that Congress intended such a sweeping interpretation. Therefore, as a matter of enforcement policy, the Commission will not require that products falling in this third category comply with the standard for art materials. This means that the Commission will not require that formulations for such products be reviewed by a toxicologist. Manufacturers of such products would not be required by the Commission to submit their review criteria or lists of products requiring chronic hazard labels to CPSC. Nor do they have to provide a conformance statement for their products. However, the FHSA requires that all household or children's products (whether art materials or not) must be appropriately labeled if they are or contain a hazardous substance. 15 U.S.C. 1261(p). Thus, even a product that falls in the third category above must be appropriately labeled if it is toxic (acutely or chronically) and may cause serious injury or illness through reasonably foreseeable use.

This discussion is intended to provide some guidance on how the Commission interprets the statutory definition. Examples given are intended to illustrate the categories the Commission envisions. In making the determination of whether a product is an art material,

the Commission would consider the intended and anticipated uses of the product as indicated by, for example, its packaging and promotion. Firms that are uncertain whether their materials fall within the scope of this enforcement policy may request guidance from the Commission staff by addressing their inquiries to the compliance staff of the headquarters or the regional offices.

LHAMA made ASTM D–4236 a Commission regulation issued under section 3(b) of the FHSA. Section 3(b) authorizes the 'Commission to issue additional labeling requirements for "hazardous substance(s) intended, or packaged in a form suitable, for use in the household or by children." 15 U.S.C. 1262(b). When Congress enacted LHAMA it did not expand the Commission's authority under section 3(b) of the FHSA. Thus, there is a very narrow category of art material products, those that have no significant marketing except to schools for adults or to businesses for the use of adults away from the household, that are not subject to the FHSA. The Commission anticipates that very few products would fall within this category. The Commission's regulations at 16 CFR 1500.3(c)(10)(i) provide guidance on what types of products are considered to be intended, or packaged in a form suitable for use in the household. That regulation states in part: "the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling."

E. Board-Certified Toxicologist

ASTM D–4236 requires that art material formulations be reviewed by a toxicologist. It defines the term "toxicologist" as "any individual who through education, training, and experience has expertise in the field of toxicology, as it relates to human exposure, and is either a toxicologist or a physician certified by a nationally recognized certification board."

LHAMA did not alter this requirement of review or the definition of toxicologist. Several commenters expressed concern that allowing only board-certified toxicologists and physicians is too limited and that many toxicologists who are not certified would also be capable of making the determinations required under ASTM D–4236. However, this requirement of board certification is part of the standard made mandatory by LHAMA. LHAMA provides for the Commission to amend the standard if it follows certain procedures. The Commission cannot abolish the requirement of board certification without following these procedures. However, in enforcing LHAMA the Commission is primarily concerned that the person reviewing formulations has sufficient knowledge based on a combination of education, training, and experience and that the reviewer uses appropriate criteria to recommend complete and accurate labeling. Any enforcement action would be based on the failure to conduct an adequate product review resulting in noncomplying cautionary labeling, rather than on the fact that a toxicologist is not certified. As a matter of enforcement policy, the Commission will not require that all art material reviews be done by a board-certified toxicologist. When the Commission considers rulemaking to amend the codified ASTM standard, it will consider deleting the requirement of board certification.

F. Amendment of ASTM D–4236

Congress provided that the Commission can revise the standard LHAMA mandated if the Commission determines that the standard is "inadequate for the protection of the public interest" and that the Commission's amendment will adequately protect the public interest. The amendment must be issued in accordance with the procedures of section 553 of the Administrative Procedure Act allowing an opportunity for notice and comment. In addition, the Commission must allow interested persons an opportunity to present oral comments.

If ASTM proposes a revision to D–4236, LHAMA provides that the Commission shall incorporate it if the Commission determines that the revision is in the public interest. The Commission must provide for notice and comment concerning the revision. 15 U.S.C. 1277(c).

G. Annexes and Appendix

ASTM D–4236 contained two annexes and one appendix. One of the annexes provides chronic hazard statements. Section 5.2 of ASTM D–4236 (§ 1500.14(b)(8)(i)(E)(*2*) in the codification) states that potentially chronic hazards must be stated "substantially in accordance with statements" in the first annex. The second annex provides precautionary statements. Section 5.4 (§ 1500.14(b)(8)(i)(E)(*4*) in the codification) states that "appropriate precautionary statements as to work practices, personal protection, and ventilation requirements shall be used substantially conforming to those" in the second annex. These annexes are §§ 1500.14(b)(8)(i) (F) and (G) in the codification below.

The Commission considers the chronic hazard statements and the precautionary statements to be examples of appropriate statements when a product presents a chronic hazard. The Commission considers these lists to be suggestive, and does not consider these to be the only statements of hazard or precaution that could be used.

Because products other than art materials that are subject to the FHSA may present similar chronic hazards, manufacturers of non-art materials may find these lists of chronic hazard statements and precautionary statements helpful in labeling their products under section 2(p) of the FHSA. All products subject to the FHSA must be appropriately labeled for any acute hazards they present.

In addition, the staff is in the process of updating its 1979 labeling guide for products that present an acute hazard. The updated version would include recommendations on designing warning labels and examples of warning statements for products that pose a chronic hazard. This labeling guide would be appropriate for all products subject to the FHSA.

ASTM D–4236 also contained an appendix which provided guidelines for organizations that certify an art material conforms to the requirements of ASTM D–4236. In the proposed codification published on April 17, this appendix was erroneously listed as § 1500.14(b)(8)(i)(H) of the codified standard rather than as an appendix. The final codification corrects this and clarifies that these guidelines are not mandatory.

IV. Issues Concerning the Chronic Hazard Guidelines

A. Broad Scope

LHAMA requires the Commission to issue guidelines for determining when an art material presents a chronic hazard. When the Commission published proposed guidelines, it stated that the guidelines could be used for non-art materials as well because the basic principles behind the guidelines would apply broadly to all products subject to the FHSA. Although the Commission received several comments concerning the scope of the guidelines, the Commission is maintaining the broad scope of the proposed guidelines.

Essential to understanding this view is the fact that the guidelines are not mandatory. The Commission's purpose in issuing these guidelines is not to

create a static classification system that must be followed by manufacturers. Rather, the FHSA makes it the manufacturers' responsibility to properly label their products. The guidelines are intended to help the manufacturer in making that determination. The process set out in the guidelines would not be affected by the classification of a product as an art material or other product subject to the FHSA. The scientific principles upon which the guidelines are based are the same. It makes sense then, that the guidance available for art materials would also be useful for non-art materials. (The codification of ASTM D-4236, however, applies only to art materials. Thus, only manufacturers and repackagers of art materials must submit their products' formulation to a toxicologist and must supply the Commission with their criteria for determining chronic toxicity and a list of art materials that require chronic hazard labeling.)

The Commission has authority to issue these guidelines under the FHSA as part of its ability to regulate hazardous substances under that statute. As discussed in section VII.A. of the preamble, the FHSA provides the Commission with clear authority over household and children's products that present a chronic hazard. Section 2(p) of the FHSA requires appropriate labeling of hazardous substances, chronic as well as acute. It is within the Commission's general authority under the FHSA to provide guidance to manufacturers on determining whether a product presents such a hazard and therefore must be labeled. By issuing the guidelines the Commission is not imposing new requirements beyond those already made by section 2(p) of the FHSA.

B. Complexity of Determination

The Commission recognizes that determining if a product presents a chronic hazard is highly complex and often relies upon incomplete or non-conclusive data. The determination requires the exercise of professional judgment.

Under the FHSA, for a substance to be a "hazardous substance" (and thus require labeling) it must have the potential both to be toxic *and* to "cause substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." The fact that a product contains a toxic substance does not make the product a "hazardous substance" under the FHSA. The second component of the definition must be considered. For instance, the manufacturer must account for the amount of the substance in the product, for the bioavailability of the substance, and for exposure to the substance. This second aspect of the definition makes the determination of the need for labeling a complex decision.

C. Customary or Reasonably Foreseeable Handling or Use

Some comments expressed concern that the Commission had not provided sufficient guidance on the meaning of the phrase "customary or reasonably foreseeable handling or use" that is part of the definition of "hazardous substance" in the FHSA. The precise meaning of the phrase will, of course, depend on the product at issue. However, the Commission's regulations at 16 CFR 1500.3(c)(7)(iv) provide some general guidance and state:

> Reasonably foreseeable handling or use includes the reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by all others in a household, especially children.

Thus, in general, the Commission has taken a fairly broad view of what is reasonably foreseeable handling or use.

As far as the guidelines are concerned, defining a reasonable use scenario can be the most uncertain part of exposure assessment. As the guidelines indicate, there are many variables to consider. Exposure assessment is a mixture of science, knowledge of the product under consideration, and common sense. Unfortunately, due to the large number of art materials and other household and children's products, it is impossible to specify typical scenarios for all cases. Nevertheless, scientists have conducted exposure and risk assessments for many products.

D. Guidelines Do Not Require Submission of Data

The guidelines are intended as an aid to manufacturers in making their determination of whether a product is a hazardous substance due to chronic toxicity and thus would require labeling under the FHSA. The guidelines themselves establish no mandatory requirements.

LHAMA and the modified version of ASTM D-4236 mandated by that law do place certain requirements upon the manufacturers and repackagers of art materials. Thus, only the formulations of art materials must be submitted to a toxicologist for review. For other products, as has always been the case under the FHSA, it is up to the manufacturer to determine proper labeling. The FHSA does not establish a required procedure for doing this. The guidelines do not change this arrangement, but they provide guidance for making that determination.

E. Risk Assessment for Children's Products

For the reasons explained below, the Commission has decided not to include additional safety factors for children's products in the final guidelines and definition. As with other scientific issues of this type, support exists both for applying an additional safety factor of ten for children's products and for not doing so. For example, a child might be more sensitive than an adult in the case of lead poisoning, while adults may be more sensitive than children in the case of neurotoxicity of certain pesticides.

Since, on the basis of much of the theory and data, it was very possible that children would be more susceptible to many substances, the additional factors of ten were proposed to provide an extra margin of safety for children. After reviewing the comments relating to this issue and considering how the additional protective levels would be implemented, the Commission has decided not to include these additional safety factors for children's products. A more detailed response to these comments and a discussion of the analysis followed by the Art & Craft Materials Institute ("ACMI") compared with that recommended in the guidelines is contained in the comment section of the preamble, section VIII.

As a result of analysis of the comments, several overall themes have become clear. First, CPSC's proposed methods of calculating the allowable daily intake ("ADI") for adults are similar, or result in a lower allowable risk, to those allowed by other agencies for both children and adults. Second, ACMI's conclusion that the labeling status of many art materials would be affected is not consistent with the intended use of CPSC's guidelines, since it appears that in many cases, ACMI has applied redundant safety factors in its exposure assessments which result in the overestimation of risk. Third, the ten-fold factor for children, if applied as the staff intended and without redundant safety factors, would have minimal economic impact.

However, there are difficulties in determining if a product that poses a chronic hazard would be used by children. Because many factors would have to be considered, determination of whether children would use these materials would have to be made on a

case-by-case basis. Factors that would be considered include the appeal of the product in attracting and sustaining use; ability of a child to use the product; ability to appreciate the product; adult's perception of intended use, marketing, packaging, advertising, and promotion of the product; and the manufacturer's stated intent. In many cases, it may be impossible to conclude that a given product would not be used by children. Thus, most products could be subject to the additional factor of ten for children. A net effect of requiring labeling for all products exceeding a cancer risk of 1×10^{-7}, for example, was not the intent of the proposed guidelines. Thus, the final guidelines do not provide additional safety factors for children's products.

F. Legal Effect of Guidelines

The guidelines are not issued as substantive binding rules, but are a non-mandatory statement of Commission policy. They explain how the Commission determines whether a product presents a chronic hazard, and they provide guidance to those in industry whose responsibility it is to determine if their product is properly labeled under the FHSA. Some minor changes have been made in the final guidelines to clarify their non-mandatory nature.

LHAMA required the Commission to issue chronic hazard guidelines for art materials. Congress directed the Commission to develop guidelines, not a binding rule that would automatically categorize all art materials. Thus, the guidelines set forth recommended procedures to be followed with the use of expert judgment rather than mechanically. As explained elsewhere, the Commission believes that these guidelines will also be helpful to the manufacturers of non-art materials subject to the FHSA.

V. Issues Pertinent to All Three Actions

A. Preemption

The Commission received numerous comments concerning the issue of preemption of state laws and regulations.

Section 18(b)(1)(A) of the FHSA provides generally that:

> If a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b).

15 U.S.C. 1261n.

LHAMA mandated ASTM D–4236, with certain modifications, as a Commission rule under section 3(b) of the FHSA. Since LHAMA amended the FHSA, the FHSA's preemption provision applies. Thus, this standard for labeling of art materials, as a 3(b) rule, preempts non-identical state and local labeling requirements that are designed to protect against the same risk of illness or injury as ASTM D–4236, as modified by LHAMA.

LHAMA directed the Commission to issue chronic hazard guidelines. The guidelines finalized today are issued pursuant to that provision of LHAMA and the Commission's general authority under the FHSA. As explained above, the standard ASTM D–4236 as mandated by LHAMA has preemptive effect if the other conditions of FHSA section 18(b)(1)(A) are met. The guidelines, however, are not a labeling requirement. They do not require that any particular product be labeled. The requirement that hazardous substances be labeled appropriately comes from section 2(p), not the guidelines. The guidelines are a non-mandatory guide for determining whether a product presents a chronic hazard. Thus, the guidelines themselves do not have a direct preemptive effect. As may affect labeling for chronic hazards, however, they may have an indirect preemptive impact because the labeling requirement of section 2(p) could preempt different state or local requirements.

The supplemental definition of "toxic" is not itself "a cautionary labeling requirement" and would not, in itself, preempt a state or local definition of "toxic." However, the supplemental definition defines a term that is necessary to the labeling requirements of section 2(p) and section 3(b) just as the existing regulatory definition of toxic, which applies to acute toxicity, works together with the labeling requirement. For example, while a different state definition of "toxic" might not be preempted automatically, a state labeling requirement that exempts from labeling a hazardous substance that is hazardous because of the risk of chronic toxicity (as defined by the supplemental regulatory definition) could be preempted.

B. The CHAP Process

Another comment raised frequently concerned the appropriateness of convening a Chronic Hazard Advisory Panel ("CHAP") to develop or evaluate chronic hazard guidelines. As most commenters seemed to recognize, neither the FHSA nor LHAMA requires the Commission to convene a CHAP before issuing chronic hazard guidelines. The Commission must establish a CHAP before initiating rulemaking to ban a substance under section 2(q)(1) of the FHSA relating to the risk of cancer, birth defects, or gene mutations from a consumer product. 15 U.S.C. 2080(b)(1). The CHAP must submit a report to the Commission concerning whether a substance in the product is a carcinogen, mutagen, or teratogen. *Id.* Thus, the only action under the FHSA that requires the Commission to consult a CHAP is rulemaking to ban a particular substance.

In issuing these guidelines, however, the Commission is not promulgating a binding rule, is not seeking to ban a substance, and is not taking action with respect to any particular substance. Issuance of these guidelines is not appropriate for CHAP review. The CHAP's purpose is to review particular products and advise the Commission on the chronic risk posed by that product or by specific substances contained in the product. The chronic hazard guidelines being issued do not relate to any particular products or substances, but they provide guidance for determining, in general, whether a product can present a chronic health hazard.

The Commission certainly agrees that the guidelines should reflect sound scientific judgment and should be widely reviewed and commented upon. Other Federal agencies and interagency groups have reviewed relevant parts of the guidelines at CPSC staff's request prior to their publication for public comment, to ensure that the latest science has been addressed. The Commission published proposed guidelines and sought written comments even though LHAMA did not require the Commission to do so. The Commission also received comments as a result of the public hearing held in October. The Commission does not believe, however, that the CHAP process is the most appropriate means to obtain views on the guidelines.

CPSC staff is involved in many government and nongovernment activities to ensure consistency, use of the latest data, and use of the most current scientific approaches to the risk assessment process. These groups include the Federal Coordinating Council on Science, Engineering, and Technology (FCCSET), the International Life Sciences Institute (ILSI), and the National Academy of Sciences (NAS) Committee on Risk Assessment Methodology (CRAM) processes. CPSC staff is also involved with a number of

interagency committees such as the Interagency Pharmacokinetics Group and the Interagency Committee on Neurotoxicity (which, at CPSC's request, reviewed the neurotoxicity guidelines before they were proposed). Participating in these efforts, the consideration of the comments received by expert scientists, and the fact that there are very few departures in the guidelines from generally accepted risk assessment methodology, lends credence to the assertion that the guidelines are scientifically defensible and reasonable.

C. Enforcement

The Commission emphasizes that there has not been, nor will there be, enforcement of the guidelines as such. Even once the guidelines become final they will not be treated as mandatory requirements which must be followed by manufacturers. A firm could follow a different but sound and scientifically supportable analysis to determine whether a product presents a chronic hazard.

However, the Commission has enforced, and will continue to enforce, the FHSA requirements that a household product that is or contains a hazardous substance must be appropriately labeled to advise of the hazard. In addition, the Commission has sought to enforce the specific, and largely procedural, requirements that LHAMA mandated for art materials. During 1991, the Commission staff contacted all known manufacturers and repackagers of art materials to advise them of the procedural requirements of LHAMA which went into effect on November 18, 1990. In 1992, inspections are being made of firms that have not given some indication of compliance or if there is some other reason to suspect noncompliance. When firms are found with products or practices that are not in compliance, they will normally be given the opportunity to voluntarily make the necessary corrections. Only when a firm has demonstrated a refusal to cooperate voluntarily would legal action be sought to obtain compliance.

VI. The Chronic Hazard Guidelines

A. General

1. Toxicity and Exposure

As explained earlier, the definition of "hazardous substance" requires both that the substance fall into one of the designated hazard categories, in this case that of "toxic," and that the substance "may cause substantial personal injury or illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Any of the chronic hazards, including but not limited to cancer, neurotoxicity, or developmental or reproductive toxicity addressed by this notice constitute "substantial personal injury or illness." In order to determine whether a product should be regarded as a hazardous substance, one must determine not only that the product has the potential to be toxic, but that in any customary or reasonably foreseeable handling or use persons are exposed to the toxic component(s) in a way that presents a significant risk of the substantial adverse health effect potentially associated with the product. This latter factor can be considered to reflect the person's exposure to the toxic component or the bioavailability of the component.

2. Nature of the Guidelines

Except as specifically noted, the current scientific knowledge concerning chronic hazards is insufficient to allow the guidelines to specify criteria that can be mechanically applied to determine whether a product is toxic. Interpretation of certain points in the guidelines will likely require expert knowledge and the application of professional judgment. Thus, the guidelines do not present a simple blueprint into which a given set of facts may be inserted to receive a certain determination. Rather, careful expert judgment must be used. If questions arise concerning matters not clarified by these guidelines, guidance may be obtained from previous Commission toxicity, exposure, and risk assessments; or from the Commission's Directorate for Health Sciences.

These guidelines contain a number of assumptions, methodologies, and procedures for determining chronic hazard and risk. While these are currently the most scientifically justified choices in the opinion of the Commission, the Commission recognizes that new data and methodologies continue to be developed. Accordingly, all default assumptions (i.e., numerical factors to be used in the absence of data for the particular substance or circumstance) contained in the following sections on hazard and risk determination may be replaced as new data become available.

In determining whether a substance should be regarded as hazardous all available scientific evidence should be considered. However, the guidelines do not require any additional laboratory tests to determine toxicity or exposure.

A condensed version of the guidelines will appear at 16 CFR 1500.135. A supplemental definition of "toxic" that defines chronic toxicity will appear at 16 CFR 1500.3(c)(2)(ii). The guidelines summarize discussions contained in documents prepared by the Commission's Directorate for Health Sciences. This preamble is also drawn from the backup documents and is intended to aid in interpretation of the guidelines. Copies of the backup documents are available at the Commission's Office of the Secretary, Consumer Product Safety Commission, room 428, 5401 Westbard Avenue, Bethesda, Maryland.

B. Carcinogenicity

1. Introduction

This section discusses the chronic hazard guidelines concerning carcinogenicity. The guidelines for determining chronic hazards by reason of carcinogenicity are especially needed because of (1) the long latency period between the initial exposure to a carcinogen and the appearance of tumors, (2) the fact that humans are exposed to multiple carcinogenic agents during the latency period under generally uncontrolled conditions (and other factors discussed below), and (3) the controversies that have surrounded the conditions under which tests showing a carcinogenic response in animals should be considered relevant to human risk. These factors make it impossible to demonstrate conclusively that such substances are human carcinogens. Nevertheless, considerable agreement exists in the scientific community as to the nature and amount of evidence that should exist in order to conclude that a substance is a likely human carcinogen.

The intent of the guidelines is to incorporate those areas where there is a substantial consensus as to the evidence needed to support a conclusion that a substance is a likely human carcinogen. For substances where the available evidence does not meet this standard, or where there is controversy about how the evidence should be evaluated, the Commission may proceed by rulemaking, as provided in section 3(a) of the FHSA, or by enforcement actions on a case-by-case basis to resolve the question of whether the substance presents sufficient evidence of an ability to be carcinogenic in humans that the substance should be considered toxic.

Evidence for carcinogenicity largely comes from two sources: Human studies (epidemiology) and animal studies (long-term carcinogen bioassay). Epidemiology is a broad medical science that deals with the incidence,

distribution, and control of disease in a population. Results from these epidemiologic and animal studies are supplemented with available information from short-term tests, pharmacokinetics (absorption, distribution, metabolism, and elimination of substances), and other relevant toxicological data. The guidelines would evaluate the toxicity of a substance on the basis of potential carcinogenicity by evaluating the available human and animal data. Under the guidelines, substances for which "sufficient evidence" exists to demonstrate carcinogenicity from studies in humans would be considered to be toxic. In addition, those substances for which there is "limited evidence" of carcinogenicity in humans or "sufficient evidence" of carcinogenicity in animals are considered toxic, except that evidence derived from animal studies that has been shown not to be relevant to humans is not included.

As noted above, it will be necessary to continue to rely on rulemaking under section 3(a) of the FHSA, or on enforcement actions, to resolve uncertainties that are not addressed by these guidelines. In this regard, the Commission is aware that the criteria stated in the guidelines do not lend themselves to a mechanical application. A number of the criteria include statements that themselves can be applied to particular chemicals only by the exercise of expert technical judgment. For example, one of the factors stated below for determining that an epidemiological study shows a causal relationship between exposure to an agent and cancer is that all possible confounding factors which could account for the observed association are eliminated after consideration. Expert technical judgment is required to identify possible confounding factors and to evaluate whether the available data are adequate to eliminate the factors as causes of the observed association. In some instances, this determination will not be straightforward. In these cases, the guidelines will not resolve the controversy, and it may be appropriate for the Commission to conduct rulemaking to resolve the controversy, or to bring enforcement actions in which the toxicity of the substance would be established on a case-by-case basis.

Although there are many difficult issues related to the interpretation of cancer studies in animals and humans, criteria for defining carcinogenicity have been established by several groups, such as the International Agency for Research on Cancer (IARC), the American National Standards Institute (ANSI), and the U.S. Environmental Protection Agency (EPA)

The following discussion explains the scientific principles and evidentiary approach upon which a determination that a substance is a "sufficient evidence" human or animal carcinogen or a "limited human evidence" carcinogen would be based. The criteria that are commonly used to evaluate the evidence derived from human and animal carcinogenesis data outlined in the following sections are similar to those of IARC and EPA, except for a few differences that are explained below.

2. Assessment of Evidence for Carcinogenicity from Studies in Humans.

a. *Discussion.* Epidemiological studies are the only direct means of assessing carcinogenicity of a substance in humans (the Office of Science Technology Assessment and Policy (OSTP), 1985, Principle # 15). Epidemiologic data are obtained from occupational, therapeutic or consumer exposure to a substance. These studies can provide sufficient evidence for a causal hypothesis (such as that between cigarette smoking and lung cancer) and compelling reasons for prevention of a health hazard (OSTP, 1985, p. 10421). They examine both the distribution of a disease using descriptive studies (correlational approaches) and determinants of a disease using analytical studies (case control and cohort methods) (OSTP, 1985, Principles ##16 & 17, p. 10377).

A good quality epidemiological study should have a clear and detailed description of the study population, disease, and exposure. The design of the study should have dealt with bias and confounding factors that can influence the risk of disease by matching, or the analysis should have dealt with bias and confounding factors by statistical adjustments (IARC, 1987, Suppl. 7, p. 26). The study should describe the determination of statistical parameters, such as relative risk, odds ratio, absolute disease rate, confidence intervals, significance tests, and adjustments made for confounding factors. The study should also describe the selection and characterization of exposed and control population, the adequacy of duration, the quality of follow up, and the identification of bias and confounding factors. A causal relationship is strengthened by the observation of a dose-response relationship, the consistency and reproducibility of results, the strength and specificity of the association, the mechanism of action, and other considerations (OSTP, 1985, p. 10421).

In assessing the strength of epidemiological studies, it is necessary to take into account the possible role of bias, confounding factors, and chance (IARC, 1987, Suppl. 7, p. 26; OSTP, 1985, Principle #18, p. 10377). "Bias" means that the operation of certain factors in the design and execution of a study lead erroneously to a stronger or weaker association between an agent and the disease than in fact exists. Confounding factors are factors associated with a test agent which create a situation in which the relationship between the test agent and a disease is made to appear stronger or weaker than it truly is as a result of the association between the confounding agent(s) and the test agent. Chance relates to the statistical significance of the observed causal association between the exposure to the agent and the development of the disease. This is ascertained by proper statistical analysis of the data. The statistical power of a study depends upon the size of the study group, the number of subjects exposed, and the level of excess risk which is required to be detected (OSTP, 1985, p. 10423).

The common problems encountered in epidemiological studies involving chemicals are: Long latent periods that exist between exposure to a carcinogenic agent and the development of cancer; inability to control for confounding risk factors; exposures to mixtures of chemicals; frequent absence of appropriate groups from the study; and difficulty in obtaining accurate and unbiased historical exposure assessment, disease ascertainment, and direct detection of relatively low level cancer risk (OSTP, 1985, p. 10424). These studies are inherently capable of detecting only comparatively large increases in the relative risk of cancer. Negative results even from high quality epidemiological studies cannot prove the absence of an association between the carcinogenic effect and the exposure (OSTP, 1985, Principle # 19, p. 10377). However, a well-designed and - conducted epidemiological study with well-defined and usable exposure data can be used to assess upper limits of risk. Such a study is especially useful in this regard if there is animal evidence from well-conducted studies to show that the agent is potentially carcinogenic in humans (EPA, 1986, p. 33996).

The criteria stated below for assessing the evidence of carcinogenicity derived from human studies agree with those outlined by EPA, except that the "No Data Available" and the "No Evidence of

Carcinogenicity" classifications are deleted because they are not necessary for the purpose of determining toxicity. The criteria also agree with those of IARC, except that the "Evidence Suggesting Lack of Carcinogenicity" classification is deleted for the same reason, and the criteria suggested below include life-threatening benign tumors in the evaluation of human studies for the purpose of protecting public health. In this regard, the Commission agrees with EPA's position on benign tumors, because the threat to life is the most important consideration in health risk evaluations. Benign tumors could be life threatening if they are critically located, such as brain tumors (gliomas), which can compress and destroy the surrounding brain tissue, or tumors located in endocrine glands (hormone producing glands, like the pancreas, or pituitary), which can cause an imbalance of critical hormones.

The American National Standards Institute (ANSI, Z129.1–1988) did not specify criteria for the evidence of carcinogenicity derived from epidemiological studies but made use of epidemiological data in its overall categorization of carcinogens.

A causal relationship between exposure to an agent and cancer is established if one or more epidemiological investigations that meet the following criteria show an association between cancer and exposure to the agent: (1) No identified bias that can account for the observed association has been found on evaluation of the evidence, (2) all possible confounding factors which could account for the observed association can be ruled out with reasonable confidence, and (3) based on statistical analysis, the association has been shown unlikely to be due to chance.

b. *Categories of human evidence.* The following categories of evidence from human studies have been developed.

i. Sufficient evidence of carcinogenicity in humans. The evidence is considered sufficient when all three of the above criteria for establishing a causal relationship between exposure to the agent and development of cancer are fully met. Evidence in this category would establish that a substance is toxic.

ii. Limited evidence of carcinogenicity in humans. The evidence is considered limited for establishing a causal relationship between exposure to the agent and cancer when a causal interpretation is credible, but chance, bias, or other confounding factors could not be ruled out with reasonable confidence. Evidence in this category would establish that a substance is toxic.

iii. Inadequate evidence of carcinogenicity in humans. The evidence is considered inadequate when all of the above three criteria for establishing a causal relationship between exposure to the agent and cancer are not met, leaving an alternative explanation to be equally likely. Evidence in this category is insufficient to establish that a substance is toxic, but does not imply that non-carcinogenicity has been proven.

3. Assessment of Evidence for Carcinogenicity in Animals

a. *Relevance of animal data to humans.* In the absence of adequate human data, the next best source of evidence of the carcinogenicity of chemicals is animal data, which are considered relevant to humans for the following reasons. (1) Mechanistically, an induction of heritable changes in the cellular DNA is generally considered to be the first and major event in carcinogenesis, and DNA is chemically similar in humans and animals. (2) Several agents, *e.g.*, 4-aminobiphenyl, bis (chloromethyl) ether, diethylstilbestrol, melphalan, methoxalen plus ultraviolet radiation, mustard gas and vinyl chloride were first found to be carcinogenic in animal studies before they were found to be carcinogenic in human studies (IARC, 1987, Suppl. 7, p. 22). (3) Information evaluated by IARC shows that, out of the 44 agents for which there is "sufficient" or "limited" evidence of carcinogenicity to humans available, all 37 agents that have been tested adequately were found to produce cancer in at least one animal species. Based on this observation, IARC stated: "Although this association can not establish that all agents that cause cancer in experimental animals also cause cancer in humans, nevertheless, in the absence of adequate data on humans, it is biologically plausible and prudent to regard agents for which there is sufficient evidence (see p. 30) of carcinogenicity in experimental animals as if they presented a carcinogenic risk to humans." (IARC, 1987 Suppl. 7, pp. 22 & 30).

b. *Factors in the consideration of animal data.* Animal studies to determine the carcinogenicity of an agent involve both exposure of laboratory animals to the agent for a long period of time (several months to the entire life span) and histopathologic examination of the animals at the end of the study to detect an exposure-related increase in tumor incidence. Criteria for assessing the quality and adequacy of animal studies have been discussed by various groups (OSTP, 1985; National Toxicology Program (NTP), 1984). A good animal study (carcinogen bioassay) requires consideration of a variety of factors. For example: (1) The species and strain of animals used in the study should have a sufficient historical data base; (2) animals should be disease free and kept under good housing conditions and animal care; (3) the number of animals/group/sex should be adequate; generally 50 or more animals of each sex/group should be used; (4) animals should be randomly distributed in the groups; (5) dose levels selected should be adequate; at least one of the doses should be close to the maximum tolerated dose (MTD); doses in excess of the MTD may lead to increased mortality excessive toxicity, or other unphysiologic conditions not considered desirable in a carcinogen bioassay (OSTP, 1985, p. 10413, Principle #4, p. 10376); and (6) exposure duration and frequency should be adequate (daily exposure by oral or inhalation routes for a two-year period is generally used in rodents) (NTP, 1984).

Other factors associated with a good animal cancer bioassay or study that must be considered in assessing the evidence are: (1) Whether data collection and reporting are complete and clear, (2) whether routes, exposure patterns, and possible mechanisms of cancer induction are relevant to the human situation, *e.g.*, tumor development only at the site of transplant or injection of a material, or bladder tumors in the presence of bladder stones (OSTP, 1985, p. 10414; Principle # 4, p. 10376), (3) whether metabolic-pharmacokinetic properties are affected, and whether pathways required for activation of the agent to produce cancer are lacking in humans; if humans do not have the same metabolic pathway found necessary in the test animal for the carcinogenic effect, the evidence may not be relevant to humans, (4) results of short-term *in vivo* and *in vitro* tests provide additional information concerning a judgment of carcinogenicity of a chemical (OSTP, 1985, Principle #5, p. 10376), and (5) whether the methods used for statistical analysis are clearly stated and are generally accepted techniques for analyzing carcinogen bioassays (IARC, 1987, Suppl. 7, p. 26; OSTP, 1985, p. 10417).

The confidence in evidence of carcinogenicity derived from animal studies increases: With an increase in the number of responding species, strains, sites, dose levels, experiments, or unusual tumor types; with the

increase in the statistical significance of increased tumor incidence over controls; with dose-related increases in the proportion of malignant tumors and total tumors; and with shorter times between the start of chemical exposure and the onset of the tumor.

Benign tumors in experimental animals frequently represent a stage in the evolution of malignant neoplasms, but they may be endpoints that do not readily undergo transition to malignancy (IARC, 1987, Suppl. 7, p. 23; OSTP, 1985, p. 10416). However, if an agent is found to induce only benign neoplasms, it should be suspected of being a carcinogen and it requires further investigation. Consistent with this observation is a recent review of over 300 National Toxicology Program (NTP) cancer bioassays which found only a few chemicals (3%) causing only benign tumors (Huff, 1988). Thus, when benign tumors occur together with malignant tumors from the same cell type in an organ or tissue, the benign tumors should be combined with the malignant tumors for evaluating the carcinogenic effect (OSTP, 1985, principle 8, p. 10376; see McConnell et al., 1986 for guidelines for combining benign and malignant tumors).

In evaluating carcinogenicity studies, tumor data at sites with high background rates, such as testicular, pituitary, and mammary tumors in certain strains of rats and lung and liver tumors in certain strains of mice, may require special consideration (OSTP, 1985, p. 10417; principle #9, p. 10377). For example, in the case of the male $B6C3F_1$ mouse (which has a high background of liver tumors), if the only tumor response is the increase in liver tumors in males, the evidence will normally be considered "sufficient" evidence of carcinogenicity if the other criteria of "sufficient" evidence as outlined in the following section (such as, tumor response in another strain, species, or experiment) are met. However, the determination could be changed on a case-by-case basis to "limited evidence" if the liver response or other high background response is necessary for the original "sufficient evidence" determination but consideration of certain factors, stated below, relating to the high background response support such a change. Factors to be considered are: (1) The tumor incidence is increased only in the highest dose, and/or only at the end of the study; (2) the proportions of malignant tumors are not substantially increased in a dose-related manner; (3) the tumors are predominantly benign; (4) shortening of the time to the appearance of tumors did not occur in a dose-related manner; (5) negative or inconclusive results are obtained from a spectrum of short-term tests for mutagenic activity; and (6) excess tumors are found to occur only in a single sex (EPA, 1986).

c. *Comparison with EPA criteria.* The guidelines concerning carcinogenicity derived from evidence from animal studies agrees with criteria promulgated by EPA, except for the following differences.

i. The "No Data Available" and the "No Evidence of Carcinogenicity" classifications of EPA are not used because they are not necessary for the purpose of assessing the toxicity of consumer products. CPSC does not maintain an inventory of chemicals, as EPA does for all chemicals in commerce (except for drugs, food additives, and cosmetics), and therefore such categories are not needed.

ii. An increased incidence of benign tumors, with an indication that the tumors have the ability to progress to malignancy, is included as a contributing response in the criteria for "sufficient evidence" of carcinogenicity. Such evidence of carcinogenicity would not be treated this way by EPA's criteria. The Commission, after careful review of the available studies, has concluded that if a benign tumor is known to have the potential to progress to malignancy, then for all practical purposes the tumor should be considered to have the same potential health risk as if it is a malignant tumor. In addition, benign tumors in experimental animals frequently represent a stage in the evolution of a malignant tumor, as stated earlier.

iii. Increased tumor incidences at independent multiple sites of origin in the same species and study are considered as separate responses. Such evidence would be considered as a single response by the EPA's criteria. The Commission believes that the ability of a chemical to independently produce tumors at multiple sites indicates that it has a wide range of carcinogenic potential, similar to such an indication from responses in multiple strains, species, or experiments.

d. *Comparison with IARC's criteria.* The consideration of carcinogenicity derived from animal studies is also in agreement with that formulated by IARC, with the following exceptions.

i. The "Evidence Suggesting Lack of Carcinogenicity" classification is deleted since it is not necessary for the purpose of determining toxicity.

ii. According to IARC's criteria, increases in incidence rates of certain neoplasms that are known to have high background rates could be viewed as a "limited evidence," as opposed to a "sufficient evidence," classification. EPA's criteria, on the other hand, provide that such evidence should contribute to the "sufficient evidence" determination, which could be changed to "limited evidence" on a case-by-case basis, depending upon the specific information as described above in the section dealing with tumor data at sites with high background rates (EPA, 1986). The Commission, after careful review of available data, concludes that EPA's criteria provide a more thorough analysis of whether the high background rate of tumors is confounding the observed correlation between exposure and cancer.

iii. An increased incidence of benign tumors only, with an indication of the ability of the tumors to progress to malignancy, would contribute to the "limited evidence" classification by IARC's criteria. However, such evidence is viewed by the Commission as a contributing response in the criteria for "sufficient evidence" of carcinogenicity, for the reasons described above in section B.3.c.(ii) discussing how the criteria differ from EPA's classification scheme.

iv. Increased incidence of tumors at independent multiple sites of origin in the same species and study are treated as discussed above in section B.3.c.(iii) concerning differences from EPA's classification scheme. IARC's approach is similar to that of EPA's.

e. *ANSI definitions.* ANSI Z129.1 (1988) did not specify criteria for the evidence of carcinogenicity derived from animal studies, but it made use of animal data in its overall definitions of carcinogenicity.

f. *Categories of animal evidence.* Based on current information, the Commission concludes that the following classifications represent the best scientific assessment and are most appropriate to classify the evidence derived from animal cancer bioassay studies.

i. Sufficient evidence of carcinogenicity in animals. "Sufficient evidence" of carcinogenicity requires that the substance has been tested in well-designed and -conducted studies (*e.g.*, as conducted by National Toxicology Program, or consistent with the OSTP guidelines) and has been found to elicit a statistically significant ($p<0.05$) exposure-related increase in the incidence of malignant tumors, combined malignant and benign tumors, or benign tumors if there is an indication of the ability of such benign tumors to progress to malignancy: (a) in one or

both sexes of multiple species, strains, or sites of independent origin or in experiments using different routes of administration or dose levels; or (b) to an unusual degree in a single experiment (one species/strain/sex) with regard to unusual tumor type, unusual tumor site, or early age at onset of the tumor. The presence of positive effects in short-term tests, dose-response effects data, or structure-activity relationships are considered additional evidence. If evidence of carcinogenicity in animals is sufficient, the substance will be considered toxic, in the absence of adequate conflicting data.

ii. Limited evidence of carcinogenicity in animals. "Limited evidence" of carcinogenicity means that the substance has been tested and found to cause any of the following: (a) a statistically significant ($p<0.05$) exposure-related increase in malignant, benign, or combined malignant and benign tumors in one or both sexes of only one species, strain, and site and such evidence otherwise does not meet the criteria defined for "sufficient evidence" in the above section; (b) evidence derived from studies which can be interpreted to show positive carcinogenic effects but which have some qualitative or quantitative limitations with respect to particulars, such as doses, exposure, followup, survival time, number of animals/group, or reporting of the data, which would prevent consideration of the evidence as "sufficient" (category i above); or (c) an increase in the incidence of benign tumors if there is no indication of the ability of the tumors to progress to malignancy. If only "limited" animal data exist for a substance, the substance will not be considered toxic under the definition on the basis of the limited animal data.

iii. Inadequate evidence of carcinogenicity in animals. "Inadequate evidence" of carcinogenicity includes that evidence which cannot be placed into "sufficient" or "limited" categories, or which is derived from poorly conducted studies with major qualitative and quantitative limitations, such as inadequate doses, too few animals/group, poor survival, or inadequate reporting, so that there can be no interpretation of the data as showing either the presence or absence of a carcinogenic effect. Data in this category do not establish a substance as toxic.

C. Neurotoxicity

1. Introduction.

This section discusses "neurotoxicity" for purposes of providing guidelines concerning neurotoxicity. The discussion presents a synopsis of criteria for the determination of the neurotoxicity of substances based on animal or human data. All neurotoxic effects, except those immediate effects which are rapidly and completely reversible following a short-term exposure, are considered chronic effects in the guidelines.

This discussion reflects the Commission's assessment of the most current scientific knowledge and consensus in this field (WHO, 1986; EPA, 1985; Spencer and Schaumburg, 1985; Hartman, 1988; OTA, 1990). For substances where the available evidence does not meet this standard, or where there is controversy about how the evidence should be evaluated, the Commission may proceed by rulemaking, as provided in section 3(a) of the FHSA, or by enforcement actions on a case-by-case basis to resolve the question of whether the substance presents sufficient evidence of an ability to be neurotoxic in humans that the substance should be considered toxic.

Test methods to determine certain neurotoxicity endpoints (manifestation of a neurotoxicological effect) are available (Anger, 1985, 1986, 1989; Baker, *et al.*, 1990; Johnson and Anger, 1983; Hartman, 1988; Tilson, 1989; EPA, 1985; WHO, 1986). Several federal agencies regulating toxic substances and drugs have guidelines to evaluate neurotoxicity as a part of acute and chronic toxicity testing and safety evaluation. The EPA has published neurotoxicity test guidelines (EPA, 1985) and is currently developing neurotoxicity risk assessment guidelines.

The U.S. National Institute of Occupational Safety and Health (NIOSH) has recommended national strategies for the prevention of neurotoxic disorders (NIOSH, 1988). NIOSH has listed 65 historically established human neurotoxic agents, major sources of exposure to them, neurotoxic effects associated with various agents, and chemicals for which neurobehavioral effects have been reported.

Evidence of neurotoxicity is evaluated by the quality and adequacy of the data and consistency of responses induced by a suspect neurotoxicant. Criteria to evaluate evidence derived from human and animal neurotoxicity data and the associated terminology outlined in the following sections are based on those of the World Health Organization (WHO), NTP, EPA, and NIOSH.

Evidence for neurotoxicity comes largely from human studies and animal studies. The guidelines would evaluate the toxicity of a substance on the basis of potential neurotoxicity based on available human and animal data. Under the guidelines, substances would be considered to be toxic if "sufficient evidence" or "limited evidence" exists to demonstrate neurotoxicity from studies in humans. In addition, those substances for which there is "sufficient evidence" of neurotoxicity in animals are considered toxic except that evidence derived from animal studies that has been shown not to be relevant to humans is not included.

The criteria in these guidelines are not intended to be mechanically applied, but rather should be interpreted with the exercise of expert technical judgment.

a. *Definition of neurotoxicity.* Neurotoxicity is any adverse effect on the structure or function of the nervous system by any substance, physical, chemical or biological in nature. The term "adverse effect" as used here means any undesirable effect on the nervous system caused by direct or indirect actions on the nervous system following acute, subchronic, or chronic exposures. The effect may be immediate or delayed, reversible or irreversible.

Characteristics of "adverse effects" include the following: (1) Side effects (unwanted effects) or effects due to overdosing; (2) functional or structural responses in the nervous system that promote compensation to restore normal function; or (3) any alteration from baseline (the individual's particular normal state), although still within "normal" range, which may diminish the ability to survive, undergo repair, or adapt to the environment. This definition includes chemicals that act directly on elements within the nervous system, such as glutamate which directly stimulates receptors, or indirectly, such as carbon monoxide which decreases the availability of oxygen.

"Adverse effects" must be considered within the context of agent usage and exposure scenario (ICON, 1990).

b. *The nervous system: Background and definition.* Effects on the nervous system will be considered in relation to the two major anatomical divisions: central and peripheral. The central nervous system consists of the parts of the nervous system contained within the skull (brain) and the vertebral column (spinal cord). The peripheral nervous system consists of nerve cells (neurons)

and their processes (axons, dendrites) which conduct information between muscles, glands, sense organs, and the spinal cord and brain. The peripheral nervous system includes afferent (sensory) and efferent (motor) fibers; both types of fibers are represented in the components of the nervous system (WHO, 1986).

Basic cellular elements of the nervous system are neurons, glial cells associated with blood vessels, and other specialized epethelial and connective tissue cells (WHO, 1986). Neurons contain multiple short processes, called dendrites, which receive information from other nerve cells, and a single long axon that conducts electrical signals to other neurons and muscles, and to and from skin, muscles, and glands. The axon terminates at a synapse where chemically-encoded information is conveyed to neurons or muscles. Glial cells in the central nervous system comprise the supporting structure of nervous tissue.

Neurons are atypical cells because the dendrites and the axon are metabolically inactive and collectively are much larger than the cell body (somata), which alone is responsible for all the metabolic activity required for maintenance of the entire cell (WHO, 1986). The structure of neurons provides an enormous surface area for chemical exposure, and consequently, chemical injury. For example, a peripheral neuron located in the lumbar portion of the spinal cord and innervating a muscle in the foot is about a meter long and contains a long column of cytoplasm.

Some chemicals may interfere in the maintenance of this cytoplasm column by, for example, interrupting transportation of nerve impulses along the axon. In this way a chemical such as n-hexane, and n-methylbutyl ketone may affect the nervous system. Chemicals such as triethyl tin may induce changes in the metabolic system of the somata, which may then cause degenerative changes in the entire neuron. A chemical such as triethyl tin, hexachlorophene, or lead, may alter myelinating cells (myelin is a fatlike substance forming a sheath around certain nerve fibers), cytoplasmic processes, or the myelin sheath, thereby causing neurotoxic effects. Intracellular elements of intraneural blood vessels may be altered by chemicals such as lead and misonidazole. Secondary changes may then occur in other tissues, such as voluntary muscles (WHO, 1986).

Several means exist for chemicals to enter the nervous system. Although the nervous system is largely protected from chemicals entering into nerve cells through blood, the blood-brain barrier is not complete. Some chemicals, especially the lipid soluble type, may still cross the barrier. Another mode of entry of chemicals is by uptake into peripheral nerve terminals. The chemical is then transported to the cell bodies in the CNS through the axon. Parts of the nervous system such as neurons of the autonomic nervous system and the sensory ganglia, certain parts of the brain (*e.g.*, near the beginning of the spinal cord), and to a limited extent, the retina in the eye, are outside the blood-brain barrier and are likely to be more exposed to neurotoxic chemicals than are other parts (WHO, 1986).

Some other factors that may influence susceptibility to effects are the size and type of the nervous system cell, the level and type of the various neurotransmitters in different regions of the nervous system, the integrity of cellular membranes, the type of intracellular organelles, and the degree of vascularity (Baker, *et al.*, 1990). For example, a poorly vascularized (*i.e.*, has fewer vessels) nervous tissue, such as the globus pallidus, is likely to be more susceptible to hypoxia (abnormal condition resulting from decrease in oxygen supplied to or used by body tissue) than a more vascularized tissue of the nervous system, such as the cerebral cortex. However, in some cases where cells have a high requirement for oxygen, they may be more sensitive to hypoxia in spite of the high vascularization than less vascularized tissue having a low requirement for oxygen. For example, neurons of the grey matter of the cerebral cortex are more vascularized than the myelinated axons of the cerebral white matter. However, the neurons are more sensitive than the axons to hypoxia because they have a higher requirement for oxygen than the axons for metabolism.

c. *Manifestations of neurotoxicity.* Common manifestations of neurotoxicity may be categorized into four types: sensory effects, motor effects, autonomic effects, and pathophysiological effects (changes to the structure and function of nerve cells and tissue).

Common signs and symptoms of sensory effects include anxiety, irritability, apathy, lethargy, attention difficulty, illusion, delusion, hallucinations, dementia (mental deterioration), depression, euphoria, stupor (partial or nearly complete unconsciousness), and coma. Other signs and symptoms of sensory effects are abnormalities of (a) smell, vision, taste, hearing, skin senses (for example, numbness, pain); (b) proprioception (reception of information given by sensory nerve terminals concerning movements and position of the body; it occurs chiefly in the muscles, tendons, and the labyrinth).

Common signs and symptoms of cognitive effects include effects upon short-term memory, learning, verbal and non-verbal long-term memory, problem solving, attentional and arousal decrement and vigilance disturbances.

Common signs and symptoms of motor effects are muscle weakness, abnormal body posture or gait, paralysis, spasticity, rigidity, tremor, dystonia (abnormal muscle tone), incoordination, hyperactivity, myoclonus (alternate cycles of rigidity and spasm in rapid succession of a muscle or of a group of muscles), fasciculations (spontaneous contractions of a number of muscle fibers supplied by a single motor nerve filament), cramps, seizures, and convulsions.

Common signs and symptoms of autonomic effects are abnormalities in control of functions related to (a) temperature that may be manifested, for example, in sweating; (b) the gastrointestinal tract that may be shown in diarrhea, salivation, or a change in appetite; (c) the cardiovascular system, for example, a change in heart rate; and (d) changes in other functions, such as, urination, sexual functions, and lacrimation (tearing).

Common pathophysiological effects on the nervous system are as follows: (a) Neuronopathies (partial or complete loss of the neuronal cell body, its processes, collaterals, or terminations); (b) myelinopathies (segmental or focal demyelination which means destruction of myelin, a fatlike substance forming a sheath around certain nerve fibers); (c) axonopathies (axonal degeneration); (d) disruptions in synaptic transmission (synthesis, storage, degradation, transport, release, and binding to specific membrane receptors of neurotransmitter chemicals); (e) changes in levels and functions of ion channels (sodium and potassium ions responsible for depolarizing and repolarizing the membrane respectively) and changes in related enzymes such as neurotoxic esterases.

2. Evidence of Neurotoxicity: General Discussion

Evidence of neurotoxicity is derived from toxicological studies related to neurobehavior, neurochemistry, neuropathophysiology, and neurodevelopment in humans and in animals. Major objectives of a neurotoxicity study are to detect and

characterize toxicity endpoints, identify changes in the structure and function of the nervous system, characterize the changes associated with exposure, assess the existence of any dose-time-response association, and elucidate the mechanism of neurotoxicity (Hartman, 1988; WHO, 1986).

Neurobehavioral studies determine the effect of a chemical exposure based on observations of the behavioral functions of the subject. Some of the behavioral functions generally tested in these studies are motor speed and steadiness, attention/response speed, manual dexterity, visual perception/memory, auditory memory, verbal abilities, attention/vigilance, profiles of mood state, and respondent and operant behavior.

Neurochemical studies determine the effect of chemical exposure on changes in the level, activity, and pattern of neurotransmitter chemicals, such as acetylcholine, noradrenaline, dopamine, glycine, serotonin, and of enzymes like neurotoxic esterases.

Neuropathophysiolgical studies determine the effect of chemical exposure on the structure and function of the nerve tissues. Observed effects and types of studies include: (1) Degeneration, or demyelination of nerve tissues; (2) encephalography (electrical activity measurements of the brain); (3) evoked potential (electrical phenomena evoked in the brain by external activity such as auditory, visual, or somatosensory stimuli); (4) electromyography (recording electrical activity from a muscle); (5) electroneurography (measurement of both motor and sensory nerve conduction velocities); (6) temperature threshold; and (7) quantitative testing for cutaneous (skin) sensation.

Developmental neurotoxicity studies are concerned with adverse effects on the structure of the nervous system or on neurobehavioral functions related to physical growth and development (Wier, *et al.*, 1989).

Several major difficulties in determining neurotoxicity of chemicals exist. Problems may arise regarding the ability of the nervous system to conform with the immediate environment, due to the scientific community's incomplete understanding of the neurotoxic effects, due to interspecies differences in structure and complexity of functions, and due to a very wide range of normal neurological and physiological functions of the nervous system which can mask the ability to observe effects due to chemical exposure. Suitable methods are unavailable to detect changes with a reasonable degree of certainty in adaptive capacity of the nervous system, in homeostatic functioning, as well as in movement pattern, fatigue, and the ability to perform complex tasks. It is, therefore, clear that a single test may not suffice to detect neurotoxicity (WHO, 1986).

Evidence for neurotoxicity comes from two sources, namely, studies in humans and studies in animals. Results from these studies are evaluated in view of the available information on histopathology (changes in tissues), enzyme inhibition, metabolism, and other relevant toxicological data to determine if there is a causal association between exposure to a chemical and neurotoxicity.

3. Evidence of Neurotoxicity Derived From Studies in Humans

a. *Discussion.* Direct evidence of human neurotoxicity comes from observations of humans. A good quality human study should have a clear and detailed description of the studied population, disease, and exposure. A neurotoxicant can produce more than one neurotoxic effect including those related to sensory, motor, learning/memory, or mood activity. The history of occurrence of the effect should be relatively complete, and past events should be substantiated by medical records if possible. The design of the study should have dealt with bias and confounding factors that can influence the risk of disease by matching, or in the analysis by statistical adjustments. The study should describe the determination of statistical parameters, such as relative risk, odds ratio, absolute disease rate, confidence intervals, significance tests, and adjustments made for confounding factors. It should also describe the selection and characterization of exposed and control populations, size of the population groups, adequacy of duration, completeness, and quality of follow up. A causal association is strengthened by the observation of a dose-response relationship, consistency and reproducibility of results, strength and specificity of the association, and an established mechanism of action.

The evaluation of human neurotoxicity studies should consider many factors including: Age, sex, socioeconomic status, health, neurological disorders and other diseases, drug treatment history, recreational drug use, motivation of the test and reference groups, life style (alcohol, smoking, etc.), education level, individual levels of alertness, emotional state, and levels of sleep and fatigue. Tests should be blind and test sites free from distractions. Confounding factors to be considered in evaluation of these studies include allergic and idiosyncratic reactions. Other complex issues to be considered are: immediate versus delayed toxicity, reversible versus irreversible effects, local versus systemic effects, acute versus chronic effects, and tolerance development (Hartman, 1988; OTA, 1990; Anger, 1989; Jonson and Anger, 1983; Hooper, 1987).

Major difficulties encountered in studies in humans are the delayed neurotoxic effects, exposures to mixtures of chemicals, and the lack of information on the effects of acutely non-toxic low-dose levels of neurotoxicants over a long period of time.

b. *Evidence of neurotoxicity derived from studies in humans.* Since neurotoxic effects are very complex and often subtle in nature, scientific judgment is necessary in classifying the evidence. The confidence in evidence of neurotoxicity derived from human studies increases with the observation of a dose-response relationship, consistency and reproducibility of results, strength and specificity of the association, and conformance with an established mechanism of action.

i. Sufficient evidence of neurotoxicity. "Sufficient evidence" for a causal association between exposure to a chemical and neurotoxicity is considered to be present when the following four criteria are met. (1) A consistent pattern of neurological dysfunction is observed in multiple studies. (2) The adverse effects/lesions in the nervous system account for the neurobehavioral dysfunction with a reasonable degree of certainty. (3) All identifiable bias and confounding factors are discounted after consideration. (4) Based on statistical analysis, the association has been shown unlikely to be due to chance with reasonable certainty.

ii. Limited evidence of neurotoxicity. "Limited evidence" of neurotoxicity means that evidence is less than convincing, *i.e.*, one of the above "sufficient evidence" criteria for establishing a causal association is not met. Thus, uncertainties exist in establishing the association between exposure to a chemical and the neurotoxic effect.

iii. Inadequate evidence of neurotoxicity. "Inadequate evidence" of neurotoxicity means that evidence does not meet the criteria of the above two categories and that no interpretation of the data shows either the presence or absence of a chemical exposure-related neurotoxic effect.

4. Evidence of Neurotoxicity Derived From Studies in Animals

a. *General considerations.* In the absence of human data, the next best source of evidence of neurotoxicity is animal data which may be considered relevant to humans for the following reasons: (1) Anatomy, physiology, histology, and biochemistry of the nervous system in humans and mammals are essentially similar; (2) chemical agents first found to be neurotoxic in humans, such as methylmercury, carbon disulfide, n-hexane, methyl ethyl ketone, methyl butyl ketone, and dichloroacetaldehyde are also neurotoxic in animals; and (3) agents, like aluminum and pyridoxin phosphate (vitamin B6), first identified in animal studies as neurotoxic were later found to be neurotoxic in humans (WHO, 1986). In neurotoxicity studies, animals are dosed acutely, subchronically, or chronically. Neurotoxicity endpoints are studied using different test methodologies designed either to screen or investigate a mechanism of action of neurotoxicity, or to gather additional data.

Criteria for assessing quality and adequacy of animal studies have been discussed by various groups (WHO, 1986; EPA, 1985; Hartman, 1988; Tilson, 1987, 1989; OTA, 1990). The major factors indicative of a good quality animal study are the following. (1) Species, sex, age, health, housing conditions, and nutrition of the animals are suitable for the test. (2) The number of animals/group/sex are adequate. (3) Animals are randomly distributed in the groups. (4) Dose levels, duration, and frequency selected are adequate to detect the adverse neurotoxic effects. (5) Data collection and reporting are complete and clear. (6) Routes and exposure pattern are relevant to the human situation. (7) Test methods used for statistical analysis are appropriate, clearly stated, and are the generally accepted techniques for analyzing neurotoxicity studies (WHO, 1986; EPA, 1985; Hartman, 1988; Tilson, 1989; OTA, 1990).

A good quality animal study requires consideration of reliability, sensitivity, and validity of the results (Vorhees, 1987). Interpretation of neurotoxicity data should consider: (1) If the neurotoxic effects are caused by a single dose (such as cholinesterase inhibitors and pyrethrins); (2) if effects are reversible or irreversible (reversible effects may indicate compensation or adaptation rather than a simple acute effect); (3) if neurotoxicity is delayed; (4) if a threshold exists (effects may appear only after changes in the nervous system caused by repeated exposures have reached a threshold limit); and (5) if circadian rhythms may influence behavior, such as, feeding, drinking, sleeping, and mating (WHO, 1986).

b. *Categories of neurotoxicity studies.* Six common representative categories of neurotoxicity studies, with a few examples of test methods in each category, to determine various neurotoxicity endpoints are listed below.

i. Neurobehavioral studies are concerned with adverse effects of a chemical on the behavior of an organism. Behavior may be defined as movement of an organism or its parts within contexts pertaining to time and space. Behavioral responses typically have been divided into three types based on the functional relations that control their occurrence (WHO, 1986). These three types are respondent behavior, operant behavior, and mixed behavior.

Respondent behavior is controlled mainly or exclusively by the prior occurrence of an event (stimulus) in the environment. The events are referred to as eliciting stimuli. A classic example of unconditioned respondent behavior is a dog's salivation when food, an unconditioned stimulus, is placed in the dog's mouth.

Operant behavior is apparent exclusively from its consequences and is also referred to as emitted behavior. Operant behavior occurs with no known observable eliciting stimulus. For example, when an animal is exposed to a novel environment, it will show a characteristic pattern of exploratory activity initially, followed by a slowdown. The environment is not an eliciting stimulus. However, the motor activity is associated with the environment.

Some behavior, known as mixed behavior, is known to have both respondent and operant components. For example, bird pecks are controlled partly by eliciting stimuli and partly by response consequences.

Both respondent and operant behaviors may be modified by the conditioning (learning) process. For example, when food (a non-conditioning stimulus) is placed in a dog's mouth only after a special note is sounded (a conditioning stimulus) and the procedure is repeated for some time, the sound of the note alone starts inducing salivation, without placing food in the dog's mouth: a conditioned respondent behavior. A conditioned operant behavior occurs, for example, when a food-deprived rat is placed in a chamber with a food dispenser and a lever, and the depression of the lever results in presentation of food, then the consequence of the behavior (pressing the lever and presentation of food) comes to control the occurrence of the response.

Common neurobehavioral studies include detection and evaluation of changes in the following neurotoxicity endpoints: cognitive functions; eating and drinking behavior; social behavior involving two or more individuals; tremors, convulsions (threshold dose of convulsants is considered in view of other unrelated toxicity), ataxia (effects on muscular coordination), paralysis, lacrimation, and the presence and absence of certain reflexes; spontaneous motor activity; motor functions; and sensory processes.

ii. Neurophysiological studies basically measure various physiological functions; such as, (1) nerve conduction velocity, (2) peripheral nerve terminal function, (3) electromyographic activity, (4) spinal reflex excitability, (5) electrocardiographic activity (EKG), (6) blood pressure, (7) electroencephalographic activity (EEG), (8) general excitability, (9) convulsive activity, (10) stimulation of the cerebral motor cortex, (11) recovery functions, (12) cognitive functions, and (13) synaptic and membrane activity.

iii. Morphological studies assess structural changes in neural and non-neural cells of the nervous system. Such changes may include: (1) The accumulation, proliferation, or rearrangement of structural elements like intermediate filaments, microtubules, or organelles (*e.g.*, mitochondria, lysosomes); (2) the degeneration of neural cells in whole or in part; (3) gross changes in morphology of cells; (4) changes in brain weight; (5) discoloration of and hemorrhage in nerve tissue; and (6) changes in glial and fibrillary acidic protein (GFAP).

iv. Biochemical and endocrinological studies may include determination of changes in: (1) RNA, DNA, and protein synthesis in nerve cells; (2) enzyme levels; (3) lipids, glycolipids, and glycoproteins synthesis; (4) synthesis, uptake, release, reuptake, metabolism, stimulation and inhibition of acetyl choline, epinephrine, serotonin and other neurotransmitters; (5) ion channels and energy metabolism; (6) anterior pituitary hormones, *e.g.*, follicle stimulating hormone, thyrotropic hormone, hypothalamic control of pituitary secretions; and (7) peripheral metabolism of endocrine secretions.

v. Developmental neurotoxicity studies consist of a battery of tests to evaluate physical growth/

developmental and neurobehavioral functions. The tests given at the preweaning stage, for example, may include measuring brain weight and pup weight, and monitoring physical development at various intervals of time. Examples of the tests given at the postweaning stage are tests of sensory and neuromuscular functions, reactivity, problem solving, and neuroendocrine functions. (Wier, *et al* 1989). Neurotoxic agents may cause qualitatively different toxicity syndromes in developing animals than in adult animals.

vi. *In vitro* neurotoxicity studies may be used to support the animal studies. However, they are not considered adequate by themselves to classify neurotoxicants. These studies generally use primary cell cultures of various tissues, such as adult mouse sensory neurons, rodent fetal cells, and cerebellar cells. The studies may also use free-living soil nematodes, *e. g., caenorhabditis elegans*, and various microorganisms (Harvey, 1988; Reinhartz, *et al.*, 1987; Davenport *et al.*, 1989; Williams, *et al.*, 1987).

vii. Other studies may include studies dealing with pharmacokinetics, blood-brain barrier, bioavailability, and structure-activity relationships.

c. *Classification of neurotoxicity evidence derived from studies in animals.* Because of the complex and often subtle nature of the neurotoxic effects, scientific judgment is necessary in classifying neurotoxicity evidence. The confidence in evidence of neurotoxicity derived from animal studies increases (becomes convincing) with (1) an increase in the number of responding species, strains, dose-levels, experiments, severity and multiplicity of effects; (2) the observation of a dose-response relationship, consistency and reproducibility of results, and specificity and strength of the association; (3) supportive *in vitro* and other studies; and (4) an increase in statistical significance of neurotoxic effects over controls.

1. Sufficient evidence of neurotoxicity. "Sufficient evidence" for a causal association between exposure to a chemical and neurotoxicity means that (1) the substance has been tested in well-designed and -conducted studies (*e.g.*, NTP's neurobehavioral test battery, Tilson 1989; EPA's neurotoxicity test guidelines, EPA, 1985), and (2) the substance has been found to elicit a statistically significant ($p < 0.05$) increase in any neurotoxic effect in one or both sexes of multiple species, strains, or experiments using different routes of administration and dose-levels.

