

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Pochard, Madagascar.	<i>Aythya innotata</i>	Madagascar	Entire	E		NA	NA
Robin, dappled mountain.	<i>Modulatrix orostruthus</i> .	Mozambique, Tanzania.	Entire	T		NA	NA
Sunbird, Marungu	<i>Nectarinia prigoginei</i>	Zaire	Entire	E		NA	NA
Thrush, Taita	<i>Turdus helleri</i>	Kenya	Entire	E		NA	NA
Turaco, Bannerman's	<i>Tauraco bannermani</i> .	Cameroon	Entire	E		NA	NA
Turtle dove, Seychelles.	<i>Streptopelia picturata rostrata</i> .	Seychelles	Entire	E		NA	NA
Vanga, Pollen's	<i>Xenopirostris polleni</i>	Madagascar	Entire	T		NA	NA
Vanga, Van Dam's ...	<i>Xenopirostris damii</i> .	Madagascar	Entire	T		NA	NA
Warbler, Aldabra	<i>Nesillas aldabranus</i>	Aldabra Island (Seychelles).	Entire	E		NA	NA
Wattle-eye, banded ..	<i>Platysteira laticincta</i>	Cameroon	Entire	E		NA	NA
Weaver, Clarke's	<i>Ploceus golandi</i>	Kenya	Entire	E		NA	NA

Dated: March 14, 1994.

Mollie H. Beattie,

Director, Fish and Wildlife Service.

[FR Doc. 94-7226 Filed 3-25-94; 8:45 am]

BILLING CODE 4310-55-P

Registered

**Monday
March 28, 1994**

Part VII

Department of Education

**Strengthening Institutions Program;
Notice Inviting Applications for New
Awards for Fiscal Year 1994; Notice**

DEPARTMENT OF EDUCATION

(CFDA NO. 84.031A)

**Strengthening Institutions Program;
Notice Inviting Applications for New
Awards for Fiscal Year 1994**

Purpose of Program: Provide grants to eligible institutions of higher education to improve their academic quality, institutional management, and fiscal stability so they can become self-sufficient.

This grant program should be seen as an opportunity for applicants to support those elements of the National Education Goals that are relevant to their unique missions.

Deadline for Transmittal of Applications: May 16, 1994.

Deadline for Intergovernmental Review: June 16, 1994.

Applications Available: Applications will be mailed by April 1 to the Office of the President of all institutions that are designated as eligible to apply for a grant under the Strengthening Institutions Program.

Available Funds: \$23,000,000.

Estimated Range of Awards: \$25,000 to \$35,000 for planning grants; \$300,000 to \$350,000 per year for development grants.

Estimated Average Size of Awards: \$30,000 for planning grants; \$325,000 per year for five-year development grants.

Estimated Number of Awards: 12 planning grants and 70 development grants.

Project Period: Up to 12 months for planning grants; 60 months for development grants.

Note: The Department is not bound by any estimates in this notice.

Special Funding Considerations: In tie-breaking situations described in 34 CFR 607.23 of the Strengthening Institutions Program regulations, 34 CFR 607.23, the Secretary awards additional points under §§ 607.21 and 607.22 to an application from an institution which has an endowment fund for which the current market value, per FTE student, is less than the average, per FTE student, at similar type institutions; and has expenditures for library materials, per FTE student, which are less than the average, per FTE student, at similar type institutions.

For the purposes of these funding considerations, an applicant must be able to demonstrate that the current market value of its endowment fund, per FTE student, or expenditures for library materials, per FTE student, is less than the following national averages for base year 1990-91.

	Average market value of endowment fund, per FTE	Average library expenditures for materials, per FTE
Two-year Public Institutions	\$1,425	\$44
Two-year Nonprofit, Private Institutions	6,683	100
Four-year Public Institutions	1,699	159
Four-year Nonprofit, Private Institutions	29,175	244.00

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 82, 85, and 86; and (b) the Strengthening Institutions Program Regulations, 34 CFR part 607.

Supplementary Information: On September 16, 1993, the Secretary published a notice of proposed rulemaking (NPRM) for this program in the *Federal Register* (58 FR 48478).