Evidence derived from animal studies that has been shown not to be relevant to humans is not included. Such evidence would result, for example, when there was an identified mechanism of action for a chemical that causes neurotoxicity in animals that has been shown not to apply to the human situation. For example, metabolic-pharmacokinetic properties concerning the need for activation of the agent to produce neurotoxicity may come into play. If humans do not have the same metabolic pathway found necessary in the test animal for the neurotoxic effect, then the study may not be relevant to humans.

ii. Limited evidence of neurotoxicity. "Limited evidence" of neurotoxicity means that the substance has been tested and (1) found to cause a statistically significant ($p < 0.05$) increase in a neurotoxic effect in one or both sexes of only one species, strain, and experiment and such evidence otherwise does not meet the criteria defined for "sufficient evidence" above; or (2) evidence derived from studies which can be interpreted to show positive neurotoxic effects, but have some qualitative or quantitative limitations with respect to particulars, *e.g.*, doses, exposure, follow-up, number of animals/group, and reporting of the data, which would prevent classification of the evidence as "sufficient" in the category above.

iii. Inadequate evidence of neurotoxicity. "Inadequate evidence" of neurotoxicity means that evidence does not meet the criteria of the above categories and that there can be no interpretation of the data as showing either the presence or absence of a chemical exposure-related neurotoxic effect. Data in this category would not establish a substance as toxic under the guidelines.

D. Reproductive and Developmental Toxicity

1. Introduction

a. *General discussion.* This section discusses the guidelines concerning reproductive and developmental toxicity. Section 2(g) of the FHSA defines toxic as applying "to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. 1261(g).

The Commission is issuing these guidelines to specify criteria that will offer consistent guidance for identifying developmental or reproductive toxicants. This guidance reflects the Commission's assessment of the most current scientific knowledge and consensus in this field.

The intent of the guidelines is to incorporate those areas in which there is a substantial consensus as to the evidence needed to support a conclusion that a substance is a likely human developmental or reproductive toxicant. For substances where there is controversy about how the evidence should be evaluated, the Commission may proceed by rulemaking, as provided in section 3(a) of the FHSA, or by enforcement actions on a case-by-case basis to resolve the question of whether the substance presents sufficient evidence of an ability to produce developmental or reproductive toxicity in humans so that the substance should be considered toxic.

Evidence for developmental or reproductive toxicity largely comes from two sources: Human studies (epidemiology) and animal studies. Results from these studies are supplemented with available information from short-term tests, pharmacokinetics, and other relevant toxicological data. The guidelines issued by the Commission evaluate the toxicity of a substance on the basis of developmental or reproductive toxicity based on human and animal data. Under the guidelines, substances would be considered to be toxic if "sufficient evidence" or "limited evidence" exists to demonstrate developmental or reproductive toxicity from studies in humans. In addition, those substances for which there is "sufficient evidence" of developmental or reproductive toxicity in animals are considered toxic, except that evidence derived from animal studies that has been shown not to be relevant to humans is not included.

As noted above, it will be necessary to continue to rely on rulemaking under section 3(a) of the FHSA, or on enforcement actions, to resolve uncertainties that are not addressed by these guidelines. In this regard, the Commission notes that the criteria stated in the guidelines do not lend themselves to unambiguous application. A number of the criteria include statements that themselves can be interpreted only by the exercise of expert technical judgment. For example, one of the factors stated below for determining that an epidemiological study shows a causal relationship between exposure to an agent and developmental or reproductive toxicity is that confounding factors such as socioeconomic status, age, smoking, alcohol consumption, drug use, environmental or occupational exposure, and other diseases should be

adjusted for. Expert technical judgment is required to identify possible confounding factors and to evaluate whether the available data are adequate to eliminate such factors as causes of the observed association. In some instances, this will not be straightforward. The guidelines will not resolve such controversy, and it may be appropriate for the Commission to conduct rulemaking to resolve the controversy or bring enforcement actions in which the toxicity of the substance would be established on a case-by-case basis.

Although there are many difficult issues related to the interpretation of developmental or reproductive toxicity studies in animals and humans, criteria for defining developmental or reproductive toxicity have been established by several groups, such as the Food and Drug Administration (FDA), the EPA, and the European Economic Community (EEC). The Commission also believes that this approach for defining known or potential developmental or reproductive toxicants in consumer products is appropriate and feasible. The evidence of developmental or reproductive toxicity is determined by the quality and adequacy of the data and the consistency of responses induced by a suspect developmental or reproductive toxicant.

The following paragraphs describe definitions and terminology used in this section and suggest guidelines for identification and classification of reproductive and developmental toxicants. These guidelines may be used as a basis for labeling of consumer products under the FHSA.

b. *Definitions and terminology.* For these guidelines, the following definitions and terminology will be used. Some of these definitions were adapted from EPA (1988a), EPA (1988b), EPA (1989), and the Medical Dictionary by Saunders (1965).

Altered growth: An alteration in offspring organ or body weight or size.

Blastocyst: A structure resulting from the repeated divisions of the fertilized ovum.

Conceptus: The whole product of conception at any stage of development from fertilization of ovum to birth.

Developmental toxicity: Adverse effects on the developing organism that may result from its exposure during prenatal development, or postnatally to the time of sexual maturation. The adverse developmental effects may be detected at any point in the life span of the organism. The major manifestations of developmental toxicity include: (1) Death of the developing organism, (2) structural abnormalities, (3) altered growth (4) functional deficiencies, and (5) behavioral deficiencies.

Embryo: Developing young in the human uterus before eight weeks. The time period varies from one species to another in animals.

Embryotoxicity: Any toxic effect on the embryo as a result of prenatal exposure. These include malformations, altered growth and in utero death.

Epididymis: The elongated cordlike structure along the posterior border of the testis, containing ducts in which sperm are stored.

Estrogen: A female sex hormone secreted by the ovary.

Estrous cycle: The cycle of changes in the female genital tract of lower mammals, which are produced as a result of ovarian hormonal activity. It is equivalent to the menstrual cycle in humans and other primates.

Female reproductive toxicant: An agent which can adversely affect the ability of a sexually mature female to produce normal offspring.

Fertility: The capacity to conceive or induce conception.

Fertilization: The fusion of a sperm with an ovum resulting in the formation of a zygote.

Fetotoxicity: Any toxic effect on the fetus as a result of prenatal exposure. These include malformations, altered growth and in utero death.

Fetus: Developing young in the human uterus after eight weeks. The time period varies from species to species in animals.

Follicle Stimulating Hormone (FSH): A pituitary hormone responsible for the development of ova and production of estrogen in females, and the development of seminiferous tubules and production of sperms in males.

Gonad: An ovary or testis.

Implantation: Attachment of the blastocyst to the epithelial lining of the uterus.

Luteinizing Hormone (LH): A pituitary hormone responsible for ovulation, development of corpus luteum, and production of progesterone in the females, and production of testosterone in males.

Male reproductive toxicant: An agent which can adversely affect the ability of a sexually mature male to produce normal offspring.

Malformation: A permanent structural change that may adversely affect survival, development, or function.

Neonate: Newborn.

Ova: Plural of ovum.

Ovary: The female gonad.

Ovum: The female reproductive cell.

Pituitary gland: A gland which is located in the brain and secretes many hormones which control growth and functions of many organs of the body including the testis in males and the ovary in females.

Postnatal: After birth.

Prenatal: Before birth.

Progesterone: An ovarian hormone primarily responsible for the maintenance of pregnancy.

Prostate: An accessory male sex gland which secretes a part of semen.

Seminal plug: A wax like material found in the vagina of the female rodents approximately 12–24 hours after successful mating.

Seminal vesicle: An accessory male sex gland which secretes a part of semen.

Sperm: The male reproductive cell.

Teratogen: An agent or factor that causes the production of a structural defect in the developing embryo or fetus.

Testis: The male gonad.

Testosterone: The male sex hormone secreted by testis.

Variation: A structural deviation that may not adversely affect survival, development, or function.

2. Identification of Developmental and Reproductive Toxicity Hazards from Studies in Humans

a. *Discussion.* Good epidemiologic studies provide the most relevant information for assessing human risk. Epidemiologic data are obtained from occupational, environmental, therapeutic, or consumer exposure to a substance. A positive good quality epidemiologic study should meet the following criteria (EPA, 1988a; EPA, 1988b; EPA, 1989): (1) There should be no identifiable bias which can be introduced through a faulty design of the experiment. For example, if hospital records are used, embryonic or early fetal loss may be underestimated since women are not necessarily hospitalized for these outcomes. These parameters may be better ascertained by random interviews. (2) Confounding factors such as socioeconomic status, age, smoking, alcohol consumption, drug use, environmental or occupational exposure, and other diseases should be adjusted for. (3) The association between an endpoint and a causal factor should not be due to chance; there must be a statistically significant association.

b. *Categories of human evidence.* The following categories of evidence from human studies have been developed.

i. Sufficient evidence of developmental or reproductive toxicity in humans. The evidence for a substance causing an adverse reproductive or developmental effect(s) is considered sufficient when i' is based on good

quality human epidemiology which meets all the requirements stated in the above discussion of human studies; the results are statistically significant and without identifiable bias or confounding factors.

ii. Limited evidence of developmental or reproductive toxicity in humans. The evidence for a substance causing an adverse reproductive or developmental effect(s) is considered limited when the human epidemiology meets the criteria for sufficient evidence except that it lacks one of the criteria described in the above discussion of human studies. Thus, evidence is limited when statistical significance is borderline as opposed to clear-cut, there is a source of bias, or there are confounding factors that have not been or cannot be corrected for.

iii. Inadequate evidence of developmental or reproductive toxicity in humans. The evidence is considered inadequate when more than one of the above criteria for establishing a causal association between exposure to the agent and reproductive or developmental effects are not met, leaving an alternative explanation to be equally likely.

3. Identification of Developmental and Reproductive Toxicity Hazards from Studies in Animals

Although human data are most relevant for predicting human hazard, in its absence animal information becomes a valuable tool for predicting effects in humans. Many chemicals which are reproductive and developmental toxicants in humans have been shown to produce similar effects in animals (Council on Environmental Quality (CEQ), 1981). Some examples are alcohol, busulfan, chlorobiphenyls, diethylstilbestrol, isotretinoins, organic mercury, thalidomide, valproic acid, aminopterin, lead, ethylenedibromide, kepone, and carbondisulfide (CEQ, 1981; EPA, 1989). In a review by FDA (1980) of 38 compounds known to be associated with birth defects in humans, 37 were found to produce similar effects in at least one species of animals (45 FR 69,823). In another review of the data of the teratologic potential of 203 chemicals by FDA (1980), FDA stated: "it is reasonable to conclude that positive animal teratology studies are at least suggestive of potential human response." (45 FR 69,824). In addition, Wilson (1977) has described the mechanism(s) and pathways which could be applicable to both humans and animals in the initiation and development of birth defects.

a. *Study protocols for studying developmental and reproductive toxicity in animals.* EPA has developed protocols for studying developmental, male reproductive, and female reproductive toxicities in laboratory animals. Each of these three study protocols is discussed briefly below.

A protocol for studying developmental toxicity has been described by EPA (1989). Developmental toxicity can be studied in animals by administering a test substance during pregnancy, and evaluating embryonal, fetal, and/or neonatal toxicity. The protocol may also include exposure of the organism during a specific period of development (*e.g.*, during organ development), evaluation of toxicity over several generations, evaluation of toxicity during the early postnatal period or even up to sexual maturity. Animals used for developmental toxicity studies are usually mice, rats, or rabbits The most important endpoints of developmental toxicity are embryonal mortality, fetal mortality, neonatal mortality, malformations (external, visceral, skeletal) at any stage of development, altered growth, as well as functional and behavioral abnormalities.

A protocol for studying male reproductive toxicity has been described by EPA (1988a). Male reproductive toxicity can be studied by exposing sexually mature male rats to a test substance for a certain period followed by cohabitation with untreated sexually mature female rats. The exposure of the males to the test material is continued during the mating period. The main endpoints for evaluating toxicity are mating ability, fertility, prenatal and postnatal developmental effects, and weight and histopathological evaluations of reproductive organs (testis, epididymus, prostrate, seminal vesicle and pituitary). Mating ability is ascertained by determining the number of animals with seminal plugs or the presence of sperm in a vaginal lavage, per number of pairs of rats cohabited. Fertility is ascertained by determining the number of animals pregnant per number of confirmed matings. The prenatal and postnatal developmental effects are ascertained by determining litter size, pre- and post-implantation loss, number of live and dead pups, sex ratios, malformation, birth and postnatal weight, and survival. Positive findings for supplemental endpoints such as sperm evaluation (count, morphology, and motility) and hormone evaluation (testosterone, FSH, and LH) increase the evidence for hazard identification.

EPA has also described a protocol for studying female reproductive toxicity (1988b). Female reproductive toxicity can be studied by exposing sexually mature female rats to a test material for a certain period followed by cohabitation with untreated sexually mature male rats. Exposure of females to the test material is continued during the mating period and throughout gestation and lactation. The main endpoints for evaluating toxicity are mating ability, fertility, prenatal and postnatal developmental effects, weight and histopathological evaluations of reproductive organs (ovary, uterus, and pituitary). Positive findings for supplemental endpoints such as estrous cycle abnormalities, and hormone evaluations (estrogen, progesterone, FSH, LH) increase the evidence for hazard identification.

Studies on reproductive toxicity are often performed where both males and females are treated, in a manner such as described above for the individual sexes. Such studies may not distinguish between "male" and "female" reproductive toxicity.

b. *Criteria for a good quality developmental or reproductive toxicity animal study.* Any reliable study of developmental or reproductive toxicity should be designed and carried out in accordance with certain recognized criteria. The following criteria should be met for a good quality developmental or reproductive toxicity animal study.

1. The study should include at least one dosed (treated) group and one concurrent control group. However, two or more differently dosed groups are preferred.

2. Maternal toxicity (*e.g.*, a reduction in maternal body weight or organ weight) should be evaluated and accounted for in the interpretation of a study. In an ideal situation, the toxic effect(s) observed in a positive study are significant at one or more doses in the absence of maternal toxicity. However, such toxicity is not automatically discounted as secondary when associated with maternal toxicity.

3. Test animals are selected based on consideration of species, strain, age, weight and health status, and should be randomized into dose groups in order to reduce bias and provide a basis for performing valid statistical tests.

4. Good historical data on developmental and reproductive toxicity should be available for the species/strain tested; ideally, such data should be obtained for animals from each supplier.

5. The number of animals per dose group should be adequate. Generally, 20 litters per group for rodents and 12 litters per group for rabbits are used (Sowinski, *et al.*, 1987).

6. Toxicity is evaluated using acceptable laboratory methods, and

data are analyzed using appropriate statistical methods.

Sufficient evidence derived from animal studies is used as a basis to predict probable developmental or reproductive toxicity of an agent in humans. The evidence for toxicity derived from animal studies is supported by observance of (1) dose-related effects over an increased number of doses, (2) an increased number of different endpoints, (3) the same route of exposure as the expected human exposure route, (4) multiple species/strains, or routes of administration exhibiting the response(s), and (5) pharmacokinetic data and information on the likely mechanism of action.

c. *Categories of evidence for developmental or reproductive toxicity derived from animal studies.* The following categories of animal evidence have been developed.

i. Sufficient evidence of developmental or reproductive toxicity in animals. The evidence for a substance is considered sufficient when obtained from a good quality animal study and there is a statistically significant ($p < 0.05$) treatment-related increase in multiple endpoints (as described in the toxicity study protocol section) in a single species/strain, or in the incidence of a single endpoint at multiple dose levels or with multiple routes of administration in a single species/strain, or increase in the incidence of a single endpoint in multiple species/strains/experiments. Evidence from animal studies which has been shown to be not relevant to humans is not used for this purpose.

ii. Limited evidence of developmental or reproductive toxicity in animals. The evidence for a substance is considered limited when (1) obtained from a good quality study and there is a statistically significant ($p < 0.05$) treatment-related increase in the incidence of a single endpoint in a single species/strain/experiment at a single dose level administered through only one route and such evidence otherwise does not meet the criteria defined for "sufficient evidence" above; or (2) the evidence is derived from studies which can be interpreted to show positive effects but have some qualitative or quantitative limitations with respect to experimental procedures (*e.g.*, doses, exposure, follow-up, number of animals/group, reporting of the data, etc.) which would prevent classification of the evidence in the category of "sufficient evidence" above.

iii. Inadequate evidence of developmental or reproductive toxicity in animals. "Inadequate evidence" means that evidence does not meet the criteria of the above categories and that there can be no interpretation of the data as showing either the presence or absence of a chemical exposure-related effect.

E. Sensitization

The Commission already has issued a supplemental definition concerning sensitization, which is at 16 CFR 1500.3(c)(5). While that discussion relates to the separate category of hazardous substance referred to in the FHSA as a "strong sensitizer," the principles contained in that section will serve also as a guide to determine when a substance is toxic due to the chronic hazard of allergic sensitization.

F. Evaluation of Risk From Exposure to Substances That May Present a Chronic Hazard

1. Guidelines for Assessing Exposure—a. *Introduction.* The FHSA defines as toxic "any substance which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface," 15 U.S.C. 1261(g). Under the FHSA, a toxic substance is "hazardous" if that substance "causes personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use," 15 U.S.C. 1261(f)(1)(A). In order for a substance to be considered a hazard by this definition, it must not only have the potential to be toxic, but it must be demonstrated that (a) persons are exposed to the substance, (b) the substance can enter the body, and (c) there is a significant risk of an adverse health effect(s) associated with the handling and use of the substance. These represent, in turn: exposure, bioavailability, and risk. This section discusses the subject of exposure, and is intended to be used in the determination of significant risk of chronic toxicity of art materials or other products subject to the FHSA.

A discussion by the Office of Science Technology Assessment and Policy (OSTP) concerning the level of evidence that a chemical or product poses a carcinogenic risk to humans and the level of exposure of the consumer when the product is used is presented in the **Federal Register** (50 FR 10372 (March 14, 1985)). Although advances have been made in the area of modeling and monitoring exposures during the five years since this publication, many of the variables concerning the use patterns, distribution of pollutants, sources, sinks, relationships between physical parameters and market penetration of products have not been defined to a level where predictive modeling can in any sense replace well-conducted field studies. Many of the strengths and weaknesses of the approaches discussed by the OSTP remain the same today as in 1985. These approaches are discussed in the following subsections.

Three routes of exposure—inhalation, dermal absorption, and oral ingestion—will be discussed in separate subsections in the following discussion. The largest current technical effort has been driven by the recent interest in indoor air quality. Thus, inhalation is the most thoroughly investigated exposure route. Oral ingestion has been largely addressed in dietary and food additive studies, while dermal contact is largely of interest to the cosmetics industry and hence also to FDA.

Protocols exist for both oral and dermal contact for foods, drugs, and cosmetics. They include procedures for considering the form of the material being studied, the site of application (for cosmetics), and amounts potentially consumed (for food). Similarly, the form of the product as used should be taken into consideration when designing exposure studies. Using pure chemicals to assess consumer exposure and subsequent health effects when the product under consideration is a mixture, is not likely to provide an accurate reflection of exposure. For example, in assessing exposure from di-2-ethylhexylphthalate (DEHP) rather than studying pure DEHP, the staff performed experiments with actual products in order to demonstrate release of DEHP from the products' plastic matrix and transfer to either skin or saliva. Exposure studies with paint removers demonstrated that studies using methylene chloride alone, rather than a formulated paint remover, would have resulted in erroneous exposure estimates.

There are a number of procedures for assessing exposure of individuals or populations to chemicals which may cause cancer or other adverse health effects. Reasonably accurate exposure data are important in the assessment of risk. The accuracy needed can not be categorically stated since such factors as potency, concentration, and strength of evidence for toxicity of the chemical of concern are all important in defining the resources required to obtain the data necessary to perform an exposure assessment. Further, when using population estimates, the broad range of use patterns, frequency of use, diversity of products, and the variations in the types of housing where the products are used, will lead to exposure limits that

are often several-fold multiples of the predicted average exposure. Information concerning use patterns, frequency of use, definition of housing stock, and definition and market penetration of the products of interest is often lacking.

b. *Background: the three routes of exposure.*—i. Inhalation. Active interest and advances in exposure assessment have been largely driven by the current concern about indoor air quality and past activities involving occupational exposure and ambient air quality criteria and monitoring. Although exposure estimation techniques are becoming more sophisticated, there is no universally accepted minimum set of specifications for either data collection or estimation of exposure from the collected data. Generally, exposure is assessed by direct monitoring of populations, predictions of exposure, or use of surrogate data. These three approaches are briefly discussed below.

(a) *Direct monitoring* involves monitoring the general population or select segments of the population for exposure to a chemical or chemicals. Past monitoring studies have provided concentrations averaged for various periods of time and concentration measured at discrete times. Such data were obtained for carbon monoxide and nitrogen dioxide, power plant plume dispersion/reaction and concentrations of various chemicals in such locations as work places, point sources, cities, and even regions. Similar data bases do not exist for equivalent populations for residential indoor air. Examples of recent studies addressing residential air quality are: The EPA TEAM study (Wallace, 1987), the Pierce Foundation New Haven study (Stolwijk, 1983), the Gas Research Institute Texas unvented gas space heater study (Koontz, 1988), the CPSC Atlanta unvented gas space heater study (TRC, 1987), and the Harvard Six Cities Study (Spengler, 1985).

These studies provide measurements of the concentration and duration of concentration for combustion products, volatile organics, particulates, and biological materials. In addition, they provide limited real time monitoring and information concerning selected health effects information. With field monitoring studies, due to the potential for exposure to pollutants other than those monitored, a health effect associated with one of the monitored pollutants may not be accurate.

(b) *Predictions of exposure (through modeling)* to a chemical(s) can be based on physical and chemical principles, mass balance principles and mathematical models. Examples of such studies are: (1) The exposure predictions presented in various CPSC staff reports on unvented kerosene and gas space heaters; (2) the CPSC–EPA and CPSC–LBL methylene chloride exposure studies from use of paint strippers; and (3) the CPSC–EPA exposure studies of perchloroethylene from dry cleaning and other uses.

Data necessary for use in predictive modeling are often obtained from studies on products in small chambers (50 to 100 liters), large chambers (20,000 to 30,000 liters), or in research houses. The studies are usually designed for specific products. In general, protocols, although having common features, are not directly applicable to other products which may be investigated.

Often such modeling studies are based on data obtained from representative products used in room-size chambers or research houses. The distinction between a modeling study and a field monitoring study is that often the modeling relates to a specific product while a field study may only attempt to identify the pollutants and their concentrations, not their sources.

(c) *Surrogate data* (data of exposure derived from chemicals of similar structure, reactivity and volatility as the chemical of interest) are used by some investigators when no data exist for the chemical of interest. Surrogate data have not been used extensively by the Commission but have been used in some instances by EPA in pesticide exposure estimates. Surrogate data should only be used for preliminary evaluations to establish the scope of additional studies that will be needed to define exposure more accurately.

ii. Ingestion. Ingestion studies have been performed for organics and inorganics in foods. The bioaccumulation of pesticides and chlorinated compounds has been studied in shellfish and edible fish. In its "total diet studies" the FDA has provided data on the concentrations of selected chemicals in approximately 200 foods purchased in grocery stores throughout the United States. These data, in conjunction with data obtained from tissue analyses for pesticides, provide estimates of the exposure, body burden and effectiveness of regulatory programs intended to limit exposure to certain pesticides.

These studies involve direct monitoring of sources of chemicals as well as fate of the chemicals in products such as foods. Laboratory simulations have been developed to estimate exposure to chemicals on a smaller scale. These latter studies do not usually involve a living species but are based on leaching or extraction of the chemical from a product with a simulated saliva or gastric fluid. Examples of such studies are studies performed by the FDA concerning lead released from decorated glassware (Soc. Glass Decorators, 1979), CPSC's studies concerning lead released from printed paper products, and CPSC's studies of nitrosamine and DEHP released from pacifiers.

The estimation of exposure from ingestion of chemicals present in foods or consumer products is then predicted based upon estimates of use of the product and its release from the product. In the case of oral ingestion of consumer products containing chemicals, data on chemical content of the products may be known. However, the exposure directly resulting from those products must be predicted on the basis of population studies of random households inquiring into the products used and their composition.

iii. Dermal exposure. Dermal exposure involves estimating the amount of substance contacting the skin. This may involve experiments measuring the amount of material leached from a product contacting a liquid layer which interfaces with the skin, or the amount of substance which migrates from a product (in solid or liquid form) which is in contact with the skin. Parameters which must be considered include surface area of the skin contacted, duration of contact, frequency of contact, and thickness of a liquid interfacial layer. Examples of how these types of experiments might be applied to exposure assessments can be found in the Commission's exposure assessments on dioxin and arsenic leached from children's playground equipment.

More recently, *in vitro* testing using animal or human skin held in specially designed cells has allowed the rate constants of penetration of various chemicals to be determined. This approach can be performed in the laboratory and, thus, is more controlled than experiments involving live animals or humans. Examples of studies using this approach are studies of the penetration of cosmetics and topical drugs performed by the FDA, and studies of the penetration of DEHP and formaldehyde performed by the CPSC.

c. *Discussion of exposure estimates.* Each of the three approaches for exposure assessment described above have certain strengths and weaknesses as discussed below.

i. Inhalation.—(a) *Direct monitoring.* Direct monitoring will provide the strongest data for demonstrating and quantifying exposure and should be used when available. The data obtained from such studies represent

measurements made in actual living conditions. The effects of weather, a residence's structural characteristics and contents, and human behavior are all reflected in the data obtained. With proper monitoring protocols, various human activities, weather conditions, source use (where the source of chemical is known), and other information directly of interest can be obtained. The resulting data base will reflect measurements of actual maximum and minimum concentrations and may provide adequate information to determine the effect of various parameters which affect the ultimate exposure. Such parameters include, but are not limited to, air exchange rate, ambient-indoor temperature differences, wind speed, type of heating system, and frequency of use of the source of interest. Direct monitoring studies can be of either randomly selected populations or selected specifically to represent a segment of the population expected to be at risk of exposure.

Data from such population studies are important not only because they provide direct measurement of human exposure, but also because, when well-designed and -conducted, they provide valuable information for the development of models to predict human exposure.

(b) *Modeling*. Mathematical modeling, another approach for assessing exposure, is based on the principles of conservation of mass; these models are often called mass balance models. The models may be one compartment where the whole house or building is treated as a single volume, or two or more compartments where rooms or portions of rooms are treated as individual exposure entities.

Model development with field validation has been largely performed using single story houses in investigations of unvented space heating appliances and gas ranges and ovens. In these cases the single compartment model has described the distribution of pollutants throughout the living space (Traynor 1983). A single compartment model in a house where there are multiple rooms appears to be adequate for predicting exposure to combustion products with heating appliances (Traynor 1987). This is a result of the heat produced by the appliances which rapidly disperses the pollutant throughout the house, leading to a uniform distribution of the pollutant. The case of multistory houses is less clear. In a study by the Gas Research Institute (Gas Research Institute in press) in a split entry research house, the distribution of pollutants from unvented gas space heaters or gas ranges/ovens was uniform at or above the levels where the heater was located. When the heater was in the lower "game room" area, pollutant distributions were uniform throughout the house. However when the heater or range/oven was operated on the second level which contained the kitchen, living room, and bedrooms, the pollutant concentrations were uniform on the second level and near background on the lower level.

During these studies the central heating system was not used. Thus, the effect of the furnace fan in distributing pollutants in the house is not known. The concent'rations of the reactive pollutant, nitrogen dioxide (NO_2), were nearly always higher in rooms distant from the heater than in the room where the heater was located. This effect was attributed to a combination of the reactive decay and convective transfer of pollutants within the house. Modeling pollutant concentrations in houses of three or more stories will be further complicated by the stack effect of the house itself and the more convoluted path required for the pollutant to move from room to room.

The following criteria are minimum inputs for use of mass balance models:

(1) Source strength of the pollutant-emitting product (obtained from literature and field or laboratory studies).

(2) Housing characteristics (obtained from literature or housing surveys specific to the pollutant source of interest), such as:

(a) Number and size of rooms,

(b) Level of insulation in floors, ceilings, and exterior and interior walls,

(c) Reactive decay rates if appropriate for certain pollutants,

(d) Air exchange rates for the sample being modeled,

(e) Construction characteristics of the housing sample,

(f) Occupant behavior involving the house,

(g) The number and usage of the pollutant source in the structure, and

(h) The type of central heating and air conditioning used in the house.

(3) Ambient conditions which are likely to be encountered for the population under study, such as:

(a) Ambient wind speed which can affect the infiltration rate (air exchange rate) and, thus, alter the concentration ranges predicted,

(b) Ambient temperature which is an important factor in air exchange and air distribution within a house, and

(c) Ambient surroundings that can affect the wind's and sun's effect on the house by providing shading or breaking the normal wind velocity.

All of these factors should be considered in modeling exposures.

The list of criteria needed for modeling is extensive and often the information is not available in the necessary detail to fill all cells of the model. It is often necessary to review the existing literature and use as inputs data representing the average and range of values reported. Although data from field studies of occupied housing should be used in exposure assessments, they are not always available. When field study data are available they should be used not only for the exposure assessment, but also for determining averages and distributions for the purpose of model development. Alternatively, where data are lacking, averages and ranges from laboratory chamber studies can be incorporated. Examples of such data are emission rates from unvented space heaters which have largely been determined in laboratory chambers the size of a small room. These data are often supplemented by small field studies of select populations using the appliance or product of interest. Such studies are used to confirm the laboratory-determined emission rates and to provide a limited validation of the predictive capability of the model. Examples of such studies are those performed by LBL (Traynor, 1983) and the Pierce Foundation (Stolwijk, 1983) with unvented gas and kerosene space heaters.

Exposure assessment models should be validated. The assumptions and limitations of the model, the validation process, and validation results should be described. Validation is generally done by comparing model predictions with the results of field or laboratory studies. Where possible, model validation should utilize input parameters independent of the field study house(s) being monitored for validation purposes. The model validation comparison should reflect the ability of the model to predict average, high, and low concentrations in a house.

Models have provided much of the exposure information for combustion products used by various federal agencies, both to determine the need for extensive field studies and to determine regulatory approaches. The modeling studies performed for combustion products predicted the concentrations measured in dwellings reasonably well, in large part, because the appliances under investigation produced a large amount of heat which drove the combustion products rapidly throughout

the dwellings. Thus, a relatively simple, one compartment model was suitable for assessing exposure. However, when there is no driving force to distribute the chemical of interest throughout the dwelling, *i.e.*, heat or a central ventilation system, the prediction of concentrations throughout a dwelling becomes less accurate. An example of the latter was the LBL study (Hodgson 1987) of paint removers tested in a room-size chamber and used inside dwellings to remove paint from standard panels or furniture. Until validation data from research house and field studies is obtained, models should only be relied on as preliminary estimates of exposure.

(c) *Surrogate data.* Surrogate data should be used only when data on a particular pollutant or source are sparse or unavailable. Care should be taken in interpreting surrogate data in order to minimize potential errors due to the following differences between the surrogate substance and the "real" substance of interest.

There may be differences in product composition. Linear extrapolation of pollutant concentrations based on differences in concentrations in the surrogate and "real" product are not appropriate. Matrix effects of the surrogate product may not be defined in sufficient detail to permit a valid extrapolation to another product.

Differences in the physical properties of the surrogate and the "real" substance may exist. Differences in such physical properties as vapor pressure, viscosity, and diffusion constants may be great enough to introduce substantial errors into the exposure assessment.

Finally, differences in reactivity/absorptivity may affect the ultimate emission rate and, thus, concentration measured or predicted.

In general, surrogate data should be used as a screening process to determine whether additional studies are necessary and what the parameters for those studies are.

ii. Oral ingestion. When chemicals are suspected to leach from a product, such as pacifiers or flame retardant treated sleepwear, studies designed to assess solubilization of the chemical using simulated saliva and chewing are required. If portions of the product may be swallowed, the product should be subjected to simulated gastric fluids to assess the chemical's release.

The diverse nature of consumer products precludes a standard protocol for exposure based on oral ingestion studies. Generally, each product will require specific procedures and techniques to assess exposure. However, once human factors data defining product use are available, the following criteria should be established to assess exposure:

(1) A stimulant or range of stimulants should be carefully selected to mimic the possible range of conditions which can occur in humans. Such conditions may represent full and empty stomachs, or various saliva compositions which differ during the course of the day.

(2) The mechanical action to which a product is submitted must be chosen to represent some range of realistic conditions to which a human may subject the product. This consideration should encompass the population using the product, such as infants, toddlers, young adults, and older adults.

(3) The simulation to be used to mimic the use of the product (*i.e.*, rubbing, abrasion, body area and areas in contact with the product) should be defined.

iii. Dermal exposure. Dermal exposure concerns the amount of a substance in contact with the skin over a period of time. In order to adequately define the amount of dermal exposure the following factors need to be considered: concentration of the substance in the product, migration of the substance from the product to the skin, site of application, skin surface contacted by the product (or substance), duration of exposure, and frequency of exposure. Examples of dermal exposure assessments previously performed by the Commission include those on dioxin in paper products (Babich, 1989), arsenic in wood playground equipment (Lee, 1990), and TRIS flame retardant in infant sleepwear (CPSC, 1977).

The diverse nature of consumer products and exposure scenarios precludes the development of a standard protocol for dermal exposure. The general protocols described below are given to illustrate the numerous factors which should be considered. One can envision that dermal exposure may occur by one of the following general pathways: (1) the substance is contained or bound in a solid matrix which is exposed to a liquid that contacts the skin (*e.g.*, dioxin in infant diapers, TRIS in infant sleepwear); (2) the substance is contained or bound in a solid matrix which contacts dry skin (*e.g.*, dioxin in communications paper, TRIS in infant sleepwear, arsenic in wood playground equipment); (3) the substance is dissolved in a liquid which contacts the skin (*e.g.*, dish detergent); and (4) the substance contacts the skin directly.

In pathways 1 and 2, the critical factor in assessing exposure is estimating the rate or extent of migration of the substance from the matrix to the skin. In pathway 1, migration is mediated by the liquid (*e.g.*, urine, perspiration), whereas migration in pathway 2 is unmediated. The distinction between pathways 1 and 2 may be contrived. Migration of dioxin from communications paper to the skin was modeled as unmediated migration by the Commission (Babich, 1989) and as liquid mediated migration with sebum as the liquid phase (A.D. Little, 1987). In pathway 1, migration may be described by a solid: liquid partition coefficient (K), defined by:

$$K = C(\text{solid})/C(\text{liquid})$$

where C(solid) is the concentration in the solid matrix and C(liquid) is the concentration in the liquid phase. Partition coefficients are generally measured in the laboratory. The conditions used in the laboratory should mimic the intended use. For example, for dioxin in infant diapers, fluff pulp with a known dioxin concentration was extracted with synthetic urine at 32 degrees for intervals up to twenty-four hours (NCASI, 1989).

The migration rate in pathway 2 may be determined by direct measurement (*e.g.*, Ulsamer, *et al.*, 1978).

d. *Conclusion.* Due to the multitude of consumer products and art materials, it is not possible to describe default scenarios for each product. Exposure scenarios should include customary or reasonably foreseeable use, including reasonably foreseeable accidental handling and use.

In most cases the best estimate of exposure (average exposure) is acceptable. Conservative estimates (i.e., those which may lead to overestimation of exposure, such as the upper confidence limit, "reasonable worst case," or "maximum exposed individual") are not required, but may be more appropriate in some cases. For example, conservative estimates should be used in cases where exposure data are lacking. Conservative estimates may also be useful to demonstrate that a certain exposure is not of concern. Exposure distributions are preferable to point estimates, provided that there are sufficient data for their development. In some cases, a range of exposures is appropriate, such as when the exposure distribution is bimodal.

It is important to note that exposure assessments for a single consumer product often represent only incremental additions to the total exposure that results from use of multiple products in the home. Thus, it may be useful to define what portion the incremental exposure is of the total environmental exposure. However, this determination may be difficult since data concerning other sources, and use

and duration of use patterns for a population or population segment, are often unavailable from the current base of human factors knowledge. While the focus of the guidelines is on individual products, exposures from other sources should be considered if they are known to the toxicologist.

In assessing exposure, all available data should be considered, including data from field studies, modeling studies, and studies of surrogate products. In general, field data are preferred over modeling studies, which are preferred over surrogate data. On a case by case basis, one must decide, for example, whether a good modeling study is better than a poor field study. Typically, the Commission uses both field data, when available, and model predictions. In most cases the Commission has utilized surrogate data only when there is reasonable assurance that they will accurately represent the chemical of interest.

2. Guidelines for Assessing Bioavailability

a. *Introduction.* The LHAMA directs the Commission to issue guidelines specifying criteria for determining when any customary or reasonably foreseeable use of an art material can result in a chronic hazard. This section discusses the LHAMA's directive to specify criteria for assessing bioavailability of chronically hazardous substances contained in art materials. Since the content of the guidelines can also apply to sources other than art materials, these guidelines should be considered for other products subject to the FHSA.

As explained in the previous section, bioavailability, which is concerned with the ability of a substance to be absorbed into the body, is one part of the inquiry into whether a toxic substance is "hazardous" under the FHSA. Therefore, these bioavailability guidelines will serve as part of a larger effort to outline the principles to be used in evaluating the risk resulting from exposure to materials that may present a chronic hazard.

b. *Bioavailability.*—i. *Background.* Bioavailability is a term used to indicate the extent to which a substance is absorbed by the body. The bioavailable dose can differ from the dose available for exposure (such as the amount ingested, the amount available for respiration, the amount deposited on the skin, etc.) and can also vary widely depending on the chemical nature of the substance and the route of entry into the body. For example, the estimated fraction of dietary lead absorbed by adults is only about eight percent (Rabinowitz, 1973). On the other hand, a volatile solvent, such as chloroform, whose vapors have high blood solubility can be expected to be almost completely absorbed during inhalation (Klaassen, 1980).

For purposes of these guidelines, an assessment of bioavailability will include, when necessary, the rate as well as the extent of absorption. Depending on the exposure scenario, the bioavailable dose may be directly affected by the rate at which a substance enters the body, particularly in the case of short-term inhalation and dermal exposures of slowly absorbed compounds. The rate of absorption may also be important when toxicity is related to a concentration of the toxicant above a critical level rather than the cumulative body burden.

The bioavailable dose, as defined in these guidelines, should also be distinguished from the dose of toxic substance that is delivered to its site of action. In addition to absorption, this delivered dose takes into account distribution, metabolism, and excretion. Therefore, estimation of delivered dose and its application to risk assessment cannot be addressed by bioavailability considerations alone, but requires a more complete pharmacokinetic (absorption, distribution, metabolism and elimination of substances) analysis. Use of pharmacokinetic information in the assessment of risk is addressed in the set of guidelines on risk assessment procedures.

The need to consider bioavailability in estimating the risk from use of a product containing a toxic substance arises when a difference is anticipated between the absorption characteristics of a substance to which there is human exposure and those characteristics for the substance when it is tested in animal toxicity or human epidemiological studies used to define the dose-response relationship. Some situations in which this might occur are outlined below.

ii. Physical or chemical forms of a toxic substance. If the physical or chemical form of a toxic substance in a product differs from the form present in the dose-response studies used to assess risk, the comparative bioavailability of the forms of the substance must be evaluated. This is particularly true of toxic metals which can exist as water soluble salts, water insoluble salts, alkyl compounds, and in various states of polymeric aggregation. All of these forms differ in their ability to be absorbed across biological surfaces. The bioavailability of toxic substances inhaled as particulates and aerosols will also vary based on particle size.

iii. Route of exposure. Bioavailability should be evaluated when it is anticipated that the route of human exposure to a toxic substance will differ from that used in the dose-response study. This could be a relatively common situation since the test substance is often administered orally in animal toxicity studies yet human exposure to chemicals from use of consumer products is frequently through the skin or by inhalation.

iv. Presence of other constituents. When a product contains constituents that are not accounted for during the dose-response study and that are reasonably anticipated to interfere with or enhance the absorption of a toxic substance, bioavailability must be considered. For example, the extent of dermal absorption of a compound can be influenced by the type of solvent present. Toxicity studies by the dermal route often use a vehicle that maximizes dermal absorption of the test substance. However, the dermal bioavailability of the substance might be quite different in the environment present in a consumer product.

v. Dose. Bioavailability should be considered during the exposure/risk assessment of a toxic substance if there is reason to believe that the dosing conditions used in the dose-response study would introduce a non-linearity in absorption when extrapolating to conditions encountered during human exposure. Animal toxicity and human epidemiology studies on which risk assessment is based often involve chemical exposures that are higher than exposures resulting from use of consumer products. Risk assessments usually predict toxicity at those lower doses using mathematical models that do not fully apply the biological non-linearities that can sometimes exist. In certain instances, non-linearities in absorption can influence low dose extrapolation. Some toxicants are absorbed from the gastrointestinal tract by carrier mediated transport systems [2] that may be saturated at the dose utilized in dose-response studies. Saturable metabolism (level of metabolism which cannot be exceeded) of toxic substances can produce non-linearities in bioavailability. This is particularly true following gastrointestinal absorption since the major metabolic organ in the body, the liver, receives the absorbed materials

[2] Carrier mediated transport requires the existence of a macromolecular carrier responsible for binding the substrate on one side of a biological membrane and releasing it on the other side. This process can be saturated at high doses.

via the portal circulation before the materials are available to the systemic circulation. The fraction of the applied dose absorbed as measured during dermal penetration studies is frequently less at high doses than at lower doses. Therefore, extrapolation of absorption data at high dermally applied doses without further study at lower doses could underestimate bioavailability.

vi. Other conditions. Other aspects of a dose-response study may make it inappropriate to estimate human risk without making adjustments in bioavailability, particularly if the animal model or human population under investigation does not adequately approximate the absorption characteristics anticipated in the population of concern. For example, certain metals, notably lead and cadmium, are more efficiently absorbed in the gastrointestinal tract of younger animals (and humans) than adults (Hoffmann, 1982). Thus, it is necessary to correct for this absorption difference when estimating risk to children based on a toxicity study in adult animals. In addition to age, other factors that might affect adjustments in bioavailability are animal species, sex, and strain. It may also be necessary to adjust bioavailability to reflect differences in dosing regimen. Often animal studies are conducted under conditions of repeated dosing while human exposure from use of a product may be intermittent.

vii. Special cases where bioavailability has been accounted for in exposure and risk assessments. Sometimes certain aspects of bioavailability are inherently accounted for during the assessment of either risk or exposure. Risk assessments that rely on pharmacokinetic models to account for non-linearities in delivered dose will usually have made a correction for bioavailability. Exposure assessments based on biological monitoring data, such as urinary metabolites or adducts present in the blood, will often have accounted for bioavailability due to the nature of the measurement. In these cases, it may be unnecessary to assess bioavailability separately.

c. *Guidelines for the assessment of bioavailability*—i. General strategy for assessing bioavailability. Three routes of exposure are normally encountered during use of consumer products: inhalation, ingestion, and dermal contact. Once the exposure assessment has established the routes of concern and the amount of toxic substance available to the appropriate absorptive surface (*i.e.*, respiratory tract, gastrointestinal tract, and skin), bioavailability should be addressed if any of the conditions described above requires it. This should be done for each toxic substance and each route of exposure presented by the product.

Two general approaches may be used to account for bioavailability in the process of estimating risk: a default value can be assumed for the amount of substance absorbed or a bioavailability assessment can be performed. The default value should be used when there are no adequate data which would lead to an alternative approach. The goal of the bioavailability assessment is to provide a quantitative estimate for the amount of substance absorbed into the body. There may be several acceptable measurements from which bioavailability can be determined.

Although all available data should be considered, it is usually best to use *in vivo* absorption studies for the substance of interest. *In vitro* data can often be used to supplement *in vivo* data. (With *in vivo* studies, the substance of interest is introduced into a live animal. With *in vitro* studies, the substance's effect on tissue or cells isolated from the animal is studied.) Bioavailability assessments based on *in vitro* data are acceptable if *in vivo* studies are not available, if *in vitro* data are shown to be of superior quality, or if *in vitro* data more closely approximate the exposure conditions anticipated from use of the product in question. In the absence of substance-specific absorption data, it is acceptable to use a bioavailability estimate based on the default assumption or a surrogate measurement of a related compound that is known or anticipated to be no less than the actual extent of absorption. In instances where no other acceptable data exist, a bioavailability estimate of a related compound whose bioavailability is expected to be less than that of the substance of interest, but not beyond the magnitude of reasonable experimental error, can be used. However, if a related compound has been chosen based on a surrogate measurement, it must be justified that small differences in the surrogate data will not cause the extent of absorption to be underestimated beyond reasonable acceptability limits. The acceptability limits and the conditions on their use apply in subsequent discussions of surrogate bioavailability data. These approaches are also useful when the risk is anticipated to be negligible as might occur with products containing very low concentrations of a toxicant or products whose use leads to very low human exposure. A bioavailability estimate that is known or anticipated to underestimate the extent of absorption should not be used. A qualitative assessment can sometimes assist in choosing a method to estimate the bioavailability of a substance. In cases where bioavailability is considered, exposure estimates must be adjusted for the fraction of substance absorbed relative to the dose-response study.

(a) *Default approach.* The default value for bioavailability assumes that 100 percent of a substance to which a person is exposed will be absorbed. Although the default assumption may overestimate absorption, it usually has the advantage of allowing a relatively quick and easy determination of an upper bound on risk without the need for a more time-consuming quantitative bioavailability assessment. Because exposure estimates must be adjusted for relative bioavailability, risk assessments based on the default value may still require a quantitative evaluation of the fraction absorbed under conditions of the dose-response study (see discussion below).

(b) *Bioavailability assessment.—Qualitative approach.* A qualitative assessment may be useful in choosing the final quantitative approach necessary to account for bioavailability. If a qualitative assessment can demonstrate that the bioavailability from use of a product is anticipated to be no greater than the bioavailability that would result under the conditions of the dose-response study, it is acceptable to assess risk based on the assumption that a substance is absorbed to the same extent as occurred in the dose-response study. Like the default assumption, this approach may overestimate bioavailability but could, nevertheless, provide an acceptable value with minimal time and effort.

A qualitative assessment can also justify utilizing bioavailability data for a related compound when data are not available for the substance of interest, provided all critical factors related to absorption by the route under consideration are taken into account. In this case, there must be compelling evidence to indicate that the bioavailability of the surrogate compound is no less than the substance under consideration. Because these are not quantitative determinations, data other than direct bioavailability measurements are sufficient to complete the assessment. For example, a knowledge of the relative solubilities of two forms of a toxicant may be sufficient to allow data on gastrointestinal bioavailability of the more soluble form to be used to estimate

the risk from ingestion of the less soluble form of the same substance. The type of measurements sufficient to produce a qualitative determination are route-specific and will be discussed below.

Quantitative approach. If a bioavailability assessment is needed and the default assumption is not used, then quantitative estimates for the amount absorbed must be determined. The necessary data may be available to sufficiently quantify bioavailability or the appropriate experimental studies can be conducted to generate this information. Acceptable methods for determining bioavailability depend on the route of exposure. However, there are some general considerations common to most bioavailability measurements that will be discussed here.

Bioavailability measurements from in vivo exposure. The most definitive method of determining bioavailability is to measure it directly after *in vivo* administration by the exposure routes of interest. When systemic bioavailability (the fraction of the administered dose that enters the systemic circulation) is the appropriate measure, the relative availability between exposure conditions and those of the dose-response study can be determined by a comparison of the total areas under the substance concentration in plasma versus time curve (area under the curve or AUC). This procedure estimates the amount of a substance to which a specific part of the body is exposed over time. The ratio of the AUCs can be shown to be equal to the relative extent of absorption (Gibaldi and Perrier, 1982) and can be used directly to adjust exposure estimates for calculation of risk. In cases where the toxicity of interest occurs at the site of exposure, such as effects on the skin following dermal exposure or respiratory toxicity from inhalation, systemic bioavailability is not a relevant measure; extent of absorption must be determined from the concentration in the tissue of interest.

For example, if a substance was given orally in a dose-response study and the principal route of exposure from use of a product was by inhalation, relative bioavailability can be calculated as $AUC_{inhalation}/AUC_{oral}$, provided comparable doses of the substance were administered. Mathematical accommodations can be made if different doses are given. The AUC method requires that plasma concentration of the substance be determined at several time points after dosing until at least 2 to 3 half-lives of elimination have occurred. Relative systemic bioavailability can also be determined using cumulative excretion data. This necessitates that excreta be collected from the major routes of elimination (urine, feces, expired air, etc.) until virtually all the substance has been expelled from the body. Regardless of the measure used, it is important to account for both the parent compound and its major breakdown products.

Use of radiolabeled compounds is usually the most effective way of insuring a complete accounting of the parent and its metabolites. Bioavailability measurements for at least two doses that span 1 to 2 orders of magnitude may be necessary in order to address possible non-linearities. In all situations, the doses employed should be such that the processes of absorption and metabolism (when it affects bioavailability) are not compromised. In general, bioavailability testing should conform with the EPA Good Laboratory Practice Standards (EPA, 40 CFR part 792) and applicable test standards for pharmacokinetics (EPA, 40 CFR part 798.7485).

Other data that may be used to quantitate bioavailability. Types of data other than *in vivo* measurement may be used to estimate bioavailability. Under the proper circumstances, absorption can be determined from *in vitro* preparations utilizing isolated organs. When estimating bioavailability from any *in vitro* preparation, it is important to ensure that it is truly representative of *in vivo* processes. For example, an isolated segment of intestine should not be utilized to assess absorption of a substance that also enters the body through the stomach or another part of the gastrointestinal tract. In most situations, it must also be demonstrated that the preparation was viable during the period of measurement and that those factors critical to bioavailability of a particular substance, such as specialized transport or metabolism, approximate the *in vivo* condition. Uptake studies using isolated cell systems, or subcellular fractions where cellular organization has been disrupted, are usually not sufficiently representative of the *in vivo* situation.

In certain defined circumstances, use of surrogate data to estimate bioavailability is acceptable. For example, the amount of substance absorbed from ingestion of a solid material can sometimes be estimated by measuring its solubility in media designed to mimic the gastrointestinal environment. Blood:gas partitioning (the relative amount in blood versus the amount in air) can sometimes assist in determining systemic bioavailability following inhalation of gases and vapors. The respirable fraction of dust and aerosols is sometimes an adequate estimate of that portion available for absorption through the alveoli of the lung. In order to use surrogate data, the test method used must accurately reflect the absorption process it is substituting for, and any results must be reproducible. Data that overestimate the bioavailability are also acceptable, as noted previously.

Physiologically based models can also provide estimates of absorption. These models mathematically describe absorption in terms of physiological and biochemical parameters, such as, ventilation rate, blood flow, partition coefficients, and absorption rate constants. Physiological models have the advantage of being able to predict systemic or tissue bioavailability under different conditions, but they frequently require access to large amounts of input data. Model-dependent parameters should always be identified and the methods used to determine their values clearly stated. Like other methods used to generate surrogate data, models must be validated to ensure that they adequately estimate the particular measurement of interest.

(c) *Adjusting exposure estimates for bioavailability.* Route-specific exposure resulting from a particular product use can be expressed as the amount of substance to which one is exposed per body weight per day. This average daily dose can then be multiplied by a relative bioavailability ratio to give the amount of substance that contributes to the body burden for a particular situation. The relative bioavailability ratio determined by the bioavailability assessment is defined as the fraction of a substance absorbed from a specified exposure as a result of product use divided by the fraction absorbed during the dose-response study. Exposure estimates must be adjusted by the relative bioavailability ratio whenever exposure to a substance from product use leads to the conditions outlined in subsection b. above. This ratio takes a value of 1 when the bioavailability is assumed to be approximated by the dose-response study itself. If a use scenario involves multiple routes of exposure, the route-specific average daily doses may be summed to get the total average daily dose for a particular use scenario.

ii. Routes of exposure. The predominant routes of exposure encountered during use of consumer products are ingestion, inhalation, and dermal contact. The biological surfaces that function as bioavailability barriers

are different for each exposure route and, thus, the factors that control and the methodologies used to measure absorption can vary. This section will discuss the critical features that must be considered in determining absorption across the gastrointestinal tract (ingestion), respiratory tract (inhalation), and skin (dermal contact).

(a) Gastrointestinal tract.—Transport characteristics. The gastrointestinal tract is the site of potential absorption for ingested substances. Although, in principle, absorption can take place along the entire length of the gastrointestinal tract from mouth to rectum, most absorption takes place in the stomach and small intestine where larger surface areas, longer residence times, and higher perfusion rates are most conducive to transport across the mucosal barrier. The most common mechanism by which toxicants are absorbed across the gastrointestinal tract is by passive transport [3] through the absorptive cells. Absorption by this mechanism is greatest for small uncharged lipid soluble molecules with adequate aqueous diffusivity. In fact, for a series of non-electrolytes of similar molecular size, gastrointestinal absorption can be shown, in general, to be proportional to lipid solubility as measured by oil:water partition coefficients. Ionizable compounds such as organic acids and bases are not well absorbed in their ionized form, and the extent and rate of absorption will be governed by the pH at the absorption site and the pKa of the chemical. Thus, organic acids are likely to be better absorbed in the acidic environment of the stomach, while organic bases would be expected to be better absorbed in the more basic pH of the intestine. While lipid soluble compounds diffuse through the gastrointestinal cells, small water soluble compounds are capable of diffusing through aqueous pores located at the junctions of the intestinal epithelial cells. This is a major mechanism by which water and small electrolytes, such as potassium and sodium ions, penetrate the gastrointestinal tract. Other water soluble chemicals with a molecular weight below about 200 daltons have also been shown to be absorbed this way (Schanker, 1962).

Several more specialized transport systems exist in the gastrointestinal tract that can be responsible for absorption of selected substances. Some chemicals are transported by a carrier mediated mechanism. This type of transport is primarily responsible for absorption of some nutrients and endogenous substances, but sometimes non-essential chemicals, including metals, such as lead and aluminum, and several quaternary ammonium compounds, are capable of utilizing these systems. Intestinal absorption of large macromolecules (10,000–60,000 daltons) have been documented in man and experimental animals. This is believed to occur by pinocytosis.[4] Particles up to 5–6 micrometers (um) in diameter can be absorbed by phagocytosis [3] (Aungst and Shen, 1986). However, the extent of absorption by pinocytosis and phagocytosis is generally low. Gastrointestinal absorption of charged substances of high molecular weight is particularly poor.

Physiological and physicochemical factors. Aside from the transport characteristics, there are several physicochemical, biochemical, and physiological factors that can influence gastrointestinal absorption and systemic bioavailability. The nature of a substance can sometimes be substantially altered during the absorption process: degradation can occur in the acid environment of the stomach; a toxicant can be altered by the action of digestive enzymes or the bacterial flora present in the intestines; once absorbed, some chemicals can undergo extensive metabolism in the liver before reaching the systemic circulation.

Most substances must be solubilized before absorption can take place. The rate and extent of dissolution can often limit the rate of absorption of a chemical ingested as a solid material. A key determinant of dissolution of solid material, as well as absorption of complex mixtures, is aqueous solubility. Absorption of some substances can be changed by formation of insoluble salts or molecular complexes. Dissolution of a compound in a solid matrix is influenced by particle size: Smaller particles are more easily absorbed than large particles because of their greater surface area. Sometimes the way in which a substance is formulated can have profound effects on gastrointestinal absorption. Lipid soluble substances administered in oily vehicles are often absorbed directly into the blood through the lymphatics bypassing the liver. The result could be a significant increase in systemic bioavailability if the substance is known to undergo extensive hepatic metabolism. Highly viscous suspensions can affect absorption by slowing dissolution of a substance and delaying gastric emptying.

Physiological factors must be considered when assessing gastrointestinal bioavailability. Delayed gastric emptying caused by a test substance or its vehicle can affect absorption particularly in the case of acid-labile (*i.e.*, decomposes in the presence of acid) compounds or situations where acidity influences dissolution. Gastrointestinal motility can affect absorption by altering the time spent at the site of absorption. This is critical for compounds whose bioavailability is limited by the amount of time they reside in the intestine. The gastrointestinal absorption of some substances is known to be age dependent: the absorption of many metals such as cadmium, iron, mercury, lead, and zinc is highest in newborns and decreases with age (Hoffmann, 1982).

Physicochemical properties can sometimes indirectly aid in the determination of bioavailability estimates. When a chemical is ingested as a solid material, measurements of solubility in media that mimic the gastrointestinal environment may be used to estimate absorption, assuming certain conditions are met. Use of solubility measurements as an estimate of bioavailability implicitly assumes that absorption of the soluble material is known. Other assumptions about absorption are acceptable provided that the actual extent of absorption will not be underestimated. It must be shown that the test method under which solubility is measured will not lead to a lower solubility than is expected to occur following ingestion. This requires that the surrogate method be validated against the appropriate *in vivo* models for the substance of interest, the type of material for which it is present, and its dose range.

Relative solubilities, pKa's and oil:water partition coefficients can also be utilized to justify using gastrointestinal bioavailability data for a related compound. A chosen surrogate compound should never be expected to have a lower bioavailability than the compound of interest. Absorption of a more soluble form of a toxicant should never be estimated using data from a less soluble form of the same toxicant. Absorption of organic acids should never be estimated using data from a related acid with a lower pKa. On the other hand, bioavailability of organic bases should never be estimated from a

[3] Passive transport refers to simple diffusion of a substance from one compartment to another controlled by a diffusion coefficient and the concentration or electrochemical gradient across the membrane.

[4] Pinocytosis and phagocytosis refer to transport processes by which substances are engulfed by the cell membrane.

related base with a higher pKa. The oil:water partition coefficient of the surrogate substance should never be lower than the compound under consideration. In these cases, it is essential that other factors critical to bioavailability, such as transport mechanism, molecular weight, first pass metabolism, and physiological effects do not cause the bioavailability of the surrogate compound to be less than the substance of interest.

(b) Respiratory tract: Factors that affect absorption from the respiratory system. Chemicals that are absorbed through the respiratory tract are gases, such as, carbon dioxide or nitrogen dioxide; vapors of volatile liquids, such as, benzene or methylene chloride; and aerosols, such as, silica, asbestos, and other dusts, smokes, fogs or mists. Aerosol deposition and the efficiency of absorption is dependent on particle size and charge. The majority of aerosol particles with a mass median aerodynamic diameter ("MMAD") greater than 5 um are deposited in the nasopharyngeal region of the respiratory tract following nasal breathing. The particles are usually trapped in the thick mucus blanket of the nasal surface and are rapidly removed by either mucociliary clearance,[5] sneezing, or nose blowing. Much of this particulate matter is made available to the gastrointestinal tract after swallowing of the secreta. As nasal breathing becomes augmented by mouth breathing, which might occur during exercise or periods of nasal blockage, nasopharyngeal deposition is reduced while both the fraction and size of particles reaching the deeper regions of the respiratory tract are enhanced. Some sufficiently soluble aerosols can dissolve in the mucus and be absorbed through the epithelium of the nasopharyngeal region into the blood.

Particles with a MMAD in the range of 2 to 5 um are increasingly deposited in the tracheobronchial region of the respiratory tract following nasal breathing. These are also cleared by the upward movement of the mucus layer lining this portion of the respiratory tract. However, the mucus is generally thinner and the clearance times longer, particularly in the terminal bronchiolar regions of the lung, allowing for greater opportunity of being absorbed across the epithelial cells into the blood. Coughing and sneezing can result in more rapid movement of particulate matter from the larger airways to the glottis to be swallowed.

Particles with diameters around 5 um also begin to reach the alveolus of the lung during nasal breathing; this region becomes the major site of deposition for particles with diameters less than 2 um. Lipid soluble aerosols are very readily absorbed from this zone of the respiratory tract due to the large surface area, high blood flow, and thin diffusion barriers. Because of the relatively inefficient clearance mechanisms available in the alveoli, insoluble particles can remain for long periods until they are either removed by the bronchial mucociliary system, phagocytysed by alveolar macrophages, cleared by lymphatic drainage, or slowly undergo dissolution and vascular removal. The long residence times of particulates deposited in the inner regions of the respiratory tract, combined with the relative ease of diffusion across the alveolar membranes, make the lung a significant site of absorption for those substances that adsorb on the surface of small aerosols. Inhaled particles less than 1 um in diameter can be expected to reach the deepest regions of the lung easily. However, the total deposition/retention of these smaller particles in the respiratory system is generally less since they can be exhaled. Recent data using nasal casts of humans and experimental animals suggest that ultrafine aerosols less than 0.2 um in diameter become increasingly deposited in the nasopharyngeal region of the respiratory tract. Other particle characteristics such as density, shape, and hygroscopicity [6] may influence the site of deposition and absorption.

The uptake of gases and vapors can occur throughout the respiratory system. The predominant mechanism for most gases is passive diffusion driven by the higher concentration in the inspired air relative to the tissue and blood. Aqueous soluble gases tend to be taken up by the nasopharyngeal region and upper airways. A greater percentage of the less water soluble gases reach the lower airways and alveolar region of the lung where absorption into the systemic blood occurs much more readily. Once in the alveoli, the amount of a gaseous substance that enters the blood is controlled not only by its concentration in the inspired air, but also by its solubility in blood, pulmonary ventilation, and blood flow. As one continues to breathe a gas or vapor at a constant tension, a steady state concentration in the blood will eventually be achieved. The time needed for a gas to reach steady-state is primarily a function of its solubility in blood, which is characterized by a blood:gas partition coefficient defined as the ratio of the concentration of dissolved gas in the blood to that in the gas phase at equilibrium.

A highly soluble gas with a large partition coefficient will be almost completely transferred to the blood with each inspiration, but the time needed to reach steady-state may be several hours. On the other hand, only a small fraction of a gas with low blood solubility will be absorbed into the blood and saturation may be achieved more quickly. Other factors will influence the ability of a gas to be absorbed in the blood: Time to steady-state will be more prolonged for gases that are highly lipid-soluble and can be stored in body fat; insoluble gases that are rapidly cleared by metabolism will also be absorbed to a greater extent than a gas of similar solubility that is not metabolized; an increase in pulmonary ventilation will often increase the absorption of a highly soluble gas, while an increase in pulmonary blood flow can increase the absorption of an insoluble gas; some carrier mediated or other specialized transport systems are known to exist in the respiratory tract, but are uncommon.

Other considerations may affect absorption from the respiratory tract. Inhaled substances that alter mucociliary flow, cause bronchconstriction, or directly damage the respiratory epithelium can significantly influence the bioavailability from this route of exposure. Although the metabolic capability of the lung is generally more limited than that of the liver, certain selected substances may undergo extensive pulmonary metabolism that could result in reduced systemic bioavailability. A more detailed discussion of the factors that determine the bioavailable dose following inhalation can be found in the EPA Interim Guidelines for Development of Inhalation Reference Doses (EPA, 1989).

The determination of administered dose from inhalation studies is more complex than with other routes since it is dependent on duration of exposure, respiratory rate and tidal volume as well as concentration. It is best for *in vivo* respiratory measurents to be done by plethysmography, but in its absence, appropriate values for the particular species of experimental animal may be assumed based on literature values.

[5] Mucociliary clearance refers to a mechanism by which particulates and bacteria are entrapped in a layer of mucus lining the respiratory tract and swept upward out of the system by the movement of small hairs called cilia attached to the epithelial cells of the tracheobronchial and nasal regions.

[6] Hygroscopicity refers to the ability of particles to accumulate moisture.