It is not the policy of the Department of Education to solicit applications before the publication of final regulations. However, in this case, it is necessary to solicit applications on the basis of the NPRM, with the modifications described below, to be able to implement section 314(c) of the HEA. That section requires the Secretary to notify an applicant by June 30, 1994 of (1) the score given the applicant by a panel of reviewers, (2) the recommendation of the panel with regard to such application, and (3) the Secretary's reasons for funding or not funding an application, and any modification in a panel recommendation with regard to an application.

Anticipated Changes to the NPRM

Since the publication of the NPRM, Congress enacted the Higher Education Technical Amendments of 1993, Public Law 103-208. One of those technical amendments revised section 313(b) of the HEA.

Prior to its amendment, section 313(b) of the HEA provided that "In awarding grants under this part, the Secretary shall give priority to applicants who are not already receiving a grant under this part." The Higher Education Technical Amendments of 1993 added the following exception to that section: "Except that a grant made under section 354(a)(1) shall not be considered a grant under this part." (Section 354(a)(1) authorizes the Secretary to fund "cooperative arrangement" grants.)

In proposed § 607.13, the Secretary had provided that an institution could

not apply for both an individual development grant and a cooperative arrangement grant. However, as a result of the amendment to section 313(b), that limitation has been eliminated and an applicant may apply for both types of grants. In addition, as a result of the amendment to section 313(b) of the HEA, a recipient of a cooperative arrangement grant does not fall into a lower funding priority, and § 607.20(b) will be amended accordingly.

The Secretary anticipates making the following two additional changes in the NPRM. If these changes are not ultimately made, applicants will be given the opportunity to revise their applications as necessary.

Under the first anticipated change, in § 607.11, an applicant must justify its failure to complete activities funded under a previous grant regardless of whether the applicant is requesting additional grant funds to complete those activities. In the NPRM, an applicant had to justify its failure to complete funded activities only if it was requesting additional grant funds to complete those activities.

Under the second anticipated change, under § 607.10, an applicant may choose a "Dean" to be a project coordinator or activity director under a grant and may use grant funds to pay the salary of that individual as long as that "Dean" does not report directly to the President of the applicant institution and does not have college-wide administrative authority and responsibility.

For Information Contact: Louis J. Venuto, U.S. Department of Education, 400 Maryland Avenue, S.W., Room 3042, ROB-3, Washington, DC 20202-5335. Telephone: (202) 708-8840. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

Information about the Department's funding opportunities, including copies of application notices for discretionary grant competitions, can be viewed on the Department's electronic bulletin board (ED Board), telephone (202) 260-9950; or on the Internet Gopher Server at GOPHER.ED.GOV (under Announcements, Bulletins and Press Releases). However, the official application notice for a discretionary grant competition is the notice published in the *Federal Register*.

Program Authority: 20 U.S.C. 1057.

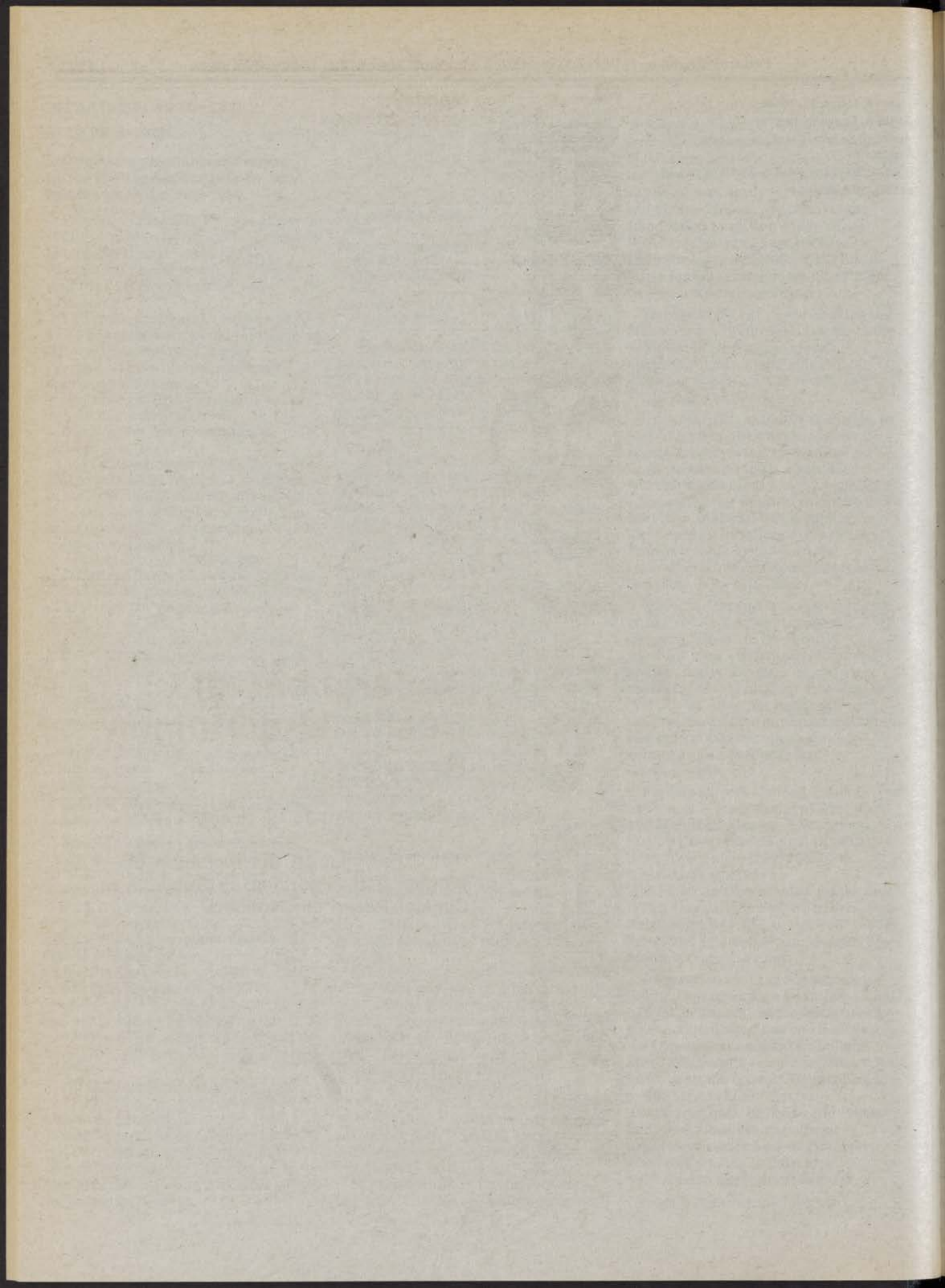
Dated: March 22, 1994.

David A. Longanecker,

*Assistant Secretary for Postsecondary
Education.*

[FR Doc. 94-7184 Filed 3-25-94; 8:45 am]

BILLING CODE 4000-01-P



Federal Register

Monday
March 28, 1994

Part VIII

Department of Health and Human Services

National Institutes of Health

NIH Guidelines on the Inclusion of
Women and Minorities as Subjects in
Clinical Research; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

RIN 0905-ZA18

NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

Editorial Note: This document was originally published at 59 FR 11146, March 9, 1994, and is being reprinted in its entirety because of typesetting errors.

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) is establishing guidelines on the inclusion of women and minorities and their subpopulations in research involving human subjects, including clinical trials, supported by the NIH, as required in the NIH Revitalization Act of 1993.

EFFECTIVE DATE: March 9, 1994.

ADDRESSES: Although these guidelines are effective on the date of publication, written comments can be sent to either the Office of Research on Women's Health, National Institutes of Health, Building 1, room 203, Bethesda, MD 20892, or to the Office of Research on Minority Health, National Institutes of Health, Building 1, room 255, Bethesda, MD 20892. During the first year of implementation, NIH will review the comments and experience with the guidelines in order to determine whether modifications to the guidelines are warranted.

FOR FURTHER INFORMATION CONTACT: Programmatic inquiries should be directed to senior extramural staff of the relevant NIH Institute or Center named at the end of this notice.

SUPPLEMENTARY INFORMATION: NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

I. Introduction

This document sets forth guidelines on the inclusion of women and members of minority groups and their subpopulations in clinical research, including clinical trials, supported by the National Institutes of Health (NIH). For the purposes of this document, clinical research is defined as NIH-supported biomedical and behavioral research involving human subjects. These guidelines, implemented in accordance with section 492B of the Public Health Service Act, added by the NIH Revitalization Act of 1993, Public Law. (Pub.L.) 103-43, supersede and

strengthen the previous policies, NIH/ADAMHA Policy Concerning the Inclusion of Women in Study Populations, and ADAMHA/NIH Policy Concerning the Inclusion of Minorities in Study Populations, published in the NIH GUIDE FOR GRANTS AND CONTRACTS, 1990.