Administered dose calculations from experimental animals must be defined in terms of an equivalent human dose. This means that the airborne concentration has to be adjusted to reflect differences in exposure duration and breathing rate between experimental conditions and humans. The default human breathing rate during typical product use is assumed to be 20 cubic meters per day. This produces a default alveolar ventilation rate of 13.4 cubic meters per day since only a fraction of the air breathed is available for gas exchange. Appropriate ventilation rates for a number of animal species have been documented (EPA, 1988). If the test material is an aerosol, particle size distribution needs to be determined as the mass median aerodynamic diameter (MMAD). For insoluble aerosols, the amount deposited in the various regions of the lung can be estimated from the aerosol size distribution, deposition efficiency, and lung surface area. Adjustments can be made to account for differences in aerosol deposition between animals and humans (Jurabek, *et al.*, 1989).

Absorption by the respiratory tract can also be predicted using physiologically based models. These can be developed to estimate blood concentration over time resulting from inhalation of a substance or doses reaching different sites of the respiratory tract. The accuracy of these models depends on precise values for a number of physiological (ventilation rate, blood flow, airway diameter, etc.), biochemical (metabolic rates), and physiochemical (blood:gas partition, diffusion coefficients, etc.) parameters. All models should be adequately validated before being used in assessing bioavailability.

Certain surrogate data may be used to assist in determining bioavailability estimates following inhalation. Aerosol/dust particulates with a MMAD less than 10 um can sometimes be used as an estimate of that fraction available for absorption across the alveolar region of the lung. Studies indicate that only a very small fraction (<10%) of aerosols greater than this size reach the respirable region even with ventilation rates that occur during moderate to heavy exercise (Miller, *et al.*, 1988). Although bioavailability from alveolar deposition of aerosols greater than 10 um may be eliminated from consideration, potential absorption of these particulates from other portions of the respiratory tract or from gastrointestinal exposure as a result of mucociliary clearance must be evaluated.

Blood:gas partition coefficients for gases and vapors can be utilized to justify the substitution of respiratory bioavailability data from a related compound, provided certain criteria are met. The blood:gas coefficient of the surrogate compound must not be less than the compound under consideration. In addition, it must be shown that other factors that control transport from the respiratory tract such as metabolism, clearance, tissue distribution, and uptake from other regions of the respiratory tract cannot be expected to cause absorption of the surrogate to be less than that of the substance of interest.

(c) Skin: permeability characteristics. The skin serves as a relatively impermeable barrier to many chemical agents. In contrast to the gastrointestinal tract and lung in which a chemical must only pass through two cells to reach the blood, the skin has multiple cell layers that must be crossed before systemic absorption takes place. The rate-limiting step in this process is usually diffusion across the stratum corneum, the outermost densely packed layer of keratinized epidermal cells. The stratum corneum of different regions of the body will vary in thickness and diffusivity, and will be reflected in different dermal permeabilities. For example, the palms and soles are much less permeable than other skin areas because of their very thick outer layer of skin. Chemicals diffuse much more readily across the inner epidermis and dermis than the stratum corneum. Some chemicals may be partially absorbed through the cells of the sweat glands and hair follicles. However, because the cross sectional area occupied by these structures in human skin is only 0.1 to 1 percent of that occupied by the epidermis, this route of absorption is unlikely to play a major role for most substances.

Absorption from the skin is believed to occur by passive diffusion. The overriding determinants for the rate of percutaneous absorption are, therefore, the concentration gradients from skin surface to blood and the permeability of the penetrant for the stratum corneum. In addition to skin thickness and membrane diffusivity, dermal permeability is controlled by molecular size and partitioning between the stratum corneum and the vehicle in which the penetrant is present. Except for some extremely nonpolar compounds, the permeability constants for many substances in aqueous solutions have been shown to correlate well with their lipid solubility as measured by the octanol:water partition coefficient, provided their diffusivity does not greatly vary. The correlation is not as strong for the highly nonpolar compounds because the transfer of chemical out of the stratum corneum into the inner epidermis can become rate-limiting. This could possibly lead to an overestimation of dermal permeability based on the octanol:water partition coefficient. The degree of polarity can influence the diffusivity of a substance in the stratum corneum. Very polar compounds appear capable of partially diffusing through the outer surface of protein filaments, while the less polar molecules must exclusively dissolve in, and diffuse through, the lipid matrix between the protein filaments. These differences in molecular mechanism can lead to quantitative differences in the diffusion coefficient among substances. Although small moderately lipid soluble molecules appear to be best absorbed from the skin, larger molecular weight and/or ionized substances will usually be absorbed to a lesser extent. More information on how physicochemical properties influence dermal absorption can be found in the EPA Guidance for Conducting Dermal Exposure Assessments (EPA, 1992).

The vehicle in which the substance of interest is applied to the skin can affect dermal absorption in several ways. A vehicle may improve skin absorption by increasing solubility, thus, providing a greater concentration gradient for diffusion. The vehicle can increase or decrease the partitioning of the penetrant in the stratum corneum, thereby altering absorption. Some vehicles such as dimethylsulfoxide, and certain lipid extraction solvents and detergents, can accelerate dermal penetration by altering the diffusivity of the dermal barrier. This can occur by chemically destroying the integrity of the stratum corneum, either by functioning as a swelling agent, removing lipid, or altering the conformational structure of the cell layer.

A number of other factors might affect dermal bioavailability. The rate of absorption is directly proportional to the amount of surface area contacted by the penetrant: a toxicant applied over a large area of skin will be absorbed faster than an equal amount over a smaller area. Diffusion across the skin increases exponentially with rising temperature. Skin hydration affects percutaneous absorption by altering the diffusivity and thickness of the stratum corneum; dehydration can decrease permeability by as much as tenfold (Klassen, 1980). Disease or damage to

the stratum corneum can cause an abrupt increase in percutaneous absorption. Like the respiratory tract, metabolism of certain chemicals by cells in the inner epidermis may significantly decrease the bioavailability from skin. Binding of penetrant within the different cell layers may also limit bioavailability. Volatility, chemical instability, and pH of the vehicle may alter the amount of toxicant in a form available for absorption. Finally, variability in skin permeability exists among species. Good models for human skin are dependent on the compound of interest; pig and monkey skin generally appear to share the greatest similarity to human skin in terms of percutaneous absorption, but skin from other animals may also be adequate. Human skin may also be available.

Percutaneous absorption can be estimated with physiologically based models. These use physiochemical, biochemical, and physiological data, such as, diffusion and partition coefficients, molecular weight, clearance, and blood flow to predict bioavailability. The parameters used as input to the model should be experimentally determined by legitimate methods and the values being estimated by the model should be appropriately validated.

Octanol: Vehicle partition coefficients can sometimes be utilized to justify using dermal bioavailability data from a related compound. The chosen surrogate must not have a partition coefficient lower than the substance of interest. Other factors that influence bioavailability, such as membrane diffusivity and skin metabolism, also should not be expected to cause the absorption of the surrogate to be less than the compound under consideration. Since dermal absorption data are often available as an experimentally determined or a mathematically derived (based on surrogate measurements) permeability constant when the skin contact is with a liquid, this measurement needs to be converted into the absorbed dose. This can be determined by multiplying the permeability constant (cm/min) by the concentration of the chemical in the medium contacting the skin, the exposed surface area (square centimeters) and the duration of exposure (min).

3. Risk Assessment Guidelines.—a. *Introduction.* The purpose of this section is to describe the procedures to be used when estimating risk for substances which are defined as toxic by nature of their carcinogenicity. Such risks are used in conjunction with exposure information to determine whether an acceptable daily intake (ADI) has been exceeded, as described in the section concerning that subject. As explained in that section, the process of quantitative risk assessment will not be applied to other chronic endpoints (reproductive/developmental effects and neurotoxicological effects) at this time. Thus, this section will only deal with carcinogenic risk assessment.

Although these guidelines will be fairly specific, further information on the rationale behind some of the assumptions, examples of how the guidelines are applied, and examples of the application of pharmacokinetics can be found in the Commission risk assessments on methylene chloride (dichloromethane) and formaldehyde (M.S. Cohn, Inhaled methylene chloride unit carcinogenic risk assessment, June, 1985; M.S. Cohn, Estimated carcinogenic risks due to exposure to formaldehyde released from pressed wood products, February, 1986; M.S. Cohn, Updated risk assessment for methylene chloride (dichloromethane), June 1987).

b. Guidelines for carcinogenic risk assessment.—i. Selection of data upon which risk is based. For a given carcinogenic substance, the data used will be obtained from those studies used to define the substance as "toxic" by virtue of its carcinogenicity. Among these, the study leading to the highest risk should normally be used. However, other factors may be considered in the choice of the study. For example, a study with three administered doses, showing a dose-response relationship, can be given more weight than a study in the same species/strain with a single administered dose. Similarly, a study with the same route of exposure as that anticipated for human use of the product under consideration can be given more weight than a study that uses the same species/strain, but uses a different route of exposure. If both sexes in the study respond significantly, they can be combined before risk analysis if the responses are similar (as done in the case of formaldehyde). Alternatively, the risks for each sex can be determined individually and then averaged for the final estimate (as done in the case of methylene chloride). If there is more than one significantly responding endpoint, the risks for each are determined individually and then added for the final estimate. See the risk assessments on methylene chloride referenced above for an example of this treatment.

ii. High-to-low dose extrapolation. The multistage model (Global83 or later version) is used in all cases unless a convincing argument can be made for an alternative model such as one addressing a distribution of thresholds. Linearity at low dose is always the default assumption, in light of the high probability that the action of any carcinogen will interact with background cancer processes and environmental agents, as opposed to acting independently. Upon request, a copy of Global83 that will run on a personal computer is available without charge from the Commission.

The risk will be based on the maximum likelihood estimate from the multistage model, unless the maximum likelihood estimate is not linear at low dose (which happens when the first-order coefficient, q_1, is zero). In such a case, the 95% upper confidence limit on risk (*i.e.*, the 95% lower confidence limit on dose) should be used. In the example risk assessments cited above, the maximum likelihood estimate was used in the case of methylene chloride and the upper confidence limit on risk was used in the case of formaldehyde.

Modification of doses put into the multistage model may be made if sufficient pharmacokinetic information is available. See the above referenced risk assessments on methylene chloride for an example of how such information can be used to account for nonlinearities in the dose-response curve due to pharmacokinetic influences.

iii. Species to species extrapolation. For systemic carcinogens, that is, those that exert an effect remote from the site of contact, a "surface area" correction will be used if estimates of human risk are made based on animal data. At present, this correction is a factor derived from dividing the assumed human weight (usually 70 kg) by the average animal weight during the study, and taking that to the ⅓ power. On a miligram per kilogram per day (mg/kg/day) basis, the human is assumed to be more sensitive than the animal by this factor. See the risk assessments on methylene chloride for an example of this approach. There is the possibility that this factor may be changed, using the ¼ power instead of the ⅓ power, as part of a unified Federal regulatory approach. If such an approach is adopted, it will apply here.

In cases where the concentration is expressed as parts per million (such as, in air or in diet) and the carcinogen acts at the site of contact (such as, nasal passages or the lung), species may be assumed to be of equivalent sensitivity on such a basis. In other words, humans and animals exposed to the same concentration (in parts per million) in air or diet for the same proportion of lifetime are assumed to be equally

sensitive. See the risk assessment on formaldehyde for an example of this approach.

At this time, pharmacokinetics should not be used to adjust for differences between species in sensitivity to a carcinogen; briefly, this is because information on sensitivity of various species to a "target" dose is not currently available. The rationale for this decision is explained in depth in the risk assessment for methylene chloride.

iv. Route to route extrapolation. If no experimental study having the same route of exposure as that anticipated for human use of a substance is available, a study by another route of exposure is used. In such cases, pharmacokinetic methods may be used if sufficient data are available, or methods described in the bioavailability section may be used. The less information available, however, the more one has to rely on default assumptions (as discussed in the bioavailability section).

v. Scenario extrapolation. Where exposure scenarios are different from those used in the underlying study upon which estimates of risk are based, proportionality should be applied. For example, if an experimental study is performed under conditions of exposure for six hours a day, five days a week for lifetime, then the risk for a single hour of exposure is the risk from the experimental study divided by a factor of: 6 (hours/day exposure) $\times$ 5 (days/week) $\times$ 52 (weeks/year) $\times$ 70 (assuming a 70-year lifetime). If pharmacokinetic methods are used to adjust for risks at high versus low exposure levels, one must be careful not to combine level-time measures (such as in calculating a lifetime average daily dose) without taking the non-linearity into account. Where such pharmacokinetic information is available, it may be used to adjust scenario extrapolations. For example, two uninterrupted days of exposure may lead to a different time versus concentration (area under the curve) estimate than two interrupted days of exposure, due to factors such as incomplete elimination of the substance after twenty-four hours, saturation of uptake processes, or saturation of metabolic processes.

4. Acceptable Risks to Children and Adults

a. *Introduction.* Under the LHAMA, the Commission is required to develop a number of criteria to be used in the determination of whether an art material is to be labeled. Two of these are addressed here, namely, (1) "criteria for determining when art materials may produce chronic adverse health effects in children and criteria for determining when art materials may produce such health effects in adults," with the added provision that "where appropriate, criteria used for assessing risks to children may be the same as those used for adults," and (2) "criteria for determining daily intake levels for chronically hazardous substances contained in art materials."

The first of these two criteria, effects in children and effects in adults, is addressed in this section. The second, criteria for acceptable daily intake, consists of two general parts: Guidelines for determination of the quantitative risk estimated to be incurred from use of an art material containing a toxic substance, and whether or not this risk is acceptable. The first general part is addressed in other sections regarding whether or not a substance is toxic, how exposure is assessed, and how risk is estimated. The second general part, what risk is acceptable, will be addressed here. This discussion is intended to address the issue of acceptable risk with regard to all products subject to the FHSA, not just art materials.

The reasons for the inclusion of these two particular elements (risks to children and adults, and whether such risks are acceptable) in this section become clear when one considers that hazard, as well as risk, cannot normally be distinguished relative to age of the person exposed. It would be extremely rare, if at all, that a case could be made that a specific chronic hazard would apply only to children and not to adults, or vice-versa. For cancer and chronic neurotoxicological effects, hazard identification is normally based on long-term studies in animals or humans, and unless there is some rare phenomenon indicating otherwise, both adults and children would be expected to be susceptible to substances causing such effects. Similarly, exposure of an adult or child to a reproductive toxicant could lead to effects in eventual offspring. A special case is that in which a substance has an effect only during pregnancy—a child exposed to such a substance would not be at risk, but exposure to a pregnant adult could affect the unborn child.

Although children may be more susceptible to the effects of chronic toxicants, current methodologies for carcinogenic or other chronic hazard risk assessment are usually unable to distinguish between risk to children and adults for most substances. This is because (1) data do not usually exist which relate ultimate risk to age at first exposure to a substance, and (2) in the absence of such data, the basic methodologies used for risk assessment have not developed to the point where such projections can be made. Such an endeavor may be further confounded by scenarios where exposure to a substance in childhood may lead to manifestation of a disease in adulthood. Of course, there are rare occasions when data have been available to allow distinction of risks relative to age of exposure, such as the methodology applied for the estimation of risk of mesothelioma due to exposure to asbestos. In this case, there are epidemiological data relating risks observed (after a lengthy period of followup) to the age at which members of the group were first exposed.

Since currently available hazard and risk assessment methods are unable to distinguish susceptibility of children and adults in most situations, the procedures for risk assessment and determination of acceptable daily intake will apply to both children and adults. Thus, the two subjects (children and adult hazard/risk, and acceptable risk) are discussed together in this section.

b. *Acceptable daily intake (ADI) based on acceptable risk.* As mentioned above, the concept of acceptable daily intake (ADI) for a substance depends upon the projected exposure to users of a product (and possibly others affected by the product) and the estimated risks at such exposures. Thus, for any specific product the ADI of a constituent hazardous substance is defined as that exposure which leads to or is below an "acceptable risk." The recommended value of such a risk is explored below.

1. ADI for carcinogens. Although no universal figure exists, several reviewers have observed that Federal agencies, when setting a value of acceptable risk to the public for carcinogens, have often used the figure of one in a million or less. A one in a million risk means that when exposure to an agent of concern occurs, the exposed individual has an estimated additional one chance in a million during his or her lifetime of developing the deleterious effect, such as cancer. The exposure scenario being evaluated can be one use, one year's use, "normal product utility," or anticipated use over a lifetime, depending on the nature of the situation being addressed. Thus, the choice of the exposure situation evaluated is important to the concept of what risk is "acceptable." The greater the exposure, the higher the risk. Risk can be expressed in terms of exposure. For example, risk can be expressed as a risk of one in a million of developing cancer from a certain level of radon measured in a house, if the person

exposed lives in the house for a lifetime. Alternatively, risk can be expressed as lifetime risk—eating an apple treated with a pesticide every day for an entire lifetimc results in a certain risk of cancer.

Federal agencies have wrestled with the notion of "acceptable risk" for many years. The FDA in 1977 (42 FR 54148), and in 1979 (44 FR 17075), concluded that a lifetime risk of below one in a million imposes no additional risk of cancer to the public. The latter **Federal Register** notice dealt with diethylstilbestrol (DES). Since the industry was unable to show that use of DES led to risks of less than one in a million, DES was banned (Marraro, 1982). EPA has considered risks in the area of one in a million to one in 100,000 as a value for "acceptable risk," although other values have certainly been considered (Lave, 1985). The range reflects the attitude that, although the line for a specific regulatory action on a substance might normally be drawn at one in a million, there is flexibility if the benefits of the particular substance drive the definition of "acceptable risk" to a higher value. Industry has also noted the one in a million value. Mieure (1984) of Monsanto Company has stated that risks less than one in a million "are not normally considered relevant for regulatory consideration; FDA, OSHA, and EPA have all stated that substances having risks below one in a million ought not be subjected to regulation."

The Commission has also acted to require labeling at estimated risks on the order of one in a million for a carcinogen. In the case of methylene chloride, some 30 products containing this compound were identified and evaluated in terms of estimated individual risks. By and large, those products having estimated risks of over one in a million were subject to a labeling requirement under an enforcement policy, and those under one in a million were exempt from this requirement. Additionally, the Commission took an action to minimize the amount of DEHP allowed in baby pacifiers when the maximum estimated risks were within the range of one to ten in a million.

The above discussion gives examples of past, present, and proposed definitions of "acceptable risk" used by Federal regulatory agencies that center around the figure of one in a million. While the discussion does not give examples of the many other figures that have also been considered or proposed, the use of one in a million has been most prominent and also has the most precedent in the case of actions taken by the Commission and other agencies for carcinogens. Other chronic endpoints (reproductive effects and neurotoxicity) should receive a similar level of concern. Therefore, for purposes of the LHAMA (and for other products subject to the FHSA), the maximum ADI under the guidelines is that exposure of a toxic (by virtue of its carcinogenicity) substance estimated to lead to a lifetime excess risk of one in a million. The term "exposure," as used in the guidelines, refers to the anticipated exposure from normal lifetime use of the product, including use by artists, art teachers, and art students. The assessment of exposure is covered in the section on exposure in these guidelines.

ii. ADI for neurotoxicological and developmental/reproductive agents. As mentioned in the section on risk assessment, no numerical risk assessment method for neurotoxicological or developmental/reproductive agents will be specified at this time. Although other Federal agencies such as EPA are developing and considering such methods for these types of chronic agents, the development is still ongoing, and they are not ready for implementation in guidelines such as these. When implementation is feasible, the Commission will specify appropriate amendments to these guidelines.

Therefore, as an alternative, a safety factor approach is specified for handling neurotoxicological or developmental/reproductive agents. Safety factors have been used extensively in the past for non-carcinogenic substances, and even for carcinogens as late as the early 1970's. Typically, a factor of ten is applied to account for potential differences in sensitivity between humans and animals, and another factor of ten is applied to account for differences in sensitivity among humans (Hutt, 1985).

Using the safety factor approach, the ADI under the guidelines is the following. If the hazard is ascertained from human data, such as that derived from epidemiological studies, a safety factor of ten will be applied to the lowest no observed effect level ("NOEL") seen among the relevant studies. For each study, the NOEL is considered to be the highest experimental exposure or dose level at and below which no significant response is observed (presumably, the next higher experimental point reflects a significant, positive response). The ADI is then tenfold less than the lowest (among the relevant studies) of these doses or exposures. If the hazard is ascertained from animal data, the ADI is one hundredfold less than the lowest NOEL.

The above concepts require some clarification. First, in the event that the only study or studies available have significantly positive responses at all levels tested (for example, only two single-point studies are available), a NOEL cannot be determined. Therefore, in such cases, the safety factor used to determine ADI will be applied to the lowest exposure or dose yielding positive results, known as the lowest observed effect level ("LOEL"). The safety factor will include an additional factor of ten (*i.e.*, ADI's of 100 and 1000 below the LOEL for situations based on human and animal data, respectively) to account for the probability that a response would occur at a lower dose or exposure.

Second, the NOEL (or LOEL) and ADI reflect daily dose levels, that is, the NOEL (or LOEL) is calculated in terms of amount per day experienced by the animals or humans under study, and the safety factor is applied to that number to determine ADI. When a specific art material (or other material subject to the FHSA) containing a toxic substance is used, if the daily exposure during use (with use, again, referring to anticipated use pattern(s)) exceeds the ADI, the product should be labeled according to provisions of the LHAMA and the FHSA.

Third, where only specific populations are susceptible, the product is still subject to the provisions of the LHAMA and the FHSA, although any labeling would identify such populations. For example, if a developmental toxicant acts only during pregnancy, this quality would be so noted on the labeling.

VII. The Supplemental Definition of Toxic

A. The Existing Statutory and Regulatory Scheme

Section 2(g) of the FHSA defines the term "toxic" very broadly as "any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. 1261(g). This broad statutory definition covers both acute and chronic toxicity.

The Commission's regulatory definitions that interpret and supplement the statutory definitions provide specific tests that can be used to determine whether a product is acutely toxic by oral ingestion, inhalation, and skin contact. 16 CFR 1500.3(c)(2). However, there currently is no

corresponding regulatory definition to apply to products presenting a risk of chronic toxicity.

The Commission has long taken the position that the statutory definition of toxic includes both acute and chronic toxicity. Several regulations issued under the FHSA have addressed chronic hazards associated with a variety of products, such as lead (a neurotoxin), 16 U.S.C. 1500.17(a)(6), asbestos (a carcinogen), *id.* § 1500.17(a)(7), and vinyl chloride (a carcinogen), *id.* § 1500.17(a)(10). Another example of the Commission's action regarding chronic hazards is its Statement of Interpretation and Enforcement Policy on methylene chloride which notified the public that, due to risk of cancer, the Commission considered household products containing methylene chloride to be hazardous substances subject to FHSA labeling requirements. 52 FR 34698 (1987).

Congress and the courts have also recognized the Commission's authority to regulate chronic hazards under the FHSA. In *Gulf South Insulation* v. *CPSC*, 701 F.2d 1137, 1148–50 (5th Cir. 1983), the Fifth Circuit ruled that the FHSA would be the proper statute under which the Commission could ban urea-formaldehyde foam insulation if the Commission could establish a proper evidentiary basis for concluding that the product presented a cancer risk (a chronic hazard). Also, Congress indicated its expectation that the Commission would address chronic hazards through the FHSA. 15 U.S.C. 2080(b)(1)(C) and (2)(A)(iii) (CHAP to review data before Commission can ban a product that contains a carcinogen, teratogen, or mutagen).

B. The Supplemental Definition

The supplemental regulatory definition finalized today amends the regulatory definition of "toxic" to provide a definition that will include chronic toxicity, not just acute. The Commission hopes that this will clarify the definition and fill the gap in the Commission's current regulatory definition of "toxic."

The Commission is issuing the supplemental definition under the authority of section 10 of the FHSA which authorizes the Commission to issue regulations "for the efficient enforcement of this Act." Having this definition will improve the Commission's enforcement capabilities since the staff would not have to prove the meaning of chronic toxicity in each enforcement action. The Commission also believes that the definition will be helpful to manufacturers since it will clarify that chronically toxic substances are "toxic" (and must be labeled appropriately) under the FHSA. The supplemental definition discusses the particular chronic hazards of cancer, neurotoxicity, and developmental or reproductive toxicity. However, the definition is not limited to these hazards, but includes other chronic hazards.

The Commission has simplified the proposed definition. Some commenters felt that the proposed definition would eliminate the flexibility necessary to properly consider all factors affecting risk. They objected to an automatic risk level and automatic safety factors.

The Commission's intention in issuing the proposed guidelines and definition was to provide a balance of flexibility and certainty. The Commission did not intend to impose an automatic system that leaves no room for expert judgment. The general principle that determination of chronic hazards is a complex matter requiring the assessment of many factors is stated throughout the proposed and final guidelines.

After reviewing the comments and considering how the proposed definition would be implemented, the Commission decided to issue a broad definition rather than the more rigid one proposed. The final definition will clearly inform the public that chronic hazards are covered under the FHSA. It will also allow the flexibility intended by the Commission. This does not mean, however, that manufacturers will lack direction on when to label products that may present chronic hazards. The guidelines present exhaustive discussions of the chronic hazards of cancer, neurotoxicity, and reproductive and developmental toxicity, as well as the principles of exposure and risk assessment. The guidelines clearly recommend a risk level of 1×10^{-6} for carcinogens and certain safety factors for neurotoxins and reproductive and developmental toxicants. The guidelines provide that these levels should generally be followed in making labeling decisions, but they recognize that sound scientific data may warrant deviation from these levels.

Rather than requiring set risk levels, the final supplemental definition defines "toxic" as including such chronic toxicants as carcinogens, neurotoxins and reproductive and developmental toxicants.

VIII. Significant Comments and Responses

A. Comments Concerning the Codification

Comment. Several commenters expressed concern that art materials intended for adults and for use outside of the household are not covered by the Commission's interpretation of LHAMA.

Response. As explained more fully in section III.D of the preamble, the Commission construes this exclusion to be very narrow. LHAMA mandated ASTM D–4236 as a Commission rule under section 3(b) of the FHSA. Section 3(b) applies to substances intended or packaged in a form suitable for use in a household or by children. Thus, a substance that is not so packaged or intended is not covered by a section 3(b) rule. However, the Commission believes that it will be a very rare art material whose use is not anticipated in the household or by children.

This is particularly true since many artists do not separate their households from the area where they use art materials.

Comment. Some commenters stated that the final rule should clearly require a conformance statement on all art material products.

Response. As explained in section III.B. of the preamble, the Commission understands ASTM D–4236 to require that art material products that do not require chronic hazard labeling provide a conformance statement indicating that they conform to the requirements of ASTM D–4236.

Comment. A few commenters observed that the Commission needs to be able to amend ASTM D–4236 if ASTM changes any provisions of the standard.

Response. LHAMA provided for the Commission to amend the standard once it has provided an opportunity for written comments. If the change is not one initiated by ASTM, oral comments must also be permitted. The procedure for amending the standard is discussed in section III.F. of the preamble.

Comment. Several commenters noted the difficulty in defining "reasonably foreseeable or customary use" of an art material. This problem was also noted for other materials.

Response. The Commission agrees that this concept is difficult to define and may be particularly so with art materials. As the discussion in section IV.C. of the preamble indicates, the Commission has generally given a broad interpretation to the term.

Comment. Several commenters questioned the need for boardcertified toxicologists to review the formulations of art materials, and some recommended deleting this requirement from ASTM D–4236.

Response. As explained in section III.E. of the preamble, ASTM D–4236 defines the term "toxicologist" for

purposes of that standard as a board certified toxicologist or physician. The Commission can only change this requirement by the rulemaking process that LHAMA provided to amend the standard. The process for amending the standard is discussed in section III.F. of the preamble.

However, the staff does not believe that, in most instances, whether a toxicologist is board certified or not will be crucial to the analysis performed. Rather, the Commission is primarily concerned that the review is conducted by a person who has sufficient knowledge based on education, training, and experience and that the review is based on appropriate criteria. Section III.E. of the preamble explains that as a matter of enforcement policy, the Commission will not require that all art material reviews be conducted by a board certified toxicologist.

Comment. One commenter stated that no scientific and epidemiological data exist to suggest that consumers are being harmed by current use of art materials.

Response. The Commission is not asserting that any particular art material does or does not present a hazard. The guidelines set up a process to determine whether a product presents a chronic hazard. Congress has made the judgment that there is a need for a standard relating to the chronic health risk of art materials and that the Commission should develop guidelines.

Comment. Some individuals and organizations have sought clarification of the term "art material," and they have asked for some guidance on how the Commission will interpret the term as defined in LHAMA.

Response. Congress provided a broad definition of the term "art material." With the exception of certain products regulated under other statutes, the term is defined as "any substance marketed or represented by the producer or repackager as suitable for use in any phase of the creation of any work of visual or graphic art of any medium." 15 U.S.C. 1277(b)(1). The Commission has not developed any supplemental definition that would further define this term. However, some guidance on the Commission's interpretation of this term is provided in the discussion earlier in the preamble in section III.D.

B. General Comments Concerning Guidelines

Comment. One commenter suggested that the Commission should issue chemical-by-chemical "guidelines" somewhat like the lists that are developed by the state of California under Proposition 65. Similar comments suggested that the Commission develop substance-specific lists of carcinogens, sensitizers, neurotoxins, and developmental/reproductive toxins.

Response. The Commissions's action fulfills the Congressional intent behind LHAMA and is consistent with the FHSA. The Commission believes that its approach strikes a balance between the desire for certainty and the need to allow expert judgment. As explained in the preamble and the guidelines, many factors must be considered and assessments made to come to the determination that a substance is a "hazardous substance" under the FHSA. A simple list of substances would not reflect the complexities involved in this determination.

Comment. Commenters expressed views on both sides of the issue of the scope of the guidelines, that is, whether they should apply to products other than art materials. Chemical Manufacturers Association ("CMA"), for one, suggested that the Commission address non-art materials in a separate proceeding.

Response. As stated elsewhere in the preamble, the guidelines are intended to help manufacturers and others in determining whether their product presents a chronic hazard and, therefore, must be labeled under the FHSA. These same considerations are equally appropriate for art materials and for other products subject to the FHSA. The guidelines are not mandatory. Thus, to say that they only "apply" to art materials makes no sense since their use will be equally helpful to the manufacturers of art materials and of other products subject to the FHSA.

Comment. Several commenters suggested that the Commission convene a Chronic Hazard Advisory Panel ("CHAP"). CMA, for example, envisions the CHAP as a "screening mechanism" to identify particular consumer products "that deserve a full evaluation for potential chronic health risks." The CHAP would conduct hazard determinations on materials nominated by CPSC. There would be an opportunity for public comment. If warranted, the CHAP would assess potential exposure and, if there was significant exposure potential, conduct a risk assessment. The CHAP would then make recommendations to CPSC regarding labeling. CSMA recognized that the Commission is not required to consult a CHAP before issuing the guidelines, but suggested this "as a matter of sound administrative practice." Another commenter suggested that the Commission should establish a CHAP to review the need to expand the chronic hazard guidelines to product categories other than art materials

Response. As explained more fully in section V.B. of the preamble, the Commission must establish a CHAP in certain specified situations. The only action under the FHSA that requires the Commission to consult a CHAP is rulemaking to ban a particular substance.

In issuing these guidelines, however, the Commission is not promulgating a binding rule, is not seeking to ban a substance, and is not taking action with respect to any particular substance. The CHAP's purpose is to review particular products and substances. CHAP review is not appropriate in this case. The chronic hazard guidelines do not relate to any particular products or substances, but they provide guidance for determining, in general, whether a product can present a chronic health hazard.

Comment. In a somewhat similar vein, some commenters suggested that the Commission should regulate chronic hazards under the CPSA rather than the FHSA. They thought that the Commission should address specific consumer products and consult CHAPs in the process of doing this.

Response. As discussed in the preamble, the FHSA provides authority for the Commission to regulate chronic hazards. Although the Commission may have the authority to proceed under the CPSA, the FHSA is the more appropriate statute. The FHSA specifically requires the labeling of hazardous substances. The Commission has acted in the past to provide for chronic hazard labeling under the authority of the FHSA (e.g., methylene chloride). In fact, if the Commission were to issue chronic hazard guidelines under the CPSA, it may have to first issue a rule under section 30(d) of the CPSA finding that it is in the public interest to proceed under the CPSA rather than the FHSA.

Comment. CMA commented that the Commission has not given adequate notice to extend the chronic hazard guidelines from art materials to other products covered by the FHSA. CMA stated that the proposed guidelines did not adequately explain the Commission's authority and did not address the economic effects of the extension.

Response. The Commission believes that adequate notice was provided. The proposed guidelines clearly stated that because the scientific principles behind the guidelines are not affected by the types of products under consideration, manufacturers could use the proposed guidelines to aid their determination of whether a product covered by the FHSA presents a chronic hazard. The

commission received 47 written comments, including several on the very issue of the scope of the guidelines, and 15 people presented testimony at the public hearing in October.

Moreover, as explained in the preamble, the chronic hazard guidelines are not mandatory and are not being issued as substantive, binding rules. Rather, they are intended as guidance for manufacturers and others who must determine if their product requires labeling under the FHSA.

The Commission believes that it has adequately addressed the economic effects of the chronic hazard guidelines. The guidelines impose no new requirements on manufacturers. It is the FHSA that requires proper labeling of hazardous substances. The guidelines represent the CPSC's interpretation of the current scientific concensus regarding chronic health hazard assessment. Furthermore, the guidelines do not require any review of non-art materials by a toxicologist. This is a requirement of LHAMA and is directed exclusively at art materials.

Some commenters, including CMA may incorrectly believe that toxicological review would be required of all products subject to the FHSA. The requirements associated with the codification of the ASTM D–4236 apply only to art materials.

Comment. Several commenters stated that the Commission should clarify that chronic hazards covered by the FHSA are those that have the potential for "substantial" injury or illness.

Response. The FHSA definition of "hazardous substance" at issue in these guidelines does concern substances that may cause "substantial personal injury or substantial illness." 15 U.S.C. 1261(f)(1). The Commission's regulatory definitions provide guidance in interpreting this term. The applicable regulation states: "Substantial, personal injury or illness' means any injury or illness of a significant nature. It need not be severe or serious. What is excluded by the word 'substantial' is wholly insignificant or negligible injury or illness." 16 CFR 1500.3(c)(7)(ii).

C. Comments On Scientific Issues of the Guidelines and Definition

I. General

Comment. Commenters noted that it is important to keep the guidelines flexible and that rigid adherence to default factors (i.e., numerical factors to be used in the absence of data for the particular substance or circumstances) should not be required.

Response. The guidelines are intended to be flexible. This is stated very clearly in the guidelines as proposed and finalized. Default assumptions such as those used in exposure and risk assessment are, by definition, to be used in the absence of appropriate data. The guidelines permit the replacement of default assumptions with data-based alternatives. Alternative approaches should be scientifically defensible and supported by appropriate data.

Comment. Some commenters suggested that the guidelines should clarify that lack of significant bioavailability (or exposure) of a substance that would otherwise be a chronic toxicant will result in that substance being exempt from consideration as a "hazardous substance" under the FHSA.

Response. The proposed guidelines explained that for a substance to be a "hazardous substance" under the FHSA it must have the potential to be toxic and present a significant risk of adverse health effect through customary or reasonably foreseeable handling or use. The proposed guidelines also explained that this second factor reflects the person's exposure to the toxic component or the component's bioavailability. 56 FR 15674. The final guidelines reiterate this point.

Comment. Several commenters suggested that CPSC should specify using a species extrapolation method based on body weight since the use of the proposed "surface area correction" is not supported by the science.

Response. The science does not more strongly support one specific choice for a species extrapolation factor over another. Such a factor is commonly used to predict human cancer risks on the basis of results in animals. It is generally agreed that the best choice for such a factor lies within the range of the body weight method cited by the commenters, and the "surface area" method proposed in the guidelines. The FDA has used the body weight method in the past, and CPSC and the EPA have used the "surface area" method.

However, CPSC staff has been working closely with EPA, FDA, OSHA, and other Federal agencies to adopt a unified approach for species extrapolation (a factor related to weight ratio of humans and animals to the three-fourths power, which is in the middle of the range previously described). The guidelines state that this approach should be used when the unified Federal effort is adopted. There is extensive scientific justification and much peer review associated with this process. The Commission does not believe any change to this discussion in the proposed guidelines is warranted.

Comment. A few commenters stated that CPSC proposes to select data which produces the highest risk estimate. They suggested that the CPSC should encourage users to evaluate all appropriate data sets, and that the most scientifically relevant data, preferably human epidemiology, should be regarded as the key data to use for dose-response modeling.

Response. The proposed and final guidelines do not specify using data that produce the highest risk estimate. In choosing which data sets will serve as the basis for risk estimates, toxicologists should review all the data. The guidelines state that expert judgment is to be used in this, as well as in the many other choices which are part of the risk characterization process. For example, a method is presented which combines the results from different sexes, as opposed to only calculating risk from the highest responding sex. Furthermore, statements are made within the guidelines indicating that human epidemiology, when adequate, is the preferred source of data for human risk characterization.

Comment. Several commenters objected that the proposed definition of "toxic" would remove flexibility and require automatic application of a specified risk level for carcinogens and safety factors for other chronic toxicants.

Response. After considering these comments and how the proposed definition would work in practice, the Commission decided to revise the definition so that it defines "toxic" with respect to chronic toxicity but does not specify particular trigger levels. The definition is discussed in section VII of the preamble.

2. Cancer

Comment. Several commenters suggested that the guidelines' consideration of benign tumors as evidence of carcinogenicity should be similar to the approach of the Environmental Protection Agency and the International Agency for Research on Cancer (IARC), which consider such tumors as "limited evidence," and not "sufficient evidence." The grouping of benign and malignant lesions, they assert, is controversial and is only appropriate when certain criteria, like histogenic cell type, are met.

Response. The basis for considering benign tumors as part of "sufficient evidence" under certain conditions, and combining benign tumors with malignant tumors was discussed in the proposed guidelines. The CPSC believes that a benign tumor, if it has the potential to progress to malignancy, or is

life-threatening, should be considered to have the same potential health risk as if it is a malignant tumor. Current information supports combining benign and malignant tumors when scientifically defensible (e.g., same cell type in an organ or tissue). This is one of the principles of the consensus document proposed by Federal government agencies under the aegis of the Office of Space and Technology Policy. As it is rarely found that chemicals cause only benign tumors (in a review of 300 National Toxicology Program bioassays by Huff in 1988), the CPSC staff believes since a benign tumor may be life-threatening itself, or may be transitioning to malignancy, it should be treated as a malignant tumor unless there is adequate evidence showing that these possibilities are unlikely to occur.

Comment. Several commenters observed that increased tumor incidence at independent multiple sites are not necessarily independent observations and should not be treated as such in the guidelines. Tumors resulting from metastasis are not considered as separate tumors. Significance of multiple site tumors should be considered in the same way as that by EPA.

Response. The issue of tumors produced at multiple sites was discussed in the proposed guidelines. The phrase "sites of independent origin" means independent cancers which originate at unique sites and not that the same cancer metastasizes to a different site where cancer is reestablished. Thus, metastasis of a primary tumor to different sites will not be counted as different primary tumors because they would not have independently originated. The staff believes that the ability of a chemical to independently produce tumors at multiple sites indicates that the chemical has a wider range of carcinogenic potential similar to such an indication from responses in multiple strains, species, or experiments. No information was found in the comments to warrant any change in this position.

Comment. Several commenters stated that according to the Commission's proposals, a single study in humans which shows only limited evidence, or a study in animals which shows "sufficient evidence," is all that is required to determine that a substance is toxic under the FHSA due to chronic toxicity. They observed that in general, consistent findings from multiple human studies or multiple species are necessary to ensure valid hazard identification for this type of toxicity.

Response. Evidence from a study or studies taken together must be evaluated by the toxicologist. If a single extremely well conducted, non-biased study shows a powerfully significant effect, it by itself can serve as a basis for "sufficient evidence" of a toxic effect.

Epidemiological studies are very complex, and generally have inherent problems, such as exposure to multiple chemicals and problems ascertaining exposure. Much of this complexity leads to the evidence falling into the "limited evidence" category. CPSC staff believes that an epidemiological study or studies, which provides convincing evidence of a causal relationship between the incidence of cancer (or other chronic effects) and exposure to a chemical, but in which chance, bias, or other confounding factors could not be absolutely ruled out (limited evidence), may warrant the characterization of a chemical as toxic (probable human carcinogenic substance) under the FHSA. The criteria in these guidelines are not intended to be mechanically applied, but rather should be interpreted with the exercise of expert technical judgment. A single animal study with a response at only one dose will not normally lead to a conclusion that the substance is "toxic" under the guidelines.

Comment. Several commenters suggested that a "weight of the evidence" approach used by EPA should be followed in place of a "strength of the evidence" approach used by IARC in categorizing the evidence. CPSC, they observed, seems to have adopted the "strength of the evidence" approach. The commenters suggested that the guidelines should emphatically direct the consideration of all available information, including tests that show negative responses, as part of any evaluation.

Response. Both approaches include evaluation of all the available data regardless of the positive or negative results. CPSC's approach, which is not designated by any name, is similar to that of EPA and IARC; it also includes evaluation of all the available data. CPSC's approach does require a certain amount and quality of positive data before a finding of "toxic" can be made, but CPSC's guidelines also state that certain data and evidence can negate the impact of the positive data. The Commission believes that the approach adopted in the guidelines to evaluate carcinogens is a sound one, because it allows consideration of all the available data and not just the positive data.

3. Neurotoxicity

Comment. Numerous commenters noted that since LHAMA is concerned with only chronic effects, acute neurotoxic effects should not be considered. Discussion in the proposed guidelines on neurotoxicity, they stated, is too broad and would cover everything including water. Consideration should be limited to the agents which primarily affect the nervous system; only direct neurotoxic effects should be included in the definition. Effects due to overdosing, or alterations from baseline should not be considered as an indication of neurotoxicity unless statistical significance can be demonstrated.

Response. The guidelines do address only chronic effects. The nervous system is integrally connected to the functioning of all the other systems in an organism, which complicates the interpretation of neurotoxic effects. Effects can be chronic under several circumstances. These include long-term exposure followed by the effect, short-term exposure followed by an effect occurring at some time in the future, and an immediate effect due to short-term exposure which then lasts for a prolonged period of time. "Acute" in this case would refer to only those immediate effects, from short-term exposure, which are rapidly and completely reversible. The terms "short," "prolonged," and "immediate" are general guides to the interpreting toxicologist, who must decide from the nature of the studies if the effect is acute or chronic.

Comment. Several commenters stated that defining "sufficient evidence" by statistics is not appropriate since some results may be statistically significant due to random variability. They suggested that results must be statistically significant and biologically plausible, that "limited evidence" should also require biological plausiblity, and that the "possible neurotoxic substances" class should be deleted. Neurotoxicity criteria, they commented, are impractical to determine an appropriate hazard warning.

Response. Although it is possible that some neurotoxicity findings may be the result of false positives, this is accounted for by the guidelines. For human studies, the studies must be of high quality, and bias (which could lead to a false positive) must be considered. For animal studies, the effects must be statistically significant in more than one good quality study. Expert technical evaluation includes examination of reliability, sensitivity, and validity along with the requirement that a study should be well designed and conducted. Biological plausibility is a factor that increases confidence in a result, but by no means is it a prerequisite for using

the study as a basis for a finding of toxicity. In addition, it is clearly stated that evidence derived from animal studies that has been shown not to be relevant to humans is not included in the consideration of the neurotoxicity of a substance. The "possible neurotoxic substances" class is important to retain because it could indicate that more work is necessary on a particular chemical, and it gives the basis why the current evidence is not sufficient to conclude that a substance is toxic.

4. Reproductive and Developmental Toxicity

Comment. Some commenters stated that it is inappropriate to list a chemical in the "sufficient" category if it has been found to be active in only one species, regardless of the number of endpoints. A single statistically significant endpoint is not "sufficient" evidence to classify a material as a reproductive or developmental toxicant.

Response. The staff believes a good quality study with significant changes in multiple endpoints using multiple doses, routes of administration, or strains, constitutes a degree of toxicity in animals that is predictive of probable harm to humans and thereby warrants further assessment of exposure, risk, and bioavailability. If an effect occurs more than once (at two dose levels or two sites, for example), or if there are multiple effects, the possibility that the observed reproductive or developmental toxicity is an anomoly is greatly reduced.

Comment. Some commenters stated that maternal toxicity and its relationship to developmental toxicity should be evaluated and integrated into the interpretation of a study. Developmental toxicity, they stated, should not be automatically discounted as secondary when it is associated with maternal toxicity.

Response. The Commission agrees with this comment. The proposed guidelines stated "maternal toxicity * * * must be evaluated and accounted for in the interpretation of a study. The toxic effect(s) observed in a positive study *should* be significant at one or more doses in the absence of maternal toxicity." 56 FR 15684 (emphasis added). The final guidelines have been revised to clarify this point and state that toxicity is not automatically discounted as secondary when associated with maternal toxicity.

5. Bioavailability.

Comment. One commenter observed that CPSC proposes to set the dermal penetration rate for chemicals present in mixtures at 100 percent. CPSC should require skin penetration rates based on the physical-chemical characteristics of an art material, the commenter stated. While direct measurement of the skin penetration is desirable, in numerous instances it is impractical. Alternatively, other indirect approaches must be relied upon to estimate systemic doses from skin contact; and any default value, particularly one as severe and overly simplistic as 100 percent, must be left to rare and extreme circumstances.

Response. The proposed CPSC bioavailability guidelines did not set the dermal penetration rate for chemicals at 100 percent. In fact, the guidelines as proposed and finalized specify the use of indirect approaches, including use of physicochemical data, to estimate dermal bioavailability where appropriate. The proposed guidelines, at section III.F.2.c.i (56 FR 15590) clearly indicated that either a default value may be assumed or a bioavailability assessment may be performed. That paragraph also states that "the default value should be used when there are no adequate data which would lead to an alternative approach." The following paragraph of the proposed guidelines generally describes the alternative approaches and the conditions under which they can be used to estimate bioavailability.

The type of data which may be used in a quantitative bioavailability assessment are discussed in subsection (b) of VI.F.2.c.i. A number of acceptable methods of measuring dermal penetration are also specifically identified in the technical support document for the bioavailability guidelines available through the CPSC's Office of the Secretary. They include *in vivo* bioavailability studies, isolated perfused skin studies, *in vitro* studies using excised skin, physiologically based dermal absorption models, surrogate data such as octanol:vehicle partition coefficients and bioavailability data from surrogate compounds. It is stressed throughout the guidelines that all factors expected to affect dermal penetration must be considered in the assessment. This is especially important when bioavailability is based on *in vitro*, surrogate compound, or physicochemical data.

Comment. One commenter states that in the proposed guidelines, CPSC fails to acknowledge the range of information that may be relied upon to make estimates of systemic doses from skin contact with chemicals reliably in the absence of direct empirical measurements. The information lacking from CPSC's proposed guidelines, the commenter states, includes viscosity of a chemical mixture, the molecular weight of each substance, the polarity of each substance in a mixture, and the lipophilicity of each compound.

Response. This comment is incorrect. Section III.F.2.c.ii(c) of the proposed guidelines (56 FR 15694) acknowledged a large number of factors that impact dermal bioavailability including three of the four examples cited in this comment. Lipophilicity, molecular size, and degree of polarity are all discussed in the second paragraph of the section as important chemical-specific determinations of dermal absorption.

This section of the guidelines describes several vehicle-specific determinants of dermal absorption but does not include viscosity. The commenter claims that "high viscosity acts as a barrier to absorption through the skin" based on "many incidental observations" related to pen and marker inks. The staff is unaware of scientific data that show viscosity retards skin penetration, although it is generally recognized that viscosity will affect dermal migration (migration of a substance from a product to the skin surface). Dermal migration is discussed in the guidelines for assessing exposure (VI.F.1.c.iii). Finally, the fourth paragraph of the skin permeability section describes the major physiological and other factors expected to influence dermal absorption. Hydration of the stratum corneum and volatility of the mixture, also mentioned elsewhere by the commenter, are discussed in that section.

Comment. One commenter asked how a hazard can be established and estimated when the exposure is infinitesimally smaller than doses known to produce any effects in animals. The commenter stated that hazards are estimated by direct exposure to a substance regardless of the route of exposure, and, more often than not in art materials, the particular ingredients of concern are not readily bioavailable.

Response. This comment is interpreted to question the basis on which CPSC can ever consider ingredients contained in art materials as hazardous when: (a) Users are exposed to much smaller amounts of these substances than cause adverse effects in experimental animals, and (b) the routes of human exposure to art materials are often such that the ingredients would not be readily bioavailable.

The first part of the question was addressed in section III.F.4.b of the proposed guidelines on acceptable daily intake. The ADI is the maximum daily dose of a chronically toxic substance (as determined by other sections of the

guidelines) to which a person can be exposed without presenting an unacceptable risk of injury and illness. The ADI will usually be considerably less than the dose observed to cause an adverse health effect in animals as discussed in subsection (i) and (ii) of this discussion in the guidelines. This is because the observed adverse effect levels in animals, in most instances, have to be adjusted (1) to assure that the toxicity observed at the high levels is acceptably reduced or eliminated at the human exposure levels, (2) to protect for the possibility that humans may be more sensitive to the toxic effect at equivalent administered doses, and (3) to account for the larger expected variation within the human population. Unfortunately, scientific data on which to determine the magnitude of these adjustments are rarely available, necessitating the use of assumptions based on longstanding policies within the regulatory community. However, the guidelines indicate that these assumptions should be replaced with biologically-based approaches when there is valid and convincing scientific evidence that an alternative is clearly superior.

The second part of the comment is addressed within the guidelines for assessing bioavailability. That section of the guidelines describes the situations in which there is a need to assess bioavailability, including when it is anticipated that the routes of human exposure to a toxic substance will differ from those used in an animal toxicity study.

If it is true that exposure to ingredients within art materials are "infinitely smaller" than the doses that produce chronic toxicity in animals and that the ingredients of concern are not bioavailable, then of course there is no hazard. However, this needs to be established through the hazard assessment process.

6. Exposure Assessment.

Comment. One commenter suggested that exposure assessment should be done in accordance with handling instructions on the product package, such as, "use with adequate ventilation."

Response. ASTM D–4236 states that reasonably foreseeable misuse should be considered in assessing risk. Use with inadequate ventilation, for example, is likely to be reasonably foreseeable. Commission regulations also state that under the FHSA "reasonably foreseeable handling or use" includes foreseeable accidental handling or use. 16 CFR 1500.3(c)(7)(iv). Thus, in the context of LHAMA and the FHSA, exposure assessment should not be limited to the manufacturer's instructions.

Comment. Two commenters suggested that CPSC eliminate consideration of incremental exposures when judging the need to label an art material, as suggested in the guidelines for assessing exposure. This provision, they stated, is impractical and unnecessary, and CPSC fails to provide adequate guidance for its implementation. They stated that it will create confusion among users if a product is labeled due to incremental exposures from other sources.

Response. It is often impractical to consider exposures from other sources, although it is sometimes desirable to do so. One example is products containing lead since there is an existing background level near the point where an effect can occur. However, in the context of LHAMA and the FHSA, the focus is clearly on individual products. The proposed guidelines stated in the discussion only that "it may be useful" to define what portion the product-specific exposure is of the total environmental exposure, but the discussion acknowledged the difficulties. The final guidelines clarify that assessment of exposures from other sources is not required, but should generally be noted. Whether other sources should be considered must be determined on a case-by-case basis.

7. Risk Assessment.

Comment. Several commenters objected to CPSC's proposal in the chronic hazard guidelines that an additional ten-fold safety factor be applied to products intended for use by children for all chronic endpoints when calculating the acceptable daily intake, to account for the possibility that children may be more sensitive than adults. Several stated that this was not supported by the scientific data. Some commenters stated that this additional ten-fold factor would have an adverse economic impact on the art materials industry, especially on manufacturers of unleaded glazes used for ceramics. As a result of this safety factor, they stated, 92 product lines which currently do not require warning labels under the Art and Craft Materials Institute's review program will be required to carry warning labels.

Response. As discussed in section IV.E. of the preamble, the Commission has decided not to include additional safety factors for children's products in the final guidelines and definition.

Although children may be more susceptible to many substances than adults, it may be difficult to differentiate between products for children and those for adults, particularly in the area of art materials. This could result in a more widespread use of the ten-fold safety factor than the Commission had intended.

Even if CPSC's proposed ten-fold safety factor were implemented, however, it is questionable whether the extra safety factor for children would actually affect the labeling status of unleaded glazes. According to Dr. Stopford (ACMI's consulting toxicologist), ACMI applies safety factors of its own to risk assessments involving children. In many cases, the ACMI safety factors, which are not required in the proposed guidelines, may be equivalent to or greater than CPSC's proposed ten-fold safety factor. In effect, ACMI's toxicologist has applied redundant safety factors and, as a result, has overestimated risk.

Multiple overestimations of exposure, in total greater than a factor of ten, have been incorporated by ACMI's analysis; these would not be used if CPSC staff were to do the analysis. Of course, ACMI's overestimation of exposure is intentional. It is its means of providing an additional safety factor for children.

In addition, for assessing cancer risk, according to Dr. Stopford, ACMI assumes that children are exposed for 70 years. In comparison, the Directorate for Health Sciences would assume that a child is exposed to a children's product only during childhood. If childhood is considered to last for ten years, then ACMI in effect is applying a seven-fold safety factor of its own which is not directed by CPSC's guidelines. Taken together, ACMI's self-imposed seven-fold safety factor and the 1×10^{-7} acceptable risk directed by the CPSC guidelines, are equivalent to a 70-fold safety factor, while the proposed guidelines required only a ten-fold factor.

Comment. Several commenters stated that the Commission's guidelines and rules should be consistent with those of other agencies, such as OSHA, EPA, and FDA.

Response. Congress mandated the voluntary standard as a Commission standard. The Commission cannot change these provisions without going through the amendment procedures specified in LHAMA. The CPSC's chronic hazard assessment guidelines are almost entirely consistent with the guidelines and methodologies of other agencies, including those mentioned by the commenters. Some of the differences relate to what is required by Congress; for example, LHAMA requires CPSC to address the determination of acceptable daily intake for chronic hazards.

The few technical differences between CPSC and other agencies have been carefully considered by CPSC. For example, two major differences between CPSC's guidelines and EPA's guidelines are the use of benign tumors and the treatment of tumor responses at multiple sites. EPA, which is in the process of revising its cancer guidelines, is reconsidering its position on these two points. It is quite possible that EPA's revised guidelines will be in agreement with CPSC's on these points.

CPSC is working with other agencies to harmonize risk assessment methodologies. For example, CPSC staff has been working with EPA, FDA, and OSHA to adopt a uniform approach for species-to-species extrapolation. CPSC's proposed guidelines state clearly that the uniform approach (body weight ratio to the three-fourths power) will be used when the proposal is finally adopted.

Under the Hazard Communication Act, OSHA may require manufacturers to warn workers if there is a single, well designed study showing a statistically significant effect for a health hazard such as cancer. The toxic potency and exposure are not necessarily considered, as they are under LHAMA and the FHSA. Therefore, it is possible that a product could require a warning in the workplace, but not require a label when sold as a consumer product. Occupational exposures are typically greater than consumer exposures from similar materials.

Regarding labels themselves, the Commission is not requiring any labeling beyond what is required by LHAMA and FHSA. The staff is revising its 1979 labeling guide so that it will provide guidance on developing chronic hazard labeling.

D. Comments Concerning Labeling

Comment. CMA suggests that the Commission adopt the ANSI standard for Hazardous Industrial Chemicals (Z129.1–1988) for precautionary labeling of chronic hazards.

Response. The Commission is not prescribing particular labeling requirements. Some requirements for art materials are mandated by LHAMA. Other materials must adhere to the requirements of section 2(p) (1) of the FHSA and regulations previously issued under that authority (e.g. for prominence, placement, and conspicuousness at 16 CFR 1500.121). The staff will, in the future, develop some general guidance about the design and content of labels warning of chronic hazards.

Comment. Several commenters noted that while the proposed guidelines and supplemental definition of toxic would apply to all products subject to the FHSA, not just art materials, the Commission did not include additional labeling requirements for what the chronic hazard labels should say except in the case of art materials.

Response. Neither the guidelines nor the definition specify labeling requirements beyond those already in force under the FHSA. ASTM D–4236, now codified as a Commission standard for art materials, does provide some examples of labels that may be appropriate to warn of chronic hazards. These warnings may also be appropriate for other products subject to the FHSA that present a chronic hazard. However, the suggested labeling may not be sufficient to satisfy all the requirements of section 2(p)(1) of the FHSA for art materials or other household products, especially mixtures containing various chemicals. It is the manufacturer's responsibility to determine the product's characteristics and to design appropriate labeling. The staff is in the process of revising its 1979 labeling guide for products that present an acute hazard. The updated version will provide guidance on developing warning statements for products that pose a chronic hazard.

Comment. One commenter suggested that since it is not known how various components of art materials interact, the most informative labeling might be to state "Contains (name of toxic substance). Use this product with caution and as intended or instructed."

Response. Art material mixtures may be more or less hazardous than the components themselves because of synergistic or antagonistic reactions. For this reason, labeling may not reflect the true effect of the mixture if it is based on the extent to which one component is a carcinogen, neurotoxicant, or reproductive or developmental toxicant. Moreover, as explained in the guidelines, bioavailability and exposure must be considered. Labeling of art materials should be accurate and as specific as possible in terms of precautionary statements and consequences of ignoring the warning. Specificity increases the likelihood that users would take precautionary measures and reduces the likelihood that the product will be used in a manner perceived as safe, but which may not include the appropriate safety measures. Thus, mixtures should be evaluated based on existing scientific data so that the label can reflect the true nature of the hazard.

E. Comments Concerning Economic Impact

Comment. Some commenters expressed concern about the burden that would be placed on each manufacturer having products assessed by toxicologists and submitting to the Commission assessments of the potential chronic hazard of each product. Additionally, if a product were mistakenly required to have chronic hazard labeling under the guidelines, this would be tantamount to banning the product, since no consumer would buy the product. Thus, the guidelines should be carefully thought through. CMA suggested that the Commission issue a separate notice of proposed rulemaking to address such economic concerns.

Response. The preamble attempts to clarify that the requirement that a manufacturer provide a toxicologist with formulations of the manufacturer's products and that the manufacturer submit to the Commission the criteria used to determine chronic toxicity only applies to art materials. As discussed in the preamble, with products other than art materials, it is the manufacturer's responsibility to see that products are properly labeled, but the means used to reach this goal are left to the manufacturer. The guidelines impose no labeling requirements beyond those already in existence in the FHSA.

Even with art materials, however, LHAMA and ASTM D–4236 do not require a risk assessment of each product be submitted to the Commission. Rather, the producer or repackager of an art material must provide the Commission with a summary of the criteria a reviewing toxicologist uses to determine chronic toxicity and a list of those specific products that require chronic hazard labeling.

Manufacturers who have credible reasons to believe that their products are safe or else are applying the appropriate warning labels, would not need to reevaluate their products against the guidelines. The guidelines and supplemental definition, in and of themselves, do not increase the regulatory burden on manufacturers. The labeling of hazardous substances is mandated by the FHSA, not by the guidelines. The choice of means used for evaluating the hazardousness of a product is left to the manufacturer. However, because failure to properly label a hazardous substance is a violation of the FHSA, and because unnecessary labeling of non-hazardous products may put the firm at a competitive disadvantage, it is in the

firm's interest to have a "carefully thought through" method for evaluating its products. The guidelines and definition should aid the manufacturer in the determination that a product must be labeled under the FHSA. As the preamble and other responses to comments explain, the Commission has given a great deal of thought to the guidelines and definition. The Commission believes that it has adequately addressed the economic concerns expressed and that a separate rulemaking is unnecessary.

Comment. Two commenters requested that the Commission extend the effective date of the final guidelines and definition to six months or one year rather than the 90 days proposed. They stated that additional time is necessary for manufacturers to ensure labeling compliance without excessive hardship.

Response. Neither of the commenters requesting an extension of the effective date are producers of art materials. Thus, only the guidelines and supplemental definition of toxic would apply to these commenters. The guidelines and definition do not impose new requirements on manufacturers of consumer products subject to the FHSA. Therefore, manufacturers of consumer products will not incur additional costs solely because of the adoption of the final guidelines and definition. It is possible that in reviewing the guidelines and definition, a firm may realize that its interpretation of the FHSA requirements has been in error and will incur costs correcting its mistake. However, these costs would be incurred whenever and for whatever reason a firm discovered that it was not in compliance with the FHSA. Furthermore, one of the above commenters stated that it has already "conducted extensive testing to ensure the safety of [its] products and has not discovered any chronic hazard concerns." If responsible evaluation has occurred, the firm is likely to be in compliance with the FHSA. The Commission does not believe that there is any economic justification to extend the effective date.

F. Comments Concerning all Actions

Comment. Several comments raised the issue of preemption. Some commenters stated that the proposed rules might lend strength to an argument that they would preempt state laws dealing with toxic chemicals, and these commenters requested the Commission to state that the rulemaking would not preempt state law. Other comments requested the Commission to indicate that its actions would preempt state law.

Response. The issue of preemption is quite complex and cannot be resolved simply by stating that all contrary state laws are or are not preempted. As the preamble explains more fully, under section 18 of the FHSA, a cautionary labeling requirement under section 2(p) or 3(b) of the FHSA designed to protect against a risk of injury or illness associated with a hazardous substance would preempt non-identical state or local cautionary labeling requirements applicable to that hazardous substance and designed to protect against the same risk of injury or illness. LHAMA mandated ASTM D–4236 as a Commission rule under section 3(b) of the FHSA. As a labeling requirement under section 3(b) of the FHSA, it has preemptive effect in the circumstances stated in section 18(b)(1)(A).

The final chronic hazard guidelines, however, are not mandatory and do not themselves impose any cautionary labeling — requirements. The requirement to place hazard labeling on a substance that is a "hazardous substance" comes from sections 2(p) and 3(b) of the FHSA. The guidelines, in contrast, are an aid to manufacturers and producers in determining whether a product is a hazardous substance. Thus, the guidelines themselves would not directly preempt any non-identical state guidelines.

The supplemental regulatory definition of "toxic" is not itself a cautionary labeling requirement. However, it does work with the labeling requirements under section 2(p) and 3(b). The regulatory definition in itself does not have direct preemptive effect, but the labeling requirements under sections 2(p) and 3(b) would preempt state and local labeling requirements that applied to hazardous substances (as defined in the FHSA and its regulations) covered by section 2(p) or 3(b) and designed to protect against the same risk.

Comment. An ancillary comment was made that the labeling requirements under the FHSA are too weak and vague to preempt state laws.

Response. The requirements of the FHSA are not vague. The FHSA defines the term "misbranded hazardous substance" at section 2(p)(1)(E) as a hazardous substance that "fails to bear a label (I) which states *conspicuously* * * * an affirmative statement of the principal hazard or hazards, * * * or similar wording *descriptive* of the hazard" (emphasis added). This means the labeling must communicate to the consumer an understanding of the potential principal hazard or hazards presented by the product in order to avoid being misbranded and subject to legal action.

In some cases simply restating the defined hazard, such as "FLAMMABLE" will provide a meaningful statement of hazard. In other cases, more descriptive language is necessary, such as for corrosive hazards, statements like "CAUSES BURNS" or "CAUSES SEVERE BURNS" are required to satisfy the FHSA.

The cautionary labeling required under the FHSA must present a balanced perspective of the potential hazards of the product. Many products which may cause chronic health effects may also be acutely toxic and present physical hazards, such as flammability. The suggested labeling for methylene chloride paint strippers had to take into consideration the product's acute inhalation toxicity in addition to the carcinogencity hazard. Therefore, the suggested front panel label statement is "VAPOR HARMFUL" with the instruction "Read Other Cautions and HEALTH HAZARD INFORMATION on back panel" and the back panel statement is "Contains methylene chloride, which has been shown to cause cancer in certain laboratory animals." For products where the only hazard is carcinogenicity and the evidence of increased risk of cancer to humans is clear, the labeling would be more straight forward. In its policy statement regarding the labeling of asbestos containing consumer products, 51 FR 33911, September 24, 1986, the following signal word and statement of hazard were suggested as adequate for asbestos cement sheet products, "WARNING: BREATHING FIBERS MAY CAUSE CANCER" with the hazardous component declared as "Contains asbestos which is known to cause cancer in humans."

Comment. The Chemical Manufacturers Association ("CMA") commented that the Commission should provide explicit protection for trade secrets.

Response. Again, there is confusion over requirements of ASTM D–4236 for art materials and requirements for other products. The requirement to submit formulation data to a toxicologist and the determining criteria to the Commission applies only to art materials. Thus, the protection of trade secret information is not as wide-spread a problem as some may have believed. A provision of ASTM D–4236, now codified at 16 CFR 1500.14 (b)(8)(i)((C)(2), states that only the reviewing toxicologist shall have access to the product formulation submitted for review. There is an exception if written

permission is given or if the data are provided on a confidential basis to a physician for purposes of diagnosis or treatment.

Section 2(p)(1) of the FHSA requires that the name of the hazardous substance be listed on the label. This is a statutory requirement and is not something the Commission can change. Listing the generic name is acceptable. There is no requirement to spell out the product formulation or the amount of the hazardous substance.

As for submission of data to the Commission, in general, the Commission does provide for protection of trade secret or proprietary information submitted to it if the material is so marked (16 CFR 1015.18). These provisions would apply to the information submitted by art material producers or repackagers under LHAMA, as well as others subject to the FHSA.

IX. Effective Dates

In order to allow sufficient time for manufacturers and packagers to evaluate the guidelines and supplemental definition, the guidelines and definition will take effect 90 days after publication. The final guidelines and definition will apply to products initially introduced into commerce on or after the effective date. The codification of ASTM D–4236 (§ 1500.14(b)(8)) will be effective upon publication.

X. Environmental Considerations

These actions are unlikely to have any effect on the quantity or physical characteristics of, or other changes in, product, materials, or packaging that could impact the environment beyond normal formulation, packaging, or promotional changes currently common among these producers of art materials and other products subject to the FHSA. Therefore, the Commission concludes that the guidelines, definition, and codification will have little or no potential for affecting the human environment and that neither an environmental assessment nor an environmental impact statement is required. See 16 CFR part 1021.

XI. Regulatory Flexibility Act Certification

The Commission is finalizing guidelines which will provide guidance for determining when a product presents a chronic hazard based on animal or human data. The supplemental definition of "toxic" reflects these guidelines and clarifies the meaning of chronic toxicity. The Commission is also codifying the provisions of ASTM D–4236 which Congress mandated as a Commission standard.

The Commission certifies that the guidelines, definition, and codification will not have a significant economic effect on a substantial number of small entities, and therefore no regulatory flexibility analysis need be prepared

List of Subjects in 16 CFR Part 1500

Arts and crafts, Consumer protection, Hazardous materials, Hazardous substances, Imports, Infants and children, Labeling, Law enforcement, Toys.

For the reasons discussed above, the Commission amends 16 CFR part 1500 as follows:

PART 1500—[AMENDED]

1. The authority citation for part 1500 is revised to read as follows

Authority: 15 USC 1261–1277

2. A new § 1500.135 is added to read as follows:

§ 1500.135 Summary of guidelines for determining chronic toxicity.

A substance may be toxic due to a risk of a chronic hazard. (A regulatory definition of "toxic" that pertains to chronic toxicity may be found at 16 CFR 1500.3(c) (2).) The following discussions are intended to help clarify the complex issues involved in assessing risk from substances that may potentially cause chronic hazards and, where possible, to describe conditions under which substances should be considered toxic due to a risk of the specified chronic hazards. The guidelines are not intended to be a static classification system, but should be considered along with available data and with expert judgment. They are not mandatory. Rather, the guidelines are intended as an aid to manufacturers in determining whether a product subject to the FHSA presents a chronic hazard. All default assumptions contained in the guidelines on hazard and risk determination are subject to replacement when alternatives which are supported by appropriate data become available. The following are brief summaries of more extensive discussions contained in the guidelines. Thus, the guidelines should be consulted in conjunction with these summaries. Copies of the guidelines may be obtained from the Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207. (In addition to the chronic hazards discussed below, issues relating to the chronic hazard of sensitization are discussed in 16 CFR 1500.3(c) (5).)

(a) *Carcinogenicity.* Substances are toxic by reason of their potential carcinogenicity in humans when they are known or probable human carcinogenic substances as defined below. Substances that are possible human carcinogenic substances or for which there is no evidence of carcinogenic effect under the following categories lack sufficient evidence to be considered toxic by virtue of their potential carcinogenicity.

(1) *Known Human carcinogenic Substances ("sufficient evidence" in humans).* Substances are toxic by reason of their carcinogenicity when they meet the "sufficient evidence" criteria of carcinogenicity from studies in humans, which require that a causal relationship between exposure to an agent and cancer be established. This category is similar to the Environmental Protection Agency's (EPA) Group A, the International Agency for Research on Cancer's (IARC) Group 1, or the American National Standards Institute's (ANSI) Category 1. A causal relationship is established if one or more epidemiological investigations that meet the following criteria show an association between cancer and exposure to the agent.

(i) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(ii) All possible confounding factors which could account for the observed association can be ruled out with reasonable confidence.

(iii) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(2) *Probable Human Carcinogenic Substances.* Substances are also toxic by reason of their probable carcinogenicity when they meet the "limited evidence" criteria of carcinogenicity in humans or the "sufficient evidence" criteria of carcinogenicity in animals described below. This category is similar to EPA's Group B, IARC's Group 2, or ANSI's Categories 2 and 3. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. For example, such evidence would result when there was an identified mechanism of action for a chemical that causes cancer in animals that has been shown not to apply to the human situation. It is reasonable, for practical purposes, to regard an agent for which there is "sufficient" evidence of carcinogenicity in animals as if it presented a carcinogenic risk to humans.

(i) *"Limited evidence" of carcinogenicity in humans.* The evidence is considered limited for establishing a causal relationship between exposure to the agent and cancer when a causal interpretation is

credible, but chance, bias, or other confounding factors could not be ruled out with reasonable confidence.

(ii) *"Sufficient evidence" of carcinogenicity in animals.* Sufficient evidence of carcinogenicity requires that the substance has been tested in well-designed and -conducted studies (*e.g.*, as conducted by National Toxicology Program (NTP), or consistent with the Office of Science Technology Assessment and Policy (OSTP) guidelines) and has been found to elicit a statistically significant ($p < 0.05$) exposure-related increase in the incidence of malignant tumors, combined malignant and benign tumors, or benign tumors if there is an indication of the ability of such benign tumors to progress to malignancy:

(A) in one or both sexes of multiple species, strains, or sites of independent origin; or experiments using different routes of administration or dose levels; or

(B) to an unusual degree in a single experiment (one species/strain/sex) with regard to unusual tumor type, unusual tumor site, or early age at onset of the tumor.

The presence of positive effects in short-term tests, dose-response effects data, or structure-activity relationship are considered additional evidence.

(3) *Possible Human Carcinogenic Substance ("limited evidence" animal carcinogen).* In the absence of "sufficient" or "limited" human data, agents with "limited" evidence of carcinogenicity from animal studies fall into this category. Such substances, and those that do not fall into any other group, are not considered "toxic." This does not imply that the substances are or are not carcinogens, only that the evidence is too uncertain to provide for a determination. This category is similar to EPA's Group C, IARC's Group 3, or ANSI's category 4.

(b) *Neurotoxicity.* Substances are toxic by reason of their potential neurotoxicity in humans when they meet the "sufficient evidence" or "limited evidence" criteria of neurotoxicity in humans, or when they meet the "sufficient evidence" criteria of neurotoxicity in animals.

(1) *Known Neurotoxic Substances ("sufficient evidence in humans").* Substances are toxic by reason of their neurotoxicity and are considered "known neurotoxic substances" when they meet the "sufficient evidence" criteria of neurotoxicity derived from studies in humans which require that a causal association between exposure to an agent and neurotoxicity be established with a reasonable degree of certainty. Substances in this category meet the definition of "neurotoxic" as stated above. "Sufficient evidence," derived from human studies, for a causal association between exposure to a chemical and neurotoxicity is considered to exist if the studies meet the following criteria.

(i) A consistent pattern of neurological dysfunction is observed.

(ii) The adverse effects/lesions account for the neurobehavioral dysfunction with reasonable certainty.

(iii) All identifiable bias and confounding factors are reasonably discounted after consideration.

(iv) The association has been shown unlikely to be due to chance, based on statistical analysis.

(2) *Probable Neurotoxic Substances.* Substances are also toxic by reason of their probable neurotoxicity when they meet the "limited evidence" criteria of neurotoxicity in humans, or the "sufficient evidence" criteria derived from animal studies. Evidence derived from animal studies that has been shown not to be relevant to humans is not included. Such evidence would result, for example, when there was an identified mechanism of action for a chemical that causes neurotoxicity in animals that has been shown not to apply to the human situation.

(i) *"Limited evidence" of neurotoxicity in humans.* The evidence derived from human studies is considered limited for neurotoxicity when the evidence is less than convincing, *i.e.*, one of the criteria of "sufficient evidence" of neurotoxicity for establishing a causal association between exposure to the agent and neurotoxicity is not met, leaving some uncertainties in establishing a causal association.

(ii) *"Sufficient evidence" of neurotoxicity in animals.* Sufficient evidence of neurotoxicity derived from animal studies for a causal association between exposure to a chemical and neurotoxicity requires that:

(A) The substance has been tested in well-designed and -conducted studies (*e.g.*, NTP's neurobehavioral battery, or conforming to EPA's neurotoxicity test guidelines); and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) increase in any neurotoxic effect in one or both sexes of multiple species, strains, or experiments using different routes of administration and dose-levels.

(3) *Possible Neurotoxic Substances.* "Possible neurotoxic substances" are the substances which meet the "limited evidence" criteria of neurotoxicity evidence derived from animal studies in the absence of human data, or in the presence of inadequate human data, or data which do not fall into any other group. Substances in this category are not considered "toxic."

(c) *Developmental and Reproductive Toxicity.—(1) Definitions of "Sufficient" and "Limited" Evidence.* The following definitions apply to all categories stated below.

(i) "Sufficient evidence" from human studies for a causal association between human exposure and the subsequent occurrence of developmental or reproductive toxicity is considered to exist if the studies meet the following criteria:

(A) No identified bias that can account for the observed association has been found on evaluation of the evidence.

(B) All possible confounding factors which could account for the observed association can be ruled out with reasonable confidence.

(C) Based on statistical analysis, the association has been shown unlikely to be due to chance.

(ii) "Limited evidence" from human studies exists when the human epidemiology meets all but one of the criteria for "sufficient evidence"; *i.e.*, the statistical evidence is borderline as opposed to clear-cut, there is a source of bias, or there are confounding factors that have not been and cannot be accounted for.

(iii) "Sufficient evidence" from animal studies exists when

(A) Obtained from a good quality animal study; and

(B) The substance has been found to elicit a statistically significant ($p < 0.05$) treatment-related increase in multiple endpoints in a single species/strain, or in the incidence of a single endpoint at multiple dose levels or with multiple routes of administration in a single species/strain, or increase in the incidence of a single endpoint in multiple species/strains/ experiments.

(iv) "Limited evidence" from animal studies exists when:

(A) Obtained from a good quality study and there is a statistically significant ($p < 0.05$) treatment-related increase in the incidence of a single endpoint in a single species/strain/ experiment at a single dose level administered through only one route and such evidence otherwise does not meet the criteria for "sufficient evidence"; or

(B) The evidence is derived from studies which can be interpreted to show positive effects but have some qualitative or quantitative limitations with respect to experimental procedures (*e.g.*, doses, exposure, follow-up, number of animals/group, reporting of the data,

etc.) which would prevent classification of the evidence in the group of "sufficient evidence."

(2) *Developmental Toxicants.* Substances are toxic by reason of their potential developmental or reproductive toxicity when they meet the "sufficient evidence" or "limited evidence" criteria of developmental or reproductive toxicity in humans, or when they meet the "sufficient evidence" criteria of developmental or reproductive toxicity in animals. The Food and Drug Administration (FDA) and the European Economic Community (EEC) have developed categories for teratogens but not other developmental toxicants. The teratogen guidelines limit the information only to structural birth defects and do not include other hazards of developmental toxicity such as embryonal death, fetal death, or functional deficiencies which are also important in assessing the overall toxicity of a substance when administered during pregnancy. Recently, EPA has proposed a system for classifying developmental toxicity. The Occupational Safety and Health Administration (OSHA) has not yet developed any classification for developmental toxicity. The commission has established the following categories for determination of developmental toxicity according to the available evidence.

(i) *Known Human Developmental Toxicant ("sufficient evidence in humans").* A substance is considered a "known human developmental toxicant" if there is "sufficient" human evidence to establish a causal association between human exposure and the subsequent occurrence of developmental toxicity manifested by death of the conceptus (embryo or fetus), or structural or functional birth defects. This category (Human Developmental Toxicant) is comparable to category 1 of the EEC and categories D and X of FDA, except that these guidelines are limited to teratogens. This category is also comparable to the category "definitive evidence for human developmental toxicity" proposed by EPA.

(ii) *Probable Human Developmental Toxicant.* A substance is considered a "probable human developmental toxicant" if there is "limited" human evidence or "sufficient" animal evidence to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. This group (Probable Human Developmental Toxicant) is comparable to the category "adequate evidence for human developmental toxicity" proposed by EPA. This category is also comparable to category 2 of the EEC and category A1 of FDA, except that these guidelines are limited to teratogens.

(iii) *Possible Human Developmental Toxicant.* A substance is considered a "possible human developmental toxicant" if there is "limited" animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and subsequent occurrence of developmental toxicity. EEC, FDA, and EPA have not developed a category comparable to this group. The Commission believes that data from well planned animal studies are important to consider even though they may provide only limited evidence of developmental toxicity.

(3) *Male Reproductive Toxicants.* Male reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies.

(i) *Known Human Male Reproductive Toxicant.* A substance is considered a "known human male reproductive toxicant" if there is "sufficient" human evidence to establish a causal association between human exposure and the adverse effects on male reproductive main endpoints which are mating ability, fertility, and prenatal and postnatal development of the conceptus. This category is comparable to the one termed "Known Positive" in the EPA guidelines on male reproductive risk assessment.

(ii) *Probable Human Male Reproductive Toxicant.* A substance is considered a "probable human male reproductive toxicant" if there is "limited" human evidence or "sufficient" animal evidence to establish a causal association between human exposure and the adverse effects on male reproductive main endpoints. This category is comparable to the one termed "Probable Positive" in the EPA guidelines on male reproductive risk assessment. However, the EPA category is based only on sufficient animal evidence. CPSC believes that limited human evidence is also sufficient for a chemical to be placed in this category.

(iii) *Possible Human Male Reproductive Toxicant.* A substance is considered a "possible human male reproductive toxicant" if there is limited animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on male reproductive main endpoints. This category is comparable to the one termed "Possible Positive A" in the EPA guidelines on male reproductive risk assessment. EPA proposes to use either limited human or limited animal evidence data to classify a toxicant as a "Possible Positive A" toxicant. As described above, CPSC would elevate limited human evidence to the category "Probable Human Male Reproductive Toxicant."

(4) *Female Reproductive Toxicants.* Female reproductive toxicants can be grouped into the following different categories based on evidence obtained from human or animal studies. EPA has proposed guidelines for assessing female reproductive risk but has not yet proposed a specific system for categorization of female reproductive toxicants.

(i) *Known Human Female Reproductive Toxicant.* A substance is considered a "known human female reproductive toxicant" if there is "sufficient" human evidence to establish a causal association between human exposure and adverse effects on female reproductive function such as mating ability, fertility, and prenatal and postnatal development of the conceptus.

(ii) *Probable Human Female Reproductive Toxicant.* A substance is considered a "probable human female reproductive toxicant" if there is "limited" human evidence or "sufficient" animal evidence to establish a causal association between human exposure and adverse effects on female reproductive function.

(iii) *Possible Human Female Reproductive Toxicant.* A substance is considered a "possible human female reproductive toxicant" if there is "limited" animal evidence, in the absence of human data, or in the presence of inadequate human data, or which does not fall into any other group, to establish a causal association between human exposure and adverse effects on female reproductive function.

(d) *Other Subjects Related to the Determination that a Substance is Toxic.* Under the FHSA, for a toxic substance to be considered hazardous, it must not only have the potential to be hazardous but there must also be the potential that persons are exposed to the substance, that the substance can enter the body, and that there is a significant risk of an adverse health effect associated with the customary handling and use of the substance. Under these guidelines, existence of an adverse health effect means that such exposure is above the "acceptable daily

intake" ("ADI"). The ADI is based on the risks posed by the substance, and whether they are acceptable under the FHSA. This section addresses those issues by providing guidelines concerning assessment of exposure, assessment of bioavailability, determination of acceptable risks and the ADI to children and adults, and assessment of risk.

(1) *Assessment of Exposure.* An exposure assessment may comprise a single exposure scenario or a distribution of exposures. Reasonably foreseeable use, as well as accidental exposure, should be taken into consideration when designing exposure studies. The following guidelines should be used in the assessment of exposure.

(i) *Inhalation.* Inhalation studies to assess exposure should be reliable studies using direct monitoring of populations, predictions of exposure through modeling, or surrogate data.

(A) *Direct Monitoring.* Populations to be monitored should be selected randomly to be representative of the general population, unless the exposure of a particular subset population is the desired goal of the assessment. The monitoring technique should be appropriate for the health effect of interest.

(B) *Modeling.* Predictions of exposure to a chemical using mathematical models can be based on physical and chemical principles, such as mass balance principles. Mass balance models should consider the source strength of the product of interest, housing characteristics, and ambient conditions likely to be encountered by the studied population.

(C) *Surrogate Data.* Surrogate data should only be used when data concerning the chemical of interest are sparse or unavailable and when there is a reasonable assurance that the surrogate data will accurately represent the chemical of interest.

(ii) *Oral Ingestion.* Oral ingestion studies may involve direct monitoring of sources of chemicals as well as laboratory simulations. The estimation of exposure from ingestion of chemicals present in consumer products is predicted based upon estimates of use of the product and absorption of the chemical from the gastrointestinal tract. The following criteria should be established for laboratory simulations to estimate exposure:

(A) A simulant or range of simulants should be carefully selected to mimic the possible range of conditions which occur in humans, such as full and empty stomachs, or various saliva compositions at different times of the day.

(B) The mechanical action to which a product is submitted must be chosen to represent some range of realistic conditions to which a human may subject the product.

(iii) *Dermal Exposure.* (A) Dermal exposure involves estimating the amount of substance contacting the skin. This may involve experiments measuring the amount of material leached from a product contacting a liquid layer which interfaces with the skin, or the amount of substance which migrates from a product (in solid or liquid form) which is in contact with the skin.

(B) Parameters to be considered include: Surface area of the skin contacted, duration of contact, frequency of contact, and thickness of a liquid interfacial layer.

(2) *Assessment of Bioavailability.* (i) The need to consider bioavailability in estimating the risk from use of a product containing a toxic substance only arises when it is anticipated that the absorption characteristics of a substance to which there is human exposure will differ from those characteristics for the substance tested in the studies used to define the dose-response relationship.

(ii) In determining the need to assess bioavailability, the factors to be examined include:

(A) The physical or chemical form of the substance,

(B) The route of exposure (inhalation, ingestion, or through the skin),

(C) The presence of other constituents in the product which interfere with or alter absorption of the toxic substance, and

(D) Dose.

(3) *Assessment of Risk.* This section on quantitative risk assessment applies to estimates of risk for substances that are toxic by reason of their carcinogenicity.

(i) Generally, the study leading to the highest risk should be used in the risk assessment; however, other factors may influence the choice of study.

(ii) Risk should be based on the maximum likelihood estimate from a multistage model (such as Global83 or later version) unless the maximum likelihood estimate is not linear at low dose, in which case the 95% upper confidence limit on risk should be used.

(iii) For systemic carcinogens, if estimates of human risk are made based on animal data, a factor derived from dividing the assumed human weight (70 kg) by the average animal weight during the study and taking that to the ⅓ power should be used. There is the possibility that this factor may be changed, using the ¼ power instead of the ⅓ power, as part of a unified Federal regulatory approach. If such an approach is adopted, it will apply here.

(iv) When dose is expressed as parts per million, and the carcinogen acts at the site of contact, humans and animals exposed to the same amount for the same proportion of lifetime should be assumed to be equally sensitive.

(v) If no experimental study having the same route of exposure as that anticipated for human use of a substance is available, a study by another route of exposure may be used. Pharmacokinetic methods may be used if sufficient data are available.

(vi) When exposure scenarios are different from those used in the underlying study upon which estimates of risk are based, proportionality should be applied. If pharmacokinetic methods are used to adjust for risks at high versus low exposure levels, level-time measures should not be combined without taking the non-linearity into account.

(4) *Acceptable Risks.*—(i) *ADI for Carcinogens.* The maximum acceptable daily intake ("ADI") is that exposure of a toxic (by virtue of its carcinogenicity) substance that is estimated to lead to a lifetime excess risk of one in a million. Exposure refers to the anticipated exposure from normal lifetime use of the product, including use as a child as well as use as an adult.

(ii) *ADI for Neurotoxicological and Developmental/Reproductive Agents.* Due to the difficulties in using a numerical risk assessment method to determine risk for neurotoxicological or developmental/reproductive toxicants, the Commission is using a safety factor approach, as explained below.

(A) *Human Data.* If the hazard is ascertained from human data, a safety factor of ten will be applied to the lowest No Observed Effect Level ("NOEL") seen among the relevant studies. If no NOEL can be determined, a safety factor of 100 will be applied to the Lowest Observed Effect Level ("LOEL"). Both the NOEL and LOEL are defined in terms of daily dose level.

(B) *Animal Data.* If the hazard is ascertained from animal data, a safety factor of one hundred will be applied to the lowest NOEL. If no NOEL can be determined, a safety factor of one thousand will be applied to the lowest LOEL. Both the NOEL and LOEL are defined in terms of daily dose level.

3. Section 1500.3(c)(2) is amended by revising paragraph (c)(2) introductory text, redesignating paragraphs (c)(2) (i) through (iii) as paragraphs (c)(2)(i) (A) through (C) and adding new paragraphs

(c)(2)(i) introductory text and (c)(2)(ii) to read as follows:

§ 1500.3 Definitions.

* * * * *

(c) * * *

(2) To give specificity to the definition of "toxic" in section 2(g) of the act (and restated in paragraph (b)(5) of this section), the following supplements that definition. The following categories are not intended to be inclusive.

(i) *Acute toxicity.* "Toxic" means any substance that produces death within 14 days in half or more than half of a group of:

(ii) *Chronic toxicity.* A substance is toxic because it presents a chronic hazard if it falls into one of the following categories. (For additional information see the chronic toxicity guidelines at 16 CFR 1500.135.)

(A) *For Carcinogens.* A substance is toxic if it is or contains a known or probable human carcinogen.

(B) *For Neurotoxicological Toxicants.* A substance is toxic if it is or contains a known or probable human neurotoxin.

(C) *For Developmental or Reproductive Toxicants.* A substance is toxic if it is or contains a known or probable human developmental or reproductive toxicant.

4. Section 1500.14 is amended by adding a new paragraph (b)(8) to read as follows:

§ 1500.14 Products requiring special labeling under section 3(b) of the Act.

(b) * * * * *

(8) *Art materials.*

Note: The Labeling of Hazardous Art Materials Act ("LHAMA"), 15 U.S.C. 1277 (Pub. L. 100-695, enacted November 18, 1988) provides that, as of November 18, 1990, "the requirements for the labeling of art materials set forth in the version of the standard of the American Society for Testing and Materials ["ASTM"] designated D-4236 that is in effect on [November 18, 1988] * * * shall be deemed to be a regulation issued by the Commission under section 3(b)" of the Federal Hazardous Substances Act, 15 U.S.C. 1262(b). For the convenience of interested persons, the Commission is including the requirements of ASTM D-4236 in paragraph (b)(8)(i) of this section, along with other requirements (stated in paragraph (b)(8)(ii) of this section) made applicable to art materials by the LHAMA. The substance of the requirements specified in LHAMA became effective on November 18, 1990, as mandated by Congress.

(i) *ASTM D-4236.*—(A) *Scope.*—(*1*) This section describes a procedure for developing precautionary labels for art materials and provides hazard and precautionary statements based upon knowledge that exists in the scientific and medical communities. This section concerns those chronic health hazards known to be associated with a product or product component(s), when the component(s) is present in a physical form, volume, or concentration that in the opinion of a toxicologist (see paragraph (b)(8)(i)(B)(*11*) of this section) has the potential to produce a chronic adverse health effect(s).

(*2*) This section applies exclusively to art materials packaged in sizes intended for individual users of any age or those participating in a small group.

(*3*) Labeling determinations shall consider reasonably foreseeable use or misuse.

(*4*) Manufacturers or repackagers may wish to have compliance certified by a certifying organization. Guidelines for a certifying organization are given in paragraph (b)(8)(i)(H) of this section.

(B) Descriptions of Terms Specific to This Standard.—(*1*) Art material or art material product—any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and suitable for users as defined herein.

(*2*) Users—artists or crafts people of any age who create, or recreate in a limited number, largely by hand, works which may or may not have a practical use, but in which aesthetic considerations are paramount.

(*3*) Chronic adverse health effect(s)—a persistent toxic effect(s) that develops over time from a single, prolonged, or repeated exposure to a substance. This effect may result from exposure(s) to a substance that can, in humans, cause sterility, birth defects, harm to a developing fetus or to a nursing infant, cancer, allergenic sensitization, damage to the nervous system, or a persistent adverse effect to any other organ system.

(*4*) chronic health hazard(s) (hereafter referred to as "chronic hazard")—a health risk to humans, resultant from exposure to a substance that may cause a chronic adverse health effect.

(*5*) Analytical laboratory—a laboratory having personnel and apparatus capable of performing quantitative or qualitative analyses of art materials, which may yield information that is used by a toxicologist for evaluation of potentially hazardous materials.

(*6*) Label—a display of written, printed, or graphic matter upon the immediate container of any art material product. When the product is unpackaged, or is not packaged in an immediate container intended or suitable for delivery to users, the label can be a display of such matter directly upon the article involved or upon a tag or other suitable labeling device attached to the art material.

(*7*) Producer—the person or entity who manufactures, processes, or imports an art material.

(*8*) Repackager—the person or entity who obtains materials from producers and without making changes in such materials puts them in containers intended for sale as art materials to users.

(*9*) Sensitizer—a substance known to cause, through an allergic process, a chronic adverse health effect which becomes evident in a significant number of people on re-exposure to the same substance.

(*10*) Toxic—applies to any substance that is likely to produce personal injury or illness to humans through ingestion, inhalation, or skin contact.

(*11*) Toxicologist—an individual who through education, training, and experience has expertise in the field of toxicology, as it relates to human exposure, and is either a toxicologist or physician certified by a nationally recognized certification board.

(*12*) Bioavailability—the extent that a substance can be absorbed in a biologically active form.

(C) Requirements.—(*1*) The producer or repackager of art materials shall submit art material product formulation(s) or reformulation(s) to a toxicologist for review, such review to be in accordance with paragraph (b)(8)(i)(D) of this section. The toxicologist shall be required to keep product formulation(s) confidential.

(*2*) Unless otherwise agreed in writing by the producer or repackager, no one other than the toxicologists shall have access to the formulation(s); except that the toxicologists shall furnish a patient's physician, on a confidential basis, the information necessary to diagnose or treat cases of exposure or accidental ingestion.

(*3*) The producer or repackager, upon advice given by a toxicologist in accordance with paragraph (b)(8)(i)(D) of this section and based upon generally accepted, well-established evidence that a component substance(s) is known to cause chronic adverse health effects adopt precautionary labeling in accordance with paragraph (b)(8)(i)(E) of this section.

(*4*) Labeling shall conform to any labeling practices prescribed by federal and state statutes or regulations and shall not diminish the effect of required acute toxicity warnings.

(*5*) The producer or repackager shall supply a poison exposure management information source the generic formulation information required for dissemination to poison control centers or shall provide a 24-hour cost-free

telephone number to poison control centers.

(*6*) The producer or repackager shall have a toxicologist review as necessary, but at least every 5 years, art material product formulation(s) and associated label(s) based upon the then-current, generally accepted, well-established scientific knowledge.

(*7*) Statement of Conformance—"Conforms to ASTM Practice D–4236," or "Conforms to ASTM D–4236," or "Conforms to the health requirements of ASTM D–4236." This statement may be combined with other conformance statements. The conformance statement should appear whenever practical on the product; however, it shall also be acceptable to place the statement on one or more of the following:

(*i*) The individual product package,

(*ii*) a display or sign at the point of purchase,

(*iii*) separate explanatory literature available on requirements at the point of purchase,

(*iv*) a response to a formal request for bid or proposal.

(D) Determination of Labeling.—(*1*) An art material is considered to have the potential for producing chronic adverse health effects if any customary or reasonably foreseeable use can result in a chronic hazard.

(*2*) In making the determination, a toxicologist(s) shall take into account the following:

(*i*) Current chemical composition of the art material, supplied by an analytical laboratory or by an industrial chemist on behalf of a manufacturer or repackager.

(*ii*) Current generally accepted, well-established scientific knowledge of the chronic toxic potential of each component and the total formulation.

(*iii*) Specific physical and chemical form of the art material product, bioavailability, concentration, and the amount of each potentially chronic toxic component found in the formulation.

(*iv*) Reasonably foreseeable uses of the art material product as determined by consultation with users and other individuals who are experienced in use of the material(s), such as teachers, or by market studies, unless such use information has previously been determined with respect to the specific art material(s) under review.

(*v*) Potential for known synergism and antagonism of the various components of the formulation.

(*vi*) Potentially chronic adverse health effects of decomposition or combustion products, if known, from any reasonably foreseeable use of the hazardous art material product.

(*vii*) Opinions of various regulatory agencies and scientific bodies, including the International Agency for Research on Cancer and the National Cancer Institute, on the potential for chronic adverse health effects of the various components of the formulation.

(*3*) Based upon the conclusion reached in conformance with review determinations set forth herein, the toxicologist(s) shall recommend precautionary labeling consistent with paragraph (b)(8)(i)(E) of this section.

(E) Labeling Practices.—(*1*) Signal Word.—(*i*) When a signal word for an acute hazard(s) is mandated and a chronic hazard(s) exists, the signal word shall be that for the acute hazard.

(*ii*) When only a chronic hazard(s) exists, the signal word WARNING shall be used.

(*iii*) The signal word shall be prominently visible and set in bold capitals in a size equal to or greater than the statement of potential chronic hazards.

(*2*) List of Potentially Chronic Hazards—Potentially chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be stated substantially in accordance with the statements listed in paragraph (b)(8)(i)(F) of this section. Potentially chronic hazards noted shall be those that are clinically significant and that might be expected with any reasonably foreseeable use of the art material. The hazards should be grouped in the order of relative descending severity.

(*3*) Name of Chronically Hazardous Component(s)—All components and known decomposition products of the formulation with a potential for chronic hazards, as determined under the procedures of paragraph (b)(8)(i)(D) of this section, shall be listed prominently. Generically equivalent names may be used.

(*4*) Safe Handling Instructions—Appropriate precautionary statements as to work practices, personal protection, and ventilation requirements shall be used substantially conforming with those listed in paragraph (b)(8)(i)(G) of this section.

(*5*) List of Sensitizing Components—To protect users from known sensitizers found within art materials, each label shall contain a list of those sensitizers present in sufficient amounts to contribute significantly to a known skin or respiratory sensitization.

(*6*) Combined Statement—If an art material contains more than one component capable of causing a chronic adverse health effect, or if a single chemical can cause several different chronic adverse health effects, the potential effects may be combined into one statement.

(*7*) Information Sources—The precautionary label shall contain a statement identifying a source for additional health information substantially in conformance with one of the phrases listed below:

(*i*) For more health information—(24 hour cost-free U.S. telephone number).

(*ii*) Contact a physician for more health information, or

(*iii*) Call your local poison control center for more health information.

(*8*) Labeling Content, Product Size—Any art material product in a container larger in size than one fluid ounce (30 ml) (if the product is sold by volume) or one ounce net weight (28 g) (if the product is sold by weight) shall have full precautionary labeling, as described in paragraph (b)(8)(i) (E) of this section. Any art material product in a container equal to or smaller than one fluid ounce or one ounce net weight shall have a label that includes a signal word in conformance with paragraph (b)(8)(i)(E)(*1*) of this section and a list of potentially harmful or sensitizing components in conformance with paragraphs (b)(8)(i)(E) (*3*) and (*5*) of this section.

(*9*) The information described in paragraph (b)(8)(i)(E) of this section must appear on:

(*i*) The outside container or wrapper, if any, unless it is easily legible through the outside container or wrapper and

(*ii*) All accompanying literature where there are directions for use, written or otherwise. Where a product that requires warning labels under paragraphs (b)(8)(i) (D) and (E) of this section is packed within a point-of-sale package that obscures the warning statement(s), the point-of-sale package shall carry the signal word conforming to paragraph (b)(8)(i)(E)(*1*) and the following wording: "Contains: (list hazardous product(s)) that may be harmful if misused. Read cautions on individual containers carefully. Keep out of the reach of children."

(*10*) Statements required under paragraphs (b)(8)(i) (D) and (E) of this section must be in the English language and located prominently in conspicuous and legible type in contrast by topography, layout, or color with other printed matter on the label.

(*11*) Supplemental Information—Where appropriate, more detailed information that relates to chronic hazard(s), such as physical properties, decomposition products, detailed safety instructions, or disposal recommendations, shall be included in supplemental documents, such as

Material Safety Data Sheets, technical brochures, technical data sheets etc.

(F) chronic Hazard Statements

MAY CAUSE STERILITY.
CONTACT MAY CAUSE PERMANENT EYE DAMAGE.
MAY BE HARMFUL BY BREATHING VAPORS/DUSTS.
MAY BE HARMFUL IF SWALLOWED.
MAY BE HARMFUL BY SKIN CONTACT.
MAY PRODUCE BIRTH DEFECTS IN THE DEVELOPING FETUS.
MAY BE EXCRETED IN HUMAN MILK.
MAY CAUSE HARM TO THE NURSING INFANT.
CANCER AGENT! EXPOSURE MAY PRODUCE CANCER.
CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
POSSIBLE CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
MAY PRODUCE ALLERGIC REACTION BY INGESTION/INHALATION/SKIN CONTACT.
MAY PRODUCE NUMBNESS OR WEAKNESS IN THE EXTREMITIES.
EXPOSURE MAY CAUSE (SPECIFY THE ORGAN(S)) DAMAGE.
HEATING/COMBUSTION MAY CAUSE HAZARDOUS DECOMPOSITION PRODUCTS.

(G) Precautionary Statements

Keep out of reach of children.
When using do not eat, drink, or smoke.
Wash hands immediately after use.
Avoid inhalation/ingestion/skin contact.
Avoid fumes from combustion.
Keep container tightly closed when not in use.
Store in well-ventilated area.
Wear protective clothing (specify type).
Wear protective goggles/face shield.
Wear NIOSH-certified mask for dusts/mists/fumes.
Wear NIOSH-certified respirator with an appropriate cartridge for (specify).
Wear NIOSH-certified supplied-air respirator.
Use window exhaust fan to remove vapors and ensure adequate cross ventilation. (Specify explosion-proof if necessary.)
Do not heat above (specify temperature) without adequate ventilation.
Use (specify type) local exhausting hood.
Do not use/mix with (specify material).

(ii) The following shall apply with respect to the standard for art materials set forth in § 1500.14(b)(8)(i).

(A) The term *art material or art material product* shall mean any substance marketed or represented by the producer or repackager as suitable for use in any phase of the creation of any work of visual or graphic art of any medium. The term does not include economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act or drugs, devices, or cosmetics subject to the Federal Food, Drug, and Cosmetics Act.

(B) The standard referred to in paragraph (b)(8)(i) of this section applies to art materials intended for users of any age.

(C) Each producer or repackager of art materials shall describe in writing the criteria used to determine whether an art material has the potential for producing chronic adverse health effects. Each producer or repackager shall submit, to the Commission's Division of Regulatory Management, Consumer Product Safety Commission, Washington, DC 20207, the written description of the criteria described above and a list of art materials that require hazard warning labels under this section. Upon request of the Commission, a producer or repackager shall submit to the Commission product formulations.

(D) All art materials that require chronic hazard labeling pursuant to this section must include on the label the name and United States address of the producer or repackager of the art materials, an appropriate United States telephone number that can be contacted for more information on the hazards requiring warning labels under this section, and a statement that such art materials are inappropriate for use by children.

(E) If an art material producer or repackager becomes newly aware of any significant information regarding the hazards of an art material or ways to protect against the hazard, this new information must be incorporated into the labels of such art materials that are manufactured after 12 months from the date of discovery. If a producer or repackager reformulates an art material, the new formulation must be evaluated and labeled in accordance with the standard set forth § 1500.14(b)(8)(i).

(F) In determining whether an art material has the potential for producing chronic adverse health effects, including carcinogenicity and potential carcinogenicity, the toxicologist to whom the substance is referred under the standard described above shall take into account opinions of various regulatory agencies and scientific bodies, including the U.S. Consumer Product Safety Commission (CPSC), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC).

(iii) Pursuant to the LHAMA, the Commission has issued guidelines which, where possible, specify criteria for determining when any customary or reasonably foreseeable use of an art material can result in a chronic hazard. These guidelines include criteria for determining when art materials may produce chronic adverse effects in children and adults, criteria for determining which substances contained in art materials have the potential for producing chronic adverse effects and what those effects are, criteria for determining the bioavailability of chronically hazardous substances contained in art materials when the products are used in a customary or reasonably foreseeable manner, and criteria for determining acceptable daily intake levels for chronically hazardous substances contained in art materials. Because these guidelines apply to hazardous substances in general as well as to hazardous substances in art materials, the guidelines are set forth in § 1500.135 and a definition of "chronic toxicity" is provided in § 1500.3(c)(2)(ii) as part of supplementation of the term "toxic" in section 2(q) of the FHSA.

Appendix A to § 1500.14(b)(8)—Guidelines for a Certifying Organization (Not Mandatory)

(a) The term "certifying organization," as used in this paragraph, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

(b) The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers' chemists, on its technical and certifying committees.

(c) Representative samples of art materials, labeled as conforming to this section and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

(d) The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

(e) In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist's decision can be presented to the advisory board of toxicologists for arbitration.

Dated: September 22, 1992.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of References

The following documents contain information relevant to this rulemaking proceeding and form the basis for the proposed guidelines and definition. They are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, room 428, 5401 Westbard Avenue, Bethesda, Maryland:

1. Memorandum from Lakshmi C. Mishra, Senior Toxicologist, to Sandra Eberle, Program Manager, EXPB, dated October 5, 1990, entitled Criteria for Determining if a Substance is Toxic on the Basis of Carcinogenicity.
2. Memorandum from Lakshmi C. Mishra, Senior Toxicologist, to Sandra Eberle, Program Manager, EXPB, dated October 5, 1990, entitled Criteria for Determining if a Substance is Toxic on the Basis of Neurotoxicity.
3. Memorandum from Vishnudutt D. Purohit, HSHE, to Sandra Eberle, Program Manager, EXPB, dated November 15, 1990, entitled Guidelines for Identification and Classification of Developmental and Reproductive Toxicants in Consumer Products.
4. Memorandum from Warren K. Porter, Jr., Director, HSHL, to Sandra Eberle, Program Manager, EXPB, dated November 15, 1990, entitled Exposure Assessment Guidelines.
5. Memorandum from Valentine H. Schaeffer, HSHE, to Sandra Eberle, Program Manager, EXPB, dated October 5, 1990, entitled Guidelines for Assessing Bioavailability of Chronically Hazardous Substances Found in Consumer Products.
6. Memorandum from Murray S. Cohn, Director, HSHE, to Sandra Eberle, Program Manager, EXPB, dated October 5, 1990, entitled FHSA Risk Assessment Guidelines.
7. Memorandum from Murray S. Cohn, Director, HSHE, to Sandra Eberle, Program Manager, EXPB, dated October 5, 1990, entitled Acceptable Risks to Children and Adults.
8. Memorandum from Michael A. Babich, Project Manager, dated March 24, 1992, entitled Responses to Public Comments and Draft Final Rule on the Labeling of Art Materials and Other Products.

The following documents are referenced in the Memoranda listed above and may have been referred to in the preamble of this rulemaking. They are listed here for the convenience of the reader.

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BILLING CODE 6355–01–M

federal register

Friday
October 9, 1992

Part III

United States Information Agency

22 CFR Part 514

Exchange Visitor Program; Final Rules and Proposed Rule

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Statement of Policy Regarding Exchange Visitor Au Pair Programs

AGENCY: United States Information Agency.

ACTION: Statement of policy regarding exchange visitor au pair programs.

SUMMARY: In September 1988, Congress enacted legislation extending Agency-designated au pair pilot programs for two years, upon the same terms and conditions previously authorized (Foreign Operations, Export Financing, and Related Programs Appropriation Act of 1989). In October 1990, Congress enacted legislation requiring the Agency to continue to implement the au pair programs designated by the Agency as of July 10, 1990, until such au pair program are authorized and implemented by another agency of the United States Government (Eisenhower Exchange Fellowship Act of 1990). Guidelines for the conduct of au pair programs were distributed to all designated au pair program sponsors in 1988–1989. Those Guidelines have not been materially changed or amended since. All designated au pair program sponsors will continue to adhere to the Guidelines and to the general regulations which apply to all Exchange Visitor Program sponsors until such time as au pair programs are authorized and implemented by another U.S. Government agency.

DATES: The Statement of Policy is effective October 9, 1992.

ADDRESSES: Stanley S. Colvin, Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 Fourth Street, SW., Washington, DC 20547, (202) 619–6829.

SUPPLEMENTARY INFORMATION: The Agency's Exchange Visitor Program designated its first au pair program in 1986. In that year, the American Institute For Foreign Study (AIFS) and Experiment In International Living (EIL) were designated to conduct a two-year au pair pilot program in which foreign youths between the ages of 18 and 25 were to come to the U.S. for one year to learn about American culture, provide a cross-cultural exchange, improve their English, and assist their host family with child care.

The programs were to be evaluated every six months by an interagency review panel composed of representatives of the Department of State, the Immigration and Naturalization Service, the Department of Labor, and USIA. The panel found that au pairs were working up to forty-five hours per week and concluded that the program in reality was a full-time home child care work program and not a valid educational and cultural exchange. The panel recommended that the program could be continued only if the hours of work were substantially reduced, and it further recommended that the Agency draft guidelines to ensure that the program became a valid educational and cultural exchange. Concurrently, the Agency's legal research concluded that the Agency had no legal authority to designate the au pair program as then designed, an opinion shared by the General Accounting Office (GAO). The Agency sought to terminate the au pair program in December 1987.

In September 1988 Congress enacted legislation extending the AIFS and EIL pilot programs for two years. Public Law 100–461. By December 1989, the Agency had designated six more au pair programs, bringing the total to eight. Each program was authorized to bring up to 2,840 participants a year into the U.S. In October 1990, Congress passed additional legislation bearing on the au pair program. Public Law 101–454 directed the Agency to continue to implement the au pair programs previously designated under the same terms and conditions previously authorized until such programs were authorized and implemented by another U.S. Government agency.

The same section of Public Law 100–461 which extended the AIFS and EIL au pair programs for fiscal years 1989 and 1990 also required the GAO to conduct an assessment of J-visa activities, including the au pair program. In February 1990 the GAO issued its report "Inappropriate Uses of Educational and Cultural Exchange Visas," which, *inter alia*, concluded that "the currently structured au pair programs are not compatible with the original intent of the 1961 [Mutual Educational and Cultural Exchange Act of 1961—the Fulbright-Hays] Act. We hold this view because current au pair programs are essentially child care work programs that do not correlate with the qualifying categories mentioned in the J-visa statute. As currently structured, au pair programs would normally be subject to Department of Labor administrative review and certification." (GAO Report, at p. 20) (material in brackets added.)

There are presently pending in Congress two bills (S. 1914 and H.R. 3962) which, if enacted, would transfer the au pair program to the Department of Justice. In light of Public Law 101–454, which requires the Agency to continue to implement the au pair programs previously designated until such programs are authorized and implemented by another U.S. Government agency, USIA-designated au pair programs shall continue to follow the previously issued "Guidelines Governing the Administration of Au Pair Programs." In addition, currently designated au pair program sponsors are required to comply with all Exchange Visitor Program regulations which appear at 22 CFR part 514.

Pending the transfer of the au pair program to the Department of Justice or some other U.S. Government agency, no additional au pair programs will be designated. Currently designated programs are not permitted to expand their programs, i.e., they are limited to bringing in au pairs only from the countries of Western Europe, and each designated program is authorized to bring only 2,840 participants a year into the U.S.

List of Subjects in 22 CFR Part 514

Cultural Exchange Programs.

Dated: September 30, 1992.

Alberto J. Mora,

General Counsel.

[FR Doc. 92–24213 Filed 10–8–92; 8:45 am]

BILLING CODE 8230–01–M

UNITED STATES INFORMATION AGENCY

22 CFR Part 514

Sponsors of Exchange Visitor Summer Student Travel/Work Programs

AGENCY: United States Information Agency.

ACTION: Notice to sponsors of exchange visitor summer student travel/work programs; statement of policy.

SUMMARY: The General Accounting Office (GAO) issued a report entitled "Inappropriate Uses of Educational and Cultural Exchange Visas" dated February 16, 1990. The report questioned the legality of summer student travel/work programs under the J-visa. On August 13, 1990 the Agency published a Statement of Policy in the Federal Register, 55 FR 32906, which served as an interim response to the GAO report.

This notice sets forth the Agency's final response.

DATES: The Statement of Policy is effective October 9, 1992.

ADDRESSES: Questions regarding this notice should be addressed to Stanely S. Colvin, Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 4th Street, SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 4th Street, SW., Washington, DC 20547, (202) 619–6829.

SUPPLEMENTARY INFORMATION: The GAO issued a report entitled "Inappropriate Uses of Educational and Cultural Exchange Visas" dated February 16, 1992. That report questions the legality of the Summer Student Travel/Work Programs under the J-visa.

The Agency has been designating Summer Student Travel/Work programs for a number of years. Regulations covering such programs presently appear to 22 CFR 514.13(d). Those programs are designed to achieve the educational objectives of international exchange by involving foreign students during their summer vacations directly in the daily life of the host country through temporary employment opportunities. Selection of participants is limited to *bona fide* foreign university students who are between 18 and 23 years of age. A participant must have a prearranged job before he or she comes to the U.S., or have firm appointments with prospective employers, or have sufficient personal funds so as to be financially independent if not employed.

Because of the potential adverse impact on labor opportunities for U.S. youth, the Agency requires program sponsors to check in advance with the Department of Labor to obtain information regarding areas which have a high unemployment rate and sponsors are directed to advise program participants to avoid such areas in seeking employment. Potential adverse labor impact is avoided further by an Agency requirement that sponsors administer their programs on a reciprocal basis, i.e., they cannot bring more students to the U.S. than they send abroad each calendar year on similar travel/work programs.

The statutory basis under which the United States Information Agency can designate programs for a J-visa is found in section 101(a)(15)(J) of the Immigration and Nationality Act, as amended, 8 U.S.C. 1101(a)(15)(J). That section defines nonimmigrants of the J category as an alien having a residence in a foreign country which he has no intention of abandoning who is a *bona fide student, scholar, trainee, teacher, professor, research assistant, specialist, or leader in a field of specialized knowledge or skill,* or other person of similar description, who is coming temporarily to the United States as a participant in a program designated by the Director of the United States Information Agency, for the *purpose of teaching, instructing or lecturing, or studying, observing, conducting research, consulting, demonstrating special skills, or receiving training* and who, if he is coming to the United States to participate in a program under which he will receive graduate medical education or training, also meets the requirements of section 1182(j) of this title, and the alien spouse and minor children of any such alien if accompanying him or following to join him. [emphasis added.]

The GAO pointed out that summer student travel/work programs, which provide foreign university students with employment opportunities in the United States during their summer vacations, do not require participants to engage in activities cited in the legislation. Some sponsors told us that the participants work at fast food restaurants, summer resorts, amusement parks, or other places where they can find work. Participants may be placed in jobs before they arrive or find work after they arrive. These are not jobs requiring special skills or distinguished merit and ability. One of the program sponsors we interviewed brings about 8,000 to 11,000 summer students a year to the United States.

In response to the GAO report, the Agency established a Task Force on Regulatory Reform of the Exchange Visitor Program. In addition to preparing an overall revision to the Exchange Visitor Program regulations, the Task Force examined the Summer Student Travel/Work program as part of the regulatory reform. The Task Force has examined the Summer Student Travel/Work Program from the perspective of overall U.S. foreign policy interests and from the perspective of the Mutual Educational and Cultural Exchange Act of 1961 (Fulbright Hays Act) and its legislative history. While the Agency believes that, from a foreign policy perspective, it is desirable to continue the program, it nevertheless has concluded that additional legislation will be required in order to bolster the Agency's authority to conduct such a program.

The Agency agrees with the GAO that participants in the Summer Student Travel/Work Program do not engage in the activities delineated in the Fulbright-Hays Act. In other words, they do not come to the U.S. for the purpose of teaching, instructing or lecturing, or studying, observing, conducting research, consulting, demonstrating special skills, or receiving training. For the most part, they come to work in the U.S. and take jobs requiring no special skills or distinguished merit or ability. Typical jobs accepted by participants in the program include work at fast food restaurants, summer resorts and camps, or amusement parks.

Nevertheless, while such programs do not fall squarely within the language of the Fulbright-Hays Act, the Agency believes that they accommodate certain foreign policy needs in that they promote mutual understanding between the people of the United States and the people of the other countries.

While Congress intended that the Fulbright-Hays Act be given a broad interpretation, the legislative history of the Act also strongly suggests, however, that although exchanges were not to be limited to the exchange of students and teachers, they were not to serve as vehicles for staffing regular industrial or commercial positions. The Agency believes that Congress recognized that there would be instances where the very nature of the exchange, e.g., a training program, would have a "work" or staffing component, but such programs would be permitted only where the "work" component was incidental to the training. The Agency believes that the principal activity of participants in existing summer student travel/work programs, for the most part, is working full-time for pay in a job which has no formal educational or cultural component, except perhaps as a product of chance, i.e., the educational/cultural component is merely incidental to the "work" component. This is the reverse of what Congress envisioned.

For this reason, the Agency has determined that it will propose a change in the Mutual Educational and Cultural Exchange Act of 1961, Public Law 87–256, as amended (the Fulbright-Hays Act) which will accommodate these programs. In the interim, the sponsors of summer student travel/work programs will continue under their present designations and will continue to abide by those regulations currently published at 22 CFR 514.13(d). Pending a legislative resolution of this issue, no new programs will be designated.

Simultaneously with the publication of this Statement of Policy the Agency is publishing, as a proposed rulemaking, an entire overhaul of the Exchange Visitor Program regulations (22 CFR part

514). When the proposed regulations become final, current § 514.13(d), which governs the Summer Student Travel/Work Program, will be renumbered as 22 CFR 514.31.

List of Subjects in 22 CFR Part 514

Cultural exchange programs.

Dated: September 30, 1992.

Alberto J. Mora,

General Counsel.

[FR Doc. 92-24214 Filed 10-8-92; 8:45 am]

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UNITED STATES INFORMATION AGENCY

22 CFR Part 514

[Rulemaking No. 100]

Exchange Visitor Program

AGENCY: United States Information Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: By this notice the Agency is proposing replacement regulations governing its administration of the Exchange Visitor Program. The Agency has undertaken a thorough review of the Program, its enabling legislation, and past history. This review has, in turn, directed the Agency upon a course of regulatory and management practice reform. The complete revision to 22 CFR part 514 set forth in detail below are proposed in an effort to define more clearly the obligations, duties and relationships of the Agency, sponsors, and exchange participants.

DATES: Comments on the proposed rule will be accepted until December 8, 1992. All written communications received by the Agency on or before the closing date will be considered by the Agency before action on a final rule is undertaken.

ADDRESSES: Please submit five copies of written comments to: Stanley S. Colvin, Assistant General Counsel, Office of the General Counsel, room 700, United States Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Assistant General Counsel, (202) 619-6829.

SUPPLEMENTARY INFORMATION: The Director of the United States Information Agency ("Agency") is authorized to facilitate and direct educational and cultural exchange activities in order to develop and promote mutual understanding between the people of the United States and other countries of the world. Now governed by the provisions of the Mutual Educational and Cultural Exchange Act of 1961 ("Fulbright-Hays Act"), educational and cultural exchange is the cornerstone of United States public diplomacy efforts.

First begun pursuant to the provisions of the United States Information and Educational Exchange Act of 1948 ("Smith-Mundt"), and subsequently incorporated into and broadened under the Fulbright-Hays Act, educational and cultural exchange activities have, over the past forty years, exposed millions of foreign nationals to the United States, its culture, philosophy, business techniques, and educational institutions. The Fulbright-Hays Act mandates reciprocal exchange and Americans traveling abroad have, in similar fashion, developed an enhanced awareness of foreign people, their cultures and societies. Originally performed by the Department of State, oversight of exchange activities, occurring under the umbrella of the Exchange Visitor Program, has been the responsibility of the Agency since 1978.

The Fulbright-Hays Act prescribed categories of eligible exchange participants. The Act provides for the exchange of students, scholars, trainees, teachers, professors, researchers, specialists, leaders in a specialized field of knowledge or skill, or other person of similar description. In addition, the Act requires that exchanges participate in bona fide teaching, study, instruction, lecturing, observation, consultation, research, training or demonstration of special skill activities. Further, the Act authorizes non-immigrant aliens falling within the statutory parameters of the Act to enter the United States under the aegis of a J visa for the purpose of participation in an exchange visitor program. Necessarily, Agency determination of the appropriate usage of the J visa is an integral element of this rulemaking.

The Exchange Visitor Program is facilitated—indeed, largely conducted—by Agency-designated program sponsors who are responsible for the recruitment, placement, and supervision of exchange participants. Congress clearly intended that the private sector was to have a major role in educational and cultural exchange activities. Indeed, when Congress assigned the Agency its mission in 1978, it reemphasized, amongst other things, that the Agency was to "encourage private institutions in the United States to develop their own exchange activities, and provide assistance for those exchange activities which are in the broadest national interest." 22 U.S.C. 1461-1 (1988). Pursuant to this Congressional mandate, utilization of private sector expertise and resources has resulted in the designation of over 5,000 exchange visitor programs during the past forty years. Currently, in excess of twelve hundred program sponsors are conducting exchange activities. In 1990, these Agency-designated sponsors facilitated the entry into the United States of more than 180,000 Exchange Visitor Program participants.

Though widely hailed as an innovative and successful foreign policy initiative, the Exchange Visitor Program is not without flaw. Debate concerning the parameters of program participation and activity has arisen in recent years. In response to this debate, the Agency has undertaken a thorough review of the Program, its enabling legislation, and past history. This review has, in turn, directed the Agency upon a course of regulatory and management practice reform. The amendments to 22 CFR part 514 set forth in detail below are proposed in an effort to define more clearly the obligations, duties, and relationships of the Agency, sponsors, and exchange participants.

Acting in response to Congressional request, the General Accounting Office ("GAO") investigated Agency oversight and administration of the Exchange Visitor Program and its attendant utilization of the J visa. In its report to Congress, dated February 5, 1990 and entitled "Inappropriate Uses of Educational and Cultural Exchange Visas," the GAO determined that certain Exchange Visitor Program activities appeared to be inconsistent with the statutory grant of authority and its underlying legislative intent. GAO summarized its findings, stating:

> Most J-visa activities appear to conform to the intent of the 1961 act. However, GAO believes that certain activities and programs in the trainee and the international visitor categories, including the summer student/travel work, international camp counselor, and au pair (child care) programs, are inconsistent with legislative intent. GAO identified instances of participants working as waiters, cooks, child care providers, amusement and leisure park workers, and summer camp counselors. Authorizing J visas for participants and activities that are not clearly for educational and cultural purposes as specified in the act dilute the integrity of the J visa and obscures the distinction between the J visa and other visas granted for work purposes.
>
> Report, p. 3.

In turn, Agency response to this criticism began with a thorough review of enabling legislation authorizing the Exchange Visitor Program and admission into the United States of foreign nationals on a J visa.

Subpart A: General Provisions

Exchange Participants and Activities

The Agency has determined that it may best prevent future confusion regarding participant eligibility by establishing eligibility criteria. To this end, the Agency proposes such criteria at § 514.4. New categories of participation, those of "short-term scholar" and "government visitor" are introduced and participation as a "student" is more clearly defined. The category of "specialist" has been expanded and that of "international visitor" restricted to Agency use.

Further, the Agency has determined that camp counselor programs do in fact fall within the Agency's statutory authority to promote exchange. All of these matters are discussed below.

The Agency has determined that the academic exchange community could readily increase the velocity of academic related exchanges through the development of "short-terms scholar" exchanges. A new category of participation, such exchanges will be limited to four months duration. In similar fashion, the Agency believes exchanges within the business community could be substantially increased through the use of the "specialist" category of participant. This category allows for experts in a field of specialized knowledge or skill to engage in observation, consultation, or demonstration of special skill activities for a period of time not to exceed one year.

To correct confusion which periodically arises from the sponsorship of student participants, the Agency proposes criteria governing student status. Given the *bona findes* requirement set forth in 8 U.S.C. 1101(a)(15)(J), the Agency believes that a student participant must pursue a full course of study. In determination of what constitutes *bona fide* study, the Agency has surveyed the catalogues of various educational institutions regarding their criteria for full-time student status. The results of this survey indicate that current practice in the field of higher education generally requires an enrolled full-time student to pursue a minimum of twelve semester hours of undergraduate or nine semester hours of graduate academic credits each semester. This minimum course load is considered satisfactory evidence of appropriate advancement toward degree completion and is commonly used as the measure for payment of full-time tuition.

The Agency has also examined Immigration and Naturalization Service regulations set forth at 8 CFR 214.2(f)(6). This regulation, first promulgated by publication at 40 FR 32312 (1975), requires an undergraduate student to complete a minimum of twelve semester hours of academic credit (or equivalent) per semester of attendance and a graduate student to complete the minimum number of credits per semester which an appropriate school official certifies as a full course of study.

Based upon the above, the Agency concludes that pursuit of *bona fide* study is best evidenced by a student's successful completion of a minimum number of academic credits per semester. Pursuant to the *bona fide* requirements of 8 U.S.C. 1101(a)(15)(J), the Agency has determined that an exchange visitor entering the United States as a "student" under the J visa must be actively engaged in the pursuit of a "full course of study." In lieu of setting forth a minimum number of semester hours of academic credit (or its equivalency) per academic term, the Agency proposes that the standard for full course of study be set by the academic institution at which the exchange student is pursuing his or her studies.

In response to a perceived need in the academic community, the Agency proposes to expand student status to also encompass participation in a specialized program of instruction of less than two year's duration. Such program shall be conducted under the aegis of an accredited educational institution and must be comprised of a structured course of study devoted to a particular academic endeavor. No requirement that the participant pursue a degree is imposed. An example of such a program would include an interdisciplinary course of study in arts management comprised of courses offered by the fine arts, business, public administration and law schools of a given academic institution.

Also set forth in § 514.4 as subparts of the "other persons of similar description" participant category are "International Visitor" and "Government Visitor." Originally intended only for Agency use, the International Visitor category has devolved to "catch-all" usage over the years. As proposed, reservation of this category only for Agency use will allow definitive and statistical illustration of the nature and scope of exchanges occurring under direct Agency sponsorship. Similar in nature to International Visitor, the proposed Government Visitor category will be utilized for exchanges directly sponsored by local, state, or federal government agencies.

The GAO report discussed *supra*, concluded that camp counselor programs are inconsistent with the legislative intent of the Fulbright-Hays Act. The Agency, having reviewed this matter in great detail, is now of the opinion that camp counselor programs may be continued. This conclusion is based upon policy and legislative analysis and will require certain programmatic reforms.

International camp counselor is not a statutorily enumerated category of exchange participation. If, however, camp counselor exchange participants are students, teachers, *bona fide* youth workers, and persons with specialized skills in their home country they will fall squarely within the statutorily authorized category of "other person of similar description." As regards activities while in the United States, camp counselors are actively engaged in teaching, observation, and instruction activities, all of which are activities specifically authorized by the statute.

Given the directive of broad interpretation found in the legislative history of the Fulbright-Hays Act, Agency designation of these programs is clearly consistent with the statutorily enumerated purpose and objective of the legislation. To avoid confusion as to the categorization of camp counselor program participants, a new category, set forth at § 514.4 as a subpart of "other persons of similar description," is proposed.

Program Designations

Agency examination of its administration of the Exchange Visitor Program has resulted in a determination that certain internal program controls should be bolstered. In part, the Agency has determined that sponsor application and designation procedures should be strengthened and more clearly delineated. To this end, the Agency proposes, pursuant to provisions set forth at § 514.5 and § 514.6, modification of existing application and designation procedures and the addition of a new requirement dictating periodic redesignation.

Confusion concerning the actual number of Agency-designated Exchange Visitor Program sponsors was an initial area of GAO investigation and proved a fertile source of criticism. Actual determination of this number proved problematic given both the Department of State's and Agency's failure to cancel sponsor designations due to program inactivity or abandonment. This failure is best illustrated by the fact that over 5,400 programs designated in the last forty years, less than a third are operating today. Through utilization of its Exchange Visitor Information System the Agency has determined that slightly more than 1,200 exchange visitor programs are currently in operation. The Agency contemplates the continued utilization of existing Form IAP-37, "Application for Program Designation" for both initial purposes. Modifications to such form will be made to reflect designation and re-designation proposed changes.

The Agency proposes to prevent this confusion concerning the number of valid exchange programs through a proposed utilization of periodic designations. This action is prompted by the Agency's recognition that many

exchange programs exhibit a life cycle of establishment, maturation, and demise. The Agency proposes to designate program sponsors for five years and require sponsors desiring to continue program operations to advise the Agency affirmatively of such intent pursuant to request for redesignation as set forth in § 514.7, *infra*. Such periodic designations will allow the Agency to track program life cycles, efficiently cancel inactive programs, and monitor the activity within and direction of designated exchange programs. Programs for which designation is not sought will be canceled through administrative action. The Agency contemplates a two-year phase-in of this requirement during which all existing designations will be reviewed and extended, if appropriate.

Program Administration

In addition to delineating sponsor and participant eligibility criteria, the Agency proposes that all exchange programs designated by the Agency meet certain eligibility requirements. As set forth at § 514.8, the Agency has determined, as in the past, that all programs should have not less than five exchange participants annually. Further, with the exception of programs for the new defined "scholar" and "government visitor" participants, all programs must provide for cross-cultural activities and afford all participants an exchange program in the United States of not less than three weeks. These requirements are currently set forth in existing regulations, but have, along with a requirement for reciprocity, been reordered and will henceforth be prerequisites to program designation.

The Agency will require sponsors to be both United States citizens as such term is defined in this Part and to affirmatively demonstrate an ability to comply, and remain in continual compliance, with all regulatory provisions. As regards exchange visitors, the Agency has defined the statutorily enumerated categories of eligible participation in terms of the activity inherent to each categorical status. Thus, by way of illustration, the Agency has determined that an eligible "student" exchange participant is one entering the United States for the purpose of pursuing a full course of study at an accredited educational institution. This approach will ensure that exchanges occurring under the aegis of the Exchange Visitor Program fall squarely within the established statutory parameters of status and activity. As participation in the Exchange Visitor Program is thus limited, strict adherence and compliance with Agency promulgated definitions of status will be expected.

A statement addressing the Agency's long-standing reciprocal exchange policy is set forth in § 514.8. Such policy contemplates that exchange sponsors will make a good faith effort to facilitate reciprocal exchange of persons to the fullest possible extent. Statutorily mandated, reciprocity is inherent in the concept of mutual exchange of persons. Confusion over the nature and scope of reciprocity has been problematic for some time. As a policy consideration, the Agency seeks to promote and foster innovative and expansive responses to this critical program requirement. Although one-for-one exchange is the ultimate objective of the foreign policy underlying passage of the Act, the Agency recognizes that circumstances may permit no, or only limited, reciprocal exchange opportunities.

Related to reciprocity is the requirement that exchange visitors be exposed to various activities designed to promote cross-cultural awareness. Sponsors will be required to offer a reasonable amount of cross-cultural activities, including sports, cultural, and social activities for the purpose of enhancing the participant's knowledge and understanding of American mores, customs, and ways of life.

Agency scrutiny of existing regulations governing the Exchange Visitor Program has revealed a lack of specificity and clarity regarding sponsor obligations and program administration. Although the Agency is secure in its belief that sponsors act in the best interests of sponsored exchange participants, the existing regulations do little to ensure uniform program administration and oversight of exchange visitors. To correct this deficiency, the Agency proposes amendment to existing regulations in an effort to provide some measure of uniformity in the conduct of exchange activities.

Recognizing that exchange visitors are dependent upon the sponsors who facilitate their entry into the United States, the Agency proposes that such sponsors demonstrate, to Agency satisfaction, their organizational and financial ability to fulfill their duties and obligations as exchange sponsors. Pursuant to proposed regulations set forth at § 514.9, non-government sponsors must affirmatively establish both their ability to pay timely all financial obligations and that sufficient funds are readily available to fulfill all obligations and responsibilities attendant to exchange sponsorship.

The Agency is obligated to introduce this requirement due to evidence of financial instability among certain Agency-designated sponsors. As a matter of administrative convenience, the Agency deems it appropriate to consider public colleges and universities as government sponsors, for the purposes of this provision only, and thereby exempts them from compliance. In addition to furnishing evidence of fiscal integrity, sponsors must also comply with additional obligations pertaining to internal organizational operations.

The proposed regulation set forth at § 514.9 also requires that sponsors adhere to Agency-promulgated regulations governing the Exchange Visitor Program. This regulation is advanced, in part, to ensure that officers, employees, and agents involved in sponsor facilitation of exchange activities are aware of the Program, its intent, and regulatory requirements. this proposed regulation will require employees, officers, and agents responsible for program administration to be adequately trained and qualified to permit assigned duties relating to exchange activities. Underlying this requirement is an Agency concern that responsibility for both exchange visitors and program administration be vested in persons who have knowingly undertaken such responsibility.

Proposed amendments governing the selection and orientation of exchange participants are set forth at § 514.10. The Agency will require that sponsors ensure that prospective exchange participants meet the eligibility criteria for program participation and that such program is suitable to the participant's background, needs, and experience. Upon selection for participation and prior to commencement of the program, sponsors will be required to provide the participant with information regarding the exchange program, travel, housing, and cost. The sponsor must also inform all exchange visitors of the two-year home residency requirement which may apply to the exchange visitor due to government funding or area of study.

Upon the exchange participant's arrival, or as soon as practical thereafter, the sponsor must provide sufficient orientation to acquaint the exchange visitor with United States customs and monitor the visitor's stay in the United States. This requirement is introduced in an effort to both facilitate the exchange visitor's adjustment to life in the United States and enhance the positive impression of the United States which is the underlying purpose of all exchange activity. Although the Agency

has determined that orientation for accompanying dependents is highly desirable, a mandatory requirement that such orientation be conducted is not proposed. The Agency strongly encourages sponsors to provide dependent orientation.

Additionally, the Agency has reviewed the health and accident insurance coverage afforded Program participants. The need for such coverage is self-evident. Given the escalating costs of U.S. health care, the current levels of coverage, in place since 1983, are now woefully inadequate. As set forth in § 514.14, the Agency proposes to increase the level of coverage to $50,000 per accident or illness. The Agency is also proposing that exchange visitors obtain coverage for repatriation of remains in the amount of $7,500 and coverage for medical evacuation to their home country in the amount of $10,000. A waiting period for pre-existing conditions, reasonable as determined by industry standards, and a deductible not in excess of $500 per accident or illness will be permitted. Provision is made for co-insurance. Policies may not exclude from coverage perils or dangers inherent to the exchange activity. For example, an insurance policy secured to cover flight training participants may not exclude injury arising from operation of small aircraft. In an effort to ensure the quality of the provided coverage, the Agency proposes that only insurance corporations having an A.M. Best policyholder rating of "A" or above, an Insurance Solvency International, Ltd. (151) rating of "A" or above, or a Standard & Poor's Claims-paying Ability rating of "AA" or above, may act as underwriters.

The proposed regulation provides for self-insurance by federal, state or local governments, state colleges and universities, and public community colleges. A non-governmental sponsor may elect to self-insure or to accept full financial responsibility for the above requirements, but may do so only with the Agency's permission.

Current regulations do not require that an accompanying spouse or dependent of an exchange visitor be covered by insurance. Proposed regulations cure this programmatic flaw by requiring accompanying dependents entering the United States on a J visa to be covered under an insurance policy. An exchange visitor's failure to secure insurance coverage for his or her self and J-2 accompanying dependents will obligate their program termination. Sponsors shall also be prepared to provide exchange visitors with information on the availability of such coverage.

Notification, Annual Reporting, and Control of Form IAP-66

A proposed regulation governing certain notification requirements is set forth at § 514.13. Such requirements include notification to the Agency of material changes in a sponsor's organizational structure which affects the citizenship requirement set forth in § 514.2, and overall ownership and control. The Agency is obligated to introduce this requirement as many designated sponsoring organizations are small entities comprised of key personnel. Upon notification of a substantial change in ownership or control, the Agency will ascertain whether designation should continue based upon the experience and expertise of the new management. It must be noted that Agency designations are not transferable.

Efficient Agency oversight and administration also dictates that sponsors apprise the Agency of any changes in responsible officers, address, or telephone number. In similar fashion, loss of licensure or accreditation, change in financial circumstances or the voluntary termination of the exchange visitor program must be reported. The Agency has also determined that notification concerning a participant's early completion or withdrawal from the sponsor's exchange visitor program is necessary. Upon receipt of such notification the Agency will deem the sponsor's obligations to an exchange visitor to have ended.

The Agency has determined that a substantial correction must be made to the current practice surrounding the care and custody of the Form IAP-66. Such forms are controlled U.S. Government documents and have been found to have a substantial black market value. The Agency has also discovered unauthorized utilization of the forms by program sponsors to facilitate the entry of foreign nationals for the purpose of participation in non-designated exchange activities. The Agency proposes to correct this abuse by institution of a strict accounting of all forms disbursed to sponsors. To this end, the Agency proposes, pursuant to the provisions of § 514.12 and § 514.13, that sponsors record and destroy damaged forms, track and record forms issued, and maintain all forms on hand in a secure fashion. An accounting for all forms will be made, in part, pursuant to an expanded annual reporting requirement.

Considerable debate has surrounded the Agency's proposal regarding annual reporting requirements. The Exchange Visitor Program is an anomaly in the U.S. immigration scheme and provides extraordinary latitude in the selection of exchange participants. As a program and an extension of U.S. foreign policy a degree of accountability is required. The burden of submitting an annual report which reflects a sponsor's activity for a year and which ensures an annual reconciliation of their usage of Forms IAP-66 is viewed by the Agency as a de minimus imposition upon designated sponsors. The Agency has elected to resurrect a one page report form which has been in use for the past thirty years and which is familiar to long established exchange sponsors. Further, the Agency takes this opportunity to advise designated sponsors that this annual reporting requirement pursuant to an oral representation made by an Agency official. Be that as it may, the regulatory requirement of an annual report has been in place since the inception of the Exchange Visitor Program. The requirement that sponsors submit an annual report will be strictly enforced.

To assist the exchange community in review of these proposed regulations, the Agency has incorporated into this Rulemaking the definitions currently set forth at 22 CFR 514.1. Minor changes, not affecting underlying meaning, have been made to most of the definitional terms. Such changes, when made, are proposed in an effort to enhance overall clarity and readability. Although definition of the term "citizenship" was the subject of a separate rulemaking, such term is included here, in final form, to facilitate overall review. Comments concerning this definition are not sought.

Finally, to assist in review of these proposed regulations the Agency attaches as appendices copies of forms which are used in conjunction with sponsor administration of exchange visitor programs. At appendix A is a modified version of the certification used to attest to the citizenship of sponsors and responsible officers. Appendix B contains the IAP-37, the Exchange Visitor Application, which has been approved by the Office of Management and Budget. The Agency anticipates that it will continue to use the form with a few minor changes to reflect § 514.4, Participant Eligibility. Appendix C contains a copy of IAP-87, Update of Information on Exchange Visitor Program Sponsor. The Agency anticipates a limited modification of this form. Finally, at appendix D, a copy of the proposed annual report form is attached for examination.

Subpart B: Specific Program Provisions

Section 514.20 Professors and Research Scholars

Although professor, researcher, and scholar exchanges are the very heart of the Exchange Visitor Program, regulations which specifically govern these exchanges have never been promulgated. In an effort toward regulatory consistency and program integrity the Agency is herein proposing regulations which specifically provide guidance regarding such exchanges.

The term "scholar," although set forth as a category of exchange in the Fulbright-Hays Act, has never before been defined in Exchange Visitor Program regulations or considered a distinct category of authorized exchange activity. This lapse is possibly due to the conceptual overlap of the term with "professor" and "researcher." The Agency proposes to correct this discrepancy by introducing the category of "short-term scholar," which is discussed below. On an additional point of terminology, the Agency has been advised that a number of academic exchange sponsors prefer to retain the current category of "research scholar" rather than "researcher." Upon deliberation, the Agency agrees that retention of this term, long used and understood within the exchange community, is appropriate.

In deciding whether to facilitate the exchange of a professor or research scholar, the sponsor shall consider the underlying purpose for which the individual is visiting the United States. It is appropriate for a professor or research scholar to come to the United States as an exchange visitor only when the underlying purpose of his or her entry into the United States is to stimulate international collaborative teaching and research efforts or to promote interchange between research and educational institutions in the United States and other countries. To this end the proposed regulations require that appointments of professors and research scholars be temporary and not on a tenure track, even if the position itself is permanent.

Recognizing that the positions of professor and research scholar are intertwined, the Agency proposes to permit professors to freely conduct research and research scholars to teach or lecture, unless disallowed by the sponsor. The definition of professor and research scholar set forth in these regulations, rather than the position description utilized by the individual educational or research institutions, is to be used by sponsors in determining the category of exchange participation.

Prior to issuance of the Form IAP–66, the responsible officer must review the parameters of the individual exchange to assess whether research or lecturing will comprise the participant's primary activity. If the exchange participant will primarily be conducting research, he or she must be categorized as a research scholar on the Form IAP–66. If the exchange participant will primarily lecture, then he or she must be categorized as a professor.

Further, the proposed regulations allow sponsors to authorize a change of category from professor to research scholar, or vise versa when the principal activities of the participant so dictate. Such change of category does not require Agency approval or notification. A change of category does not extend the duration of the exchange visitor's program beyond what is permitted at § 514.20(i).

Professors or research scholars may conduct their exchange activity at the location(s) listed on the Form IAP–66, which could be either at the location of the exchange visitor sponsor or the site of a third party facilitation the exchange. Pursuant to § 514.20(g), exchange visitors may also engage in activities at locations not listed on the Form IAP–66 if such activities constitute lectures or consultations authorized in advance by the sponsor. By way of illustration, a research scholar may conduct research at the universities listed on his or her Form IAP–66, and may also conduct short-term consultations at any location when the conditions set forth in the regulations are satisfied.

Over the years the Agency has received numerous requests from the academic community to extend the permitted duration of participation for research scholars. The National Institutes of Health and other United States Government agencies have also requested greater flexibility in arranging the duration of participation for the professors and research scholars that they sponsor. In revisiting this issue, the Agency has determined that a greater degree of flexibility in the permitted period of participation is desirable.

To this end, the Agency proposes that up to three additional years beyond the duration of participation set forth in § 514.20(i) may be authorized by the Agency when exceptional or unusual circumstances so warrant. The Agency proposes the additional time in an effort to be responsive to needs which arise from the participation of exchange visitors in international research projects and in medical and biomedical research. Based upon representations made by designated sponsors, the Agency anticipates that a small percentage of professor and research scholar exchanges will encounter the exceptional or unusual circumstances which would warrant such an extension. Requests for such extensions shall be made directly to the Agency's Exchange Visitor Program Services.

The proposed regulations also allow responsible officers to approve short-term extensions of six months or less beyond the duration of participation allowed in § 514.20(i). In addition, the Agency will entertain sponsors' request to extend the permitted period of participation for a group of research scholars engaged in specific fields of endeavor on a blanket petition basis. The Agency believes that such short-term extensions and blanket approvals will provide both desired flexibility and enhanced administrative efficiency.

Section 514.21 Short-term Scholars

The agency proposes to create the category of "short-term scholar," which is defined as a professor, research scholar, specialist, or a person with similar education or accomplishments coming to the United States on a short-term visit for the purpose of lecturing, observing, consulting, training, or demonstrating special skills at research institutions, museums, libraries, post-secondary accredited educational institutions, or similar types of institutions. Educators, scientists, research fellows, writers, museum administrators, librarians, and similar persons of recognized expertise are examples of participants appropriate for this category.

The goal of short-term scholar exchanges is to increase the velocity of the interchange of knowledge and skills and collaborative research efforts between foreign and American scholars. This may be accomplished by providing foreign scholars the opportunity to share ideas with their American colleagues, participate in educational and professional programs, confer on common problems and projects, and thereby promote improved professional relationships and communications.

Because these exchanges are of limited ratio and the participants are often senior in their field, the Agency has determined that it will not be necessary for sponsors to provide orientation or cross-cultural activities for short-term scholars. The proposed regulations exempt short-term scholars from the minimum duration of participation set forth at § 514.8(b) but limit the maximum duration of participation to four months. As this category is intended only as a vehicle

for short-term collaboration and interchange, these participants will not be eligible for a program extension.

Section 514.22 Training

Following the passage of the Smith-Mundt Act in 1948, the Department of State, the Agency's predecessor in implementing exchange programs, promulgated regulations governing educational and cultural exchanges. Among other things, these regulations recited various categories of aliens allowed to participate in exchange visitor programs pursuant to the statutory language of the Act. Among these categories were "trainee", defined as an alien seeking to enter the United States temporarily in order to participate in an exchange visitor program "for the purpose of obtaining practical training in public administration, industry, medicine, agriculture, or some other specialized field of knowledge or skill * * *" 22 CFR part 68 (1949).

In 1961, Congress in turn passed the Fulbright-Hays Act, again directing the inclusion of training as a category of exchange participation. Although an integral part of Agency-administered exchanges, it was not until 1983 that separate regulations governing training activities utilizing the J-visa were promulgated. 22 CFR 514.13(c) (1983). These regulations have not been amended or revised since first promulgated.

In response to the General Accounting Office (GAO) investigation noted above, the Agency has reviewed the legislation and legislative history underlying the Exchange Visitor Program and existing regulations to determine whether such regulations comport with the statute governing this program. As discussed below, the Agency proposes to amend existing regulations in such a manner that the criticisms raised by the GAO are addressed and distinctions between training and work are obvious and clearly drawn.

The Agency is proposing regulations which address the criticisms of the GAO and clearly distinguish between training and work that is not training. Thus, the Agency proposes that all training conducted under the aegis of the Acts be clearly defined and structured, and on a level appropriate to the trainee's background and experience.

GAO Report

The controversy over the legitimacy of certain activities of foreign nationals in the United States on exchange visitor visas sparked Congressional concern as to the propriety of certain educational and cultural exchange programs administered by the Agency. A GAO investigation and report followed.

The report by GAO, entitled "Inappropriate Uses of Educational and Cultural Exchange Visas," and dated February 16, 1990, (GAO Report) concluded that:

> A number of J-visa activities in the practical training and international visitor categories, including summer student travel/work, camp counselor, and au pair activities—some of which have been ongoing for years—do not conform to the original legislative intent concerning educational and cultural exchanges.

GAO Report at 23.

While the words "trainee" and "receiving training" are not expressly defined in either of the educational and cultural exchange Acts, the GAO noted that the existing training sanctioned by the Agency "did not have the same status as the categories mentioned in the statutes and would not generally be considered to have the same educational and cultural value." *Id.* at 16.

The Agency is of the opinion that the vast preponderance of the exchange visitor training programs are conducted well within the legislative authorities created by the Act. However, the GAO found that certain training programs inappropriately "consisted primarily of employment in commercial enterprises with no cultural or educational emphasis placed on the participants' activities. This training involved participants in such capacities as waiters, cooks, hotel workers, and automobile body repairers." *Id.* at 3. It is noted that the GAO Report stated only that "some" training programs consisted primarily of employment in commercial enterprises with no cultural or educational emphasis placed on the participants' activities.

Distinction Between Work and Training

As noted above, the Agency has been criticized for allowing the Exchange Visitor Program to be used to circumvent the immigration and labor laws of the United States by allowing foreign workers to use the program under the guise of educational and cultural exchange. This criticism has centered on designated private sector training programs and generated considerable debate concerning the distinction between work, i.e. gainful employment, and legitimate training. Recognizing that training more often than not occurs in a work place setting, the Agency has determined that the distinction between unauthorized gainful employment and authorized training may best be drawn through examination of the components of a *bona finde* training program. The requirements for a *bona fide* training program are set forth in § 514.22(f).

The Training Plan

As a prerequisite to Agency designation, the Agency proposes that applicants submit a training plan which describes what the training objectives are, the competencies which the trainee will obtain through participation in the training program, a general description of the schedule of the training activities, and a justification for the use of on-the-job training to achieve the objectives of the training course. Special skills, e.g., computer training, to which the trainee will be exposed should also be noted.

The Agency has received many comments suggesting that the training plan requirement will be unduly burdensome in all cases, and in some cases, impossible to comply with because the sponsor is active in many different training areas. The Agency believes that the revised proposed regulations set forth herein meet those objectives.

Applicants need not submit a training plan for each trainee. However, the applicant must submit a training plan for each type of training it intends to conduct. For purposes of these regulations, the Agency has listed eleven broad categories and it believes that every conceivable type of training will fall within one of these eleven categories. See § 514.22(i)(2). Moreover, the Agency believes that the submission of a maximum of eleven general training plans is not unduly burdensome. Specific comment on this matter is invited.

Proposed §§ 514.22 (f) and (g) set forth that information which the applicant is to include in the training plan and describes three types of training plans which an applicant may utilize in order to comply with the regulation.

The Agency recognizes that at the time the applicant is applying for designation it may not have identified individual trainees who are going to participate in the program. In such instances, the applicant need only submit a generalized, hypothetical training plan which illustrates the training the applicant proposes to provide.

In other instances, the applicant may not have prepared the training plan at the time it applied for designation. However, if the applicant has previously been engaged in the same sort of training for which it is now seeking designation it may submit a copy of a previously used training plan.

If the applicant has already designed a structured training plan at the time it is applying for designation, a copy of such training plan should be submitted with the application.

If all of the above instances, the applicant should bear in mind that the Agency's interest is not in creating needless paperwork, but in having sufficient facts to determine that the applicant is capable of conducting the training for which designation is sought.

Points to be discussed and included in the training plan are set forth in the Appendix to the proposed regulations. In addition, the general training plan must indicate whether the training is in a specialty occupation or a non-specialty occupation.

The Agency is aware that many sponsors will expand the breadth of their programs. If a sponsor desires to add additional training areas to its program, it does not need to apply formally for re-designation. The sponsor may simply request the Agency to amend its designation to include the added training areas. The sponsor must, however, submit a general training plan for each new training area added to its designation.

Specialty and Non-Specialty Occupations

The Agency does not necessarily view a specialty occupational trainee as a worthier participant in the Exchange Visitor Program than a non-specialized occupational trainee. Therefore, non-specialty occupational training programs will be designated if otherwise in compliance with the regulations. However, the Agency considers the distinction to be significant because past experience has shown that some of the non-specialty occupational training programs were, in reality, work programs designed to meet the staffing needs of an employer. Thus, the Agency has determined that non-specialty occupational programs may require closer monitoring after designation than was previously undertaken in the past.

The Agency has concluded that the potential for inappropriate usage of the J visa is most pronounced in those non-specialized occupational areas which are generally considered unskilled in nature. For example, the Agency would not approve an application for designation of a program to train persons in clerk typist skills or in nurses' aides or orderly skills. The Agency will presume that such training would in reality be designed for staffing purposes and, therefore, inconsistent with the Agency's mission. A listing of those occupations which the Agency considers to be unskilled is set forth. Applications for designation of training programs in such occupations will not be approved.

Justification for the distinction between "specialty occupation" and "non-specialty occupation" may be found in both the original regulations governing the Exchange Visitor Program and in the legislative history of the Acts. In 1949, the Department of State permitted "trainee" participants pursuing training in "public administration, industry, medicine, agriculture, or some other *specialized* field of knowledge or skill * * *." 22 CFR part 68 (1949) (emphasis added). The legislative history of the Smith-Mundt Act refers to the training of meteorologists, agricultural research by the operation of collaborative experiments and research stations, hydroelectric experts, malaria experts, and experts in the fields of economics, business administration, agricultural design and construction, communications, and distribution of electric power. United States Information and Educational Exchange Act of 1948: Hearings on H.R. 3342 Before a Special Subcomm. of the House Comm. on Foreign Affairs, 80th Cong., 1st Sess. 148–50 (1947).

While most of the early exchange visitor training programs fell in specialized areas such as those noted above, the legislative history of the 1961 Fulbright-Hays Act strongly suggests that Congress intended the program to be broadly construed and highly flexible and adaptable to changing needs and conditions. In recognition that non-specialty occupational training programs can be an important part of our foreign policy, the Agency does not propose to exclude them from the Exchange Visitor Program. Since the passage of the Fulbright-Hays Act, the world has seen a major expansion in non-specialty occupational training and such programs have become an important part of our foreign policy, which the Agency intends to continue. However, for the reasons set forth above, the Agency will monitor non-specialty occupational training on an *ad hoc* basis in order to ensure that such training is *bona fide*.

As noted above, while the Agency will not require that a detailed training plan be submitted for each trainee, we anticipate that sponsors engaged in bona fide training programs will, in the ordinary course of business, prepare such plans and retain them in their files. The Agency may from time to time request an opportunity to inspect these training plans in order to verify sponsor compliance with Agency regulations.

Sponsor Supervision

In the proposed regulations, the sponsor of the program must be directly responsible for all aspects of the trainee's activities while the trainee is in the United States, including the selection, orientation, training, supervision, and evaluation of the trainee. The purpose of this proposal is to assure that responsibility for the trainee resides in one place. It has always been the policy of the Exchange Visitor Program that sponsors be directly responsible for these aspects of the Program, yet analysis of some programs reveals that this policy has not always been observed. The proposed regulations codify and strengthen this existing long-standing policy.

In order to carry out the actual training set forth in a sponsor's approved training plan, the Agency has determined that utilization of a third party by the sponsor may be appropriate. If the sponsor elects to delegate its responsibility for providing approved training to a third party, the sponsor is nevertheless accountable for ensuring that the third party complies with these regulations. A third party's violation of these regulations shall be imputed to the sponsor; therefore, the sponsor's obligation to monitor, control, and oversee the third party is absolute. Simply put, a third party may act for or in place of the sponsor; however, the accountability of the sponsor shall be non-delegable.

When a third party is utilized by the sponsor, the Agency requires evidence of an express written agreement between the sponsor and the third party Any such agreement shall specifically recite the third party's obligation to act in accordance with all Agency promulgated regulations applicable to the sponsor. In addition, the sponsor must provide the third party with the individualized training plan to be used to train the trainee. The sponsor shall retain a copy of such training plan for a period of three years.

The Agency will no longer approve an organization as a sponsor of a training program where the organization or its agent abdicates its responsibility to directly train and supervise the trainee. The regulations, as noted, will require that the sponsor retain full responsibility for the conduct of the program. Simply placing a trainee in a third-party training program will not be allowed in the future if the sponsor abdicates accountability for the training and well-being of the trainee.

Flight Training Programs

Included amongst the exchange visitor programs currently designated by the Agency are flight training programs. The Agency considers flight training to be in an important yet sensitive occupational area which requires that particular attention be given to quality assurance. Additionally, flight training schools require more financial resources than many other types of training programs.

Over the past two years, five of the thirty Agency-designated flight training programs have met with financial failure and recently one flight training program was suspended by the Agency for various violations of Agency regulations. These incidents suggest that the Agency must monitor more closely the flight training programs in order to ensure that program participants are adequately protected.

The Agency has engaged in considerable dialogue with representatives of flight training programs during the course of the Agency's regulatory reform effort. The Agency has conveyed to the sponsors its concerns about the financial stability of a number of sponsors and its concerns about the "work vs. training" issue involved in flight training programs. Similarly, the flight training sponsors and those seeking to become designated flight training sponsors have expressed their concern over the eighteen month maximum duration, arguing that flight trainees require more time to complete their training.

Flight training sponsors have also argued that participants in flight training programs should more properly be treated by the Agency as "students" rather than as "trainees" because typically flight training programs are more like schools than training programs in that they follow fixed curricula, have classroom instruction, and, at least in some cases, are accredited by nationally recognized accrediting agencies. It is further argued that placing flight training program participants in the student, rather than the trainee category, would also entitle the flight student to a total of eighteen months of training at the conclusion of the classroom portion of the program, rather than the maximum of eighteen months period of participation permitted under the training regulations.

The Agency has considered these arguments and has concluded that the flight training participants more appropriately fit under the training category than the student category. Moreover, the stated goals of the flight training program participants are better met under the trainee category than under the student category. For example, proposed § 514.23 ("College and University Students") requires that the student be studying at a degree-granting post-secondary educational institution. Most flight training schools do not grant degrees. Also, before a student can commence "academic training," the proposed regulation requires that the student first must have been a student in the exchange visitor program for the preceding nine months. See § 514.23(g)(2)(i)(A). The Agency has been advised that most flight students spend no more than six months in a full-time classroom or academic setting.

Therefore, in order to meet the Agency's concerns about quality assurance and financial stability of flight training programs, while at the same time allowing flight trainees to gain more training time in the U.S., the Agency is proposing the following:

1. All flight training programs must be accredited by a nationally recognized accrediting authority. If the proposed regulation is made final, the Agency will consider only the applications of those programs which have already been accredited as set forth in the regulation, or which have formally commenced the accreditation process. The Agency is aware that accreditation may take as long as one year to be completed. The Agency will, therefore, accept applications for designation from flight schools which have commenced the accreditation process, but will only conditionally designate them for up to twelve months. Similarly, currently-designated flight training programs will be conditionally redesignated for up to twelve months, but only if they have commenced the accreditation process.

2. With respect to duration of participation, flight trainees are to be granted an additional six months of training time beyond the normal 18-month maximum duration of participation. The Agency believes that a longer stay is justified in the case of flight training because of the strict training requirements of the international aviation community. As under current regulations, any extension of the program beyond twenty-four months must be specifically approved by the Agency, and such extensions will be granted only under highly unusual circumstances.

The Agency believes that this proposal is a reasonable accommodation to the need of the Agency and the needs of the flight training industry. Recognizing that there are both time and cost considerations in the accreditation process, the Agency is willing to extend the training time allowed to flight trainees in return for the flight training sponsors' acceptance of the accreditation requirement.

The Duration of Participation

The Agency had considered limiting training programs to twelve months. Upon consultation with a number of current sponsors, the Agency decided to keep the duration of training programs to a maximum of eighteen months, as is presently provided for in the regulations. The primary purposes of training under the Exchange Visitor Program are to expose the visitor to uniquely American techniques, methodology, and philosophy in the visitor's field of endeavor and to provide an opportunity for open interchange of ideas between the visitors and Americans. The law envisions that exchange visitors will return to their home country to share with their compatriots their experiences in the United States, including the fruits of their training. While many of the exchange visitor training programs funded by the United States Government are for less than eighteen months in duration, the Agency concludes that many private sector programs may require eighteen months to maximize the benefits to the trainee. An exception is being proposed for flight training programs in order to allow additional time to complete this highly specialized training. As noted above, flight training programs will be given a twenty-four month duration of participation.

Section 514.23 College and University Students

In response to requests from the academic community the Agency has undertaken the task of clearly defining when and under what circumstances a student should be issued a J visa. Sponsors should place foreign college and university students in their exchange visitor program when the students academic programs are funded by the United States Government, the government of the exchange visitor's home country, an international organization of which the United States is a member, or when the program is carried out under an agreement between the United States and a foreign government. Sponsors may also place foreign students in their exchange visitor program if the program is carried out under a written agreement between American and foreign educational institutions, or when foreign students are supported substantially by scholarships designed to promote international educational exchanges.

Further, the Agency proposes that the category of college and university

students shall be limited to exchange participants at post-secondary accredited educational institutions who are (i) pursuing a recognized full course of study leading to or culminating in the award of a U.S. degree; or (ii) engaged full-time in a prescribed course of study of up to 24 months duration. The latter category is proposed in order to allow and encourage college or university students who seek to pursue a clearly defined non-degree academic program.

8 U.S.C. 1101(a)(15)(J) provides, in part, that an exchange visitor may enter the United States under the aegis of a J visa if such visitor is a *bona fide* student actively engaged in *bona fide* academic study. 22 U.S.C. 2460(b) directs the Agency to ensure that exchange visitor programs sponsored by its Bureau of Educational and Cultural Affairs are of the highest academic standards. Pursuant to these statutes, Agency stewardship of the Exchange Visitor Program requires that the *bone fides* of an exchange visitor's academic studies be ascertained.

In order to quantify *bona fide* academic study and enhance Agency administration and oversight of the Exchange Visitor Program, definition of the term "accredited educational institution" is proposed. The Agency proposed to (i) define the *bona fides* of an educational institution by way of its accreditation status; and (ii) define the *bona fides* of student status in terms of attendance at an accredited educational institution and successful completion of the minimum number of academic credits per semester which best evidences full-time study.

It is Agency opinion and belief that accreditation is an objective and independent measurement of the *bona fides* of an "established school or institution of learning." Evidence of Agency policy and practice regarding accreditation is set forth at the current 22 CFR 514.15. This regulation authorizes the Agency to require evidence of accreditation from applicants seeking sponsor designation under the Exchange Visitor Program. The absence of a specific definition concerning accreditation was, in part, the basis of recent litigation. This litigation arose due to an Agency determination that a non-accredited educational institution was not an appropriate sponsor within the purview of the Exchange Visitor Program. Although the Agency prevailed in this litigation, the Agency now desires to amend existing regulations explicitly to enunciate the Agency's accreditation policy.

Recognizing that the expertise for determining accredited educational institutions lies with various independent accrediting authorities, the proposed Agency definition makes provision for the use of such findings on accreditation made by these independent authorities. Specifically, in review of the *bona fide* status of a post-secondary educational institution, the Agency proposes to utilize the annual listing of accreditation authorities promulgated by the Secretary of Education pursuant to 20 U.S.C. 1141(a). As explained in 34 CFR 602.1, accreditation is both a prerequisite to eligibility for various types of Federal financial assistance and a reliable measure concerning the quality of education offered by an educational institution. Agency use of such annual listing is also appropriate given the Department of Education's expertise and responsibility for oversight and implementation of Federal education initiatives. Pursuant to the proposed definition, post-secondary academic study completed at a non-accredited educational institution will not be deemed to comply with the *bona fide* requirement set forth in 8 U.S.C. 1101(a)(15)(J).

The proposed regulations set forth the requirement that exchange visitor students possess sufficient proficiency in the English language to enable them to participate in their program or are provided English language training. In addition, exchange visitor students are required to take a full course of study at a post-secondary accredited educational institution as such terms are defined in this Part. Pursuant to exceptions to this requirement set forth at § 514.23(f), provision has been made to ensure that students may maintain their status in the event of sickness or academic difficulties.

Recognizing the importance of academic training, the Agency proposes liberal regulations governing the pursuit of such opportunities. Such training may include internships, practicums, and cooperative educational programs. It may occur before graduation, after graduation, or a combination of both when the requirements set forth in § 514.23(g) are satisfied. Academic training may be as long as the period of the classroom instruction at the accredited educational institution, but shall not exceed a total of 18 months for any exchange visitor student. The Agency strongly supports training for college and university students but will require that it be an integral or critical part of the exchange visitor's academic program.

The Agency proposes that academic training be allowed for exchange visitor students when the exchange visitor: (1) Has been a student in the exchange visitor program for the preceding nine months; (2) is participating in academic training that is directly related to his or her major field of study; (3) is in good academic standing with the post-secondary accredited educational institution; (4) will adhere to the period of time permitted for academic training; (5) receives approval in advance and in writing by the responsible officer for the duration and type of training; and (6) satisfies the other requirements set forth in these regulations.

When students do not receive compensation for services when they participate in academic training during their studies, the requirements set forth in § 514.23(g) are not applicable. In this situation, the student needs only to obtain approval for such training by the academic dean or advisor and the responsible officer.

The Agency recognizes the benefits of exchange visitor students working while studying. At the same time, the Agency recognizes the importance of students completing their studies in a timely manner. The proposed regulations allow exchange visitor students to engage in part-time employment when it is approved by the responsible officer and is (1) pursuant to a scholarship, fellowship, or assistantship, or (2) necessary because of serious, urgent, and unforeseen economic circumstances which have arisen since acquiring the exchange visitor status. The regulations require that the exchange visitor student is in good academic standing and continues to comply with the full course of study requirement. Exchange visitor students shall be permitted to be employed no more than 20 hours per week, except during official school breaks and summer vacations.

A number of sponsors and other interested parties have asked the Agency to increase the maximum duration of training for Ph.D. graduates for 18 to 36 months. The rationale for such requests has been that these students need the time to complete their post-doctoral research. The Agency views academic training for exchange students as an opportunity for exposure or introduction to their profession or field of study. Foreign students often spend four to eight years or longer in the United States to complete their studies. The Agency believes the advantage of foreign students returning home to share their experiences and to contribute to their country home overrides the benefit of academic training longer than 18 months. As discussed in § 514.41, below, post-doctoral students may, in unusual or exceptional circumstances, petition

the Agency for a change of category to research scholar.

Section 514.24 Teachers

Although teacher exchanges are a vital component of the Exchange Visitor Program, regulations governing such exchanges have never been promulgated. The Agency seeks to correct this programmatic inconsistency by herein proposing regulations designed specifically to provide guidance to sponsors of such teacher exchanges.

The proposed regulations define at teacher as an individual teaching full-time in a primary or secondary accredited educational institution. As for primary and secondary schools, accredited educational institution is defined as any publicly or privately operated primary or secondary institution of learning duly recognized and declared as such by the appropriate authority of the state in which the institution is located. Teachers at the post-secondary level are under the category of professors, rather than teachers.

In deciding whether to include a teacher as a participant in its program, the sponsor shall consider the purpose for which the foreign national is visiting the United States. It is appropriate for a teacher to come to the United States as an exchange visitor teacher if (a) the individual will teach full-time at a primary or secondary accredited educational institution, and (b) the objective of the program is to promote the purpose of the Exchange Visitor Program. The proposed regulations require that the appointment of teachers be temporary and not involve permanent or long-term employment. This requirement is consistent with the intent that the exchange visitors return home after their program to share their experience with those in their country. The teaching position shall be also in compliance with any applicable collective bargaining agreement, where one exists.

As stated previously, the teacher category is reserved for primary and secondary teachers who come to the United States to teach full-time. The Agency wants to encourage educational administrators, curriculum developers, and other educational specialists at the primary and secondary level to participate in exchange visitor programs. The Agency intends that the latter group participate in exchange visitor programs under the specialist or government category, depending on who is sponsoring and selecting the exchange visitors.

Section 514.25 Secondary Students

Secondary school student exchanges are designed to afford students an opportunity to study in the United States for up to one year while living with an American host family. Such exchanges provide secondary school students an in-depth and broad exposure to American ideas and institutions through immersion in the everyday aspects of living and attending school in the United States.

Secondary school student exchange programs have been a part of United States public diplomacy efforts since 1949. Expanding from a small base of non-profit organizations dedicated to student exchange, the Agency currently designates sixty-two organizations to conduct such exchanges. Secondary student programs vary in size from 50 to 4,000 participants. In 1990, Agency-designated sponsors facilitated the entry of 24,552 secondary school students, accounting for approximately fifteen percent of all exchanges conducted under the aegis of the Exchange Visitor Program. Although generally viewed as a highly successful category of exchange activity, some secondary school student exchanges encounter problems which are best addressed through regulation.

Over the years concerns have arisen regarding the administration and operation of secondary school exchange programs. In 1982, the Agency awarded a grant to the Council of Chief State School Officers to conduct a study of such exchange activity and to make recommendations concerning possible areas of improvement. From this study sprang the impetus for the formation of the Council for Standards in International Education Travel (CSIET). Devoted to the establishment of standards to govern organizations conducting educational international travel and exchanges, CSIET evaluates such organizations seeking CSIET endorsement on the basis of their compliance with none performance standards. The Agency considers these nine standards to be appropriate guideposts for organizations engaged in international educational travel in that such standards are a distillation of current Agency regulations governing secondary school student exchanges. The proposed regulations set forth below continue to incorporate these standards but also impose additional requirements that are unique to exchange programs.

Part of an all-encompassing regulatory reform effort, the revision of regulations governing secondary school exchanges comes at an opportune moment. Nationwide, states and local school districts are beginning to devote considerable attention to the enrollment of non-resident foreign students in their schools. Although not all foreign students enrolled in local schools are participating in an exchange program, the perception of the general public is that all such students are, in fact, exchange students. Given this perception, the Agency is determined to ensure the highest possible standards for those exchanges under its auspices.

In response to egregious experiences related to the enrollment of non-resident foreign students, state and local school authorities have begun to enact various rules and regulations governing such enrollments. This piecemeal legislation is creating a patchwork of administrative requirements which hamper the ability of Agency-designated sponsors to facilitate secondary student exchanges. The Agency is concerned about this development and is devoted to achieving an overall strengthening of regulations and monitoring of program administration in an effort to forestall any further piecemeal legislation.

Program Administration

Mindful of the unique program considerations inherent to secondary school student exchanges, the Agency seeks to delineate clearly the obligations and responsibilities program sponsors must meet in administering such exchanges. Student participants are placed in a vulnerable position, far from home at a tender age. Due to this position, students are dependent upon program sponsors whose integrity, expertise, and professionalism must be above reproach.

Apparent to all observers is the fiduciary duty a sponsor owes to a student exchange participant. Such duty necessarily requires the sponsor to undertake responsibility for all aspects of the student participant's stay in the United States from the selection of a suitable host family and enrollment in a secondary school through on-going monitoring of the exchange and the student's return to the home country. To meet this duty satisfactorily the Agency concludes that an adequately trained and supervised staff, including agents or volunteers acting on the sponsor's behalf, is of paramount importance to secondary school exchange programs. The Agency therefore proposes, pursuant to the provisions of § 514.25(d) that sponsors properly train and supervise all staff members and volunteers acting on their behalf.

Working with adequately trained and supervised staff and volunteers, the Agency proposes that all sponsors

maintain a monthly schedule of personal contact with the student, school, and host family. The Agency contemplates that this degree of contact will provide adequate assurance that the student is successfully adapting to his or her new home and school environment. This proposed monthly schedule of contact is a minimum. Sponsors will be expected to increase the level of contact with the student, school, and host family when adjustment problems so dictate.

To ensure that all students are properly supervised, the Agency proposes a new requirement that program sponsors arrange no host family placement outside a 150 mile radius of the home of an organizational representative authorized to act on the sponsor's behalf in both routine and emergency matters. A geographical limitation is proposed to enhance the sponsor's ability to maintain the proposed level of contact. This geographical limitation is a maximum. If staff members or volunteers are unavailable in a given geographic location, the sponsor must necessarily refrain from placing a student in such location.

Student Selection, Enrollment, and Orientation

Considerable debate surrounds the selection criteria for student participants. Currently, students must be between the ages of 15 and 19 years of age, be capable of functioning in an English speaking environment and must demonstrate maturity, good character, and scholastic aptitude. These criteria were developed to ensure that foreign exchange students entering United States schools could benefit from the exchange experience and provide a meaningful contribution to the educational experience of their American counterparts. Such criteria are by nature somewhat subjective but do provide general guidance to both sponsors and local school officials. The Agency has determined that modification of these selection criteria is needed.

8 U.S.C. 1101(a)(15)(J) provides, in part, that an exchange visitor may enter the United States under the aegis of a J visa if such visitor is a *bona fide* student actively engaged in *bona fide* academic study. Pursuant to this statute, Agency stewardship of the Exchange Visitor Program requires that the bona fides of an exchange visitor's academic studies be ascertained. The Agency concludes, in light of this statutory requirement, that a modification of the maximum age for participation in a secondary school student exchange program is required.

The Agency is obligated to utilize the United States standard of 12 years of primary and secondary school study in assessing *bona fide* student status. Students who have completed not more than eleven years of primary and secondary study will be deemed, automatically, *bona fide* secondary school students. Attendance in kindergarten should be excluded for the purpose of calculating years of study under this 12 year standard. This standard is of limited importance except to those students who continue their studies into A-level or international baccalaureate programs or their equivalent. Students who complete this additional level of study are, in academic terms, the equivalent of United States college and university students.

Students intending to continue their studies in an A-level or international baccalaureate program may participate in a secondary school student exchange program prior to their enrollment in A-level or international baccalaureate studies. Such students will not have completed 12 years of study as determined by United States standards and would therefore be appropriately placed with their United States peers at the senior year of high school level.

After consultation with Agency-designated sponsors, and in an effort to accommodate potential secondary school student exchange participants who have completed international baccalaureate or A-level studies, the Agency has determined that *bona fide* secondary school student status should also be extended to participants who are not more than 18 and a half years of age at the time of enrollment in a United States secondary school.

It has come to the Agency's attention that some students have returned to the United States in an exchange program for a second year of study. The Agency concludes that this is an inappropriate practice which must be curtailed. Current regulations limit secondary school exchanges to no more than one year. The proposed regulations continue this limitation. To this end, the Agency proposes at § 514.25(e), below, that sponsors specifically inquire whether a potential exchange student has previously participated in a secondary school exchange program and disqualify for further participation any student who has.

Provisions governing the enrollment in United States schools of selected student participants are set forth at § 514.25(f). The Agency proposes to safeguard this program's integrity and good reputation among school administrators by continuing to require the prior written acceptance of the student by an appropriate school official. Each September the Agency is contacted by local school principals who have been surprised to find an unannounced exchange student on the school's doorstep. Given the administrative burden and inconvenience which accompanies unanticipated arrivals, the Agency will henceforth strictly enforce the regulatory requirement that all students be authorized for school enrollment prior to their entry into the United States.

As a policy matter, the Agency seeks to ensure that all exchange participants are properly and timely informed of matters germane to their exchange experience. Pursuant to § 514.25(g) set forth below, the Agency proposes that secondary student exchange sponsors provide all participants with advance notice of travel, school, community, and host family arrangements. This information must be provided well enough in advance of the student's departure from the home country to be of use to the student. Additionally, the student must be apprised of all operating procedures, rules, and regulations governing participation in the exchange program.

Host Family Selection, Placement, and Orientation

The Agency has considered, at some length, the recurrent problems associated with host family placements. Aware that tensions will develop naturally from the obligations which arise from serving as a host, the Agency seeks to introduce some measure of uniformity to host family selections. Specific provisions governing host family selection are set forth at § 514.24(j), below.

First and foremost among such proposed selection criteria is the need to ascertain that potential host families fully understand both the rewards of hosting an international student as well as the duties and obligations attendant thereto. To this end, the Agency proposes that sponsors utilize a standard application form which solicits a detailed profile of the family and conduct an in-person interview with all family members residing in the home. In-person interviews will allow the sponsor to determine whether the potential host family is capable of providing a comfortable and nurturing home environment and that the decision to serve as a host family is one which is supported by all family members.

Due to the vulnerable position in which a student is placed by the nature of these exchanges, sponsors will be expected to undertake appropriate safeguards to ensure that the potential host family is of good reputation and character. Recognizing that one incident of abuse is beyond the pale of acceptability, the Agency must insist that sponsors exercise due diligence in the screening of all potential host families. A mere superficial compliance with this regulatory requirement will not be tolerated. Recommendations from members of the community as well as solicitation of the local school official's opinion of the potential host family may be considered a bare minimum in this regard. In similar fashion, sponsors must also satisfy themselves that the potential host family possess adequate financial resources to undertake hosting obligations.

Having adequately screened the potential host family, sponsors will in turn be expected to properly orient the family concerning the exchange activity. Host families must be fully informed of the sponsor's rules and regulations which govern the exchange program and be provided with a copy of Agency promulgated Exchange Visitor Program regulations. In addition to these requirements, the Agency proposes, pursuant to § 514.25(k) below, that sponsors conduct orientation workshops designed to familiarize the host family with cultural differences and practices as well as strategies for effective cross-cultural interaction.

Finally, the Agency has concluded that the quality and integrity of secondary school student exchanges are best safeguarded by requiring sponsors to secure a host family placement for a student participant prior to his or her departure from the home country. This requirement, set forth at § 514.25(1), below, when coupled with the requirement of advance written acceptance by local school officials will remove any uncertainly from the parameters of the student's exchange.

The Agency has been advised by sponsors that host family placements are always made before the student arrives in the United States. Without debating the veracity of this statement, the Agency concludes that a mechanism to ensure that such placements have been made in timely fashion is required.

To ensure that such host family placements, as well as school placements, have been made the Agency proposes that sponsors submit to the Agency, by August 1st of each school year a listing of student participants, their school and host family placement. This requirement is proposed in lieu of listing the name and address of the host family and school placement on the Form IAP-66 and embodies the suggestions of various exchange sponsors. The Agency concludes that such a listing will provide the desired certainty in respect to the parameters of each individual exchange but will also allow sponsors to continue their administrative process as long as possible.

Section 514.25 Specialists

Exchanges of American and foreign specialists exemplify the reciprocal exchanges of persons that the Fulbright-Hays Act seeks to promote. These exchanges have resulted in a flow of specialists between the United States and other countries, and have contributed to the growth of mutual understanding and dissemination of knowledge that is at the heart of the Exchange Visitor Program. Such exchanges are primarily nonacademic and provide opportunities to increase the interchange of knowledge and ideas between American and foreign specialists, and promote improved professional relationships and communications.

Although specialists have played an important role in the Exchange Visitor Program, regulations which specifically address this category of exchange visitor participation have never been promulgated. The Agency is herein proposing regulations which are designed specifically to provide this guidance to sponsors and to clarify the relationship between sponsors, the Agency, and exchange visitors.

Specialists may be appropriately sponsored as an exchange participant if the underlying purpose of such exchange is to stimulate international collaboration between individuals in the professions, businesses, and government. The proposed regulations require that the appointment of a specialist be temporary and not involve permanent or long-term employment.

Section 514.27 Alien Physicians

Federal law requires that foreign physicians seeking to pursue graduate medical education or training in the United States must do so on a J visa. This centralization of authority for the admission of such clients is due, in part, to past concerns regarding the academic and medical qualifications of foreign trained physicians. Since 1971, the Educational Commission for Foreign Medical Graduates ("ECFMG") has administered the issuance of Form IAP-66 for foreign medical graduates coming to the United States to pursue graduate medical education or training.

Foreign physicians must successfully complete examinations administered by ECFMG which measure their command of medical sciences. Such exam was, until 1983, the Visa Qualifying Examination. Currently, the required exam is Parts I and II of the National Board of Medical Examiners Examination. The National Board of Medical Examiners plan, however, to adopt as of January 1993 a new examination, the United States Medical Licensure Examination Steps I, II, and III. In light of this impending change the proposed regulations require an alien physician participant to successfully pass this examination.

The remaining proposed regulations reflect past practice regarding administration of these exchanges. A statement of need from the participant's home country and an annual statement executed by the participant reflecting intent to return to the home country remain in place.

Section 514.28 International Visitors

The Agency proposes that the category of international visitors be for its exclusive use. Sponsors other than the Agency will have comparable categories to use for short-term exchanges as discussed below. In the proposed regulations, international visitors programs are for foreign nationals who are recognized or potential leaders and are selected by the Agency to participate in observation tours, discussions, consultations, professional meetings, conferences, workshops, and travel.

The international visitors category is for people-to-people programs which seek to develop and strengthen professional and personal ties between key foreign nationals, Americans, and American institutions. The Agency proposes to continue the general limitation of participation for international visitors to one year. Such exchanges are intended specifically for short-term exchanges.

The Agency encourages the private sector and other government agencies to sponsor similar types of short-term exchange programs. The active participation of all parties is critical to the development and success of short-term exchange programs. In the proposed regulations, the Agency sets forth the categories of short-term scholar and specialist, especially for the private sector, and government visitors for exchangees selected by U.S. federal, state, and local government agencies.

Section 514.29 Government Visitors

The Agency is proposing to create the government visitors category to encourage U.S. federal, state, and local government agencies to expand their role in the Exchange Visitor Program. Currently, a number of government agencies are designated sponsors of the Exchange Visitor Program. The Agency intends that government sponsors continue to use a variety of categories for their exchange visitors, including the category of government visitors.

For the purpose of this section, government agencies include such entities as U.S. federal, state, and local government agencies (e.g., federal agency or commission, a state department of education, county government, incorporated city, and local school district). A government agency as used in this category does include an international organization of which the U.S. is a member by treaty or statute. However, a government agency as used in this section does not include state colleges or universities, unless such programs are sponsored by their state department of education.

The Agency is proposing that foreign nationals be eligible for a government visitors program when they meet the following three criteria. They shall be (a) selected by a U.S. federal, state, or local government agency, (b) engaged in consultation, observation, training, or demonstration of special skills, and (c) an influential or distinguished person. Under this category, exchange visitors would be eligible to participate in such activities as observation tours, discussions, consultations, professional meetings, conferences, workshops, and travel.

Government visitors programs are people-to-people programs designed to enable government visitors to better understand American culture and society, and to contribute to enhanced American knowledge of foreign cultures. The objective of government visitors programs is to develop and strengthen professional and personal ties between key foreign nationals and Americans and American institutions. These programs are for such persons as editors, business and professional persons, government officials, and labor leaders. This category is for programs of up to 18 months in duration.

Section 514.30 Camp Counselors

As discussed in Subpart A above, the Agency has determined that camp counselor programs are an appropriate addition to the matrix of exchange activities conducted under the Exchange Visitor Program. Such exchanges have a long history and have provided thousands of foreign nationals the opportunity to observe the United States and its people through their employment with domestic summer camp facilities.

Although the Agency has traditionally viewed these exchanges as a youth activity, upon review it appears appropriate to expand permissible participants to include *bona fide* youth workers and individuals demonstrating special skills. The Agency proposes that all participants be at least eighteen years of age and have not previously participated more than once in a camp counselor exchange. This latter requirement is proposed in an effort to ensure that as many persons as possible are recruited for these exchanges and that the participants are not utilized for staffing purposes inconsistent with exchange objectives.

Sponsors must conduct in-person interviews with all potential participants and secure references regarding the participant's suitability for a camp placement. Most importantly, sponsors must under no circumstance facilitate the entry of a participant for whom no camp placement has been arranged. The very nature of an exchange requires a prearranged placement. Recruitment of individuals and their "warehousing" in hotels awaiting placement arising from staff shortages is not viewed as an acceptable practice by the Agency. To ensure that placements are arranged in advance a placement report, reflecting the participant's name and placement, must be submitted to the Agency no later than July 1st of each program year.

Subpart C: Status of Exchange Visitors

Regulations proposed in this subpart govern various administrative chores relating to an exchange participant's visa status. At § 514.40, the Agency proposes criteria for termination of a program participant's exchange visitor status. This regulation directs the sponsor to terminate a participant for failure to maintain insurance coverage. Such provision is necessary to prompt compliance with the proposed insurance requirements. Sponsors may terminate an exchange participant for serious violation of sponsor program guidelines and directives. Sponsors shall terminate a participant due to his or her failure to pursue the activities for which sponsored.

At § 514.41 the Agency proposes regulations governing changes to a visitor's category of participation. Few participants request a change in their category of participation and the Agency has generally discouraged such action as a program matter. Recognizing that a change of category may often benefit both the participant and the Exchange Visitor Program, the Agency proposes that requests for such change be submitted to the Agency for approval. The Agency intends to approve only those requests which are due to unusual or exceptional circumstances. A change in category must be clearly consistent and closely related to the participant's original exchange objective. By way of illustration, a Ph.D. student participant may, upon a showing of unusual and exceptional circumstance, change to the research scholar category.

In an effort to simplify the visa status requirements for exchange participants, the Agency proposes that transfer of program transactions be facilitated by the sponsors involved without INS adjudication or Agency review. As set forth at § 514.42 sponsors seeking to facilitate a change of program for an exchange participant shall secure the participant's release from the original sponsor and notify the Agency by submitting a duly executed Form IAP–66 reflecting such transfer. In similar fashion, the mechanics of extending a participant's program have also been simplified.

The Agency proposes that sponsors extend a participant's program by executing a new Form IAP–66 which reflects the new program termination date. INS adjudication of this extension will not be required so long as the extension does not exceed the categorical duration of participation limitation. As illustration, a sponsor may extend a research participant's program, one year at a time, so long as the three year category limitation on research scholar programs is not exceeded. As set forth in § 514.43, the sponsor shall notify the Agency of this action by forwarding a duly executed Form IAP–66 reflecting such extension. In those circumstances in which an extension past the categorical duration of participation is sought, Agency approval in INS adjudication will be required.

Finally, the provisions governing application of the two-year home-country physical presence requirement are set forth at § 514.44. This long-standing program requirement is applicable to participants for whom government financing of the exchange was made or who have acquired skills for which there is a need in their home country. The Agency has developed, in cooperation with foreign governments, a listing of such skills. This "skills list" may be found at 49 FR 24194, *et seq.* (June 12, 1984). Revision of the skills list

will begin in the near future. Waiver of the two-year home country requirement is possible and provisions governing such waiver requests are also set forth in this regulation. Provisions addressing waiver procedures as well as the composition and functions of a Waiver Review Board are also set forth.

Subpart D: Sanctions

The Agency first promulgated regulations providing for sanctions for violations of the exchange Visitor Program regulations in 1978. The regulations were expanded in 1978 to provide additional procedural due process rights of those threatened with suspension or revocation for violations of the Exchange Visitor Program Designation Suspension and Revocation Board ("the Board").

That the Board has had to be convened only once since 1987 to hear a revocation case speaks highly of the thousands of institutions which have been designated over the years as exchange visitor program sponsors. Nevertheless, the Agency has long been hamstrung in its oversight of the Exchange Visitor Program by the absence of regulations providing for sanctions of less severity than suspension or revocation. As part of the overall regulatory reform of the Exchange Visitor Program, the Agency believes that the sanctions regulations need, on the one hand, to be strengthened so as to provide violations of the Exchange visitor Program regulations and, on the other hand, to provide the sponsors with clearly defined procedural due process rights. This will improve the Agency's managerial oversight and allow the Agency to move rapidly against a sponsor whose acts or omissions endanger the health, safety or welfare of a program participant.

As is true of all the Exchange Visitor Program regulations, the ultimate goals of the sanctions regulations are to further the foreign policy interest of the United States and to protect the health, safety and welfare of Exchange Visitor Program participants. A violation of the regulations may result in both of those goals being frustrated. For example, a secondary school student exchange program sponsor that willfully or negligently allows a teenage exchangee to come to the U.S. without first having placed the exchangee with a host family, or that fails to confirm transportation arrangements for the exchangee, may have endangered that teenager's health, safety and/or welfare. Should a teenager be injured in an accident or as a victim of a crime, it is not only a personal tragedy, but there well may be adverse foreign policy effects arising from the incident.

To hypothesize another situation, if a sponsor fails to ensure that a participant in an exchange visitor training program is covered by health and accident insurance, and the trainee is injured in the course of his or her training and requires extensive medical treatment for which the trainee is unable to pay, then not only does the health care provider suffer financially but the reputation of the Exchange Visitor Program suffers as well. Indeed, resulting claims made by the health care provider may well have adverse foreign policy effects.

Clearly, not all violations of the Exchange Visitor Program regulations are of equal gravity. The proposed regulations recognize that violations of the regulations range over a spectrum from, for example, an inadvertent, negligent failure to comply with a program reporting requirement, at one end of the spectrum, to a willful act endangering the health or safety of a program participant, at the other end of the spectrum. Recognition of this spectrum of violations is reflected in the various sanctions provided for in the proposed regulations. Like the spectrum of violations, the sanctions also cover a spectrum, ranging from "lesser sanctions" for less serious violations to revocation for the most serious violations. The proposed regulations provide procedural due process safeguards at each level of sanctioning. The sanctions fall into four categories.

1. Lesser Sanctions

For minor violations of the regulations, which interfere with the Agency's proper administration of the Exchange Visitor Program but do not rise to the level of endangering the health, safety or welfare of program participants or of bringing the Program or the Agency into notoriety or disrepute, the proposed regulations provide for the imposition of sanctions of less severity than suspension or revocation. Examples of such violations may include, but are not limited to, the following: Failure to timely provide the Agency with an annual report; failure to provide the Agency with specially requested information to which it is entitled under the regulations; failure to adequately safeguard Forms IAP-66; negligent misrepresentations made by a sponsor in its promotional literature. The proposed regulations provide that, with respect to such violations of the regulations, the Agency may, in its discretion, impose any or all of the following sanctions: A letter of reprimand, warning that repeated or persistent violations of the regulations may result in a suspension or revocation of the sponsor's designation, or a directive to the sponsors that it must reduce the scope of its exchange programs numerically, geographically, or in terms of the types of exchange programs it offers.

Upon being given notice that the agency is imposing such a sanction, the sponsor has the opportunity to submit to the Agency any arguments in explanation or mitigation of the alleged violation. The sponsor may request a conference to discuss its submission. However, the Agency is not required to grant such a conference. The Exchange Visitor Program Office, upon its review of such submission may, in its discretion, modify, withdraw, or continue the imposition of the sanctions.

2. Suspension

The proposed regulations provide that in all suspension actions, other than the summary suspension, the sponsor is given notice in writing that the Agency intends to suspend the sponsor's designation for a period not to exceed one hundred twenty (120) days, specifying the grounds for the suspension. Before the suspension takes effect, the sponsor has an opportunity to submit a response to the Agency, setting forth any reason as to why the Agency should not suspend, and may include any documentary evidence or affidavits in support thereof. After the Agency reviews the sponsor's submission, it notifies the sponsor of its decision on whether or not to effect the suspension. If the decision is to effect the suspension and of its right to a formal hearing before the Board.

The proposed regulations also set forth the sponsor's procedural rights before the Board. The key difference between the "summary suspension" and all other suspension proceedings is that in the former the suspension takes effect immediately upon notice being given to the sponsor, whereas in the latter the suspension does not take effect until the Board decides to effect the suspension after the completion of the appeal and hearing.

3. Summary Suspension

Current regulations provide for a form of summary suspension. 22 CFR 514.17(b). However, the current regulations require the Agency to give the sponsor at least ten days notice that it intends to suspend the designation. The suspension does not take effect until the Office of General Counsel considers and takes into account any response submitted by the sponsor. If the Office of General Counsel decides to

effect the suspension, then the sponsor may appeal to the Board, which must make a decision within ten working days from receipt of the appeal. Thus, the summary suspension is summary in name only; the process, even in the best of circumstances, is lengthy. The health, safety or welfare of a program participant might already have been endangered. Under current regulations the Agency is virtually powerless to act in a prompt and decisive manner.

In order to remedy this deficiency, the proposed regulations provide for a true summary suspension which empowers the Agency to send a sponsor a written notice of the Agency's intent to suspend the sponsor's designation for up to sixty (60) days. Prior to the suspension becoming effective, however, the sponsor has a right to submit a protest to the Agency setting forth any reason why its designation should not be suspended. The Agency will review the protest and decide whether or not to effect the suspension. If the decision is made to effect the suspension the sponsor may appeal the suspension to the Board. However, the suspension is not stayed during the pendency of the appeal.

The summary suspension, as is set forth in the proposed regulation, is to be used only in the most serious situations where the sponsor's acts of omission or commission could have the effect of endangering the health, safety or welfare of an exchange visitor program participant and the Agency deems that immediate action is necessary.

4. Revocation

For serious willful violations of the Exchange Visitor Program regulations or for the omission or commission or an act which has or could have the effect of endangering the health, safety or welfare of an exchange visitor, where the Agency concludes that a continuation of the sponsor's designation is detrimental to the Exchange Visitor Program a revocation of the sponsor's designation may be the most appropriate sanction. Revocation is also the only realistic sanction to impose on the sponsor who willfully or through gross negligence repeatedly violates the regulations and takes no meaningful steps to bring itself into compliance.

Whereas the current regulations require that revocation must be preceded by suspension, the proposed regulations eliminates that requirement. Revocation commences with the Agency giving the sponsor not less than thirty days notice in writing, specifying the grounds for such revocation and the effective date of the revocation. The grounds for the revocation shall be stated in the notice, and before the revocation may take effect the sponsor has an opportunity to submit a response to the Agency providing any information in explanation or mitigation of the violations charged.

Upon receipt of such submission, the Agency will review same and notify the sponsor, in writing, of its decision. The sponsor is also notified of its right to appeal the revocation and of its right to a formal hearing. Within ten days of its receipt of the notice effecting the revocation, the sponsor may file its appeal with the Board. The filing of the notice of appeal serves to stay the revocation pending the appeal. The proposed regulation set forth the procedural rights accorded the sponsor at the hearing before the board.

5. Denial of Application for Redesignation

Current regulations make no provision for an appeal by an applicant in those cases where the Agency denies approval of an application for designation of an exchange visitor program. The proposed regulation creates a right of appeal for the applicant whose application is denied by the Office of Exchange Visitor Program Services and gives to that applicant the same procedural due process protections as are granted to sponsors against whom sanctions are imposed.

The proposed regulations also set forth the composition of the Board, which remains the same as under current regulations and set forth in detail the powers of the Board in conducting hearings under this subpart.

Sponsors should also be aware that certain sanctions, other than those set forth in this section of the regulations, may be available. For example, 18 U.S.C. 10001 makes it a crime to knowingly and willingly make any false, fictitious or fraudulent statements or representations in any matter within the jurisdiction of any Agency of the United States.

Implementation Schedule

The Agency recognizes the impact of a major regulatory revision upon program sponsors. Accordingly, informed comment regarding implementation of these regulations is specifically requested.

The Agency anticipates that implementation upon promulgation of a final rule will not result in substantial disruption of sponsor operations. Provisions governing insurance requirements, however, may prove problematic. For this reason the Agency proposes that insurance requirements need not be met until the start of the 93–94 academic year.

Public Comment

The Agency is inviting comments from the public on the proposed regulations notwithstanding that it is under no legal requirement to do so. The designation of exchange visitor sponsors and administration of the Exchange Visitor Program are a foreign affairs function. The Administrative Procedure Act, 5 U.S.C. 553(a)(1) (1989), specifically exempts form application of the Act a "foreign affairs function of the United States."

In the interest of preserving its valuable working relationship with the exchange community, the Agency is providing a sixty-day period for written comments on the proposed regulations. In order to expedite review of the comments the Agency requests that interested parties submit five copies of their comments.

The Agency informally circulated a prior draft of the proposed regulations to some members of the exchange community and received informal comments in response. The Agency reviewed those comments and incorporated suggestions into these proposed regulations. If these parties wish further consideration of their position, or wish to influence the outcome of the final rule, they must submit written comments to the Agency in response to this proposal.

The information collection requirement contained in this regulation will be submitted to the Office of Management and Budget (OMB) for review and approval under the provision of the Paperwork Reduction Act.

In accordance with 5 U.S.C. 605(b), the Agency certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with Executive Order 12612.

The reporting and regulatory requirement associated with this rule is being submitted to the Office of Management and Budget for approval in accordance with 44 U.S.C. chapter 35. The Agency has previously sought, and OMB has cleared, a portion of the reporting requirements set forth in this proposed rule, specifically those related to Forms IAP–66 (15 minutes), IAP–37 (1 hour) and IAP–87 (20 minutes per respondent). It is estimated that an additional one-time reporting

requirement will be imposed upon the currently designated 1,200 sponsors regarding their proposed obligation to seek redesignation. This burden will be approximately one hour per sponsor. Further, an annual reporting requirement regarding program activity will result in an estimated 30 minutes burden per sponsor.

Comments on this matter should be submitted to both the Agency and OMB and addressed as follows:

Office of Management and Budget, New Executive Office Building, room 3228, Washington, DC 20503, Attn: USIA Desk Officer.

United States Information Agency, Office of the General Counsel, 301 4th St., SW., room 700, Washington, DC 20547, Attn: Stanley S. Colvin.

List of Subjects in 22 CFR Part 514

Cultural Exchange Programs.

Dated: September 30, 1992.

Alberto J. Mora,

General Counsel.

Accordingly, 22 CFR part 514 is revised to read as follows:

PART 514—EXCHANGE VISITOR PROGRAM

Subpart A—General Provisions

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514.1 Purpose.
514.2 Definitions.
514.3 Sponsor Eligibility.
514.4 Categories of Participant Eligibility.
514.5 Application Procedure.
514.6 Designation.
514.7 Redesignation.
514.8 General Program Requirements.
514.9 General Obligations of Sponsors.
514.10 Program Administration.
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514.13 Notification Requirements.
514.14 Insurance.
514.15 Annual Reports.
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Subpart B—Specific Program Provisions

514.20 Professors and Research Scholars.
514.21 Short-term Scholars.
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514.23 College and University Students.
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514.26 Specialists.
514.27 Alien Physicians.
514.28 International Visitors.
514.29 Government Visitors.
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Subpart C—Status of Exchange Visitors

514.40 Termination of Exchange Visitor Status.
514.41 Change of Category.
514.42 Transfer of Program.
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514.44 Two-Yr. Home-Country Physical Presence Requirement.

Subpart D—Sanctions

514.50 Sanctions.

Subpart E—Termination and Revocation of Programs

514.60 Termination of Designation.
514.61 Revocation.
514.62 Responsibilities of the Sponsor Upon Termination or Revocation.

Appendix A to Part 514—Certification of Responsible Officers and Sponsors.

Appendix B to Part 514—Exchange Visitor Program Services, Exchange Visitor Program Application.

Appendix C to Part 514—Update of Information on Exchange Visitor Program Sponsor.

Appendix D to Part 514—Annual Report.

Appendix E to Part 514—Unskilled Occupations.

Authority: 8 U.S.C. 1101(a)(15)(J), 1182, 1258; 22 U.S.C. 1431–1442, 2451–2460; Reorg. Plan No. 2 of 1977; E.O. 12048 of March 27, 1978; USIA Delegation Order No. 85–5 (50 FR 27393).

Subpart A—General Provisions

§ 514.1 Purpose.

(a) The regulations set forth in this part implement the Mutual Educational and Cultural Exchange Act of 1961 (the "Act"). 22 U.S.C. 2451 (1988). The purpose of the Act is to increase mutual understanding between the people of the United States and the people of other countries by means of educational and cultural exchanges. Educational and cultural exchanges assist the Agency in furthering the foreign policy objectives of the United States. These exchanges are defined by section 102 of the Act and are limited to the activities that are described therein and are in compliance with the Immigration and Nationality Act.

(b) The Director of the United States Information Agency facilitates activities specified in the Act, in part, by designating public and private entities to act as sponsors of the Exchange Visitor Program. The purpose of the Program is to provide foreign nationals with opportunities to participate in educational and cultural programs in the United States and return home to share their experiences, and to encourage Americans to participate in educational and cultural programs in other countries. Exchange visitors enter the United States on a J visa. The regulations set forth in this subpart are applicable to all sponsors.

§ 514.2 Definitions.

Accredited educational institution means any publicly or privately operated primary, secondary, or post-secondary institution of learning duly recognized and declared as such by the appropriate authority of the state in which such institution is located; *provided, however,* That in addition to any state recognition, all post-secondary institutions shall also be accredited by a nationally recognized accrediting agency or association as recognized by the United States Secretary of Education but shall not include any institution whose offered programs are primarily vocational in nature.

Act means the Mutual Educational and Cultural Exchange Act of 1961, as amended.

Agency means the United States Information Agency.

Citizen of the United States means:

(1) An individual who is a citizen or permanent resident of the United States or one of its territories or possessions; or,

(2) A general or limited partnership created or organized under the laws of the United States, or of any State, the District of Columbia, or a territory or possession of the United States, of which a majority of the partners are citizens of the United States; or,

(3) A for-profit corporation, association, or other legal entity created or organized under the laws of the United States, or of any state, the District of Columbia, or a territory or possession of the United States, which:

(i) Has its principal place of business in the United States, and

(ii) Has its shares or voting interests publicly traded on a U.S. stock exchange; or, if its shares or voting interests are not publicly traded on a U.S. stock exchange, it shall nevertheless be deemed to be a citizen of the United States if a majority of its officers, Board of Directors, and its shareholders are citizens of the United States; or,

(4) A non-profit corporation, association, or other legal entity created or organized under the laws of the United States, or any state, the District of Columbia, or territory or possession of the United States, and

(i) Which is qualified with the Internal Revenue Service as a tax-exempt organization pursuant to § 501(c) of the Internal Revenue Code; and

(ii) Which has its principal place of business in the United States; and,

(iii) In which a majority of its officers and a majority of its Board of Directors or other like body vested with its management are citizens of the United States; or,

(5) An accredited college, university, or other post-secondary educational institution created or organized under the laws of the United States, or of any

State, including a county, municipality, or other political subdivision thereof, the District of Columbia, or of a territory or possession of the United States; or,

(6) An agency of the United States, or of any state or local government, the District of Columbia, or a territory or possession of the United States.

Consortium means a not-for-profit corporation or association formed by two or more accredited educational institutions for the purpose of sharing educational resources, conducting research, and/or developing new programs to enrich or expand the opportunities offered by its members.

Country of nationality or last legal residence means either the country of which the exchange visitor was a national at the time status as an exchange visitor was acquired or the last foreign country in which the visitor had a legal permanent residence before acquiring status as an exchange visitor.

Cross-cultural activity is an activity designed to promote exposure and interchange between exchange visitors and Americans so as to increase their understanding of each other's society, culture, and institutions. Examples of such activities are intercultural workshops, receptions for American and foreign faculty, educational field trips, international festivals, international conferences, and local community events. A cross-cultural activity is in addition to the principal activity of the exchange visitor's program (e.g., teaching, lecturing, training, studying, or demonstrating special skills).

Designation means the written authorization given by the Agency to an exchange visitor program applicant to conduct an exchange visitor program as a sponsor.

Director means the Director of the United States Information Agency or an employee of the Agency acting under a delegation of authority from the Director.

Exchange visitor means a foreign national who has been selected by a sponsor to participate in an exchange visitor program and who is seeking to enter or has entered the United States temporarily on a J–1 visa. The term does not include the visitor's immediate family.

Exchange Visitor Program means the international exchange program administered by the Agency to implement the Act by means of educational and cultural programs. When "exchange visitor program" is set forth in lower case, it refers to the individual program of a sponsor which has been designated by the Agency.

Exchange Visitor Program Services means the Agency staff delegated authority by the Director to administer the Exchange Visitor Program in compliance with the regulations set forth in this part.

Exchange visitor's government means the government of the country of the exchange visitor's nationality or the country where the exchange visitor has a legal permanent residence.

Financed directly means financed in whole or in part by the United States Government or the exchange visitor's government with funds contributed directly to the exchange visitor in connection with his or her participation in an exchange visitor program.

Financed indirectly means:

(1) Financed by an international organization, with funds contributed by either the United States or the exchange visitor's government for use in financing international educational and cultural exchanges, or

(2) Financed by an organization or institution with funds made available by either the United States or the exchange visitor's government for the purpose of furthering international educational and cultural exchange.

Form IAP–66 means a Certificate of Eligibility, a controlled document of the Agency.

Full course of study means enrollment in an academic program of classroom participation and study at an accredited educational institution as follows:

(1) Secondary school students shall satisfy the attendance and course requirements of the State in which the school is located;

(2) College and university students shall register for and complete a full course of study, as defined by the accredited educational institution in which the student is registered, unless exempted in accordance with § 514.23(f).

Graduate medical education or training means participation in a program in which the alien physician will receive graduate medical education or training, which generally consists of a residency or fellowship program involving health care services to patients, but does not include participation in a program involving observation, consultation, teaching or research in which there is no element or only incidental elements of patient care. This program may consist of a medical specialty, a directly related medical subspecialty, or both.

Home-country physical presence requirement means the requirement that an exchange visitor who is within the purview of section 212(e) of the Immigration and Nationality Act (substantially quoted in § 514.44) must reside and be physically present in the country of nationality or last legal permanent residence for an aggregate of at least two years following departure from the United States before the exchange visitor is eligible to apply for an immigrant visa or permanent residence, a nonimmigrant H visa as a temporary worker or trainee, or a nonimmigrant L visa as an intracompany transferee, or a nonimmigrant H or L visa as the spouse or minor child of a person who is a temporary worker or trainee or an intracompany transferee.

Immediate family means the alien spouse and minor unmarried children of an exchange visitor who are accompanying or following to join the exchange visitor and who are seeking to enter or have entered the United States temporarily on a J–2 visa or are seeking to acquire or have acquired such status after admission. For the purpose of these regulations, a minor is a person under the age of 21 years old.

J. visa means a non-immigrant visa issued pursuant to 8 U.S.C. 1101(a)(15)(J). A J–1 visa is issued to the exchange visitor. J–2 visas are issued to the exchange visitor's immediate family.

Non-specialty occupation means any occupation that is not a specialty occupation (q.v.). Non-specialty occupations range from unskilled occupations up to and including skilled occupations requiring at least two years training or experience.

On-the-job training means an individual's observation of and participation in given tasks demonstrated by experienced workers for the purpose of acquiring competency in such tasks.

Prescribed course of study means a non-degree academic program with a specific educational objective. Such course of study may include intensive English language training, classroom instruction, research projects, and/or academic training to the extent permitted in § 514.23.

Reciprocity means the participation of a United States citizen in an educational and cultural program in a foreign country in exchange for the participation of a foreign national in the Exchange Visitor Program. Where used herein, "reciprocity" shall be interpreted broadly; unless otherwise specified, reciprocity does not require a one-for-one exchange or that exchange visitors be engaged in the same activity. For example, exchange visitors coming to the United States for training in American banking practices and Americans going abroad to teach foreign nationals public administration would be considered a reciprocal exchange,

when arranged or facilitated by the same sponsor.

Responsible officer means the employee or officer of a designated sponsor who has been listed with the Agency as assuming the responsibilities outlined in § 514.11. The designation of alternate responsible officers is permitted and encouraged. The responsible officer and alternate responsible officers must be United States citizens or permanent residents.

Specialty occupation means an occupation that requires theoretical and practical application of a body of highly specialized knowledge to perform fully in the stated field of endeavor. It requires completion of a specified course of education, where attainment of such knowledge or its equivalent is the minimum competency requirement recognized in the particular field of endeavor in the United States. Some examples of specialized fields of knowledge are public and business administration, agricultural research, architecture, engineering, computer and physical sciences, accounting, and print and broadcast journalism.

Sponsor means a legal entity designated by the Director of the United States Information Agency to conduct an exchange visitor program.

Third party means an individual or organization to whom the sponsor has delegated partial responsibilities to carry out its Exchange Visitor Program obligations and responsibilities.

§ 514.3 Sponsor eligibility.

(a) Entities eligible to apply for designation as a sponsor of an exchange visitor program are:

(1) United States Local, State and Federal government agencies;

(2) International agencies or organizations of which the United States is a member and which have an office in the United States; or

(3) Reputable organizations which are "citizens of the United States," as that term is defined in § 514.2.

(b) To be eligible for designation as a sponsor, an entity is required to:

(1) Demonstrate, to the Agency's satisfaction, its ability to comply and remain in continual compliance with all provisions of part 514; and

(2) Meet at all times its financial obligations and responsibilities attendant to successful sponsorship of its exchange visitor program.

§ 514.4 Categories of participant eligibility.

Sponsors may select foreign nationals to participate in their exchange visitor programs. Participation by foreign nationals in an exchange visitor program is limited to individuals who shall be engaged in the following activities in the United States:

(a) *Student.* An individual who is:

(1) Studying in the United States:

(i) pursuing a full course of study at a secondary accredited educational institution;

(ii) pursuing a full course of study leading to or culminating in the award of a U.S. degree from a post-secondary accredited educational institution; or

(iii) engaged full-time in a prescribed course of study of up to 24 months duration conducted by a post-secondary accredited educational institution;

(2) Engaged in academic training as permitted in § 514.23(g); or

(3) Engaged in English language training at:

(i) a post-secondary accredited educational institution, or

(ii) an institute approved by or acceptable to the post-secondary accredited educational institution where the college or university student is to be enrolled upon completion of the language training.

(b) *Short-term scholar.* A professor, research scholar, or person with similar education or accomplishments coming to the United States on a short-term visit for the purpose of lecturing, observing, consulting, training, or demonstrating special skills at research institutions, museums, libraries, post-secondary accredited educational institutions, or similar types of institutions.

(c) *Trainee.* An individual participating in a structured training program conducted by the selecting sponsor.

(d) *Teacher.* An individual teaching full-time in a primary or secondary accredited educational institution.

(e) *Professor.* An individual primarily teaching, lecturing, observing, or consulting at post-secondary accredited educational institutions, museums, libraries, or similar types of institutions. A professor may also conduct research, unless disallowed by the sponsor.

(f) *Research scholar.* An individual primarily conducting research, observing, or consulting in connection with a research project at research institutions, museums, libraries, post-secondary accredited educational institutions, or similar types of institutions. The research scholar may also teach or lecture, unless disallowed by the sponsor.

(g) *Specialist.* An individual who is an expert in a field of specialized knowledge or skill coming to the Untied States for observing, consulting, or demonstrating special skills.

(h) *Other person of similar description.* An individual of description similar to those set forth in paragraphs (a) through (g) coming to the United States, in a program designated by the Agency under this category, for the purpose of teaching, instructing or lecturing, studying, observing, conducting research, consulting, demonstrating special skills, or receiving training. The programs designated by the Agency in this category consist of:

(1) *International visitor.* An individual who is a recognized or potential leader, selected by the Agency for consultation, observation, research, training, or demonstration of special skills in the United States.

(2) *Government visitor.* An individual who is an influential or distinguished person, selected by a U.S. Federal, State, or local government agency for consultation, observation, training, or demonstration of special skills in the United States.

(3) *Camp counselor.* An individual selected to be a counselor in a summer camp in the United States who imparts skills to American campers and information about his or her country or culture.

§ 514.5 Application procedure.

(a) Any entity meeting the eligibility requirements set forth in § 514.3 may apply to the Agency for designation as a sponsor. Such application shall be made on Form IAP-37 ("Exchange Visitor Program Application") and filed with the Agency's Exchange Visitor Program Services.

(b) The application shall set forth, in detail, the applicant's proposed exchange program activity and shall demonstrate its prospective ability to comply with Exchange Visitor Program regulations.

(c) The applicant must provide:

(1) Evidence of legal status as a corporation, partnership, or other legal entity (e.g., charter, proof of incorporation, partnership agreement, as applicable) and current certificate of good standing;

(2) Evidence of financial responsibility as set forth at § 514.9(e);

(3) Evidence of accreditation if the applicant is a post-secondary educational institution;

(4) Evidence of licensure, if required by local, State, or Federal law, to carry out the activity for which it is to be designated;

(5) A resolution or directive by the applicant's governing body authorizing the application for sponsor designation; and

(6) Certification by the applicant that it and its responsible officer and alternate responsible officers are citizens of the United States as defined

at § 514.2 using the language set forth in appendix A.

(d) The Agency may request any additional information and documentation which its deems necessary to evaluate the application.

(e) An organization seeking designation should allow the Agency no less than six months to process its application for designation.

§ 514.6 Designation.

(a) Upon a favorable determination that the proposed exchange program meets all statutory and regulatory requirements, the Agency may, in its sole discretion, designate an entity meeting the eligibility requirements set forth in § 514.3 as an exchange visitor program sponsor.

(b) Designation shall confer upon the sponsor authority to engage in one or more activities specified in § 514.4. A sponsor shall not engage in activities not specifically authorized in its written designation.

(c) Designations are effective for a period of five years. In its discretion, the Agency may designate programs, including experimental programs, for less than five years.

(d) Designations are not transferable or assignable.

§ 514.7 Redesignation.

(a) Upon expiration of a given designation term, a sponsor may seek redesignation for another five-year term.

(b) To apply for redesignation, a sponsor shall submit to the Exchange Visitor Program Services a letter indicating its desire for redesignation.

(c) Request for redesignation shall be evaluated according to the criteria set forth at § 514.6(a) taking into account the sponsor's annual reports and other documents reflecting its record as an exchange visitor program sponsor.

(d) A sponsor seeking redesignation should apply to the Agency no less than four months prior to the expiration date of its designation.

§ 514.8 General program requirements.

(a) *Size of program.* Sponsors, other than Federal government agencies, shall have no less than five exchange visitors per calendar year.

(b) *Minimum duration of program.* Sponsors, other than federal government agencies, shall provide each exchange visitor, except short-term scholars, with a minimum period of participation in the United States of three weeks.

(c) *Reciprocity.* In the conduct of their exchange programs, sponsors shall make a good faith effort to achieve the fullest possible reciprocity in the exchange of persons.

(d) *Cross-cultural activities.* Sponsors shall offer or make available to exchange visitors cross-cultural activities both at and away from the site where the exchange activities are centered. The extent and types of the cross-cultural activities shall be determined by the needs and interests of the particular category of exchange visitors. Sponsors will be responsible to determine the appropriate type and number of cross-cultural programs for their exchange visitors. The Agency encourages sponsors to give their exchange visitors the broadest exposure to American society, culture and institutions.

§ 514.9 General Obligations of Sponsors.

(a) *Adherence to agency regulations.* Sponsors are required to adhere to all regulations set forth in part 514.

(b) *Legal status.* Sponsors shall maintain legal status. A change in a sponsor's legal status (e.g. partnership to corporation) shall require application for designation of the new legal entity.

(c) *Accrediation and licensure.* Sponsors shall remain in compliance with all local, state, federal, and professional requirements necessary to carry out the activity for which they are designated, including accreditation and licensure, if applicable.

(d) *Representations and disclosures.* Sponsors shall:

(1) Provide accurate and complete information, to the extent lawfully permitted, to the Agency regarding their exchange visitor programs and exchange visitors;

(2) Provide only accurate information to the public when advertising their exchange visitor programs or responding to public inquires;

(3) Provide literature to prospective exchange visitors which clearly explains the activities, costs, conditions, and restrictions of the program;

(4) Not use program numbers on any advertising materials or publications intended for general circulation; and

(5) Not represent that any program is endorsed, sponsored, or supported by the Agency or the United States Government, except for United States Government sponsors or exchange visitor programs financed directly by the United States Government to promote international educational exchanges. However, sponsors may represent that they are designated by the Agency as a sponsor of an exchange visitor program.

(e) *Financial responsibility.* (1) Sponsors shall maintain the financial capability to meet at all times their financial obligations and responsibilities attendant to successful sponsorship of their exchange visitor programs.

(2) The Agency may require non-government sponsors to provide evidence satisfactory to the Agency that funds necessary to fulfill all obligations and responsibilities attendant to sponsorship of exchange visitors are readily available and in the sponsor's control, including such supplementary or explanatory financial information as the Agency may deem appropriate such as, for example, audited financial statements.

(3) The Agency may require any non-government sponsor to secure a payment bond in favor of the Agency guaranteeing all financial obligations arising from the sponsorship of exchange visitors.

(f) *Staffing and support services.* Sponsors shall ensure:

(1) Adequate staffing and sufficient support services to administer their exchange visitor programs; and

(2) That their employees, officers, agents, and third parties involved in the administration of their exchange visitor programs are adequately qualified, appropriately trained, and comply with the Exchange Visitor Program regulations.

(g) *Appointment of responsible officer.* (1) The sponsor shall appoint a responsible officer and such alternate responsible officers as may be necessary to perform the duties set forth at § 514.11.

(2) The responsible officer and alternate responsible officers shall be employees or officers of the sponsor. The Agency may, however, in its discretion, authorize the appointment of an individual who is not an employee or officer to serve as an alternate responsible officer.

(3) The Agency may recommend or direct the replacement of the responsible officer or any alternate responsible officer as provided for in § 514.50.

(4) The Agency may limit the number of alternate responsible officers appointed by the sponsor.

§ 514.10 Program administration.

Sponsors are responsible for the effective administration of their exchange visitor programs. These responsibilities include:

(a) *Selection of exchange visitors.* Sponsors shall provide a system to screen and select prospective exchange visitors to ensure that they are eligible for program participation, and that:

(1) The program is suitable to the exchange visitor's background, needs, and experience; and

(2) The exchange visitor possesses sufficient proficiency in the English

language to participate in his or her program.

(b) *Pre-arrival information.* Sponsors shall provide exchange visitors with pre-arrival materials including, but not limited to, information on:

(1) The purpose of the Exchange Visitor Program;

(2) Home-country physical presence requirement;

(3) Travel and entry into the United States;

(4) Housing;

(5) Fees payable to the sponsor;

(6) Other costs that the exchange visitor will likely incur (e.g., living expenses) while in the United States;

(7) Health care and insurance; and

(8) Other information which will assist exchange visitors to prepare for their stay in the United States.

(c) *Orientation.* Sponsors shall offer orientation for all exchange visitors. Sponsors are encouraged to provide orientation for the exchange visitor's immediate family, especially those who are expected to be in the United States for more than one year. Orientation shall include, but not be limited to, information concerning:

(1) Life and customs in the United States;

(2) Local community resources (e.g., public transportation, medical centers, schools, libraries, recreation centers, and banks), to the extent possible;

(3) Available health care, emergency assistance, and insurance coverage;

(4) A description of the program in which the exchange visitor is participating;

(5) Rules that the exchange visitors are required to follow under the sponsor's program;

(6) Address of the sponsor and the name and telephone number of the responsible officer; and

(7) Address and telephone number of the Exchange Visitor Program Services of the Agency and a copy of the Exchange Visitor Program brochure outlining the regulations relevant to the exchange visitors.

(d) *Form IAP–66.* Sponsors shall ensure that only the responsible officer or alternate responsible officers issue Forms IAP–66.

(e) *Monitoring of exchange visitors.* Sponsors shall monitor, through employees, officers, agents, or third parties, the exchange visitors participating in their programs. Sponsors shall:

(1) Ensure that the activity in which the exchange visitor is engaged is consistent with the category and activity listed on the exchange visitor's Form IAP–66;

(2) Monitor the progress and welfare of the exchange visitor to the extent appropriate for the category; and

(3) Require the exchange visitor to keep the sponsor apprised of his or her address and telephone number, and maintain such information.

(f) *Requests by the agency.* Sponsors shall, to the extent lawfully permitted, furnish to the Agency within a reasonable time all information, reports, documents, books, files, and other records requested by the Agency on all matters related to their exchange visitor programs.

(g) *Inquiries and investigations.* Sponsors shall cooperate with any inquiry or investigation that may be undertaken by the Agency.

(h) *Retention of records.* Sponsors shall retain all records related to their exchange visitor program and exchange visitors for a minimum of three years.

§ 514.11 Duties of Responsible Officers.

Responsible officers shall train and supervise alternate responsible officers. Responsible officers and alternate responsible officers shall:

(a) *Knowledge of regulations and codebook.* Be thoroughly familiar with the Exchange Visitor Program regulations and the Agency's current *Codebook and Instructions for Responsible Officers.*

(b) *Advisement and assistance.* Ensure that the exchange visitor obtains sufficient advice and assistance to facilitate the successful completion of the exchange visitor's program.

(c) *Communications.* Conduct the official communications relating to the exchange visitor program with the Agency, the United States Immigration and Naturalization Service, or United States Department of State. Reference to the sponsor's program number shall be made on any correspondence with the Agency.

(d) *Custody of the Form IAP–66.* Act as custodian for the control, issuance, and distribution of Form IAP–66 as set forth in § 514.12.

§ 514.12 Control of Forms IAP–66.

Forms IAP–66 shall be used only for authorized purposes. To maintain adequate control of Forms IAP–66, responsible officers or alternate responsible officers shall:

(a) *Requests.* Submit written requests to the Agency for a one-year supply of Forms IAP–66, and allow four to six weeks for the distribution of these forms. The Agency has the discretion to determine the number of Forms IAP–66 to be sent to a sponsor. The Agency will take into consideration the current size of the program and the projected expansion of the program in the coming 12 months. If requested, the Agency will consult with the responsible officer prior to determining the number of Forms IAP–66 to be sent to the sponsor. Additional forms may be requested later in the year if needed by the sponsor.

(b) *Verification.* Prior to issuing Form IAP–66, verify that the exchange visitor:

(1) Is eligible, qualified, and accepted for the program in which he or she will be participating;

(2) Possesses adequate financial resources to complete his or her program; and

(3) Possesses adequate financial resources to support any accompanying dependents.

(c) *Issuance of Form IAP–66.* Issue the Form IAP–66 only so as to:

(1) Facilitate the entry of a new participant of the exchange visitor program;

(2) Extend the stay of an exchange visitor;

(3) Facilitate program transfer;

(4) Replace a lost or stolen Form IAP–66;

(5) Facilitate entry of an exchange visitor's alien spouse or minor unmarried children into the United States separately;

(6) Facilitate re-entry of an exchange visitor who has traveled outside the United States during the program; or

(7) Facilitate a change of category when permitted by the Agency.

(d) *Safeguards.* (1) Store Forms IAP–66 securely to prevent unauthorized use;

(2) Prohibit transfer of any blank Form IAP–66 to another sponsor or other person unless authorized in writing (by letter or facsimile) by the Agency to do so;

(3) Notify the Agency promptly by telephone (confirmed promptly in writing) or facsimile of the document number of any completed Form IAP–66 that is presumed stolen or any blank Form IAP–66 lost or stolen; and,

(4) Forward the completed Form IAP–66 only to an exchange visitor, either directly or via an employee, officer, or agent of the sponsor, or to an individual designated by the exchange visitor.

(e) *Accounting.* (1) Maintain a record of all Forms IAP–66 received and/or issued by the sponsor;

(2) Destroy damaged and unusable Forms IAP–66 on the sponsor's premises after making a record of such forms (e.g. forms with errors or forms damaged by a printer); and

(3) Request exchange visitors and prospective exchange visitors to return any unused Form IAP–66 sent to them and make a record of Forms IAP–66

which are returned to the sponsor and destroy them on the sponsor's premises.

§ 514.13 Notification requirements.

(a) *Change of circumstances.* Sponsors shall notify the Agency promptly in writing of any of the following circumstances:

(1) Change of its address, telephone, or facsimile number;

(2) Change in the composition of the sponsoring organization which affects its citizenship as defined by § 514.2;

(3) Change of the responsible officer or alternate responsible officers;

(4) A major change of ownership or control of the sponsor's organization;

(5) Change in financial circumstances which may render the sponsor unable to comply with its obligations as set forth in 512.9(e);

(6) Loss of licensure or accreditation;

(7) Loss or theft of Forms IAP–66 as specified at § 514.12(d)(3);

(8) Litigation related to the sponsor's exchange visitor program, when the sponsor is a party; and

(9) Termination of its exchange visitor program.

(b) *Serious problem or controversy.* Sponsors shall inform the Agency promptly by telephone (confirmed promptly in writing) or facsimile of any serious problem or controversy which could be expected to bring the Agency or the sponsor's exchange visitor program into notoriety or disrepute.

(c) *Status of exchange visitor.* Sponsors shall notify the Agency and the United States Immigration and Naturalization Service in writing when:

(1) The exchange visitor has completed or withdrawn from a program prior to the ending date on his or her Form IAP–66;

(2) The exchange visitor ceases to maintain exchange visitor status; or

(3) An exchange visitor's participation in the Exchange Visitor Program is terminated in accordance with § 514.40.

§ 514.14 Insurance.

(a) Sponsors shall require each exchange visitor to have insurance in effect which covers the exchange visitor for sickness or accident during the period of time that an exchange visitor participates in the sponsor's exchange visitor program. Minimum coverage shall provide:

(1) Medical benefits of at least $50,000 per accident or illness;

(2) Repatriation of remains in the amount of $7,500;

(3) Expenses associated with the medical evacuation of the exchange visitor to his or her home country in the amount of $10,000; and,

(4) A deductible not to exceed $500 per accident or illness.

(b) An insurance policy secured to fulfill the requirements of this section:

(1) May require a waiting period for pre-exisitng conditions which is reasonable as determined by current industry standards;

(2) May include provision for co-insurance under the terms of which the exchange visitor may be required to pay up to 25% of the covered benefits per accident or illness; and,

(3) Shall not unreasonably exclude coverage for perils inherent to the activities of the exchange program in which the exchange visitor participates.

(c) Any insurance policy secured to fulfill the above requirements must be underwritten by an insurance corporation having an A.M. Best rating of "A" or above, an Insurance Solvency International, Ltd. (ISI) rating of "A" or above, a Standard & Poor's Claims-paying Ability rating of "AA" or above, a Weiss Research, Inc. rating of B+ or above, or such other rating service as the Agency may from time to time specify. Insurance coverage backed by the full faith and credit of the government of the exchange visitor's home country shall be deemed to meet this requirement.

(d) Federal, state or local government agencies, state colleges and universities, and public community colleges may, if permitted by law, self-insure any or all of the above-required insurance coverage.

(e) At the request of a non-governmental sponsor of an exchange visitor program, and upon a showing that such sponsor has funds readily available and under its control sufficient to meet the requirements of this section, the Agency may permit the sponsor to self-insure or to accept full financial responsibility for such requirements.

(f) The Agency, in its sole discretion, may condition its approval of self-insurance or the acceptance of full financial responsibility by the non-governmental sponsor by requiring such sponsor to secure a payment bond in favor of the Agency guaranteeing the sponsor's obligations hereunder.

(g) An accompanying spouse or dependent of an exchange visitor is required to be covered by insurance in the amounts set forth in § 514.14(a) above. Sponsors shall inform exchange visitors of this requirement, in writing, in advance of the exchange visitor's arrival in the United States.

(h) An exchange visitor who fails to maintain the insurance coverage set forth above while a participant in an exchange visitor program or who makes a material misrepresentation to the sponsor concerning such coverage shall be deemed to be in violation of these regulations and shall be subject to termination as a participant.

(i) A sponsor shall terminate an exchange visitor's participation in its program if the sponsor determines that the exchange visitor or any accompanying spouse or dependent fails to remain in compliance with this section.

§ 514.15 Annual reports.

Sponsors shall submit an annual report to the Agency. Such report shall be filed on an academic or calendar year basis, as directed by the Agency, and shall contain the following:

(a) *Program report and evaluation.* A brief summary of the activities in which exchange visitors were engaged, including an evaluation of program effectiveness;

(b) *Reciprocity.* A description of the nature and extent of reciprocity occurring in the sponsor's exchange visitor program during the reporting year;

(c) *Cross-cultural activities.* A summary of the cross-cultural activities provided for its exchange visitors during the reporting year;

(d) *Proof of insurance.* Certification of compliance with insurance coverage requirements set forth in § 514.14.

(e) *Form IAP–66 usage.* A report of Form IAP–66 usage during the reporting year setting forth the following information:

(1) The total number of blank Forms IAP–66 received from the Agency during the reporting year;

(2) The total number of Forms IAP–66 voided or destroyed by the sponsor during the reporting year and the document numbers of such forms;

(3) The total number of Forms IAP–66 issued to potential exchange visitors that were returned to the sponsor or not used for entry into the United States; and

(4) The total number and document identification number sequence of all blank Forms IAP–66 in the possession of the sponsor on December 31 of the reporting year.

§ 514.16 Employment.

(a) Except as provided in § 514.23 and § 514.25, *infra*, the exchange visitor shall not engage in gainful employment that both produces income from U.S. sources and is unrelated to the exchange visitor's program.

(b) An exchange visitor who engages in unauthorized employment shall be deemed to be in violation of his or her lawful status and be subject to

termination as participant in an exchange visitor program.

(c) The acceptance of employment by an accompanying spouse or minor child of an exchange visitor is governed by Immigration and Naturalization Service regulations.

§ 514.17 Fees and charges. [Reserved]

Subpart B—Specific Program Provisions

§ 514.20 Professors and research scholars.

(a) *Introduction.* These regulations govern professors and research scholars, except:

(1) Alien physicians in graduate medical education or training, who are governed by regulations set forth at § 514.27; and

(2) Short-term scholars, who are governed by regulations set forth at § 514.21.

(b) *Purpose.* A primary purpose of the Exchange Visitor Program is to foster the exchange of ideas between Americans and foreign nationals and stimulate international collaborative teaching and research efforts. The exchange of professors and research scholars promotes interchange, mutual enrichment, and linkages between research and educational institutions in the United States and foreign countries. It does so by providing foreign professors and research scholars the opportunity to engage in research, teaching, and lecturing with their American colleagues, to participate actively in cross-cultural activities with Americans, and to ultimately to share their experiences and increased knowledge about the United States and their substantive fields.

(c) *Designation.* The Agency may, in its sole discretion, designate bona fide programs which offer foreign nationals the opportunity to engage in research, teaching, lecturing, observing, or consulting at research institutions, museums, libraries, post-secondary accredited educational institutions, or similar types of institutions in the United States.

(d) *Visitor eligibility.* An individual participating in a program which furthers the objectives under § 514.20(b) and whose activities are compatible with said objectives shall be eligible to participate in an exchange visitor program as a professor or research scholar. The exchange visitor's appointment to a position shall be temporary, even if the position itself is permanent. The individual shall not be on a tenure track.

(e) *Issuance of Form IAP–66.* The Form IAP–66 shall be issued only after the professor or research scholar has been accepted by the institution(s) where he or she will participate in an exchange visitor program.

(f) *Location of the exchange.* Professors or research scholars shall conduct their exchange activity at the location(s) listed on the Form IAP–66, which could be either at the location of the exchange visitor sponsor or the site of a third party facilitating the exchange. An exchange visitor may also engage in activities at locations not listed on the Form IAP–66 if such activities constitute occasional lectures or consultations as permitted by § 514.20(g).

(g) *Occasional lectures or consultations.* Professors and research scholars may participate in occasional lectures and short-term consultations without compensation for services, unless disallowed by the sponsor. Such lectures and consultations must be incidental to the exchange visitor's primary program activities. For the purpose of this section, reimbursement for travel, lodging and other out-of-pocket expenses for participating in conferences, seminars, meetings, and similar types of short-term activities shall not be considered compensation for services. If the occasional lectures and short-term consultations involve compensation for services, then the following criteria and procedures shall be satisfied:

(1) *Criteria.* The occasional lectures or short-term consultations shall:

(i) Be directly related to the objectives of the exchange visitor's program;

(ii) Be incidental to the exchange visitor's primary program activities; and

(iii) Not delay the completion date of the visitor's program.

(2) *Procedures.* (i) To obtain authorization to engage in occasional lectures or short-term consultations involving compensation for services, the exchange visitor shall present to the responsible officer:

(A) A letter from the offeror setting forth the terms and conditions of the offer to lecture or consult, including the duration, number of hours, field or subject, amount of compensation, and description of such activity; and

(B) A letter from his or her department head or supervisor recommending such activity and explaining how it would enhance international exchange.

(ii) The responsible officer shall review the letters required in § 514.20(g)(2)((i) above and make a written determination whether such activity is warranted and satisfies the criteria set forth in § 514.20(g)(1).

(h) *Category.* At the discretion of the responsible officer, professors may freely engage in research and research scholars may freely engage in teaching and lecturing, unless disallowed by the sponsor. Because these activities are so intertwined, such a change of activity will not be considered a change of category necessitating a formal approval by the responsible officer or reporting to the Agency. Any Form IAP–66 issued to the exchange visitor should reflect the current category of the exchange visitor, either professor or research scholar.

(i) *Duration of participation.* The exchange professor and research scholar shall be authorized to participate in the Exchange Visitor Program for the length of time necessary to complete the program, which time shall not exceed three years. A change of category shall not extend the exchange visitor's period of participation beyond the permitted three-year maximum duration.

(j) *Extension of program.* Professors and research scholars may be considered for program extensions for up to 36 months as follows:

(1) *Six-month extension.* The responsible officer has the discretion to approve an extension of up to six months for professors or research scholars beyond the three year duration of participation permitted under § 514.20(i), when exceptional or unusual circumstances so warrant. The purpose of such an extension is to provide the professor or research scholar the necessary time to complete his or her teaching and research responsibilities. The responsible officer shall notify the Agency as required in § 514.43(c) when authorizing such an extension.

(2) *Additional extension.* The Agency, in its discretion, may approve an extension for a professor or research scholar for exceptional or unusual circumstances. Applications to the Agency for such extension should be filed no later than 45 days before the expiration of the exchange visitor's authorized stay. The application shall be in writing and shall:

(i) State the period of time the sponsor is requesting the extension for the exchange visitor; and

(ii) Include a letter from the department head or supervisor of the exchange visitor;

(A) Indicating the expected date of completion of the exchange program; and

(B) Providing a description of the exceptional or unusual circumstances which warrant such an extension.

§ 514.21 Short-term scholars.

(a) *Introduction.* These regulations govern scholars coming to the United States for a period of up to four months

to lecture, observe, consult, and to participate in seminars, workshops, conferences, study tours, professional meetings, or similar types of educational and professional activities.

(b) *Purpose.* The Exchange Visitor Program promotes the interchange of knowledge and skills among foreign American scholars. It does so by providing foreign scholars the opportunity to exchange ideas with their American colleagues, participate in educational and professional programs, confer on common problems and projects, and promote professional relationships and communications.

(c) *Designation.* The Agency may, in its sole discretion, designate bona fide programs which offer foreign nationals the opportunity to engage in short-term visits for the purpose of lecturing, observing, consulting, training, or demonstrating special skills at research institutions, museums, libraries, post-secondary accredited educational institutions, or similar types of institutions.

(d) *Visitor eligibility.* A person participating in the Exchange Visitor Program under this section shall satisfy the definition of a short-term scholar as set forth in § 514.4.

(e) *Cross-cultural activities and orientation.* Due to the nature of such exchanges, sponsors of programs for short-term scholars shall be exempted from the requirements of providing cross-cultural activities and orientation as set forth in § 514.8(d) and § 514.10(c). However, sponsors are encouraged to provide such programs for short-term scholars whenever possible.

(f) *Location of the exchange.* The short-term scholar shall participate in the Exchange Visitor Program at the conferences, workshops, seminars, or other events or activities stated on his or her Form IAP-66.

(g) *Duration of participation.* The short-term scholar shall be authorized to participate in the Exchange Visitor Program for the length of time necessary to complete the program, which time shall not exceed four months. Programs under this section are exempted from § 514.8(b) governing the minimum duration of program. Extensions beyond the duration of participation are not permitted under this category.

§ 514.22 Trainees.

(a) *Introduction.* These regulations govern all exchange visitor programs under which foreign nationals are provided with opportunities for receiving training in the United States. Regulations dealing with training opportunities which may, under certain conditions, be authorized for foreign students who are studying at post-secondary accredited educational institutions in the United States are found at § 514.23. Regulations governing medical trainees are found at § 514.27.

(b) *Purpose of Training.* The primary objectives of training are to enhance the exchange visitor's skills in his or her specialty or non-specialty occupation through participation in a structured training program and to improve the participant's knowledge of American techniques, methodologies, or expertise within the individual's field of endeavor. Such training programs are also designed to enable the exchange visitor trainee to understand better American culture and society and to enhance American knowledge of foreign cultures and skills by providing the opportunity for an open interchange of ideas between the exchange visitor trainees and their American counterparts. Use of the Exchange Visitor Program for employment or work purposes is strictly prohibited. For this reason the regulations in this section are designed to distinguish between receiving training, which is permitted, and gaining experience, which is not permitted unless as a component of a *bona fide* training program.

(c) *Designation of training programs.* (1) The Agency groups are occupations into specialty, non-specialty, or unskilled occupational categories. The Agency will designate training programs in specialty and non-specialty occupations. Training programs in unskilled occupations or occupations in other categories which the Agency may from time to time identify by publication in the Federal Register will not be designated. For purposes of these regulations, the Agency considers those occupations listed in the United States Department of Labor's "Schedule B" to be unskilled occupations, and the Agency will not designate training programs in those occupations. See appendix to part 514.

(2) For purposes of designation, the Agency will designate specialty and skilled non-specialty occupational training programs in any of the following occupational categories:

(i) Arts and Culture;

(ii) Information Media and Communications;

(iii) Education;

(iv) Business and Commercial;

(v) Banking and Financial;

(vi) Aviation;

(vii) Science, Mechanical and Industrial;

(viii) Construction and Building Trades;

(ix) Agricultural;

(x) Public Administration;

(xi) Training, Other (Specify).

(3) Once designated, the sponsor may provide training in any occupation falling within the designated category, if not otherwise prohibited from doing so. Sponsors shall provide training to exchange visitors only in the category or categories for which they have obtained Agency designation.

(d) *Obligations of training program sponsors.* (1) Sponsors designated by the Agency to provide training to foreign exchange visitors shall:

(ii) Possess and maintain the demonstrable competence to provide training in the subjects offered to exchange visitors.

(ii) Impart skill, knowledge, and competencies to the trainee through a structured program of activities supportive of the training experience. These may include, for example, classroom training, seminars, rotation through several departments, on-the-job training, and attendance at conferences, as appropriate.

(iii) Develop, prior to the start of training, a detailed training plan geared to defined objectives for each trainee or group of similarly-situated trainees.

(iv) Provide for continuous supervision and periodic evaluation of each trainee.

(v) Have available sufficient plant, equipment, and trained personnel to provide the training specified.

(2) Sponsors designated by the Agency to provide training to foreign exchange visitors shall not:

(i) Provide training in unskilled occupations; or

(ii) Place trainees in positions which are filled or would be filled by full-time or part-time employees.

(e) *Use of third parties.* (1) The sponsor may utilize the services of third parties in the conduct of the designated training program. If a third party is utilized, the sponsor and the third party shall execute a written agreement which delineates the respective obligations and duties of the parties, and specifically recites the third party's obligation to act in accordance with these regulations. The sponsor shall maintain a copy of such agreement in its files.

(2) The sponsor's use of a third party in the conduct of a designated training program does not relieve the sponsor of its obligation to comply, and to ensure the third party's compliance, with all applicable regulations. Any failure on the part of the third party to comply with all applicable regulations will be imputed to the sponsor.

(f) *Application for designation of training programs.* (1) An applicant for

designation as an exchange visitor training program shall demonstrate to the Agency its ability to comply with both the General Provisions set forth in subpart A, and the obligations of training sponsors set forth in § 514.22(d).

(2) (i) An applicant shall provide the Agency with documentary evidence of its competence to provide the training for which designation is sought.

(ii) If a third party will be used to conduct the training, documentary evidence of the third party's competence to conduct the training shall be included.

(iii) If the applicant intends to utilize the services of third parties to conduct the training, a copy of an executed third-party agreement or, if one has not yet been executed; an illustrative copy of the type of agreement the applicant intends to execute with third parties shall be submitted with the application.

(3) If the training program is accredited in accordance with § 514.22(n), the applicant shall include a copy of the accreditation in its application.

(4) The application shall include a certification that:

(i) The applicant will dedicate sufficient physical plant, equipment, and trained personnel to provide the training specified;

(ii) The training program is not designed to recruit and train aliens for employment in the United States;

(iii) The applicant will not place trainees in positions which displace full-time or part-time employees.

(5) As to each occupational division for which the applicant seeks designation, the applicant shall indicate whether it intends to provide training in specialty or non-specialty occupations, or both.

(6) In order to meet the requirements of this subsection and to evidence the applicant's competence to provide training, the applicant for designation may submit any one of the following types of training plans for each division for which designation is sought:

(i) If the applicant has already designed a structured training plan to use in the proposed exchange visitor program, a copy of such training plan may be submitted with the application;

(ii) If the applicant has not yet prepared a new training plan, but has been engaged previously in the type of training for which designation is being sought, the applicant may demonstrate its capability to conduct such training by submitting a copy of a previously used training plan;

(iii) If the applicant proposes to create individualized training plans for as yet unidentified trainees, then the applicant may submit a hypothetical training plan which illustrates the training the applicant proposes to provide.

(g) *The training plan.* Each training plan required to be prepared by a sponsor for each trainee pursuant to § 514.22(d)(1)(iii) above, shall include, at a minimum,

(1) a statement of the objectives of the training;

(2) the skills to be imparted to the trainee;

(3) a copy of the training syllabus or chronology;

(4) a justification for the utilization of on-the-job training to achieve stated course competencies; and,

(5) a description of how the trainee will be supervised and evaluated.

(h) *Agency consultation with experts.* The Agency may consult experts whenever its examination of a training plan or its evaluation of application for designation indicates the need for such expertise in making an evaluation.

(i) *Records.* Sponsors shall retain for three years all records pertaining to individual trainees, including training plans, trainee evaluations, and agreements with third parties. Such records shall be made available to the Agency upon the Agency's request.

(j) *Selection of trainees.* In addition to meeting the requirements of § 514.10(a), trainees shall be fully qualified to participate successfully in a structured training program at a level appropriate for the individual trainee's career development. However, such training shall not be duplicative of the trainee's prior training and experience.

(k) *Duration of participation.* The duration of participation shall correspond to the length of the program set forth in the sponsor's designation. The maximum period of participation in the Exchange Visitor Program for a trainee shall not exceed 18 months total.

(l) *Financial and program disclosure.* Sponsors shall provide trainees, prior to their arrival in the United States, with:

(1) A written statement which clearly states the stipend, if any, to be paid to the trainee;

(2) The costs and fees for which the trainee will be obligated;

(3) An estimate of living expenses during the duration of the trainee's stay, and;

(4) A summary of the training program which recites the training objectives and all significant components of the program.

(m) *Evaluation.* In order to ensure the quality of the training program, the sponsor shall develop procedures for the on-going evaluation of each training segment. Such evaluation shall include, as a minimum, semi-annual and concluding evaluation reports from the trainee and his or her immediate supervisor, signed by both parties. For training courses of less than nine months duration, evaluation reports are required, at a minimum, at mid-point and upon conclusion of the training course. Evaluation reports shall be kept in the custody of the sponsor for a period of three years and shall be made available to the Agency upon request.

(n) *Flight training.* (1) The Agency will consider the application for designation of a flight training program if such program complies with the above regulations, and, additionally,

(i) is, at the time of making said application, a Federal Aviation Administration certificated pilot school pursuant to title 14, Code of Federal Regulations, part 141; and

(ii) at the time of making said application is accredited as a flight training program by an accrediting agency which is listed in the current edition of the United States Department of Education's "Nationally Recognized Accrediting Agencies and Associations," or is accredited as a flight training program by a member of the Council on Postsecondary Accreditation; or,

(iii) at the time of making said application has formally commenced the accreditation process with an accrediting agency which is listed in the current edition of the United States Department of Education's "Nationally Recognized Accrediting Agencies and Associations," or with a member of the Council on Postsecondary Accreditation. If the application for designation is approved, such designation shall be for up to twelve months duration, with continued designation thereafter conditioned upon completion of the accreditation process.

(2) Notwithstanding the provisions of § 514.22 (k), *supra*, the maximum period of participation for exchange visitors in designated flight training programs shall not exceed 24 months total. Any request for extension of time in excess of that authorized under this subsection shall be made in accordance with § 514.43, *infra*.

§ 514.23 College and University students.

(a) *Purpose.* Programs under § 514.23 provide foreign students the opportunity to participate in a designated exchange program while studying at a degree-granting post-secondary accredited educational institution. Such exchanges are intended to promote mutual understanding by fostering the exchange of ideas between foreign students and their American counterparts.

(b) *Designation.* The Agency may, in its sole discretion, designate bona fide programs which offer foreign nationals the opportunity to study in the United States at post-secondary accredited educational institutions.

(c) *Selection criteria.* Sponsors select the college and university students who participate in their exchange visitor programs. Sponsors shall secure sufficient background information on the students to ensure that they have the academic credentials required for their program. Students are eligible for the Exchange Visitor Program, if at any time during their college studies in the United States:

(1) They or their program are financed directly or indirectly by:

(i) The United States Government;

(ii) The government of the student's home country; or

(iii) An international organization of which the United States is a member by treaty or statute;

(2) The programs are carried out pursuant to:

(i) An agreement between the United States Government and a foreign government; or

(ii) A written agreement between American and foreign educational institutions; or

(3) The exchange visitors are supported substantially by one or more scholarships from public or private organizations, rather than personal or family funds, for the purpose of promoting international educational exchanges.

(d) *Admissions requirement.* In addition to satisfying the requirements of § 514.10(a), sponsors shall ensure that the exchange visitor student has been admitted to the post-secondary accredited educational institution(s) listed on the Form IAP-66 before issuing the form.

(e) *Full course of study requirement.* Exchange visitor students shall pursue a full course of study at a post-secondary accredited educational institution in the United States as defined in § 514.2, except under the following circumstances:

(1) *Vacation.* During official school breaks and summer vacations if the student is eligible and intends to register for the next term.

(2) *Medical problem.* If the student is compelled to reduce or interrupt a full course of study due to an illness or medical condition and the student presents to the responsible officer:

(i) A written statement from a physician requiring or recommending an interruption or reduction in studies; and

(ii) Written approval by the academic dean or advisor to reduce the number of credits for the school term.

(3) *Academic difficulties.* If the student is compelled to pursue less that a full course of study for a term and:

(i) Receives a statement from the academic dean or advisor recommending that the student reduce his or her academic load to less than a full course of study due to academic difficulties; and

(ii) Obtains written approval from the responsible officer to pursue less than a full course of study for the term.

(4) *Non-degree program.* If the student is engaged full-time in a prescribed course of study in a non-degree program of up to 24 months duration conducted by a post-secondary accredited educational institution.

(5) *Academic training.* If the student is participating in authorized academic training in accordance with § 514.23(g).

(6) *Graduation.* If the student needs less than a full course of study to complete all degree requirements in the final term.

(f) *Academic training.* (1) A student may participate in academic training programs during his or her studies, without compensation for services, with the approval of the academic dean or advisor and the responsible officer.

(2) A student may participate in academic training programs during his or her studies, with compensation for services, and/or immediately after completion of the formal course work or graduation, with or without compensation, when the following criteria, procedures, and evaluation requirements are satisfied.

(i) *Criteria.* The exchange visitor:

(A) Has been a student in the exchange visitor program for the preceding nine months;

(B) Is participating in academic training that is directly related to his or her major field of study at the post-secondary accredited educational institution listed on his or her Form IAP-66;

(C) Is in good academic standing with the post-secondary accredited educational institution;

(D) Will participate in academic training programs for the period necessary to complete the goals and objectives of the training, provided that the total amount of time for an exchange visitor to participate in academic training programs shall not exceed any of the following:

(*1*) The time recommended by the academic dean or advisor and approved by the responsible officer;

(*2*) The period of the classroom instruction at the post-secondary accredited educational institution; and

(*3*) A total of 18 months for all academic training programs of the exchange visitor; and

(E) Receives approval in advance and in writing by the responsible officer for the duration and type of academic training.

(ii) *Procedures.* To obtain authorization to engage in academic training:

(A) The exchange visitor shall present to the responsible officer a letter of recommendation from the student's academic dean or advisor setting forth:

(*1*) The goals and objectives of the specific training program;

(*2*) A description of the training program, including its location, the name and address of the training supervisor, number of hours per week, and dates of the training;

(*3*) Hope the training relates to the student's major field of study; and

(*4*) Why it is an integral or critical part of the academic program of the exchange visitor student.

(B) The responsible officer shall:

(*1*) Determine if and to what extent the student has previously participated in academic training as an exchange visitor student, in order to ensure the student does not exceed the period permitted in § 514.23(g);

(*2*) Review the letter required in section (A) above; and

(*3*) Make a written determination whether the academic training currently being requested is warranted, and the criteria set forth in § 514.23(g)(2)(i) are satisfied.

(iii) *Evaluation requirements.* To ensure the quality of the academic training program, the sponsor shall develop procedures to evaluate its effectiveness and appropriateness in achieving the stated goals and objectives.

(A) Evaluations shall include, at a minimum, mid-point and concluding evaluation reports from the exchange visitor and his or her immediate supervisor, signed by both parties.

(B) The responsible officer shall maintain copies of evaluation reports or have reasonable access to such reports.

(G) *Student employment.* Exchange visitor students may engage in part-time employment when the following criteria and conditions are satisfied.

(1) The student employment:

(i) Is pursuant to the terms of a scholarship, fellowship, or assistantship; or

(ii) Is necessary because of serious, urgent, and unforeseen economic

circumstances which have arisen since acquiring exchange visitor status.

(2) Exchange visitor students may engage in employment as provided in paragraph (g)(1) of this section if the:

(i) Student is in good academic standing at the post-secondary accredited educational institution;

(ii) Student continues to engaged in a full course of study, except for official school breaks and summer vacations;

(iii) Employment totals no more than 20 hours per week, except during official school breaks and summer vacations; and

(iv) The responsible officer has approved the specific employment in advance and in writing. Such approval may be valid up to twelve months, but is automatically withdrawn if the student's program is ferminated.

(h) *Duration of participation.* (1) *Degree of students.* Exchange visitor students who are in degree program shall be authorized to participate in the Exchange Visitor Program as long as they are either:

(i) Studying at the post-secondary accredited educational institution listed on their Form IAP–66 and are:

(A) Pursuing a full course of study as set forth in § 514.23(f), and

(B) Maintaining satisfactory advancement towards the completion of their academic program; or

(ii) Participating in an authorized academic training program as permitted in § 514.23(g).

(2) *Non-degree students.* Exchange visitors who are non-degree students shall be authorized to participate in the Exchange Visitor Program for up to 24 months, if they are:

(i) Participating full-time in a prescribed course of study conducted by a post-secondary accredited educational institution; and

(ii) Maintaining satisfactory advancement towards the completion of their academic program.

§ 514.24 Teachers.

(a) *Purpose.* These regulations govern exchange visitors who teach full-time in primary and secondary accredited educational institutions. Programs under § 514.24 promote the interchange of American and foreign teachers in public and private schools and the enhancement of mutual understanding between people of the United States and other countries. They do so by providing foreign teachers opportunities to teach in primary and secondary accredited educational institutions in the United States, to participate actively in cross-cultural activities with Americans in schools and communities, and to return home ultimately to share their experiences and their increased knowledge of the United States. Such exchanges enable visitors to understand better American culture, society, and teaching practices at the primary and secondary levels, and enhance American knowledge of foreign cultures, customs, and teaching approaches.

(b) *Designation.* The Agency may, in its discretion, designate bona fide programs satisfying the objectives in section (a) above as exchange visitor programs in the teacher category.

(c) *Visitor eligibility.* A foreign national shall be eligible to participate in an exchange visitor program as a full-time teacher if the individual:

(1) Meets the qualifications for teaching in primary or secondary schools in his or her country of nationality or last legal residence;

(2) Satisfies the standards of the U.S. state in which he or she will teach;

(3) Is of good reputation and character;

(4) Seeks to come to the United States for the purpose of full-time teaching at a primary or secondary accredited educational institution in the United States; and

(5) Has a minimum of three years of teaching or related professional experience.

(d) *Visitor Selection.* Sponsors shall adequately screen teachers prior to accepting them for the program. Such screening, in addition to the requirements of § 514.10(a), shall include:

(1) Evaluating the qualifications of the foreign applicants to determine whether the criteria set forth in § 514.24(c) are satisfied; and

(2) Securing references from colleagues and current or former employers, attesting to the teachers' good reputation, character and teaching skills.

(e) *Teaching position.* Prior to the issuance of the Form IAP–66, the exchange visitor shall receive a written offer and accept in writing a teaching position from the primary or secondary accredited educational institution in which he or she is to teach. Such position shall be in compliance with any applicable collective bargaining agreement, where one exists. The exchange visitor's appointment to a position at a primary or secondary accredited educational institution shall be temporary, even if the teaching position is permanent.

(f) *Program disclosure.* Before the program begins, the sponsor shall provide the teacher, in addition to what is required in § 514.10(b), with:

(1) Information on the length and location(s) of his or her exchange visitor program;

(1) Information on the length and location(s) of his or her exchange visitor program;

(2) A summary of the significant components of the program, including a written statement of the teaching requirements and related professional obligations; and

(3) A written statement which clearly states the compensation, if any, to be paid to the teacher and any other financial arrangements in regards to the exchange visitor program.

(g) *Location of the exchange.* The teacher shall participate in an exchange visitor program at the primary or secondary accredited educational institution(s) listed on his or her Form IAP–66 and at locations where the institution(s) are involved in official school activities (e.g., school field trips and teacher training programs).

(h) *Duration of participation.* The teacher shall be authorized to participate in the Exchange Visitor Program for the length of time necessary to complete the program, which shall not exceed three years.

§ 514.25 Secondary School Students.

(a) *Introduction.* These regulations govern Agency designated exchange visitor programs under which foreign national secondary students are afforded the opportunity for up to one year of study in a United States public or private secondary school, while living with an American host family. As used herein, the term "sponsor" shall mean an Agency designated non-profit organization and its officers, employees, and agents; the term "student" shall mean a foreign national whose entry into the United States is for the purpose of study and attendance at a United States secondary school.

(b) *Program Sponsor Eligibility.* Eligibility for designation as a secondary school student exchange program sponsor shall be limited to;

(1) Organizations with tax-exempt status as conferred by the Internal Revenue Service pursuant to section 501(c)(3); and

(2) Organizations which are United States citizens as such terms is defined § 514.2.

(c) *Program Eligibility.* Secondary school students exchange programs designated by the Agency shall:

(1) Require all participants to pursue a full course of study at an accredited educational institution as such terms are defined in this Part of not less than one academic semester (or quarter

equivalency) nor more than two academic semesters (or quarter equivalency) duration; and

(2) Be conducted on an academic calendar year basis provided, however, participants may begin in the second semester of an academic year if specifically permitted to do so, in writing, by the school in which the exchange visitor is enrolled.

(d) *Program administration.* Sponsors shall ensure that all officers, employees, agents, and volunteers action on their behalf:

(1) Are adequately trained and supervised;

(2) Make no student placement outside a 150 mile radius of the home of an organizational representative authorized to act on the sponsors behalf in both routine and emergency matters arising from a student's participation in their exchange program;

(3) Ensure that no organizational representative act as both host family and area supervisor for any student participant whom that organizational representative may host;

(4) Maintain a monthly schedule of personal contact with the student, school, and host family; and

(5) Adhere to all regulatory provisions set forth in this Part and all additional terms and conditions governing program administration that the Agency may from time to time impose.

(e) *Student selection.* In addition to satisfying the requirements of § 514.10(a), sponsors shall ensure that all participants in a designated secondary school student exchange program:

(1) Are *bona fide* students who:

(i) Are secondary school students in their home country who have not completed more than eleven years of primary and secondary study, exclusive of kindergarten; or

(ii) Are at least 15 years of age but not more than 18 and six months years of age at the time of initial school enrollment;

(2) Demonstrate maturity, good character, and scholastic aptitude; and

(3) Have not previously participated in an academic year or semester secondary school student exchange program in the United States.

(f) *Student enrollment.* (1) Sponsors shall secure prior written acceptance for the enrollment of any student participant in a United States public or private secondary school. Such prior acceptance shall:

(i) Be secured from the school principal or other authorized school administrator of the school or school system that the student participant will attend; and

(ii) Include written arrangements concerning the payment of tuition or waiver thereof if applicable.

(2) Sponsors shall maintain copies of all written acceptances and make such documents available for Agency inspection upon request.

(3) Sponsors shall submit to the school placement a written English language summary of the student's complete academic course work prior to commencement of school.

(4) Under no circumstance shall a sponsor facilitate the entry into the United States of a student for whom a school placement has not been secured.

(5) Sponsors shall not facilitate the enrollment of more than five students in one school unless the school itself has requested, in writing, the placement of more than five students.

(g) *Student orientation.* In addition to the orientation requirements set forth herein at § 514.10, all sponsors shall provide students, prior to their departure from the home country, with the following information:

(1) A summary of all operating procedures, rules, and regulations governing student participation in the exchange program;

(2) A detailed profile of the school, family, and community in which the student is placed;

(3) A detailed summary of travel arrangements;

(4) An identification card which lists the student's name, United States home placement address and telephone number, and a telephone number which affords immediate contact with both the Agency and sponsor in case of emergency. Such cards may be provided in advance of home country departure or immediately upon entry into the United States.

(h) *Student extra-curricular activities.* Students may participate in school sanctioned and sponsored extra-curricular activities, including athletics, if such participation is:

(1) authorized by the local school district in which the student is enrolled; and

(2) authorized by the state authority responsible for determination of athletic eligibility, if applicable.

(i) *Student employment.* Students may not be employed on either a full or part-time basis but may accept sporadic or intermittent employment such as babysitting or yard work.

(j) *Host family selection.* Sponsors shall adequately screen all potential host families and at a minimum shall:

(1) provide potential host families with a detailed summary of the exchange program and the parameters of their participation, duties, and obligations;

(2) utilize a standard application form for all host family applicants which provides a detailed summary and profile of the host family, the physical home environment, family composition, and community environment;

(3) conduct an in-person interview with all family members residing in the home;

(4) ensure that the host family is capable of providing a comfortable and nurturing home environment;

(5) ensure that the host family is of good reputation and character by securing two personal references for each host family from the school or community, attesting to the host family's good reputation and character;

(6) ensure that the host family has adequate financial resources to undertake hosting obligations; and

(7) maintain a permanent record of application forms, evaluations, and interviews for all selected host families for a period of three years.

(k) *Host family orientation.* In addition to the orientation requirements set forth in § 514.10, sponsors shall:

(1) inform all host families of the philosophy, rules, and regulations governing the sponsor's exchange program; and

(2) provide all selected host families with a copy of Agency promulgated Exchange Visitor Program regulations; and

(3) advise all selected host families of strategies governing cross cultural interaction and conduct workshops which will familiarize the host family with cultural differences and practices.

(l) *Host family placement.* (1) Sponsors shall secure, prior to the student's departure from the home country, a host family placement for each student participant. Sponsors shall not:

(i) Facilitate the entry into the United States for a student for whom a host family placement has not been secured; and

(ii) Place more than one student with a host family without the express prior written consent of the Agency.

(2) Sponsors shall advise both the student and host family, in writing, of the respective family compositions and backgrounds of each and shall facilitate and encourage the exchange of correspondence between the two prior to the student's departure from the home country.

(3) In the event of unforeseen circumstances which necessitate a change of host family placement, the sponsor shall document the reasons

necessitating such change and provide the Agency with an annual statistical summary reflecting the number and the reason for such change in host family placement.

(m) *Placement report.* In lieu of listing the name and address of the host family and school placement on a participant's Form IAP–66, sponsors must, no later then August 1st of each academic year, submit to the Agency a report of all academic year program participants. Such report shall set forth the participant's name, school, and host family placements. A report of semester participants entering United States schools during the January to June term shall be submitted to the Agency by December 15th of the preceding year.

§ 514.26 Specialists.

(a) *Introduction.* These regulations govern experts in a field of specialized knowledge or skill coming to the United States for observing, consulting, or demonstrating special skills, except:

(1) Research scholars and professors, who are governed by regulations set forth at § 514.20;

(2) Short-term scholars, who are governed by regulations set forth at § 514.21; and

(3) Alien physicians in graduate medical education or training, who are governed by regulations set forth at § 514.27.

(b) *Purpose.* The Exchange Visitor Program promotes the interchange of knowledge and skills among foreign and American specialists, who are defined as experts in a field of specialized knowledge or skills, and who visit the United States for the purpose of observing, consulting, or demonstrating their special skills. It does so by providing foreign specialists the opportunity to observe American institutions and methods of practice in their professional fields, and to share their specialized knowledge with their American colleagues. The exchange of specialists promotes mutual enrichment, and furthers linkages among scientific institutions, government agencies, museums, corporations, libraries, and similar types of institutions. Such exchanges also enable visitors to better understand American culture and society and enhance American knowledge of foreign cultures and skills. This category is intended for exchanges with experts in areas, for example, as mass media communication, environmental science, youth leadership, international educational exchange, museum exhibitions, labor law, public administration, and library science. This category is not intended for experts covered by the exchange visitor categories listed in § 514.26(a)(1)–(3) above.

(c) *Designation.* The Agency may, in its discretion, designate bona fide programs satisfying the objectives in section (b) above as an exchange visitor program in the specialist category.

(d) *Visitor eligibility.* A foreign national shall be eligible to participate in an exchange visitor program as a specialist if the individual:

(1) Is an expert in a field of specialized knowledge or skill;

(2) Seeks to travel to the United States for the purpose of observing, consulting, or demonstrating his or her special knowledge or skills; and

(3) Does not fill a permanent or long-term position of employment while in the United States.

(e) *Visitor selection.* Sponsors shall adequately screen and select specialists prior to accepting them for the program, providing a formal selection process, including at a minimum:

(1) Evaluation of the qualifications of foreign nationals to determine whether they meet the definition of specialist as set forth in § 514.4(g); and

(2) Screening foreign nationals to ensure that the requirements of § 514.10(a) are satisfied.

(f) *Program disclosure.* Before the program begins, the sponsor shall provide the specialist, in addition to what is required in § 514.10(b), with:

(1) Information on the length and location(s) of his or her exchange visitor program;

(2) A summary of the significant components of the program; and

(3) A written statement which clearly states the stipend, if any, to be paid to the specialist.

(g) *Issuance of Form IAP–66.* The Form IAP–66 shall be issued only after the specialist has been accepted by the organization(s) with which he or she will participate in an exchange visitor program.

(h) *Location of the exchange.* The specialist shall participate in an exchange visitor program at the location(s) listed on his or her Form IAP–66.

(i) *Duration of participation.* The specialist shall be authorized to participate in the Exchange Visitors Program for the length of time necessary to complete the program, which shall not exceed one year.

§ 514.27 Alien physicians.

(a) *Purpose.* Pursuant to the Mutual Educational and Cultural Exchange Act, as amended by the Health Care Professions Act, Public Law 94–484, the Agency facilitates exchanges for foreign medical graduates seeking to pursue graduate medical education or training at accredited schools of medicine or scientific institutions. The Agency also facilitates exchanges of foreign medical graduates seeking to pursue programs involving observation, consultation, teaching, or research activities.

(b) *Clinical exchange programs.* The Educational Commission for Foreign Medical Graduates must sponsor alien physicians who wish to pursue programs of graduate medical education or training conducted by accredited U.S. schools of medicine or scientific institutions if they:

(1) Have adequate prior education and training to participate satisfactorily in the program for which they are coming to the United States;

(2) Will be able to adapt to the educational and cultural environment in which they will be receiving their education or training;

(3) Have the background, needs, and experiences suitable to the program as required in § 514.10(a)(1);

(4) Have competency in oral and written English;

(5) Have passed either Parts I and II of the National Board of Medical Examiners Examination, the Foreign Medical Graduate Examination in the Medical Sciences, the United States Medical Licensing Examination, Step I and Step II, or the Visa Qualifying Examination (VQE) prepared by the National Board of Medical Examiners, administered by the Educational Commission for Foreign Medical Graduates. N.B. Graduates of a school of medicine accredited by the Liaison Committee on Medical Education is exempted by law from the requirement of passing either Parts I and II of the National Board of Medical Examiners Examination or the Visa Qualifying Examination (VQE); and,

(6) Provide a statement of need from the government of the country of their nationality or last legal permanent residence. Such statement must provide written assurance, satisfactory to the Secretary of Health and Human Services, that there is a need in that country for persons with the skills the alien physician seeks to acquire and shall be submitted to the Educational Commission for Foreign Medical Graduates by the participant's government. The statement of need must bear the seal of the concerned government and be signed by a duly designated official of the government. The text of such statement of need shall read as follows:

Name of applicant for Visa: _____. There currently exists in (Country) a need for qualified medical

practitioners in the specialty of _____. (Name of applicant for Visa) has filed a written assurance with the government of this country that he/she will return to this country upon completion of training in the United States and intends to enter the practice of medicine in the specialty for which training is being sought.

Stamp (or Seal and signature) of issuing official of named country.

Dated:_____

_____

Official of named Country.

(c) *Non-clinical exchange programs.* (1) A United States university or academic medical center which has been designated an exchange visitor program by the Director of the United States Information Agency is authorized to issue From IAP–66 to alien physicians to enable them to come to the United States for the purposes of observation, consultation, teaching, or research if:

(i) The responsible officer or duly designated alternate of the exchange visitor program involved signs and appends to the Form IAP–66 a certification which states "this certifies that the program in which (name of physician) is to be engaged is solely for the purpose of observation, consultation, teaching, or research and that no element of patient care is involved" or,

(ii) The dean of the involved accredited United States medical school or his or her designee certifies to the following five points and such certification is appended to the Form IAP–66 issued to the prospective exchange visitor alien physician:

(A) The program in which (name of physician) will participate is predominantly involved with observation, consultation, teaching, or research.

(B) Any incidental patient contact involving the alien physician will be under the direct supervision of a physician who is a U.S. citizen or resident alien and who is licensed to practice medicine in the State of _____.

(C) The alien physician will not be given final responsibility for the diagnosis and treatment of patients.

(D) Any activities of the alien physician will conform fully with the State licensing requirements and regulations for medical and health care professionals in the State in which the alien physician is pursuing the program.

(E) Any experience gained in this program will not be creditable towards any clinical requirements for medical specialty board certification.

(2) The Educational Commission for Foreign Medical Graduates may also issue Form IAP–66 to alien physicians who are coming to the United States to participate in a program of observation, consultation, teaching, or research provided the required letter of certification as outlined in this paragraph is appended to the Form IAP–66.

(d) *Public health and preventive medicine programs.* A United States university, academic medical center, school of public health, or other public health institution which has been designated as an exchange visitor program by the Director of the United States Information Agency is authorized to issue Form IAP–66 to alien physicians to enable them to come to the United States for the purpose of entering into those programs which do not include any clinical activities involving direct patient care. Under these circumstances, the special eligibility requirements listed in paragraphs _____ and _____ of this section need not be met.

The responsible officer or alternate responsible officer of the exchange visitor program involved shall append a certification to the Form IAP–66 which states:

This certifies that the program in which (name of physician) is to be engaged does not include any clinical activities involving direct patient care.

(e) *Duration of participation.* (1) The duration of an alien physician's participation in a program of graduate medical education or training is limited to the time typically required to complete such program. Duration shall be determined by the Director of the United States Information Agency at the time of the alien physician's entry into the United States. Such determination shall be based on criteria established in coordination with the Secretary of Health and Human Services and which take into consideration the requirements of the various medical specialty boards as evidenced in the Directory of Medical Specialties published by Marquis Who's Who for the American Board of Medical Specialties.

(2) Duration of participation is limited to seven years unless the alien physician has demonstrated to the satisfaction of the Director that the country to which the alien physician will return at the end of such specialty education or training has an exceptional need for an individual with the additional qualifications.

(3) Subject to the limitations set forth above duration of participation may, for good cause shown, be extended beyond the period of actual training or education to include the time necessary to take an examination required for certification by a specialty board.

(4) The Director may include within the duration of participation a period of supervised medical practice in the United States if such practice is an eligibility requirement for certification by a specialty board.

(i) Alien physicians shall be permitted to undertake graduate medical education or training in a specialty or subspecialty program whose board requirements are not published in the Director of Medical Specialists if the Board requirements are certified to the Director and to the Educational Commission for Foreign Medical Graduates by the Executive Secretary of the cognizant component board of the American Board of Medical Specialties.

(ii) The Director may, for good cause shown, grant an extension of the program to permit an alien physician to repeat one year of clinical medical training.

(5) The alien physician must furnish the Attorney General each year with an affidavit (Form I–644) that attests the alien physician:

(i) Is in good standing in the program of graduate medical education or training in which the alien physician is participating, and

(ii) Will return to the country of his nationality or last legal permanent residence upon completion of the education or training for which he came to the United States.

(f) *Change of program.* The alien physician may, once and not later than two years after the date the alien physician enters the United States as an exchange visitor or acquires exchange visitor status, change his designated program of graduate medical education or training if the Director approves the change and if the requirements of paragraphs 514.27 (b) and 514.27 (e) of this section are met for the newly designated specialty.

(g) *Applicability of Section 212(e) of the Immigration and Nationality Act.* (1) Any exchange visitor physician coming to the United States on or after January 10, 1977 for the purpose of receiving graduate medical education or training is automatically subject to the two-year home-country physical presence requirement of section 212(e) of the Immigration and Nationality Act, as amended. Such physicians are not eligible to be considered for section 212(e) waivers on the basis of "No Objection" statements issued by their governments.

(2) Alien physicians coming to the United States for the purpose of observation, consultation, teaching, or research are not automatically subject to the two-year home-country physical presence requirement of section 212(e) of the Immigration and Nationality Act,

as amended, but may be subject to this requirement if they are governmentally financed or pursuing a field of study set forth on their countries' Exchange Visitor Skills List. Such alien physicians are eligible for consideration of waivers under section 212(e) of the Immigration and Nationality Act, as amended, on the basis of "No Objection" statements submitted by their governments in their behalf through diplomatic channels to the Director of the United States Information Agency.

§ 514.28 International Visitors.

(a) *Purpose.* The international visitor category is for the exclusive use of the Agency. Programs under § 514.28 are for foreign nationals who are recognized or potential leaders and are selected by the Agency to participate in observation tours, discussions, consultation, professional meetings, conferences, workshops, and travel. These programs are designed to enable the international visitors to better understand American culture and society and contribute to enhanced American knowledge of foreign cultures. The category is for people-to-people programs which seek to develop and strengthen professional and personal ties between key foreign nationals and Americans and American institutions.

(b) *Selection.* The Agency and third parties assisting the Agency shall adequately screen and select prospective international visitors to determine compliance with § 514.10(a) and the visitor eligibility requirements set forth below.

(c) *Visitor eligibility.* An individual participating in an exchange visitor program as an international visitor shall be:

(1) Selected by the Agency;

(2) Engaged in consultation, observation, research, training, or demonstration of special skills; and

(3) A recognized or potential leader in a field of specialized knowledge of skill.

(d) *Program disclosure.* At the beginning of the program, the sponsor shall provide the international visitor with:

(1) Information on the length and location(s) of his or her exchange visitor program; and

(2) A summary of the significant components of the program.

(e) *Issuance of Form IAP–66.* The Form IAP–66 shall be issued only after the international visitor has been selected by the Agency.

(f) *Location of the exchange.* The international visitor shall participate in an exchange visitor program at locations approved by the Agency.

(g) *Duration of participation.* The international visitor shall be authorized to participate in the Exchange Visitor Program for the length of time necessary to complete the program, which shall not exceed one year.

§ 514.29 Government visitors.

(a) *Purpose.* The government visitor category is for the exclusive use of the U.S. federal, state, or local government agencies. Programs under § 514.29 are for foreign nationals who are recognized as influential or distinguished persons, and are selected by U.S. federal, state, or local government agencies to participate in observation tours, discussions, consultation, professional meetings, conferences, workshops, and travel. These are people-to-people programs designed to enable government visitors to better understand American culture and society, and to contribute to enhanced American knowledge of foreign cultures. The objective is to develop and strengthen professional and personal ties between key foreign nationals and Americans and American institutions. The government visitor programs are for such persons as editors, business and professional persons, government officials, and labor leaders.

(b) *Designation.* The Agency may, in its sole discretion, designate as sponsors U.S. federal, state, and local government agencies which offer foreign nationals the opportunity to participate in people-to-people programs which promote the purpose as set forth in (a) above.

(c) *Selection.* Sponsors shall adequately screen and select prospective government visitors to determine compliance with § 514.10(a) and the visitor eligibility requirements set forth below.

(d) *Visitor eligibility.* An individual participating in an exchange visitor program as a government visitor shall be:

(1) Selected by a U.S. federal, state, and local government agency;

(2) Engaged in consultation, observation, training, or demonstration of special skills; and

(3) An influential or distinguished person.

(e) *Program disclosure.* Before the beginning of the program, the sponsor shall provide the government visitor with:

(1) Information on the length and location(s) of his or her exchange visitor program;

(2) A summary of the significant components of the program; and

(3) A written statement which clearly states the stipend, if any, to be paid to the government visitor.

(f) *Issuance of Form IAP–66.* The Form IAP–66 shall be issued only after the government visitor has been selected by a U.S. federal, state, or local government agency and accepted by the private and/or public organization(s) with whom he or she will participate in the exchange visitor program.

(g) *Location of the exchange.* The government visitor shall participate in an exchange visitor program at the locations listed on his or her Form IAP–66.

(h) *Duration of participation.* The government visitor shall be authorized to participate in the Exchange Visitor Program for the length of time necessary to complete the program, which shall not exceed eighteen months.

§ 514.30 Camp Counselors.

(a) *Introduction.* In order to promote diverse opportunities for participation in educational and cultural exchange programs, the Agency designates exchange sponsors to facilitate the entry of foreign nationals to serve as counselors in U.S. summer camps. These programs promote international understanding by improving American knowledge of foreign cultures while enabling foreign participants to increase their knowledge of American culture. The foreign participants are best able to carry out this objective by serving as counselors per se, that is, having direct responsibility for supervision of groups of American youth and of activities that bring them into interaction with their charges. While it is recognized that some chores are an essential part of camp life for all counselors, this program is not intended to assist American camps in bringing in foreign nationals to serve as administrative personnel, cooks, or menial laborers, such as dishwashers or janitors.

(b) *Participant eligibility.* Participation in camp counselor exchange programs is limited to foreign nationals who:

(1) Are at least 18 years of age;

(2) Are bona fide youth workers, students, teachers, or individuals with specialized skills; and

(3) Have not previously participated more than once in a camp counselor exchange.

(c) *Participant selection.* In addition to satisfying the requirements in § 514.10(a), sponsors shall adequately screen all international candidates for camp counselor programs and at a minimum:

(1) Conduct an in-person interview; and

(2) Secure references from a participant's employer or teacher

regarding his or her suitability for participation in a camp counselor exchange.

(d) *Participant orientation.* Sponsors shall provide participants, prior to their departure from the home country, detailed information regarding:

(1) Duties and responsibilities relating to their service as a camp counselor;

(2) Contractual obligations relating to their acceptance of a camp counselor position; and

(3) Financial compensation for their service as a camp counselor.

(e) *Participant placements.* Sponsors shall place eligible participants at camping facilities which are:

(1) Accredited;

(2) A member in good standing of the American Camping Association;

(3) Officially affiliated with a nationally recognized non-profit organization; or

(4) Have been inspected, evaluated, and approved by the sponsor.

(f) *Participant compensation.* Sponsors shall ensure that international participants receive pay and benefits commensurate with those offered to their American counterparts.

(g) *Participant supervision.* Sponsors shall provide all participants with a phone number which allows 24 hours immediate contact with the sponsor.

(h) *Program administration.* Sponsors shall:

(1) Comply with all provisions set forth in Subpart A of this part;

(2) Not facilitate the entry of any participant for a program of more than four months duration; and

(3) Under no circumstance facilitate the entry into the United States of a participant for whom a camp placement has not been pre-arranged.

(i) *Placement report.* In lieu of listing the name and address of the camp facility at which the participant is placed on Form IAP-66, sponsors shall submit to the Agency, no later than July 1st of each year, a report of all participant placements. Such report shall reflect the participant's name and camp placement.

Subpart C—Status of Exchange Visitors

§ 514.40 Termination of exchange visitor status.

A sponsor shall terminate an exchange visitor's participation in its program when the exchange visitor:

(a) Fails to pursue the activities for which he or she was admitted to the United States;

(b) Is unable to continue, unless otherwise exempted pursuant to these regulations;

(c) Violates the Exchange Visitor Program regulations and/or the sponsor's rules governing the program, if, in the sponsor's opinion, termination is warranted;

(d) Fails to maintain the insurance coverage required under § 514.14 of these regulations; or,

(e) Engages in unauthorized employment.

§ 514.41 Change of category.

(a) The Agency may, in its discretion, permit an exchange visitor to change his or her category of exchange participation. Any change in category must be clearly consistent with and closely related to the participant's original exchange objective and necessary due to unusual or exceptional circumstances.

(b) A request for change of category along with supporting justification must be submitted to the Agency by the participant's sponsor. Upon Agency approval the sponsor shall issue to the exchange visitor a duly executed Form IAP-66 reflecting such change of category and provided a notification copy of such form to the Agency.

§ 514.42 Transfer of program.

(a) Program sponsors may permit an exchange visitor to transfer from one designated program to another designated program. The responsible officer of the program to which the exchange visitor is transferring must:

(1) Verify the exchange visitor's visa status; and

(2) Obtain, prior to transfer, a release signed by the responsible officer of the exchange visitor's current sponsor.

(b) The responsible officer of the program to which the exchange visitor is transferring shall issue to the exchange visitor a duly executed Form IAP-66 reflecting such transfer and provide a notification copy of such form to the Agency.

§ 514.43 Extension of program.

(a) Responsible officers may, pursuant to the provisions set forth in this section, extend an exchange visitor's participation in the Exchange Visitor Program.

(b) Responsible officers shall, under no circumstance, authorize an extension which would permit an exchange visitor to exceed the permissible period of participation authorized for his or her specific category.

(c) A responsible officer extending the program of an exchange visitor shall issue to the exchange visitor a duly executed Form IAP-66 reflecting such extension and provide a notification copy of such form to the Agency.

(d) An exchange visitor seeking a program extension in excess of that authorized for his or her specific category of participation shall:

(1) Adequately illustrate why exceptional or unusual circumstances justify such extension;

(2) Secure the prior written approval of the Agency for such extension; and

(3) Apply to the United States Immigration and Naturalization Service for approval of such extension.

§ 514.44 Two-Year Home-country physical presence requirement.

(a) **Statutory Basis for Rule.** § 212(e) of the Immigration and Nationality Act, as amended, provides in substance as follows:

(1) No person admitted under § 101(a)(15)(J) or acquiring such status after admission

(i) whose participation in the program for which he came to the United States was financed in whole or in part, directly or indirectly, by an agency of the United States Government or by the government of the country of his nationality or of his last legal permanent residence;

(ii) who at the time of admission or acquisition of status under § 101(a)(15)(J) was a national or resident of a country which the Director of the United States Information Agency, pursuant to regulations prescribed by him, had designated as clearly requiring the services of persons engaged in the field of specialized knowledge or skill in which the alien was engaged [See "Exchange Visitor Skills List", 49 FR 24194, *et seq.* (June 12, 1984) as amended];

(iii) who came to the United States or acquired such status in order to receive graduate medical education or training shall be eligible to apply for an immigrant visa, or for permanent residence, or for a nonimmigrant visa under section 101(a)(15)(H) or section 101(a)(15)(L) until it is established that such person has resided and been physically present in the country of his nationality or his last legal permanent residence for an aggregate of at least two years following departure from the United States.

(2) Upon the favorable recommendation of the Director of the United States Information Agency, pursuant to the request of an interested United States Government agency, or of the Commissioner of Immigration and Naturalization after the latter has determined that departure from the United States would impose exceptional hardship upon the alien's spouse or child (if such spouse or child is a citizen

of the United States or a legal permanent alien), or that the alien cannot return to the country of his nationality or last legal permanent resident because he would be subject to persecution on account of race, religion, or political opinion, the Attorney General may waive the requirement of such two-year foreign residence abroad in the case of any alien whose admission to the United States is found by the Attorney General to be in the national interest.

(3) Except in the case of an alien who is a graduate of a medical school pursuing a program in graduate medical education or training, the Attorney General, upon the favorable recommendation of the Director of the United States Information Agency, may also waive such two-year foreign residency requirement in any case in which the foreign country of the alien's nationality or last legal permanent residence has furnished the Director of the United States Information Agency a statement in writing that it has no objection to such waiver in the case of such alien.

(b) *Request for waiver on the basis of exceptional hardship or probable persecution on account of race, religion, or political opinion.* (1) An exchange visitor who seeks a waiver of the two-year home-country physical presence requirement on the grounds that such requirement would impose exceptional hardship upon the exchange visitor's spouse or child (if such spouse of child is a citizen of the United States or a legal permanent resident alien), or on the grounds that such requirement would subject the exchange visitor to persecution on account of race, religion, or political opinion, shall submit the application for waiver (INS Form I-612) to the District Office of the Immigration and Naturalization Service having administrative jurisdiction over the exchange visitor's place of temporary residence in the United States, or, if the exchange visitor has already departed the United States, to the district Office having administrative jurisdiction over the exchange visitor's last legal place of residence in the United States.

(2)(i) If the Commissioner of Immigration and Naturalization Service ("Commissioner") determines that compliance with the two-year home-country physical presence requirement would impose exceptional hardship upon the spouse or child of the exchange visitor, or would subject the exchange visitor to persecution on account of race, religion, or political opinion, the Commissioner shall transmit a copy of his determination together with a summary of the details of the expected hardship or persecution, to the Waiver Review Branch, office of Exchange Visitor Program Services, in the Agency's Office of General Counsel.

(ii) With respect to those cases in which the Commissioner has determined that compliance with the two-year home-county physical presence requirement would impose exceptional hardship upon the spouse or child of the exchange visitor, the Waiver Review Branch shall review the Commissioner's determination, together with the supporting evidence accompanying it, make a recommendation, and forward it to the Commissioner. If deem appropriate the Agency may request the views of each of the exchange visitors sponsors concerning the waiver application. Except as set forth in § 514.44(e)(2), *infra*, the recommendation of the Waiver Review Branch shall constitute the final decision of the Agency and such recommendation shall be forwarded to the Commissioner.

(iii) With respect to those cases in which the Commissioner has determined that compliance with the two-year home-country physical presence requirement would subject the exchange visitor to persecution on account of race, religion, or political opinion, the Waiver Review Branch shall review the Commissioner's determination, together with the supporting evidence accompanying it, and after consulting thereon with the Bureau of Human Rights and Humanitarian Affairs of the United States Department of State, make a recommendation, and forward such recommendation to the Commissioner. Except as set forth in § 514.44(e)(2), *infra*, the recommendation of the Waiver Review Branch shall constitute the final decision of the Agency and such recommendation shall be forwarded to the Commissioner.

(c) *Requests for waiver made by an interested United States Government agency.* If an exchange visitor is a participant in an exchange visitor program sponsored by or of interest to an agency of the United States Government, said agency may apply to the Waiver Review Branch for a waiver of the two-year home-country physical presence requirement on the grounds that the granting of the waiver would be in the national interest and the exchange visitor's compliance with said requirement would be detrimental to a program or activity of interest to that agency. The application shall identify by name or location the organization which will utilize the exchange visitor's services and the name and address of the exchange visitor in the United States. The Waiver Review Branch shall review the application and forward its recommendation to the Commissioner. Except as set forth in § 514.44(e)(2), *infra*, the recommendation of the Waiver Review Branch shall constitute the final decision of the Agency and such recommendation shall be forwarded to the Commissioner.

(d) *Requests for waiver made on the basis of a statement from the exchange visitor's home country that it has no objection to the waiver.* (1) Applications for waiver of the two-year home-country physical requirement may be supported by a statement of no objection by the exchange visitor's country of nationality of last legal permanent residence. The statement of no objection shall be directed to the Director through diplomatic channels; i.e., from the country's Foreign Office to the Agency through the U.S. Mission in the foreign country concerned, or through the foreign country's head of mission or duly appointed designee in the United States to the Director in the form of a diplomatic note. This note shall include applicant's full name, date and place of birth, and present address. Upon receipt of the no objection statement, the Waiver Review Branch shall instruct the applicant to complete a data sheet and to provide all Forms IAP-66 and the data sheet to the Waiver Review Branch. If deemed appropriate, the Agency may request the views of each of the exchange visitor's sponsors concerning the waiver application.

(2) Except as set forth in § 514.44(e)(2), *infra*, the recommendation of the Waiver Review Branch shall constitute the final decision of the Agency and such recommendation shall be forwarded to the Commissioner.

(3) An exchange visitor who is a graduate of a foreign medical school and who is pursuing a program in graduate medical education or training in the United States is prohibited under section 212(e) of the Immigration and Nationality Act from applying for a waiver on the basis of no objection from his or her country of nationality or last legal permanent residence.

(e) *The Exchange Visitor Waiver Review Board.* (1) The Exchange Visitor Waiver Review Board ("Board") shall consist of the following Agency officers:

(i) The Deputy Associate Director of the Bureau of Educational and Cultural Affairs, or his or her designee, who shall serve as presiding officer of the Board;

(ii) An officer appointed by the Deputy Associate Director of the Bureau of Educational and Cultural Affairs from an appropriate office of the Bureau; and

(iii) The country desk officer for the geographic area office responsible for the geographical area of the waiver applicant, or his or her designee.

(2) The Director of the office of Exchange Visitor Program Services or his or her designee shall serve as the Executive Secretary of the Board and shall present the facts of the waiver case to the Board, but shall not take part in the Board's deliberations.

(3) A person who has had substantial prior involvement in the particular case pending before the Board shall not be appointed to serve on the Board.

(4) The following waiver cases shall be referred to the Board for review:

(i) Cases involving requests of interested United States Government agencies, in which the recommendation of the Waiver Review Branch was unfavorable;

(ii) Cases in which another federal agency has provided the Agency with a written opposition to a waiver in which the recommendation of the Waiver Review was favorable;

(iii) Cases in which a no objection letter has been submitted by the government of the exchange visitor's country of nationality or last legal residence, and in which the exchange visitor's participation in an exchange visitor program was financed by the United States Government in an amount not exceeding $2,000, and as to which the recommendation of the Waiver Review Branch was unfavorable;

(iv) Cases involving claims of probable persecution on the grounds of race, religion, or political opinion, in which the Department of State has provided the Agency with a written opinion that there is no genuine basis for a claim of probable persecution on the ground alleged by the applicant, and as to which the recommendation of the Waiver Review Board was favorable; and,

(v) Cases in which for any reason the Waiver Review Branch requests Board review of its decision.

(f) *Action on cases referred to the Board.* (1) In each case to be referred to the Board pursuant to § 514.44(e), *supra*, the Waiver Review Branch shall transmit its complete file on the case along with a request to convene the Board, to the General Counsel of the Agency.

(2) The General Counsel shall promptly convene the Board.

(3) The General Counsel shall appoint, on a case-by-case basis, from among the attorneys in the Office of the General Counsel, one attorney to serve as legal advisor to the Board.

(4) Upon being convened, the Board shall review the case file and the policy, program, and foreign relations implications of the case.

(5) The Board may consult with the attorney in the Office of the General Counsel who has been designated to serve as legal advisor to the Board.

(6) The Board may request that officers of the Waiver Review Branch appear before the Board and explain orally the basis for the recommendation of the Waiver Review Branch; however, no persons other than members of the Board and the Board's legal advisor may be present during the Board's deliberations.

(7) At the conclusion of its review of the case, the Board shall make a written recommendation either granting or denying the waiver application.

(8) Each member of the Board shall sign the recommendation and promptly transmit the recommendation to the Waiver Review Branch for forwarding to the Commissioner.

(9) The recommendation of the Board in any case reviewed by it shall constitute the final recommendation of the Agency and such recommendation shall be forwarded to the Commissioner.

Subpart D—Sanctions

§ 514.50 Sanctions.

(a) *Reason for sanctions.* The Agency may, upon a determination by the office of Exchange Visitor Program Services ("EVPS"), impose sanctions against a sponsor which has:

(1) Willfully or negligently violated one or more provisions of this part;

(2) Evidenced a pattern of willful or negligent failure to comply with one or more provisions of this part;

(3) Committed an act of omission or commission which has or could have the effect of endangering the health, safety, or welfare of an exchange visitor; or,

(4) Committed an act or acts which may have the effect of bringing the Agency or the Exchange Visitor Program into notoriety or disrepute.

(b) *Lesser sanctions.* (1) In order to ensure full compliance with the regulations in this part, the Agency, in its discretion and depending on the nature and seriousness of the violation, may impose any or all of the following sanctions ("lesser sanctions") on a sponsor for any of the reasons set forth in § 514.50(a):

(i) a written reprimand to the sponsor, with a warning that repeated or persistent violations of the regulations in this Part may result in suspension or revocation of the sponsor's exchange visitor program designation, or other sanctions as set forth herein;

(ii) A declaration placing the exchange visitor sponsor or probation, for a period of time determined by the Agency in its discretion, signifying a pattern of serious willful or negligent violation of regulations such that further violations could lead to suspension or revocation;

(iii) A corrective action plan designed to cure the sponsor's violations; or,

(iv) A limitation or reduction in the authorized number of exchange visitors in the sponsor's program or in the geographic area of the sponsor's recruitment or activity.

(2) Within ten days of service of the written notice to the sponsor imposing any of the sanctions set forth in this paragraph, the sponsor may submit to EVPS any statement or information, including, if appropriate, any documentary evidence or affidavits in opposition to or mitigation of the sanction, and may request a conference. Upon its review and consideration of such submission, the Agency may, in its discretion, modify, withdraw, or confirm such sanction. The decision of EVPS with regard to lesser sanctions (i) to (iii) and (iv), if the proposed limitation in the size of the sponsor's program is equivalent to 10 percent or less of the number of authorized visitors in the sponsor's program during the previous calendar year, is not appealable.

(c) *Suspension or significant program limitation.* (1) Upon a finding that a suspension, or a reduction in the sponsor's program equivalent to a number greater than 10 percent of the number of authorized visitors, is warranted for any of the reasons set forth at § 514.50(a), EVPS shall given written notice to the sponsor of the Agency's intent to impose the sanction, specifying therein the reasons for such sanction and the effective date thereof, which shall be not sooner than 30 days after the date of the letter of notification.

(2) Prior to the proposed effective date of such sanction, the sponsor may submit a protest to EVPS, setting forth therein any reasons why suspension should not be imposed, and presenting any documentary evidence in support thereof.

(3) EVPS shall review and consider the sponsor's submission and, within seven (7) days of receipt thereof, notify the sponsor in writing of its decision on whether the sanction is to be affected. In the event that the decision is to impose the sanction, such notice shall inform the sponsor of its right to appeal the sanction and of its right to a formal hearing thereon.

(4) The sponsor may within ten (10) days after receipt of the aforesaid notice effecting the sanction, appeal the sanction to the Exchange Visitor

Program Designation, Suspension and Revocation Board ("Board") by filing a notice of appeal with the Agency's General Counsel, room 700, 301 4th Street, SW., Washington, DC 20547. The filing of the notice of appeal shall serve to stay the effective date of the sanction pending appeal.

Upon receipt of the notice of appeal, the General Counsel or his or her designee shall forthworth convene the Board. Thereafter, proceedings before the Board shall follow the regulations set forth in § 514.50(i), *infra*.

(d) *Summary suspension.* (1) EVPS may, upon a finding that a sponsor has willfully or negligently committed a serious act of omission or commission which has or could have the effect of endangering the health, safety, or welfare of an exchange visitor, and upon written notice to the sponsor specifying the reason therefor and the effective date thereof, notify the sponsor of the Agency's intent to suspend the designation of the sponsor's program for a period not to exceed sixty (60) days.

(2) No later than three (3) days after receipt of such notification, the sponsor may submit a rebuttal to the EVPS, setting forth therein any reasons why a suspension should be imposed.

(3) The sponsor may present any statement or information in such protest, including, if appropriate, any documentary evidence or affidavits in opposition to or mitigation of the sanction. Within three (3) days of receipt of such submissions, EVPS shall notify the sponsor in writing of its decision whether to effect the suspension. In the event the decision is to effect the suspension, such notice shall advise the sponsor of its right to appeal the suspension and of its right to a formal hearing thereon.

(4) The sponsor may, within ten (10) days after receipt of the aforesaid notice continuing the suspension, appeal the suspension to the Board by filing a notice of appeal with the Agency's General Counsel, room 700, 301 4th Street, SW., Washington, DC 20547. The filing of the notice of appeal of a summary suspension shall not serve to stay the suspension pending appeal.

(5) Upon receipt of the notice of appeal, the General Counsel or his or her designee shall, within three (3) days, convene the Board. Thereafter, proceeding before the Board shall follow the regulations set forth in § 514.50(i), *infra*.

(e) *Revocation.* (1) EVPS may, for any reason set forth at § 514.50(a), give the sponsor not less than thirty (30) days notice in writing of its intent to revoke the sponsor's exchange visitor program designation, specifying therein the grounds for such revocation and the effective date of the revocation. Revocation need not be preceded by the imposition of a summary suspension, a suspension, or any lesser sanctions.

(2) Within ten (10) days of receipt of the aforesaid notice of intent to revoke, the sponsor shall have an opportunity to show cause as to why such revocation should not be imposed, and may submit to EVPS any statement of information, including, if appropriate, any documentary evidence or affidavits in opposition to or mitigation of the violations charged.

(3) EVPS shall review and consider the sponsor's submission and thereafter notify the sponsor in writing of its decision on whether the revocation is to be effected. In the event that the decision on whether the revocation is to effect the revocation, such notice shall advise the sponsor of its right to appeal the revocation and of its right to a formal hearing thereon.

(4) The sponsor may, within twenty (20) days after receipt of the aforesaid notice effecting the revocation, appeal the revocation to the Board by filing a notice of appeal with the Agency's General Counsel, room 700, 301 4th Street, SW., Washington, DC 20547. The filing of the notice of appeal shall serve to say the effective date of the revocation pending appeal.

(5) Upon receipt of the notice of appeal the General Counsel or his or her designee shall, within ten (10) days, convene the Board. Thereafter, proceedings before the Board shall follow the regulations set forth in § 514.50(i), *infra*.

(f) *Denial of application for redesignation.* (1) EVPS shall give an applicant for redesignation not less than thirty (30) days notice in writing of its intentions to deny the application for exchange visitor program redesignation, specifying therein the grounds for such denial.

(2) Within ten (10) days of receipt of the aforesaid notice of intent to deny the application, the applicant shall have an opportunity to demonstrate why the application should be approved, and may submit to EVPS any statement or information including, if appropriate, any documentary evidence or affidavits in support of its application.

(3) EVPS shall review and consider the applicant's submission and thereafter notify the applicant in writing of its decision on whether the application for redesignation will be approved. In the event that the decision is to deny the applicant, such notice shall advise the applicant of its right to appeal the denial and of its right to a formal hearing thereon.

(4) The applicant may, within twenty (20) days after receipt of the aforesaid notice of denial, appeal the denial to the Board by filing a notice of appeal with the Agency's General Counsel, room 700, 301 4th Street, SW., Washington, DC 20547.

(5) Upon receipt of the notice of appeal the General Counsel or his or her designee shall, within ten (10) days, convene the Board. Thereafter, proceedings before the Board shall follow the regulations set forth in § 514.50(i), *infra*.

(g) *The Exchange Visitor Program Designation, Suspension, and Revocation Board.* (1) The Exchange Visitor Program Designation, Suspension, and Revocation Board ("Board") shall consist of:

(i) The Deputy Associate Director of the Bureau of Educational and Cultural Affairs, or his or her designee, who shall serve as presiding officer of the Board;

(ii) The Deputy Director of the relevant geographic area office, or his or her designee; and

(iii) A member of the public appointed by the Deputy Associate Director of the Bureau of Educational and Cultural Affairs. A different public member shall be appointed for each sanction case brought before the Board.

(2) The General Counsel of the Agency shall appoint an attorney in the Office of the General Counsel to prosecute the case before the Board on behalf of the Agency. Such attorney shall not take part in the deliberations of the Board.

(3) The General Counsel of the Agency shall also appoint an attorney in the Office of the General Counsel to serve as a legal advisor to the Board. Such attorney shall not have had any substantial prior involvement with the particular case pending before the Board.

(h) *General powers of the Board.* At any hearing before the Board pursuant to this Part, the Board may:

(1) Administer oaths and affirmations;

(2) Rule on offers of proof and receive any oral or documentary evidence;

(3) Require the parties to submit lists of proposed witnesses and exhibits, and otherwise regulate the course of the hearing;

(4) Hold conferences for the settlement or simplification of the issues by consent of the parties;

(5) Dispose of motions, procedural requests, or similar matters; and

(6) Make decisions, which shall include findings of fact and conclusions of law on all the material issues of fact and conclusions of law on all the material issues of fact, law or discretion

presented on the record, and the appropriate sanction or denial thereof.

(i) *Proceedings before the Board.* The following procedures shall govern all designation, suspension, summary suspension, and revocation proceedings before the Board:

(1) Upon being convened, the Board shall schedule a hearing, within ten (10) days, at which hearing the parties may appear on their own behalf or by counsel, present oral or written evidence, and cross-examine witnesses. A substantially verbatim record of the hearing shall be made and shall become a part of the record of the proceeding;

(2) At the conclusion of the hearing, the Board shall promptly review the evidence and issue a written decision within ten (10) days, signed by a majority of the members, stating the basis for its decision. The decision of the majority shall be the decision of the Board. If a Board member disagrees with the majority, the member may write a dissenting opinion;

(3) If the Board decides to affirm the suspension, summary suspension, revocation, or denial of redesignation, a copy of its decision shall be delivered to EVPS, the sponsor, the Immigration and Naturalization Service, and the Bureau of Consular Affairs of the Department of State. EVPS, at its discretion, may distribute the Board's decision as it deems appropriate; and

(4) The suspension, revocation, or denial of designation shall be effective as of the date of the Board's decision.

(j) *Effect of suspension, summary suspension, revocation, or denial of redesignation.* A sponsor against which an order of suspension, summary suspension, revocation, or denial of redesignation has been entered shall not thereafter issue any Forms IAP–66, advertise, recruit, or otherwise promote its program, and under no circumstances shall the sponsor facilitate the entry of an exchange visitor. Suspension, summary suspension, revocation, or denial of redesignation shall not invalidate any Forms IAP–66 issued prior to the effective date of the suspension, summary suspension, revocation, or denial of redesignation, nor shall the suspension, summary suspension, revocation, or denial of redesignation in any way diminish or restrict the sponsor's legal or financial responsibilities to existing program participants.

(k) *Miscellaneous*—(1) *Computation of time.* In computing any period of time prescribed or allowed by these regulations, the day of the act or event from which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included unless it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day which is not one of the aforementioned days. When the period of time prescribed or allowed is less than eleven (11) days, intermediate Saturdays, Sundays, or legal holidays, shall be excluded in the computation.

(2) *Service of notice on sponsor.* When used in these regulations the terms "written notice to the sponsor" shall mean service of written notice upon either the president, managing director, responsible officer, or alternate responsible officer of the sponsor.

Subpart E—Termination and Revocation of Programs

§ 514.60 Termination of Designation.

Designation shall be terminated when any of the circumstances set forth in this section occur.

(a) *Voluntary termination.* A sponsor may voluntarily terminate its designation by notifying the Agency of such intent. The sponsor's designation shall terminate upon such notification. Such sponsor may reapply for designation.

(b) *Inactivity.* A sponsor's designation shall automatically terminate for inactivity if the sponsor fails to comply with the minimum size or duration requirements, as specified in §§ 514.8 (a) and (b), in any twelve month period. Such sponsor may reapply for program designation.

(c) *Failure to file annual reports.* A sponsor's designation shall automatically terminate if the sponsor fails to file annual reports for two consecutive years. Such sponsor is eligible to reapply for program designation upon the filing of the past due annual reports.

(d) *Change in ownership or control.* An exchange visitor program designation is not assignable or transferable. A major change in ownership or control automatically terminates the designation. However, the successor sponsor may apply to the Agency for redesignation and may continue its exchange visitor activities while approval of the application for redesignation is pending before the Agency.

(1) With respect to a for-profit corporation, a major change in ownership shall be deemed to have occurred when thirty-three and one-third percent (33⅓ percent) or more of its stock is sold or otherwise transferred within a 12 month period;

(2) With respect to a not-for-profit corporation, a major change of control shall be deemed to have occurred when fifty percent or more of the board of trustees, or other like body vested with its management, is replaced within a 12 month period.

(e) *Loss of licensure or accreditation.* A sponsor's designation shall automatically terminate in the event that the sponsor fails to remain in compliance with local, state, federal, or professional requirements necessary to carry out the activity for which it is designated, including loss of accreditation or licensure.

(f) *Failure to apply for redesignation.* Prior to the conclusion of its current designation period, the sponsor is required to apply for redesignation pursuant to the terms and conditions of § 514.7. Failure to apply for redesignation will result in the automatic termination of the sponsor's designation. If so terminated, the former sponsor may apply for a new designation, but the program activity will be suspended during the pendency of the application.

§ 514.61 Revocation.

A designation may be terminated by revocation for cause as specified in § 514.60. A sponsor whose designation has been revoked may not apply for a new designation within a five-year period.

§ 514.62 Responsibilities of the sponsor upon termination or revocation.

Upon termination or revocation of its designation, the sponsor shall:

(a) Fulfill its responsibilities to all exchange visitors who are in the United States at the time of the termination or revocation;

(b) Notify exchange visitors who have not entered the United States that the program has been terminated unless a transfer to another designated program can be obtained; and

(c) Return all Forms IAP–66 in the sponsor's possession to the Agency within 30 days of program termination or revocation.

Appendix A to Part 514—Certification of Responsible Officers and Sponsors

In accordance with the requirement at § 514.5(c)(6), the text of the certifications shall read as follows:

1. Responsible Officers and Alternate Responsible Officers

I hereby certify that I am the responsible officer (or alternate responsible officer, specify) for exchange visitor program number _____, and that I am a United States citizen or permanent resident. I understand that the United States Information Agency may request supporting documentation as to my citizenship or permanent residence at any

time and that I must supply such documentation when and as requested. (Name of organization) agrees that my inability to substantiate the representation of citizenship or permanent residence made in this certification will result in the immediate withdrawal of its designation and the immediate return of or accounting for all Forms IAP-66 transferred to it.

Signed in ink by

_____

(Name)

_____

(Title)

Witness:

_____

This _____ day of _____, 19____.
Subscribed and sworn to before me this _____ day of _____, 19 .

_____

Notary Public

2. Sponsors

I hereby certify that I am an officer of (Name of Organization) with the title of (specify); that I am authorized by the (Board of Directors, Trustees, etc.) to sign this certification and bind (Name of Organization); and that a true copy certified by (Board of Directors, Trustees, etc.) of such authorization is attached. I further certify that (Name of Organization) is a citizen of the United States as that term is defined at 22 CFR § 514.2. (Name of Organization) agrees that inability to substantiate the representation of citizenship made in this certification will result in the immediate withdrawal of its designation and the immediate return of or accounting for all Forms IAP-66 transferred to it.

Signed in ink by

_____

(Name)

_____

(Title)

Attestation/Witness:

_____

This _____ day of _____, 19____.
Subscribed and sworn to before me this _____ day of _____, 19 .

_____

Notary Public

Appendix B to Part 514—Exchange Visitor Program Services; Exchange-Visitor Program Application

FORM APPROVED OMB _____
Serial No. _____

_____

1. Name and Address of Sponsoring Organization

_____

2. Name and Title of Responsible Officer

_____

Telephone Number

_____

3. Name and Title of Alternate Responsible Officer

Telephone Number _____

4. Type of Application (check one)

New _____ Re-Apply _____
Re-Designation _____

Section I—Program Participant Data (For Definition & Length of Stay See 22 CFR _____)

5. Participation by Category (indicate total no. and approximate duration of stay in each category)

A. Student
B. Teacher
C. Professor
D. Researcher
E. Short-Term Scholar
F. Specialist
G. Trainee
  1. Specialty
  2. Nonspeciality
H. Int'l Visitor
I. Gov't Visitor
J. Physicians
k. Camp Cnslr
L. Sumr/Wk/Trvl

_____

6. Method of Selection

_____

7. Arrangements for Financial Support of Exchange Visitor while in the U.S.

_____

Section II—Program Data

8. Outline of Proposed Activities (If training, See Reverse)

_____

9. Arrangements for Supervision and Direction

_____

10. Purpose of Objective

_____

11. Role of other Organizations Associated with Program (if any)

_____

Section III—Certification

12. Citizenship Certification of Organization and Responsible Officer (see reverse)

13. I certify that information given in this application is true to the best of my knowledge and belief and that I have completed appropriate information on reverse of this form.

_____

Signature of Responsible Officer
Date _____

_____

(See Reverse side for instructions)

Instructions for all Programs

If additional space is needed in supplying answers to any questions, please use continuation sheets on plain white paper

1–3. Names and address of organization and telephone numbers.

4. Select type of application.

5. Select appropriate categories (see 22 CFR prior to filling out this data.

6–7. Complete information on program sponsor.

8–11. Complete information on program.

IF TRAINING PROGRAM, identify appropriate fields: 01–Arts & Culture; 02–Information Media and Communications; 03–Education; 04–Business and Commercial; 05–Banking and Financial; 06–Aviation; 07–Science, Mechanical and Industrial; 08–Construction and Building Trades; 09–Agricultural; 10–Public Administration; 11–Training, Other.

Reapplication and Redesignation

If your organization is making reapplication as an exchange visitor program, or applying for redesignation under 22 CFR _____, please certify to the following:

I hereby certify that as an officer of the organization making application for an exchange program under 22 CFR _____ or 22 CFR _____ that the following documents which have been submitted to the United States Information Agency, Exchange Visitor Program Services, remain in effect and not altered in any way:

(1) Legal status as a corporation such as Articles of Incorporation and By Laws. Provide dates and state of both: _____.

(2) Accreditation. Provide date, type of accreditation, and State of accreditation: _____.

(3) Evidence of Licensure. Provide date, type of license, and state of licensure: _____.

(4) Authorization of governing body authorizing application. Please provide date of such authorization and authorizing body: _____.

(5) Activities in which the organization has been engaged have not changed since application dated: _____

(6) Citizenship. Provide the date of compliance with citizenship requirements: _____. If citizenship compliance is not current, please complete the following: Organization: I hereby certify that I am an officer of _____ with the title of _____; that I am authorized by the Board of Directors, Trustees, etc.) to sign this certification and bind _____; and that a true copy certified by the Board of Directors, Trustees, etc.) of such authorization is attached. I further certify that _____ is a citizen of the United States as that term is defined at 22 CFR 514.1.

Responsible Officer or Alternate Responsible Officer: I hereby certify that I am the responsible officer (or alternate responsible officer) for _____, and that I am a citizen of the United States (or a person lawfully admitted to the United States for permanent residence. _____ agrees that my inability to substantiate my citizenship or status as a permanent resident will result in the immediate withdrawal of its designation

and immediate return of or accounting for all IAP–66 forms transferred to it.

Certification as to (1)–(6) Requirements

I understand that false certification may subject me to criminal prosecution under 18 U.S.C. 1001, which reads: "Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than $10,000 or imprisoned not more than five years, or both."

Signed in ink by (Name _____

Title _____

Subscribed and sworn to before me this _____ day of _____, 19____.

Notary Public

USIA Use Only

Type of program: _____

Subtype if applicable: _____

No. Forms IAP–66: _____

Categories: _____

Please return form to: Exchange Visitor Program Services-GC/V, United States Information Agency, Washington, DC 20547.

Note: Public reporting burden for this collection of information (Paperwork Reduction Project: OMB No. 3116–0011) is estimated to average ____ minutes/hours per response, including time for reviewing instructions, researching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to USIA Clearance Officer, M/ASP, U.S. Information Agency, 301 4th Street, S.W., Washington, DC 20547; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Appendix C to Part 514—Update of Information on Exchange-Visitor Program Sponsor

Please amend the United States Information Agency records for Exchange-Visitor Program Number _____ assigned to _____ as follows:

(Name of institution/organization)

1. Change the name of the Program Sponsor from the above to _____

_____

2. Change the address of the Program Sponsor

From: _____

_____

_____

_____

To: _____

_____

_____

(city) (state) (zip)

_____

(city) (state) (zip)

3. ( ) Change the telephone number from _____ to _____

( ) Change the fax number from _____ to _____

4. ( ) Change the name of the Responsible Officer of the above program from _____ to _____

5. a. Delete the following Alternate Responsible Officer:

_____

_____

_____

_____

_____

5. b. Add the following Alternate Responsible Officer:

_____

_____

_____

_____

_____

(Citizenship is required for all Responsible and Alternate Responsible Officers—See Reverse)

6. ( ) Send _____ (Indicate number) IAP–66 forms. (Please allow four to six weeks for response and remember to submit the annual report)

7. ( ) Send _____ copies of this form.

8. ( ) Send _____ copies of *Codes for Educational and Cultural Exchange.*

9. ( ) Cancel the above named Exchange Visitor Program.

_____

(Signature of Responsible or Alternate Responsible Officer)

_____

(Date)

_____

(Title of Signing Officer)

Appendix D to Part 514—Annual Report; Exchange Visitor Program Services (GC/V), United States Information Agency, Washington, DC 20547, (202–401–7964)

Exchange Visitor Program No. _____

Reporting Period _____

Provide range of forms IAP–66 documents covered by this report

(_____ - _____). _____

(a) Statistical Report

(1) Activity by Category

	Number
Professor	
Research Scholar	
Short-term Scholar	
Trainee	
Student (College and University)	
Student (Practical Trainee)	
Teacher	
Student (Secondary)	
Specialists	
Physicians	
International Visitors	
Government Visitors	
Camp Counselors	
Total	

(2) Forms IAP–66 Reconciliation

(i) Number of Forms IAP–66 voided or otherwise not used by participant _____

(ii) Number of Forms IAP–66 issued for dependents _____

(iii) Number of Forms IAP–66 currently on hand _____

(b) Program Evaluation

On a separate sheet, please provide a brief narrative report on program activity, difficulties encountered and their resolution, program transfers, anticipated growth and the proposed new activity, cross-cultural activities, as well as the reciprocal component of the program.

I, The Responsible Officer of the program indicated above, certify that we have complied with the insurance requirement (22 CFR 514.14). I also certify that the information contained in this report is complete and correct to the best of my knowledge and belief.

_____

Responsible Officer (signed)

Date _____

_____

Name and address of sponsoring institution

Appendix E to Part 514—Unskilled Occupations

The current descriptions of Schedule B occupations appear following the list at 20 CFR 656.11 and are incorporated herein by reference. Schedule B currently lists the following occupations.

(1) Assemblers

(2) Attendants, Parking Lot

(3) Attendants (Service Workers such as Personal Services Attendants, Amusement and Recreation Service Attendants)

(4) Automobile Service Station Attendants

(5) Bartenders

(6) Bookkeepers

(7) Caretakers

(8) Cashiers

(9) Charworkers and Cleaners

(10) Chauffeurs and Taxicab Drivers

(11) Cleaners, Hotel and Motel

(12) Clerks, General

(13) Clerks, Hotel

(14) Clerks and Checkers, Grocery Stores
(15) Clerk Typist
(16) Cooks, Short Order
(17) Counter and Fountain Workers
(18) Dining Room Attendants
(19) Electric Truck Operators
(20) Elevator Operators
(21) Floorworkers
(22) Groundskeepers
(23) Guards
(24) Helpers, any industry
(25) Hotel Cleaners
(26) Household Domestic Service Workers
(27) Housekeepers
(28) Janitors
(29) Key Punch Operators
(30) Kitchen Workers
(31) Laborers, Common
(32) Laborers, Farm
(33) Laborers, Mine
(34) Loopers and Toppers
(35) Material Handlers
(36) Nurses' Aides and Orderlies
(37) Packers, Markers, Bottlers and Related
(38) Porters
(39) Receptionists
(40) Sailors and Deck Hands
(41) Sales Clerks, General
(42) Sewing Machine Operators and Handstitchers
(43) Stock Room and Warehouse Workers
(44) Streetcar and Bus Conductors
(45) Telephone Operators
(46) Truck Drivers and Tractor Drivers
(47) Typist, Lesser Skilled
(48) Ushers, Recreation and Amusement
(49) Yard Workers

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Friday
October 9, 1992

Part IV

Department of Health and Human Services

Administration for Children and Families

45 CFR Part 1305
Head Start Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1305

RIN 0970-AB02

Head Start Program

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Administration on Children, Youth and Families is amending 45 CFR part 1305 which governs eligibility requirements for enrollment of children in Head Start.

Currently, most Head Start grantees have more children living in their service areas than they are able to serve. Each grantee must make decisions regarding recruitment, selection and enrollment of children.

The purpose of this rule is to specify procedures that will assure that these decisions are carefully planned and made at the local level; give all interested families an opportunity to be considered for enrollment; and help maintain full enrollment, allowing as many eligible children as possible to be served.

EFFECTIVE DATE: This rule is effective November 9,1992.

FOR FURTHER INFORMATION CONTACT: Douglas Klafehn, Acting Associate Commissioner, Head Start Bureau. (202)205-8569.

SUPPLEMENTARY INFORMATION:

I. Program Purpose

Head Start, as authorized under the Head Start Act (the Act), section 635 of Public Law 97-35, the Omnibus Budget Reconciliation Act of 1981, (42 U.S.C. 9831 *et seq.*) is a national program providing comprehensive child development services. These services are provided primarily to low-income children, age three to five, and their families. To help enrolled children achieve their full potential, Head Start programs provide comprehensive health, nutritional, educational, social and other services. In addition, Head Start programs are required to provide for the direct participation of parents of enrolled children. Parents receive training and education that fosters their understanding of and involvement in the development of their children. They also become involved in the development, conduct, and direction of local programs.

In fiscal year 1991, Head Start served 582,325 children through a network of approximately 1,340 grantees and 620 delegate agencies. Delegate agencies have approved written agreements with grantees to operate Head Start programs.

While Head Start is intended to serve primarily low-income children and their families, Head Start's regulations permit up to 10 percent of the children in local programs to be from families who are not low-income. The Act requires that a minimum of 10 percent of enrollment opportunities in each State be made available to children with disabilities. Such children are expected to participate in the full range of Head Start activities with their non-disabled peers, and to receive needed special education and related services.

II. Purpose of the Final Rule

The purpose of this rule is to define a process to be used by local Head Start programs for the recruitment, enrollment and selection of Head Start children that is organized, focused, and more uniform among grantees and which provides opportunities for the greatest number of children to be considered for Head Start services.

Currently, Head Start grantees are funded to serve a geographic area. This area may be a city, county, multicity, multicounty, or other area that possesses a commonality of interest needed to operate a Head Start program. In the past, we have assumed that a grantee is responsible for providing Head Start services to its entire service area, even though its operations may have long been concentrated in certain parts of the area because resources were limited. We are concerned that, as funding for Head Start programs increases, grantees may tend to expand services in the areas where they are already operating, rather than move into unserved parts of their service area. We are, therefore, requiring: (1) That grantees clearly identify a specific service area which is agreed to, in writing, by the responsible HHS official, and (2) that grantees consider the needs of and recruit children from the entire geographic area they have agreed to serve, to the extent their financial resources allow. This, combined with the establishment of new grantees in currently unserved communities or service areas, will enable the maximum number of children to have an opportunity to enroll in Head Start.

In order to help children carry the gains they have made in Head Start into school, we are also requiring that once a child is enrolled in Head Start as either a three or a four year old, he or she is to remain in the program until kindergarten or first grade is available to the child in the child's community, except when there are compelling reasons for the child not to remain in Head Start. This would, in most instances, prevent a child from being enrolled as a three year old but not served at age four, as is possible under current regulations. This rule would also draw attention to the importance of grantees carefully weighing the need for more than one year of Head Start services when making decisions to enroll younger children, since serving a child for more than one year means that another child will not have the opportunity for a Head Start experience.

Under current regulations, when there are more income-eligible children than can be served, programs must select those families with the lowest income. When programs adhere to this single criterion, it limits their ability to respond to a variety of special circumstances in their communities, such as the needs of families involved in substance abuse or of single parents who are working.

In addition, the current regulation may cause programs to enroll three year old children and serve them for two years, not because they believe they need an additional year of service, but simply because their family income is slightly lower than another child's.

We are expanding the criteria for selecting among income-eligible children by allowing each program to define other criteria, in addition to lowest income. Such criteria might include the age of children or the special needs that a family may have. We believe this will result in programs establishing criteria for selection that are more closely based on the needs in their communities and the capacity of their programs. However, as programs determine their own selection criteria based on local needs and circumstances, we want to urge programs to consider serving the maximum number of children during the year before they enter public school. Programs are expected to serve the children with the greatest need for and who can benefit the most from Head Start. When a program's resources are limited, such choices should involve considering whether the needs of three year olds justify providing them with two years of service at the expense of eligible four year olds who would thereby not be served at all.

In addition to these major elements, this rule requires that Head Start grantees:

• Make decisions about the design of their program based on a periodic community needs assessment that includes the collection and analysis of data about demographics, available resources and the needs of families and children.

• Implement a recruitment process that is designed to inform all income-eligible families within their recruitment area of the availability of services so families may have a fair opportunity to apply and be considered for enrollment when the number of children who can be served is limited.

• Maintain funded enrollment so that resources can be used efficiently.

• Implement appropriate family support procedures for those children with patterns of unexcused absences so these children have a greater opportunity to obtain the benefits of regular attendance.

III. Rulemaking History

This Rule was published in the **Federal Register** (55 FR 29970) on July 23, 1990 as a Notice of Proposed Rulemaking (NPRM). The NPRM proposed amendments to part 1305 based on changing conditions that have affected the Head Start program over the past several years. The most significant factors are the following:

• Some grantees are not maintaining funded enrollment levels throughout the program year. In some cases, grantees achieve full enrollment in the beginning of the year but are not able to fill vacancies that occur during the year. In other cases, grantees are not able to achieve full enrollment at any time during the program year.

• Some grantees are serving children for more than one year simply because they need to fill vacancies. In some instances, this occurs because the program's recruitment area is too small and children must be served for two years simply to meet agreed upon enrollment levels, while children receive no services in communities outside the recruitment area.

• Many grantees are experiencing high turnover rates among program enrollees. The national average for children who drop out of the program after they have been enrolled is 20 percent of an agency's funded enrollment. There is a need to make sure that all grantees have systems in place for filling vacancies as they occur.

• Many grantees are finding that the number and location of eligible children in their service area have changed considerably over time. In some cases, there are many more children eligible to be served than in the past. Other grantees have experienced significant population shifts from one part of their service area to another. There is a need to make sure that enrollment opportunities are available where the need for Head Start services is greatest.

• The number of State and locally funded preschool programs continues to increase. In some cases, this means a significant decrease in the number of children who are available to be served by Head Start. Grantees must take into account other preschool services for low-income children in their community when determining the need for Head Start services in specific areas.

This final rule reorganizes the content of part 1305 and sets forth additional actions to be taken by Head Start grantees and delegate agencies to recruit, select and enroll those children and families who are most in need of or who will benefit the most from Head Start services.

The final rule contains revisions to the NPRM which incorporate, as appropriate, the comments received from the general public, local Head Start staff and parents, national organizations and other interested agencies.

IV. Section by Section Discussion of the NPRM

We received 85 letters with over 250 separate comments on various sections of the proposed revisions to part 1305. Many of the comments were positive and supportive of the clarity and comprehensive nature of the revisions. A number of comments also expressed specific concerns regarding particular sections of the proposed regulation. We have reviewed all of the comments received and, after full consideration, have modified some sections of the NPRM. Discussed below are the revised sections and the rationale for making a change from the NPRM.

Section 1305.2 Definitions

The definition of children with disabilities in paragraph (a) was changed since the publication of the NPRM. It now reflects the amended definition in the Individuals with Disabilities Education Act (IDEA) as required by section 640(d) of the Head Start Act.

In response to comments received, the phrase "within the past 12 months" was added to the definition of migrant families in paragraph (1) to make it clear that children served by Migrant Head Start programs are to be from mobile migrant families that have moved within the past 12 months.

Section 1305.3 Determining Community Needs

With respect to paragraph (a), we have made a small clarifying change, requiring grantee service areas to be approved by the responsible HHS official.

Several respondents from programs serving migrant farmworker families expressed concern about their ability to identify their service area at the time they submit a refunding application unless the service area could be broadly defined. For example, if crops fail or if the weather is bad, migrants may not return to an area where they have been in the past. We believe that the language in the NPRM is adequate to allow for negotiation with the responsible HHS official to approve a geographic area that would be broad enough to meet the needs of Migrant Head Start programs. However, the final rule has been changed to require that the responsible HHS officials approve each grantee's service area in writing.

A number of comments were received concerning the requirement in paragraph (b) that each grantee must conduct a community needs assessment once every three years and that it contain specific data regarding the local community. Some of the respondents supported the community needs assessment information requirements and indicated that the data are reasonable and available. Some indicated that the data are typical of those currently being used in their agencies. Other respondents disagreed. Some indicated that Census data are the only reliable data available in their communities and that these data are only useful for a limited number of years. Some indicated that the racial and ethnic data are not reliable because of undercounting in some communities. Several indicated that data on the numbers of low-income children with disabilities are not available, since disabling conditions are not identified by income categories.

In response to these concerns, we modified some of the data requirements. We ordered the data requirements into a more logical sequence of information and we clarified some of the wording. We also acknowledge that some of the data, particularly Census data, may not remain accurate over the length of time that they are needed. We expect that grantees will estimate some of the information, particularly the numbers of eligible children, and may have to use proxy data or make adjustments as decennial Census data become less current. We have inserted the word

"estimated" regarding the number, geographic location and racial and ethnic composition of children in the grantee's service area.

Comments received on paragraph (c) of this section of § 1305.3 were favorable. A technical change was made for clarification.

Paragraph (d) of § 1305.3 proposed an annual update of the community needs assessment to assure that changes in the community are reflected in the Head Start program decision-making process. Several respondents suggested that we eliminate the updates in years two and three since communities do not change that much. We believe that there may be instances where there are significant changes in community circumstances over a one or two year period, and, therefore, we are keeping the language as it was proposed. We do not expect grantees to conduct an extensive review of community needs assessment information in the second and third years, but rather to limit analysis and information to those areas where there have been significant changes that require a program to adjust plans for Head Start services.

There were no comments regarding paragraphs (e) and (f) of § 1305.3 and no changes have been made.

Section 1305.4 Age of Children and Family Income Eligibility

Paragraph (a) of § 1305.4 proposed a change in the age eligibility requirement by stating that a child would be eligible for Head Start services when the child is at least three years of age by the date used in the community to determine eligibility for public school, unless the approved grant award specifies otherwise. All comments on this paragraph were positive and no changes have been made.

Several respondents were concerned that the discussion regarding giving four-year-old children priority over other age groups implied that programs were limited to serving four-year-old children. The purpose of the discussion in the preamble to the NPRM was to emphasize the principle that programs must make decisions regarding the needs of each child when selecting those to be served by Head Start. Some children may have needs that would warrant more than one year of Head Start services. Others may not have the same level of need. All children, once enrolled in Head Start, are to remain in the program until they are eligible for public school, unless there are compelling reasons for the child not to remain in Head Start.

Paragraph (b) reiterates the current requirement contained in § 1305.4 that at least 90 percent of the children who are enrolled in the program must be from low-income families. Several respondents, many of them parents of children enrolled in the same Head Start Program, requested that the income-eligibility guidelines be raised to allow programs the option of serving children from families that are barely over the income-eligibility guidelines. Others suggested that Head Start income eligibility should be the same as that of the USDA Child Care Feeding Program for free and reduced meals. We are not changing the requirement that at least 90 percent of families must be at or below the income-eligibility guidelines, since we are currently serving only a portion of the eligible children from families that are at or below the guidelines. In addition, changing this requirement would involve a change in the Head Start legislation regarding how the poverty line is determined.

There were no comments on paragraphs (c), (d), and (e) of § 1305.4 and no changes have been made.

Section 1305.5 Recruitment of Children

This section describes actions to be taken by Head Start grantees and delegate agencies when recruiting Head Start children.

Paragraph (a) requires that each Head Start Program employ a recruitment process that assures full enrollment in the Head Start Program. Several respondents wrote in support of this requirement, indicating that it reflects current practice in their Head Start Programs. Others, while supporting an intensive recruitment effort, were concerned that the NPRM implied door-to-door recruitment that is not always possible because of limited staff and safety factors. This paragraph is a restatement of the existing policy contained in the Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A. 1.a., 1.b and 1.c. The intent of this requirement is to reach those children most in need of or who could benefit most from Head Start services in order to provide them with an opportunity to apply for admission to the program. In response to the concern stated above, we changed the word "must" to "may" in the last sentence of paragraph (a) concerning activities in the recruitment process.

Paragraph (b) of the NPRM added a new requirement that, during the recruitment process that occurs prior to the beginning of the enrollment year, a Head Start program must solicit applications from as many Head Start eligible families within the recruitment area as possible. If necessary, the program must assist families in filling out the application form in order to assure that all application requirements for the program are completed before the selection process begins. There was one comment supporting this section and no change has been made.

Paragraph (c) of the NPRM added a new requirement that, for each program, except migrant programs, the number of applications obtained during the recruitment process that occurs prior to the beginning of the enrollment year must be at least 20 percent greater than the enrollment opportunities that are anticipated to be available over the course of the next enrollment year. There were 21 comments on this section. Some respondents supported having a specific, measurable requirement regarding the number of applications each program must obtain during the major recruitment effort. Most, however, disagreed, indicating that the amount was not realistic, especially for large programs. Some indicated that it would not eliminate the need for ongoing recruitment to fill vacancies within 30 days of their occurrence, since families on the waiting list are often as transient as families enrolled in the program. Others indicated that, as programs begin to serve a higher percentage of the eligible population in certain communities, it will become more difficult to adhere to this requirement. We agree that current and future increases in the number of children served by each grantee may make it increasingly difficult for grantees to meet the requirement for a fixed percentage of applications. We are modifying paragraph (c) of this section by dropping a fixed percentage of applications that programs are required to obtain during recruitment and are requiring programs simply to obtain a number of applications that is greater than the enrollment opportunities that are available over the course of the year. This will allow each Head Start program to establish an individualized target.

We proposed a new requirement to address the drop-out pattern of migrant programs in paragraph (d) of the NPRM that, prior to beginning Head Start services in a new community, migrant programs must obtain a number of applications that is at least 20 percent greater than the enrollment opportunities that are available while they are providing services in that community. Respondents from programs serving children of migrant farmworkers did not believe that this requirement was realistic for their programs, since it is often difficult to anticipate the number of families that will require

Head Start services. Most families are enrolled as they arrive in a community and need Head Start services. Enrollment is often gradual in the first few weeks of services. We agree that this requirement would be difficult to implement for programs serving migrant children and we are eliminating this paragraph from the final regulation.

Paragraph (e) in the NPRM contained an exception to the requirements contained in paragraphs (c) and (d) for programs that do not obtain sufficient applications from Head Start eligible families to meet the requirement. Since we are eliminating the requirements of obtaining twenty percent more applications than the enrollment opportunities that are available that were contained in paragraphs (c) and (d), it is not necessary to retain paragraph (e) and it has been eliminated from the final regulation.

Section 1305.6 Selection Process

This section contains requirements for establishing and implementing a process for selecting children and families to be enrolled in the program. Using selection criteria that are based on the information obtained from the community needs assessment, each program must go through a process that selects those children and families that are most in need of and who could benefit most from Head Start services. This is intended to assure that each program considers all of the children and families applying for admission to the program in order to identify the children and families that are most in need of Head Start services, as defined by each program for the community it is serving.

Paragraph (a) incorporates the requirement found in the Enrollment and Attendance Policies, S–30–317–1–40, A.1.e., regarding the selection of children and families. It requires that each grantee and delegate agency must establish a written process for selecting children and families that is based on the program's specific selection criteria. A single comment on this paragraph came from a director of a program serving migrant farmworker families. The respondent indicated that it is difficult for migrant programs to have an extensive selection process since families are enrolled as they arrive in a community. While it may be difficult for programs serving migrant farmworker families to compare all children and families that could be served when selecting which families have the greatest need for Head Start services, we believe that it is important for migrant programs to have pre-established criteria for selecting each family as they apply for services. Families and children that meet the criteria would then be selected for services. We, therefore, are not changing this paragraph.

Paragraph (b) requires that, in selecting children and families to be served, the Head Start program shall consider income, age, and individual child and family needs. This would change the current requirement in § 1305.4 that children from the lowest income families shall be given preference. All comments related to this paragraph were positive, supporting the opportunity to consider child and family needs in addition to income when selecting children to be served by the Head Start program. We have, however, added new language previously contained in the NPRM in paragraph (d) of this section, that proposed to require programs to give priority to serving children for whom kindergarten or first grade is not available.

Based on comments received on paragraph (d) of the NPRM, we are eliminating the requirement to give priority and, instead, are making the availability of kindergarten or first grade to the child one of several criteria to consider when selecting children for enrollment in Head Start. If kindergarten or first grade is available to the child in the child's community, we encourage programs to give that child a lower priority for service. We recognize that for reasons that include those discussed in comments on paragraph (d), there will be situations when a child should remain in Head Start when kindergarten or first grade is available. For example, we recognize that, in some instances, children who are age-eligible for kindergarten do not have the option of going to kindergarten because of local circumstances that include readiness testing, and lack of transportation. Head Start programs, therefore, may provide services to the child who does not pass a kindergarten readiness test and would otherwise remain at home for the entire year. On the other hand, if a child can attend kindergarten or first grade, we believe the child should receive a lower priority for enrollment in Head Start than a child who cannot be enrolled in school. To do otherwise may deny another eligible child the opportunity to participate in Head Start.

Paragraph (c) of the NPRM added a new requirement that each grantee and delegate agency must make available at least 10 percent of the enrollment opportunities in its program to children with disabilities who meet the definition of children with disabilities in § 1305.2(a). Such children must also meet the Head Start eligibility requirements contained in § 1305.4. The Head Start Act requires that 10 percent of enrollment opportunities within each State be made available to children with disabilities. Paragraph (c) proposes to require each Head Start program to meet the 10 percent figure in order to assure that all programs are serving children with disabilities in all areas in the State.

There were several comments on this paragraph. Some supported requiring grantees and delegate agencies to provide at least 10 percent of their enrollment opportunities to children with disabilities, since that is already the practice with most programs. Others were concerned about the feasibility of achieving this requirement at the grantee level in light of the growth of early intervention programs for preschool children that are operated by public school systems. We agree that there is an increase in the number of programs serving preschool children with disabilities and that it may be more difficult to recruit children for Head Start services. In recent years, 13 percent of Head Start's enrollment has consisted of children with disabilities. Most programs have successfully achieved enrollment levels of at least 10 percent. We are retaining this requirement as it was written in the NPRM because we believe that there are many children with disabilities who would be best served in a Head Start program. In some instances, children are served by Head Start for some portion of each week and by another local agency for the remainder of the week. We continue to encourage this arrangement.

Paragraph (c) also states that an exception to the requirement can be granted by the responsible HHS official if a program made an attempt to comply but could not because income-eligible children with disabilities are being served by other agencies or when Head Start is not the most appropriate placement for them. There were several comments related to obtaining an exception. Most respondents were concerned about the growing competition for serving children with disabilities in early intervention programs. This could mean that many programs would be requesting an exception on a regular basis. In response to this, we are retaining the possibility of an exception to the requirement, but we are broadening the reason for an exception by eliminating the words "income eligible." This requires programs to make enrollment opportunities available to children with

disabilities, regardless of family income, before requesting an exception. We believe that this broader interpretation is more in keeping with the intent of the Head Start Act's requirement to provide enrollment opportunities for children with disabilities.

We are further clarifying that, when enrolling a child with disabilities in Head Start, programs must consider whether the type of program services provided by Head Start are the most appropriate placement for the child according to his or her Individual Education Plan (IEP).

Paragraph (d) of § 1305.6 of the NPRM added a new requirement that a program must not enroll any child who is eligible for kindergarten or first grade and for whom kindergarten or first grade is available in the child's community unless the program has first enrolled all interested and Head Start eligible children living in the program's service area for whom kindergarten or first grade is not available. A large number of respondents commented on this paragraph. A small number of respondents supported the requirement, stating that it would strengthen their position when school systems want children to return to Head Start even though they are eligible for public school. Most respondents disagreed with the requirement, wanting to retain the option of giving priority for enrollment to children when they are age-eligible for kindergarten, because they believe it to be in the child's best interest to remain in Head Start. Many respondents were particularly concerned that they be allowed to retain the option of serving children with disabilities who are of kindergarten age.

The National Head Start Association thought that this requirement would violate section 645(c) of the Head Start Act that allows programs to serve children through compulsory school attendance.

Some respondents indicated that, because kindergarten is not mandatory in many school districts, some school districts do not provide transportation, leaving many low-income families without a way to get their children to school. These children frequently stay home for the year they could be in kindergarten.

We have considered all of these comments and are eliminating this paragraph from the final regulation. We have, however, added language to paragraph (b) of this section that requires programs to consider the availability of kindergarten or first grade to the child when selecting children who are to receive Head Start services. We believe that children that do have kindergarten or first grade available to them should be given a lower priority for services than those that do not. We do, however, understand that there may be situations, such as those received in comments on this paragraph, when programs will decide that it is in the best interest for the child to remain in Head Start, even though this may preclude another child from receiving a Head Start experience.

Paragraph (e) incorporates an existing policy contained in the Enrollment and Attendance Policies in Head Start, S-30-317-1-40, A.2.c.l., regarding the maintenance of waiting lists of Head Start eligible children and families. It requires that, at the beginning of each enrollment year and throughout each year, a Head Start program must develop and maintain a waiting list that ranks children and families according to the program's selection criteria to help assure that eligible children and families are immediately available for enrollment in the program when vacancies occur. No comments were received on this paragraph and no changes have been made.

Section 1305.7 Enrollment and Re-enrollment

This section contains requirements for the ongoing enrollment of children in a Head Start program.

Paragraph (a) is intended to assure continuity for the Head Start child between Head Start and kindergarten or first grade. As stated in the NPRM, it requires that all children who are enrolled in a Head Start program, except children enrolled in a migrant program or a Parent and Child Center, must be allowed to remain in the program until kindergarten or first grade is available in the child's community. Most of the comments received on this paragraph were positive, supporting the continuity of services to children once they are enrolled in Head Start. One respondent who disagreed with the requirement stated that there are times when meeting this requirement would be difficult. For example, when centers are moved from one community to another because of population shifts, programs would be required to continue serving children who could be returning to Head Start for a second year of services. We believe that, in this situation, parents could be offered the opportunity for services in another center, but programs should not have to make extraordinary arrangements for transportation or other services in order to continue serving some children.

Another respondent thought that this requirement would mean that programs first enrolling a child at age three would have to continue serving children for a second year when another child might have a greater need for Head Start services.

We believe that continuity is an important aspect of Head Start services, since one of the purposes of the program is to prepare children for entry into public school. We believe that once a child is enrolled, it is important for the child to continue to build on the gains achieved in Head Start. In order to maintain these gains, we think that all children should be enrolled with the understanding that they are to continue receiving Head Start services until they are eligible for public school. However, because of the comments that were received, we have added the option for an exception when there are compelling reasons for the child not to remain in Head Start. A compelling reason for not re-enrolling a child might be when the child is from a family whose income has risen and the program wishes to enroll a different child from a more needy family.

We have also added that, rather than simply being generally available, kindergarten or first grade must be available for an individual child in the child's community to emphasize the continuity of services once a child is enrolled in Head Start. This would allow programs the option of serving children who are age eligible for kindergarten but cannot attend because of local circumstances that include readiness testing or lack of transportation. In addition, we have dropped the proposed exemption for continuity of enrollment for children in Parent and Child Centers from paragraph (a) of this section. Since the NPRM was published, the most recent Head Start Act in section 640 added a requirement that agencies receiving funding for Parent and Child Centers are to provide continuous services to children through compulsory school age, to the maximum extent practicable.

Paragraph (b) requires that each Head Start grantee must maintain an enrollment level that is not less than the enrollment level indicated on its grant award. Paragraph (b) also includes two exceptions to this requirement: (1) When a program determines that a vacancy exists, up to 30 calendar days may elapse before the vacancy is filled; and (2) a center-based program may elect not to fill a vacancy when it would result in a child being enrolled less than 60 calendar days from the end of the program's enrollment year. Most of the comments received on this paragraph were positive. Respondents particularly supported the option of leaving

vacancies unfilled when they occur during the last 60 days of program services. There were a few respondents that disagreed with this option, stating that 60 days of Head Start services are often better than no Head Start services. Since leaving vacancies in the final days of a program is an option that programs may choose to exercise or not, we are leaving the wording of the final rule substantially the same.

Paragraph (c) reiterates the existing requirement contained in § 1305.6(b) which states that a child participating in the Head Start program remains income eligible through the initial enrollment year and the immediately succeeding enrollment year. Only two comments were received on this paragraph. One was positive and the other respondent thought that allowing two years of eligibility did not assure that Head Start would be serving children with the greatest need for services. We believe that programs, in selecting younger children, must select those who would benefit from more than one year of Head Start services. We have also given grantees the authority not to enroll a child for a second year if there are compelling reasons for this decision. Therefore, we have not changed the regulation.

Section 1305.8: Attendance

This section incorporates requirements for attendance in a Head Start program that are currently found in the Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.3.

Paragraph (a) includes the current requirement that a Head Start program must analyze the causes of absenteeism when the monthly average daily attendance rate in a center-based program falls below 85 percent. Most of the comments received on this paragraph stated that 85 percent attendance was an unrealistic requirement. We believe that these comments reflect a misperception regarding average daily attendance, since it is not our intention to require that a daily attendance rate of 85% be maintained. Rather, we view 85 percent as a reasonable point of measurement below which Head Start programs must review patterns of attendance to identify causes of absenteeism and to determine if there are intervention strategies that should be taken with families of children who have been absent for unknown reasons. Head Start programs are to take such action when the monthly average daily attendance rate in a center-based program falls below 85 percent. The 85% rate itself has been incorporated into Head Start policy for many years and has been considered a reasonable level by which to measure attendance. We recognize that there will be instances where programs are serving families with severe problems, such as homelessness, when average daily attendance rates of less than 85 percent may be expected and unavoidable if such families are to be served. We believe that it continues to be an appropriate management strategy for programs to analyze attendance patterns in order to address attendance problems that could be corrected through appropriate family intervention strategies to encourage regular attendance. We have not changed the regulation.

Paragraph (b) requires that programs must take action when a child has been absent without a documented excuse for four consecutive days. Only a few comments were received on this paragraph. Some wanted to retain the requirement contained in current policy that programs follow-up after three consecutive days of absence. We disagree and think that four days is more appropriate. This makes the number of days of unexcused absences that can occur before follow-up action is required consistent with the Head Start Performance Standards, 45 CFR 1304.4–2(a)(8). Programs are not prohibited, however, from following up with families sooner than four consecutive absences, if it is appropriate.

Paragraph (c) includes the current requirement in the Enrollment and Attendance Policies, S–30–317–1–40, A.3., that, in circumstances where chronic absenteeism persists, and it is not feasible to include the child in another program option, the child's slot should be considered an enrollment vacancy. No comments were received on this paragraph and no changes have been made.

Section 1305.9 Policy on Fees

This section contains the current language of section 1305.8 except that it proposes to add a requirement that payments obtained voluntarily from the family of a child participating in the program are to be recorded as program income. A small number of respondents thought that Head Start programs should not be allowed to accept voluntary payments from families. Some respondents were unclear about what the word voluntary means and suggested that we define the term. We believe that the most important aspect of this section is that programs may not require parents to pay fees. This is clearly stated in this section and, therefore, no changes have been made.

Section 1305.10 Compliance

This section expands the existing policy found in the Enrollment and Attendance Policies in Head Start, S–30–317–1–20, 2., regarding adverse action for a grantee's continued failure to maintain funded enrollment. It states that a grantee's failure to comply with any requirement of this Part may result in a denial of refunding or termination in accordance with 45 CFR Part 1303, "Procedures for Appeals for Head Start Delegate Agencies, and for Opportunities to Show Cause and Hearings for Head Start Grantees". Adverse action against a grantee for failure to comply with any requirement of this Part would not occur before the grantee was made aware of non-compliance issues and provided an opportunity and appropriate technical assistance to remedy the problem area or areas. No comments were received on this section and no changes have been made.

In addition to the changes from the NPRM described in this section, minor technical changes were made for purposes of clarification.

REDESIGNATION TABLE

Section of the final rule	Superseded rule or policy or identification of new requirement
1305.1	1305.1
1305.2	1305.2 and Enrollment and Attendance Policies in Head Start, S–30–317–1–30
	New requirement
1305.3	New requirement
1305.4(a)	1305.3
	New requirement
1305.4(b)	1305.4
1305.4(c)	1305.7(a)
1305.4(d)	1305.7(b)
1305.4(e)	1305.7(c)
1305.5(a)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.1.a., 1.b., and 1.c.
	New requirement
1305.5(b)	New requirement
1305.5(c)	New requirement
1305.6(a)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.1.e.
1305.6(b)	1305.4 [Amended]
1305.6(c)	1305.5 [Amended]
1305.6(d)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.2.c.1.
1305.7(a)	New requirement
1305.7(b)	Enrollment and Attendance Policies in Head Start, S–30–317–40, A.2.b.
	New Requirement
1305.7(c)	1305.6(b)
1305.8(a)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.3.
1305.8(b)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40,.A.3. [Amended]
1305.8(c)	Enrollment and Attendance Policies in Head Start, S–30–317–1–40, A.3.

REDESIGNATION TABLE—Continued

Section of the final rule	Superseded rule or policy or identification of new requirement
1305.9	1305.8 [Amended]
1305.10	Enrollment and Attendance Policies in Head Start, S-30-317-1-20, 1. and 2.
	New Requirement

IV. Impact Analysis

Executive Order 12291

Executive Order 12291 requires that a regulatory impact analysis be prepared for major rules, which are defined in the Order as any rule that has an annual effect on the national economy of $100 million or more, or certain other specified effects. The Department has determined that these rules are not major rules within the Executive Order because they will not have an annual effect on the economy of $100 million or more; nor result in a major increase in costs or prices for consumers, any industries, and governmental agencies, or any geographic region; and, they will not have an adverse effect on competition, employment, investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or import markets.

This final rule specifies procedures that will assure that decisions regarding Head Start recruitment, selection and enrollment of children are carefully planned and made at the local level; give all interested families an opportunity to be considered for enrollment; and help maintain full enrollment, allowing as many eligible children as possible to be served. Such procedures are necessary to address changing conditions that have affected the Head Start program over the past several years.

We expect any additional costs attributable to these provisions to be significantly less than $100 million. The main reason for this is that many grantees already meet most of the new requirements. For example, with respect to the community needs assessment requirement, Head Start grantees have always been required to complete a community needs assessment as part of the application for refunding. In the past, the grant application instructions have not included specific data requirements or explicit requirements for analyzing the data to determine key program decisions. The added specificity of this rule will assist grantees by focusing their community needs assessment efforts on specific data. Grantees will not be required to conduct demographic surveys or create new data bases, thereby minimizing costs.

The Department has always monitored grantee recruitment practices along with other program requirements. In addition, the Department has reviewed community needs assessment data during the grant review process. These efforts will not change as a result of this rule and the costs should remain stable for Federal government activities and for many of the grantees in complying with this rule as a whole, the intent of which is to assure that minimum and consistent standards in this important area are achieved nationally.

When grantees design their program and recruitment systems, they are currently required to consider community needs. Most grantees comply with this requirement. We do not have data that allows us to estimate the number that will need major changes in their recruitment practices. However, since carrying out recruitment and enrollment activities is an existing requirement for grantees, we do not believe the new requirements will result in significant added costs in this area nationally. Some of the specific rules some grantees follow in recruiting and enrolling children may change but not their overall level of effort.

Costs associated with implementing this rule will be mainly administrative and minimal given the fact that the changes required will not affect the entire grantee population and the fact that the changes required are "best practices" that many grantees have been successfully using in their programs. Thus, the Department concluded that these regulations are not major rules within the meaning of the Executive Order because they do not meet the threshold criteria.

We believe the benefits derived from this rule will far outweigh any costs incurred. The benefits include a more focused and uniform process for Head Start recruitment, enrollment and selection activities, thereby, resulting in the provision of services to as many eligible children as possible who are most in need of Head Start services.

Regulatory Flexibility Act of 1980

Consistent with the Regulatory Flexibility Act of 1980 (5 U.S.C. ch. 6), we try to anticipate and reduce the impact of rules and paperwork requirements on small businesses. For each rule with a "significant economic impact on a substantial number of small entities" we prepare an analysis describing the rule's impact on small entities. Small entities are defined by the Act to include small businesses, small non-profit organizations, and small governmental entities. While this regulation would affect small entities, it is not substantial. In many instances small entities already meet most of the requirements, since many are restatements of current policy and since they are considered best practice. For these reasons, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1980 (the Act), Public Law 96-511, all Departments are required to submit to the Office of Management and Budget (OMB) for review and approval any reporting or recordkeeping requirements in a proposed or final rule. The final rule contains information collection requirements in section 1305.3 concerning community needs assessment. We estimate that this requirement will take each grantee 40 hours to complete annually. As one-third of the grantees (447) will be doing the needs assessment each year, the total number of hours annually will be 17,800. The requirement for the update reports in years two and three have minimal burden hours because we anticipate only a very small number of grantees will have any significant changes in their communities to report. In accordance with section 3504(h) of the Act, the Department has submitted § 1305.3 of the final rule to OMB for its review and approval.

Organizations and individuals desiring to submit comments on the information collection requirement should direct them to the agency official designated for this purpose whose name appears in this preamble, and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building (room 308), Washington, DC 20503, Attention Desk Officer for the Administration for Children and Families.

List of Subjects in 45 CFR Part 1305

Head Start Enrollment, Education of Disadvantaged, Grant Programs/Social Programs, Disabilities, Preschool Education.

(Catalog of Federal Domestic Assistance Program Number 93.600, Project Head Start)

Dated: May 21, 1992.

Anne B. Barnhart,

Assistant Secretary for Children and Families.

Approved: June 29, 1992.

Louis W. Sullivan,

Secretary.

For the reasons set forth in the preamble, title 45, chapter XIII, subchapter B, part 1305 of the Code of Federal Regulations is amended as follows:

Part 1305 is revised to read as follows:

PART 1305—ELIGIBILITY, RECRUITMENT, SELECTION, ENROLLMENT AND ATTENDANCE IN HEAD START

Sec.
1305.1 Purpose and scope.
1305.2 Definitions.
1305.3 Determining community needs.
1305.4 Age of children and family income eligibility.
1305.5 Recruitment of children.
1305.6 Selection process.
1305.7 Enrollment and re-enrollment.
1305.8 Attendance.
1305.9 Policy on fees.
1305.10 Compliance.

Authority: 42 U.S.C. 9831 et seq.

§ 1305.1 Purpose and scope.

This part prescribes requirements for determining community needs and recruitment areas. It contains requirements and procedures for the eligibility determination, recruitment, selection, enrollment and attendance of children in Head Start programs and explains the policy concerning the charging of fees by Head Start programs.

§ 1305.2 Definitions.

(a) *Children with disabilities* means children with mental retardation, hearing impairments including deafness, speech or language impairments, visual impairments including blindness, serious emotional disturbance, orthopedic impairments, autism, traumatic brain injury, other health impairments or specific learning disabilities, and who, by reason thereof, need special education and related services. The term children with disabilities for children aged 3 to 5, inclusive, may, at a State's discretion, include children experiencing developmental delays, as defined by the State and measures by appropriate diagnostic instruments and procedures, in one or more of the following areas: physical development, cognitive development, communication development, social or emotional development, and who, by reason thereof, need special education and related services.

(b) *Enrollment* means the official acceptance of a family by a Head Start program and the completion of all procedures necessary for a child and family to begin receiving services.

(c) *Enrollment opportunities* mean vacancies that exist at the beginning of the enrollment year, or during the year because of children who leave the program, that must be filled for a program to achieve and maintain its funded enrollment.

(d) *Enrollment year* means the period of time, not to exceed twelve months, during which a Head Start program provides center or home-based services to a group of children and their families.

(e) *Family* means all persons living in the same household who are:

(1) Supported by the income of the parent(s) or guardian(s) of the child enrolling or participating in the program, and (2) related to the parent(s) or guardian(s) by blood, marriage, or adoption.

(f) *Funded enrollment* means the number of children which the Head Start grantee is to serve, as indicated on the grant award.

(g) *Head Start eligible* means a child that meets the requirements for age and family income as established in this regulation or, if applicable, as established by grantees that meet the requirements of section 645(a) (2) of the Head Start Act. Up to ten percent of the children enrolled may be from families that exceed the low-income guidelines.

(h) *Head Start program* means a Head Start grantee or its delegate agency(ies).

(i) *Income* means gross cash income and includes earned income, military income (including pay and allowances), veterans benefits, social security benefits, unemployment compensation, and public assistance benefits.

(j) *Income guidelines* means the official poverty line specified in section 652 of the Head Start Act.

(k) *Low-income family* means a family whose total annual income before taxes is equal to, or less than, the income guidelines. For the purpose of eligibility, a child from a family that is receiving public assistance or a child in foster care is eligible even if the family income exceeds the income guidelines.

(l) *Migrant family* means, for purposes of Head Start eligibility, a family with children under the age of compulsory school attendance who change their residence by moving from one geographic location to another, either intrastate or interstate, within the past twelve months, for the purpose of engaging in agricultural work that involves the production and harvesting of tree and field crops and whose family income comes primarily from this activity.

(m) *Recruitment* means the systematic ways in which a Head Start program identifies families whose children are eligible for Head Start services, informs them of the services available, and encourages them to apply for enrollment in the program.

(n) *Recruitment area* means that geographic locality within which a Head Start program seeks to enroll Head Start children and families. The recruitment area can be the same as the service area or it can be a smaller area or areas within the service area.

(o) *Responsible HHS official* means the official of the U.S. Department of Health and Human Services having authority to make Head Start grant awards, or his or her designee.

(p) *Selection* means the systematic process used to review all applications for Head Start services and to identify those children and families that are to be enrolled in the program.

(q) *Service area* means the geographic area identified in an approved grant application within which a grantee may provide Head Start services.

(r) *Vacancy* means an unfilled enrollment opportunity for a child and family in the Head Start program.

§ 1305.3 Determining community needs.

(a) Each grantee must identify its proposed service area in its Head Start grant application and define it by county or sub-county area, such as a municipality, town or census tract or a federally recognized Indian reservation. A grantee's service area must be approved, in writing, by the responsible HHS official in order to assure that the service area is of reasonable size and does not overlap with that of other Head Start grantees.

(b) Each Head Start grantee must conduct a community needs assessment within its service area once every three years. The community needs assessment must include the collection and analysis of the following information about the grantee's Head Start service area:

(1) The demographic make-up of Head Start eligible children and families, including their estimated number, geographic location, and racial and ethnic composition;

(2) Other child development and child care programs that are serving Head Start eligible children, including publicly funded State and local preschool programs, and the approximate number of Head Start eligible children served by each;

(3) The estimated number of children with disabilities four years old or

younger, including types of disabilities and relevant services and resources provided to these children by community agencies;

(4) Data regarding the education, health, nutrition and social service needs of Head Start eligible children and their families;

(5) The education, health, nutrition and social service needs of Head Start eligible children and their families as defined by families of Head Start eligible children and by institutions in the community that serve young children;

(6) Resources in the community that could be used to address the needs of Head Start eligible children and their families, including assessments of their availability and accessibility.

(c) The Head Start grantee must use information from the community needs assessment to:

(1) Help determine the grantee's philosophy, and its long-range and short-range program objectives;

(2) Determine the type of component services that are most needed and the program option or options that will be implemented;

(3) Determine the recruitment area that will be served by the grantee, if limitations in the amount of resources make it impossible to serve the entire service area.

(4) If there are delegate agencies, determine the recruitment area that will be served by the grantee and the recruitment area that will be served by each delegate agency.

(5) Determine appropriate locations for centers and the areas to be served by home-based programs; and

(6) Set criteria that define the types of children and families who will be given priority for recruitment and selection.

(d) In each of the two years following completion of the community needs assessment, the grantee must conduct a review to determine whether there have been significant changes in the information described in paragraph (b) of this section. If so, the community needs assessment must be updated and the decisions described in paragraph (c) of this section must be reconsidered.

(e) The recruitment area must include the entire service area, unless the resources available to the Head Start grantee are inadequate to serve the entire service area.

(f) In determining the recruitment area when it does not include the entire service area, the grantee must:

(1) Select an area or areas that are among those having the greatest need for Head Start services as determined by the community needs assessment; and

(2) Include as many Head Start eligible children as possible within the recruitment area, so that:

(i) The greatest number of Head Start eligible children can be recruited and have an opportunity to be considered for selection and enrollment in the Head Start program, and

(ii), the Head Start program can enroll the children and families with the greatest need for its services.

§ 1305.4 Age of children and family income eligibility.

(a) To be eligible for Head Start services, a child must be at least three years old by the date used to determine eligibility for public school in the community in which the Head Start program is located, except in cases where the Head Start program's approved grant provides specific authority to serve younger children. Examples of such exceptions are programs serving children of migrant families and Parent and Child Center programs.

(b) At least 90 percent of the children who are enrolled in each Head Start program must be from low-income families. Up to ten percent of the children who are enrolled may be children from families that exceed the low-income guidelines but who meet criteria the program has established for selecting such children and who would benefit from Head Start services.

(c) The family income must be verified by the Head Start program before determining that a child is eligible to participate in the program.

(d) Verification must include examination of any of the following: Individual Income Tax Form 1040, W–2 forms, pay stubs, pay envelopes, written statements from employers, or documentation showing current status as recipients of public assistance.

(e) A signed statement by an employee of the Head Start program, identifying which of these documents was examined and stating that the child is eligible to participate in the program, must be maintained to indicate that income verification has been made.

§ 1305.5 Recruitment of children.

(a) In order to reach those most in need of Head Start services, each Head Start grantee and delegate agency must develop and implement a recruitment process that is designed to actively inform all families with Head Start eligible children within the recruitment area of the availability of services and encourage them to apply for admission to the program. This process may include canvassing the local community, use of news releases and advertising, and use of family referrals and referrals from other public and private agencies.

(b) During the recruitment process that occurs prior to the beginning of the enrollment year, a Head Start program must solicit applications from as many Head Start eligible families within the recruitment area as possible. If necessary, the program must assist families in filling out the application form in order to assure that all information needed for selection is completed.

(c) Each program, except migrant programs, must obtain a number of applications during the recruitment process that occurs prior to the beginning of the enrollment year that is greater than the enrollment opportunities that are anticipated to be available over the course of the next enrollment year in order to select those with the greatest need for Head Start services.

§ 1305.6 Selection process.

(a) Each Head Start program must have a formal process for establishing selection criteria and for selecting children and families that considers all eligible applicants for Head Start services. The selection criteria must be based on those contained in paragraphs (b) and (c) of this section.

(b) In selecting the children and families to be served, the Head Start program must consider the income of eligible families, the age of the child, the availability of kindergarten or first grade to the child, and the extent to which a child or family meets the criteria that each program is required to establish in § 1305.3(c)(6).

(c) At least 10 percent of the total number of enrollment opportunities in each grantee and each delegate agency during an enrollment year must be made available to children with disabilities who meet the definition for children with disabilities in § 1305.2(a). An exception to this requirement will be granted only if the responsible HHS official determines, based on such supporting evidence as he or she may require, that the grantee made a reasonable effort to comply with this requirement but was unable to do so because there was an insufficient number of children with disabilities in the recruitment area who wished to attend the program and for whom the program was an appropriate placement based on their Individual Education Plans (IEP), with services provided directly by Head Start or in conjunction with other providers.

(d) Each Head Start program must develop at the beginning of each

enrollment year and maintain during the year a waiting list that ranks children according to the program's selection criteria to assure that eligible children enter the program as vacancies occur.

§ 1305.7 Enrollment and re-enrollment.

(a) Each child enrolled in a Head Start program, except those enrolled in a migrant program, must be allowed to remain in Head Start until kindergarten or first grade is available for the child in the child's community, except that the Head Start program may choose not to enroll a child when there are compelling reasons for the child not to remain in Head Start, such as when there is a change in the child's family income and there is a child with a greater need for Head Start services.

(b) A Head Start grantee must maintain its funded enrollment level. When a program determines that a vacancy exists, no more than 30 calendar days may elapse before the vacancy is filled. A program may elect not to fill a vacancy when 60 calendar days or less remain in the program's enrollment year.

(c) If a child has been found income eligible and is participating in a Head Start program, he or she remains income eligible through that enrollment year and the immediately succeeding enrollment year.

§ 1305.8 Attendance.

(a) When the monthly average daily attendance rate in a center-based program falls below 85 percent, a Head Start program must analyze the causes of absenteeism. The analysis must include a study of the pattern of absences for each child, including the reasons for absences as well as the number of absences that occur on consecutive days.

(b) If the absences are a result of illness or if they are well documented absences for other reasons, no special action is required. If, however, the absences result from other factors, including temporary family problems that affect a child's regular attendance, the program must initiate appropriate family support procedures for all children with four or more consecutive unexcused absences. These procedures must include home visits or other direct contact with the child's parents. Contacts with the family must emphasize the benefits of regular attendance, while at the same time remaining sensitive to any special family circumstances influencing attendance patterns. All contacts with the child's family as well as special family support service activities provided by program staff must be documented.

(c) In circumstances where chronic absenteeism persists and it does not seem feasible to include the child in either the same or a different program option, the child's slot must be considered an enrollment vacancy.

§ 1305.9 Policy on fees.

A Head Start program must not prescribe any fee schedule or otherwise provide for the charging of any fees for participation in the program. If the family of a child determined to be eligible for participation by a Head Start program volunteers to pay part or all of the costs of the child's participation, the Head Start program may accept the voluntary payments and record the payments as program income.

Under no circumstances shall a Head Start program solicit, encourage, or in any other way condition a child's enrollment or participation in the program upon the payment of a fee.

§ 1305.10 Compliance.

A grantee's failure to comply with the requirements of this Part may result in a denial of refunding or termination in accordance with 45 CFR part 1303.

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Friday
October 9, 1992

Part V

Office of Management and Budget

Budget Rescissions and Deferrals; Notice

OFFICE OF MANAGEMENT AND BUDGET

Budget Rescissions and Deferrals

To the Congress of the United States:

In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report seven deferrals of budget authority, totaling $930.9 million.

These deferrals affect International Security Assistance programs as well as programs of the Agency for International Development and the Departments of Agriculture, Defense, Health and Human Services, and State. The details of these deferrals are contained in the attached report.

George Bush,

The White House, October 1, 1992.

BILLING CODE 3110-01-M

CONTENTS OF SPECIAL MESSAGE
(in thousands of dollars)

DEFERRAL NO.	ITEM	BUDGET AUTHORITY
	Funds Appropriated to the President:	
	International Security Assistance:	
D93–1	Economic support fund	492,736
	Agency for International Development	
	Demobilization and transition	
D93–2	fund	13,750
	Department of Agriculture:	
	Forest Service:	
D93–3	Cooperative work	364,582
D93–4	Expenses, brush disposal	40,241
	Department of Defense, Civil:	
D93–5	Wildlife conservation	2,175
	Department of Health and Human Services:	
	Social Security Administration:	
	Limitation on administrative	
D93–6	expenses	7,267
	Department of State:	
	Bureau of Refugee Programs:	
	United States emergency refugee and	
D93–7	migration fund	10,123
	Total, deferrals	930,875

Deferral No. 93–1

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Funds Appropriated to the President	New budget authority..... $ _____
BUREAU: International Security Assistance	Other budgetary resources..... $ 492,736,396
Appropriation title and symbol: Economic support fund 1/ 112/31037 11X1037	Total budgetary resources..... $ 492,736,396
	Amount to be deferred: Part of year..... $ 492,736,396 Entire year..... _____
OMB identification code: 11–1037–0–1–152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [X] Yes [ ] No	
Type of account or fund: [ ] Annual [X] Multi–year: September 30, 1993 (expiration date) [X] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other _____

Coverage:

Appropriation	Account Symbol	OMB Identification Code	Deferred Amount Reported
Economic support fund.....	11X1037	11–1037–0–1–152	30,495,496
Economic support fund.....	112/31037	11–1037–0–1–152	462,240,900
			492,736,396

JUSTIFICATION: This account provides economic and counternarcotics assistance to selected countries in support of U.S. efforts to promote stability and U.S. security interests in strategic regions of the world. This account also includes contributions to the International Fund for Ireland. This action defers funds pending approval of specific loans and grants to eligible countries. This interagency review process will ensure that each approved transaction is consistent with the foreign and financial policies of the United States and will not exceed the limits of available funds. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–1A).

Deferral No. 93–2

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Funds Appropriated to the President	New budget authority.....
BUREAU: Agency for International Development	Other budgetary resources..... $ 13,750,000
Appropriation title and symbol: Demobilization and transition fund 11X1500	Total budgetary resources:..... $ 13,750,000
	Amount to be deferred: Part of year..... $ 13,750,000
	Entire year.....
OMB identification code: 11–1500–0–1–152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [ ] Yes [X] No	[ ] Other
Type of account or fund: [ ] Annual	**Type of budget authority:** [X] Appropriation
[ ] Multi–year: (expiration date)	[ ] Contract authority
[X] No–Year	[ ] Other

JUSTIFICATION: This account was established to facilitate cease–fire monitoring, demobilization, and transition to peace in El Salvador. Funds were transferred into this account pursuant to P.L. 101–513, Section 531(f) (2). These funds are available solely to support costs of demobilization, retraining, relocation, and reemployment in civilian pursuits of former combatants in the conflict in El Salvador. Funds are available for obligation and expenditure only upon notification by the President to the Congress that the Government of El Salvador and representatives of the Farabundo Marti National Liberation Front (FMLN) have reached a permanent settlement of the conflict, including a final agreement on a cease– fire. This action is taken pursuant to the Antideficiency Act (31 U.S. C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–9).

Deferral No. 93-3

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93-344

AGENCY: Department of Agriculture	New budget authority..... $ 242,572,000 (16 U.S.C. 576b)
BUREAU: Forest Service	Other budgetary resources..... $ 483,617,206
Appropriation title and symbol: Cooperative Work 1/ 12X8028	Total budgetary resources..... $ 726,189,206
	Amount to be deferred: Part of year..... $ _____ Entire year..... $ 364,582,206
OMB identification code: 12-8028-0-7-999	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [ ] Yes [X] No	
Type of account or fund: [ ] Annual [ ] Multi-year: _____ (expiration date) [X] No-Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other

JUSTIFICATION: Under the Cooperative work account, funds are received from States, counties, timber sale operators, individuals, associations, and others. These funds are expended by the Forest Service as authorized by law and the terms of the applicable trust agreements. The work benefits the national forest users, research investigations, reforestation, and administration of private forest lands. Much of the work for which deposits have been made cannot be done, or is not planned to be done, during the same year that the collections are being realized. Examples include areas where timber operators have not completed all of the contract obligations during the year funds are deposited. As a result, restoration efforts cannot begin, and the funds cannot be obligated this year. This deferral action is taken under the provisions of the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92-3).

Deferral No. 93–4

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of Agriculture	New budget authority..... $ 27,278,000 (16 U.S.C. 490)
BUREAU: Forest Service	Other budgetary resources..... $ 81,975,029
Appropriation title and symbol: Expenses, brush disposal 1/ 12X5206	Total budgetary resources..... $ 109,253,029
	Amount to be deferred: Part of year..... $ _____ Entire year..... $ 40,241,029
OMB identification code: 12–9922–0–2–302	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [ ] Yes [X] No	
Type of account or fund: [ ] Annual [ ] Multi–year: _____ (expiration date) [X] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other

JUSTIFICATION: Purchasers of National Forest timber are required to deposit to the Forest Service the established cost for disposing of brush and other debris resulting from timber cutting operations authorized by 16 U.S.C. 490. The deposits becoming available in the current year are estimated, and the related disposal operations are planned for the following year. Efficient program planning and accomplishment is facilitated by operating a stable program well within the funds available in any one year for this purpose. Much of the brush disposal work for which fees are collected cannot be done in the same year because of weather conditions or because harvesting is not completed. The Forest Service is planning for a stable year–to–year program, which will require $69 million in 1993. The current fiscal year reserve of $40 million is established pursuant to the provisions of the Antideficiency Act (31 U.S.C. 1512) as a reserve for contingencies.

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–10).

Deferral No. 93–5

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of Defense – Civil	New budget authority.....$ 2,525,000 (16 U.S.C. 670F)
BUREAU: Wildlife Conservation Military Reservations 1/	Other budgetary resources...$ 1,975,000
Appropriation title and symbol: Wildlife Conservation, Army 21X5095; Wildlife Conservation, Navy 17X5095; Wildlife Conservation, Air Force 57X5095	Total budgetary resources....$ 4,500,000
	Amount to be deferred: Part of year..... _____ Entire year.....$ 2,175,000
OMB identification code: 97–5095–0–2–303	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [ ] Yes [X] No	
Type of account or fund: [ ] Annual [ ] Multi–year: _____ (expiration date) [X] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other _____

Coverage:

Appropriation	Account Symbol	OMB Identification Code	Deferred Amount Reported
Wildlife Conservation, Army.....	21X5095	97–5095–0–2–303	$ 1,600,000
Wildlife Conservation, Navy.....	17X5095	97–5095–0–2–303	$ 175,000
Wildlife Conservation, Air Force....	57X5095	97–5095–0–2–303	$ 400,000
			$ 2,175,000

JUSTIFICATION: These are permanent appropriations of receipts generated from hunting and fishing fees in accordance with the purpose of the law -- to carry out a program of natural resource conservation. These programs are carried out through cooperative plans agreed upon by the local representatives of the Secretary of Defense, the Secretary of the Interior, and the appropriate agency of the State in which the reservation is located. These funds are being deferred (1) until, pursuant to the authorizing legislation (16 U.S.C. 670f(a)), installations have accumulated funds over a period of time sufficient to fund a major

1/ These accounts were the subject of a similar deferral in FY 1992 (D92–4).

D93–5

project; (2) until individual installations have designed and obtained approval for the project; and (3) because there is a seasonal relationship between the collection of fees and their subsequent expenditure since most of the fees are collected during the winter and spring months. Funds collected in a prior year are deferred in order to be available to finance the program during summer and fall months or in subsequent years. Additional amounts will be apportioned when projects are identified and project approval is obtained. This deferral is made under the provisions of the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

Deferral No. 93–6

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of Health and Human Services	**New budget authority**.....
BUREAU: Social Security Administration	**Other budgetary resources**..... $ 14,517,051
Appropriation title and symbol: Limitation on administrative expenses 1/ 75X8704	**Total budgetary resources**..... 14,517,051
	Amount to be deferred: Part of year.....
	Entire year..... $ 7,267,051
OMB identification code: 20–8007–0–7–651	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [ ] Yes [X] No	[ ] Other
Type of account or fund: [ ] Annual	**Type of budget authority:** [X] Appropriation
[ ] Multi–year: _____ (expiration date)	[ ] Contract authority
[X] No–Year	[ ] Other

JUSTIFICATION: This account contains the no–year funds appropriated to the Social Security Administration (SSA) for construction and renovation of SSA facilities, and for Information Technology Systems (ITS). It has been determined that obligational authority for construction projects in the amount of this deferral is not currently needed. Should new requirements arise, subsequent apportionments will reduce this deferral. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–5).

Deferral No. 93–7

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of State	New budget authority..... $ _____
BUREAU: Bureau of Refugee Programs	Other budgetary resources..... $ 10,126,000
Appropriation title and symbol: United States emergency refugee and migration assistance fund 1/ 11X0040	Total budgetary resources..... $ 10,126,000
	Amount to be deferred: Part of year..... $ 10,123,000
	Entire year..... _____
OMB identification code: 11–0040–0–1–151	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [ ] Yes [X] No	[ ] Other _____
Type of account or fund: [ ] Annual	**Type of budget authority:** [X] Appropriation
[ ] Multi–year: _____ (expiration date)	[ ] Contract authority
[X] No–Year	[ ] Other _____

JUSTIFICATION: Section 501(a) of the Foreign Relations Authorization Act of 1976 (Public Law 94–141) and Section 414(b) (1) of the Refugee Act of 1980 (Public Law 96–212) amended Section 2(c) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601) by authorizing a fund to enable the President to provide emergency assistance for unexpected urgent refugee and migration needs.

Executive Order No. 11922 of June 16, 1976, allocated all funds appropriated to the President for the Emergency Fund to the Secretary of State but reserved for the President the determination of assistance to be furnished and the designation of refugees to be assisted by the Fund.

These funds have been deferred pending Presidential decisions required by Executive Order No. 11922. Funds will be released as the President determines assistance to be furnished and designates refugees to be assisted by the Fund. This deferral action is taken under the provisions of the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–6A).

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BILLING CODE 3110–01–C

federal register

Friday
October 9, 1992

Part VI

Department of Labor

Employment Standards Administration
Wage and Hour Division

29 CFR Part 541

Fair Labor Standard Act: Computer-related Occupations; Exemption from Minimum Wage and Overtime Compensation Requirements; Final Rule

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division

29 CFR Part 541

RIN 1215-AA65

Defining and Delimiting the Terms "Any Employee Employed in a Bona Fide Executive, Administrative, or Professional Capacity (Including any Employee Employed in the Capacity of Academic Administrative Personnel or Teacher in Elementary or Secondary Schools), or in the Capacity of Outside Salesman"

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: This document provides the final regulations for certain workers employed in computer-related occupations under 29 CFR part 541. These rules implement the provisions of Public Law 101-583, enacted November 15, 1990, which requires the issuance of regulations to permit computer systems analysts, computer programmers, software engineers, and other similarly skilled professional workers to qualify for exemption under section 13(a)(1) of the Fair Labor Standards Act (FLSA). Regulations in 29 CFR part 541, contain the criteria for exemption under section 13(a)(1) of the Act from the minimum wage and overtime compensation requirements of the Act for executive, administrative, professional and outside sales personnel.

DATES: These rules are effective November 9, 1992.

FOR FURTHER INFORMATION CONTACT: Karen R. Keesling, Acting Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, room S-3502, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 219-8305. This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act

There are no reporting or recordkeeping requirements contained in these regulations.

II. Background

Section 13(a)(1) of the FLSA exempts any employee employed in a bona fide executive, administrative, or professional capacity (including any employee employed in the capacity of academic administrative personnel or teacher in elementary or secondary schools), or in the capacity of outside salesman (as such terms are defined and delimited from time to time by regulations of the Secretary). The existing regulations, 29 CFR part 541, provide that, in order to be exempt as a bona fide executive, administrative or professional employee, an individual must meet certain tests with respect to job duties and responsibilities and must be compensated on a salary basis at no less than a specified amount.

Section 2 of Public Law 101-583, enacted November 15, 1990, provides that not later than 90 days after the date of enactment of the Act, the Secretary of Labor shall promulgate regulations that permit computer systems analysts, computer programmers, software engineers, and other similarly skilled professional workers as defined in such regulations to qualify as exempt executive, administrative, or professional employees under section 13(a)(1) of the Fair Labor Standards Act of 1938 (29 U.S.C. 213(a)(1)). Such regulations shall provide that if such employees are paid on an hourly basis they shall be exempt only if their hourly rate of pay is at least 6½ times greater than the applicable minimum wage rate under section 6 of the Act (29 U.S.C. 206).

Pursuant to Public Law 101-583, an interim final rule was published in the **Federal Register** on February 27, 1991 (56 FR 8250), with a comment period that closed April 29, 1991. This rule added a new § 541.5c to 29 CFR part 541 to exempt workers in the computer field who met the new duties tests specified in the regulations and whose regular rate of pay, regardless of whether paid on a salary basis or on an hourly basis, was in excess of 6½ times the FLSA minimum wage. The interim final rule did not alter the exemption criteria for salaried workers in computer-related occupations who earn an amount equal to or less than 6½ times the minimum wage. Such workers continued to be eligible for exemption if the existing requirements in 29 CFR part 541 (i.e., duties and responsibilities) were met, typically in either an executive or administrative capacity. However, such salaried workers were not exempt by virtue of their employment in the specified computer-related occupations. Likewise, such workers paid on an hourly basis at rates of pay equal to or less than 6½ times the minimum wage continued to be ineligible for exemption for failure to meet the "salary basis" requirement generally applicable to all other exempt categories in the private sector.

Sixty-eight comments were received during the comment period on the interim final rule from employers, trade associations, law firms, and individuals. The major commenters and the issues they raised are discussed below, as are the significant changes that have been made in the final regulatory text in response to the comments received.

III. Discussion of Major Comments Received

National Association of Computer Consultant Businesses, the law firm of Epstein, Becker & Green, the law firm of Blackwell, Sanders, Matheny, Weary & Lombardi, Total System Services, Association of Data Processing Service Organizations (ADAPSO), Professional Services Council, CDI Corporation, and the Texas Employment Commission all commented that the interim final rule was inconsistent with the intent of Public Law 101-583. These commenters, for the most part, argue that the statutory language specifically requires the Secretary of Labor to permit salaried workers employed in the specified computer-related occupations to qualify as exempt executive, administrative, or professional employees, regardless of whether their pay exceeds 6½ times the minimum wage, and that the exemption must also be made available to such workers who are compensated on an hourly basis provided that they receive more than 6½ times the minimum wage.

L.J. Gonzer Associates, Additional Technical Support, Inc., and the law firm of Devin & Drohan generally viewed the interim final rule as too narrow and suggested that the term "other similarly skilled professional workers" should not be limited to computer-related occupations, as provided by the statute, but expanded to additional areas not within the scope of Public Law 101-583 such as to hardware engineers, other engineers, or all other categories of "professional" employees whether or not in the computer field. Similarly, the National Technical Services Association, without endorsing or objecting to the interim final rule, posed several questions about other highly-skilled workers not included in the statute who perform tasks that are facilitated by the use of computers, e.g., an engineer conducting flight systems analysis, and requested that the status of these and similar workers be clarified.

The American Engineering Association commented that Public Law 101-583 was prejudicial, repressive, and targets a very small percentage of the nation's technical workforce, and urged the Department, through hearings, to seek repeal by those who initiated the legislation.

The Department of Personnel of Washington County Courthouse (WI) and the Dalkon Shield Claimants Trust objected to the requirement of 6½ times the minimum wage as being too high.

In addition, another 53 comments were received from individuals working as computer systems analyst/programmers or engineers who ordinarily obtain employment in their fields through service firms, some of whom referred to themselves as "job shoppers".[1] For the most part, these individuals are accustomed to compensation on an hourly basis with premium pay for overtime, and they expressed general opposition to the enactment of Public Law 101–583.

The Department also has included in the record correspondence from members of the House Committee on Education and Labor who were the principal House sponsors of the amendment, Representatives Austin Murphy (Chairman, Labor Standards Subcommittee) and William Goodling (Ranking Minority Member), who contended that the interim final rule was inconsistent with the language of the statutory amendment, as well as to the underlying Congressional intent. They stated that the two sentences of the amendment should be read separately. The first, which states that certain highly-skilled computer professionals should qualify for exemption, contains no reference to any particular wage or salary requirement. The second sentence, they contend, then adds an additional requirement for those computer professionals who are compensated on an hourly basis. Similar views were also expressed by Senator John F. Kerry, a sponsor of the amendment in the Senate, in recent correspondence.

In issuing the interim final rule, the Department concluded that Congress intended that the exemption was applicable to highly-skilled computer workers paid more than the equivalent of 6½ times the minimum wage, regardless of how paid. The Department has carefully considered the comments received and made a further review of the statutory provision and its legislative history. In light of the fact that the legislative history is not free from doubt,[2] and that the language of the provision itself is more conducive to the reading suggested by the commenters, the Department has concluded that the new exemption for certain highly-skilled computer professionals is not limited to employees whose pay exceeds 6½ times the minimum wage. Rather, that limitation is imposed only upon those computer professional employees who are paid on an hourly basis.

Thus, this final regulation provides that the statutory exemption for highly-skilled computer-related occupations is not limited to those employees whose pay exceeds 6½ times the minimum wage, regardless of whether paid on a salary or on an hourly basis, as was provided by the interim final rule. In addition, consistent with the statutory characterization of these employees as professionals, the Department has deleted § 541.5c in the interim final rule and is adopting new exemption criteria in § 541.3 to permit the specified computer-related occupations to qualify for exemption as professional employees. The exemption in § 541.3 for these occupations is defined more fully in subpart B—Interpretations, under a new § 541.303. Section 541.302(h) of existing subpart B (renumbered herein as § 541.301), which discussed why computer programmers and systems analysts were not included in the learned professions prior to Public Law 101–583, is deleted, and § 541.312 is revised to permit an exception from the "paid on a salary basis" requirements of § 541.118 for those computer professional employees who are paid on an hourly basis at a rate in excess of 6½ times the minimum wage.

In addition to the substantive comments on the scope of Public Law 101–583 discussed above, commenters also submitted technical suggestions, some of which have been adopted. While the basic requirements for exemption as contained in § 541.5c of the interim final rule are retained in the new § 541.303, the final rule makes the following clarifying changes:

—The exemption is expressly limited to employees in computer systems analysis, programming, software engineering, or related work in software functions;
—A list of the more common job titles in use in the industry is added for illustration purposes;
—Editorial changes are made in the primary duties test for exemption;
—The exemption is not dependent on any particular academic requirements, but rather on proficiency in the theoretical and practical application of a body of highly-specialized knowledge in computer systems analysis, programming, and software engineering;
—The exemption excludes employees who operate computers or who are engaged in the manufacture, repair, or maintenance of computer hardware; and
—Employees within the scope of the exemption may also qualify for exemption under § 541.1 or § 541.2, if applicable.

Executive Order 12291

This final rule in not a "major rule" within the meaning of Executive Order 12291, in that it is not likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions, or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Therefore, no regulatory impact analysis is required.

Regulatory Flexibility Analysis

The Department has determined that the final regulation will not have a significant economic impact on a substantial number of small entities. This conclusion is based on the fact that the proposal merely incorporates a narrow, technical modification imposed by statute. Therefore, no regulatory flexibility analysis is required. The Secretary of Labor has certified to this effect to the Chief Counsel for Advocacy of the Small Business Administration.

Document Preparation

This document was prepared under the direction and control of Karen R. Keesling, Acting Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

List of Subjects in 29 CFR Part 541

Labor, Minimum wages, Overtime pay, Salaries, Wages.

Accordingly, part 541 of title 29 of the Code of Federal Regulations is amended as set forth below.

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[1] Of these comments, one was co-signed by 55 individuals.

[2] Sponsors of the legislation and others making floor statements during the debate suggested that the exception was narrowly crafted and intended to apply only to those employees who are paid in excess of 6½ times the minimum wage. On the other hand, Senator Kerry, one of the Senate sponsors, was of the view that the legislation called for a revamping of outdated regulations that failed to recognize certain computer industry employees as professionals.

Signed at Washington, DC on this 2d day of October 1992.

Lynn Martin,

Secretary of Labor.

Judith A. Sotherlund,

Deputy Assistant Secretary for Employment Standards.

Karen R. Keesling,

Acting Administrator, Wage and Hour Division.

PART 541—DEFINING AND DELIMITING THE TERMS "ANY EMPLOYEE EMPLOYED IN A BONA FIDE EXECUTIVE, ADMINISTRATIVE, OR PROFESSIONAL CAPACITY (INCLUDING ANY EMPLOYEE EMPLOYED IN THE CAPACITY OF ACADEMIC ADMINISTRATIVE PERSONNEL OR TEACHER IN ELEMENTARY OR SECONDARY SCHOOLS), OR IN THE CAPACITY OF OUTSIDE SALESMAN"

The authority citation for part 541 continues to read as follows:

Authority: 29 U.S.C. 213; Public Law 101–583, 104 Stat. 2871; Reorganization Plan No. 6 of 1950 (3 CFR 1945–53 Comp., p. 1004); Secretary's Order No. 13–71 (36 Federal Register 8755).

2. Section 541.3 of subpart A is amended by deleting the semicolon and the word "and" and substituting a comma and the word "or" at the end of paragraph (a)(3); by adding a new paragraph (a)(4); and by revising paragraph (e) to read as follows:

§ 541.3 Professional.

(a) * * *

(4) Work that requires theoretical and practical application of highly-specialized knowledge in computer systems analysis, programming, and software engineering, and who is employed and engaged in these activities as a computer systems analyst, computer programmer, software engineer, or other similarly skilled worker in the computer software field, as provided in § 541.303; and

* * * * *

(e) Who is compensated for services on a salary or fee basis at a rate of not less than $170 per week ($150 per week, if employed by other than the Federal Government in Puerto Rico, the Virgin Islands, or American Samoa), exclusive of board, lodging, or other facilities: *Provided*, That this paragraph shall not apply in the case of an employee who is the holder of a valid license or certificate permitting the practice of law or medicine or any of their branches and who is actually engaged in the practice thereof, nor in the case of an employee who is the holder of the requisite academic degree for the general practice of medicine and is engaged in an internship or resident program pursuant to the practice of medicine or any of its branches, nor in the case of an employee employed and engaged as a teacher as provided in paragraph (a)(3) of this section: *Provided further*, That an employee who is compensated on a salary or fee basis at a rate of not less than $250 per week (or $200 per week, if employed by other than the Federal Government in Puerto Rico, the Virgin Islands, or American Samoa), exclusive of board, lodging, or other facilities, and whose primary duty consists of the performance either of work described in paragraph (a) (1), (3), or (4) of this section, which includes work requiring the consistent exercise of discretion and judgment, or of work requiring invention, imagination, or talent in a recognized field of artistic endeavor, shall be deemed to meet all of the requirements of this section: *Provided further*, That the salary or fee requirements of this paragraph shall not apply to an employee engaged in computer-related work within the scope of paragraph (a)(4) of this section and who is compensated on an hourly basis at a rate in excess of 6½ times the minimum wage provided by section 6 of the Act.

§ 541.5C [Removed]

3. Section 541.5c is removed.

§ 541.302 [Amended]

4. In subpart B of part 541, § 541.302 is amended by removing paragraph (h).

§§ 541.301, 541.302, and 541.303 [Redesignated as 541.300, 541.301 and 541.302]

5. In subpart B of part 541, existing §§ 541.301, 541.302, and 541.303 are redesignated as 541.300, 541.301, and 541.302, respectively, and a new § 541.303 is added to read as follows:

§ 541.303 Computer Related Occupations Under Public Law 101–583.

(a) Pursuant to Public Law 101–583, enacted November 15, 1990, § 541.3(a)(4) provides that computer systems analysts, computer programmers, software engineers, or other similarly skilled workers in the computer software field are eligible for exemption as professionals under section 13(a)(1) of the Act. Employees who qualify for this exemption are highly-skilled in computer systems analysis, programming, or related work in software functions. Employees who perform these types of work have varied job titles. Included among the more common job titles are computer programmer, systems analyst, computer systems analyst, computer programmer analyst, applications programmer, applications systems analyst, applications systems analyst/programmer, software engineer, software specialist, systems engineer, and systems specialist. These job titles are illustrative only and the list is not intended to be all-inclusive. Further, because of the wide variety of job titles applied to computer systems analysis and programming work, job titles alone are not determinative of the applicability of this exemption.

(b) To be considered for exemption under § 541.3(a)(4), an employee's primary duty must consist of one or more of the following:

(1) The application of systems analysis techniques and procedures, including consulting with users, to determine hardware, software, or system functional specifications;

(2) The design, development, documentation, analysis, creation, testing, or modification of computer systems or programs, including prototypes, based on a related to user or system design specifications;

(3) The design, documentation, testing, creation or modification of computer programs related to machine operating systems; or

(4) a combination of the aforementioned duties, the performance of which requires the same level of skills.

(c) The exemption provided by § 541.3(a)(4) applies only to highly-skilled employees who have achieved a level of proficiency in the theoretical and practical application of a body of highly-specialized knowledge in computer systems analysis, programming, and software engineering, and does not include trainees or employees in entry level positions learning to become proficient in such areas or to employees in these computer-related occupations who have not attained a level of skill and expertise which allows them to work independently and generally without close supervision. The level of expertise and skill required to qualify for this exemption is generally attained through combinations of education and experience in the field. While such employees commonly have a bachelor's or higher degree, no particular academic degree is required for this exemption, nor are there any requirements for licensure or certification, as is required for the exemption for the learned profession.

(d) The exemption does not include employees engaged in the operation of computers or in the manufacture, repair, or maintenance of computer hardware

and related equipment. Employees whose work is highly dependent upon, or facilitated by, the use of computers and computer software programs, e.g., engineers, drafters, and others skilled in computer-aided design software like CAD/CAM, but who are not in computer systems analysis and programming occupations, are also excluded from this exemption.

(e) Employees in computer software occupations within the scope of this exemption, as well as those employees not within its scope, may also have managerial and administrative duties which may qualify the employees not within its scope, may also have managerial and administrative duties which may qualify the employees for exemption under § 541.1 or § 541.2 (see §§ 541.205(c)(7) and 541.207(c)(7) of this subpart).

6. In subpart B of part 541, § 541.312 is revised to read as follows:

§ 541.312 Salary basis.

The salary basis of payment is explained in § 541.118 in connection with the definition of "executive." Pursuant to Public Law 101-583, enacted November 15, 1990, payment "on a salary basis" is not a requirement for exemption in the case of those employees in computer-related occupations, as defined in § 541.3(a)(4) and § 541.303, who otherwise meet the requirements of § 541.3 and who are paid on an hourly basis if their hourly rate of pay exceeds 6½ times the minimum wage provided by section 6 of the Act.

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