The 1993 guidelines continue the 1990 guidelines with three major additions. The new policy requires that, in addition to the continuing inclusion of women and members of minority groups in all NIH-supported biomedical and behavioral research involving human subjects, the NIH must:

- Ensure that women and members of minorities and their subpopulations are included in all human subject research.
- For Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished;
- Not allow cost as an acceptable reason for excluding these groups; and,
- Initiate programs and support for outreach efforts to recruit these groups into clinical studies.

Since a primary aim of research is to provide scientific evidence leading to a change in health policy or a standard of care, it is imperative to determine whether the intervention or therapy being studied affects women or men or members of minority groups and their subpopulations differently. To this end, the guidelines published here are intended to ensure that all future NIH-supported biomedical and behavioral research involving human subjects will be carried out in a manner sufficient to elicit information about individuals of both genders and the diverse racial and ethnic groups and, in the case of clinical trials, to examine differential effects on such groups. Increased attention, therefore, must be given to gender, race, and ethnicity in earlier stages of research to allow for informed decisions at the Phase III clinical trial stage.

These guidelines reaffirm NIH's commitment to the fundamental principles of inclusion of women and racial and ethnic minority groups and their subpopulations in research. This policy should result in a variety of new research opportunities to address significant gaps in knowledge about health problems that affect women and racial/ethnic minorities and their subpopulations.

The NIH recognizes that issues will arise with the implementation of these guidelines and thus welcomes comments. During the first year of implementation, NIH will review the comments, and consider modifications,

within the scope of the statute, to the guidelines.

II. Background

The NIH Revitalization Act of 1993, PL 103-43, signed by President Clinton on June 10, 1993, directs the NIH to establish guidelines for inclusion of women and minorities in clinical research. This guidance shall include guidelines regarding—

- (A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate * * *;
- (B) the manner in which clinical trials are required to be designed and carried out * * *; and
- (C) the operation of outreach programs * * * 492B(d)(1)

The statute states that

In conducting or supporting clinical research for the purposes of this title, the Director of NIH shall * * * ensure that—
A. women are included as subjects in each project of such research; and
B. members of minority groups are included in such research. 492B(a)(1)

The statute further defines "clinical research" to include "clinical trials" and states that

In the case of any clinical trial in which women or members of minority groups will be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial. 492B(c)

Specifically addressing the issue of minority groups, the statute states that

The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established * * * defines the terms "minority group" and "subpopulation" for the purposes of the preceding sentence. 492B(g)(2)

The statute speaks specifically to outreach and states that

The Director of NIH, in consultation with the Director of the Office of Research of Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in the projects of clinical research. 492B(a)(2)

The statute includes a specific provision pertaining to the cost of clinical research and, in particular clinical trials.

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is (sic) not a permissible consideration in determining whether such inclusion is inappropriate. 492B(d)(2)

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is (sic) not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality. 492B(d)(2)

Exclusions to the requirement for inclusion of women and minorities are stated in the statute, as follows:

The requirements established regarding women and members of minority groups shall not apply to the project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(1) Is inappropriate with respect to the health of the subjects;

(2) Is inappropriate with respect to the purpose of the research; or

(3) Is inappropriate under such other circumstances as the Director of NIH may designate. 492B(b)

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) The effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) The effects that variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required. 492B(d)(2)

III. Policy

A. Research Involving Human Subjects

It is the policy of NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made by the Director, NIH, upon the recommendation of a Institute/Center Director based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. The research plan should describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Such a plan should contain a description of the proposed outreach programs for recruiting women and minorities as participants.

B. Clinical Trials

Under the statute, when a Phase III clinical trial (see Definitions, Section V-A) is proposed, evidence must be reviewed to show whether or not clinically important gender or race/ethnicity differences in the intervention effect are to be expected. This evidence may include, but is not limited to, data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies.

As such, investigators must consider the following when planning a Phase III clinical trial for NIH support.

- If the data from prior studies strongly indicate the existence of significant differences of clinical or public health importance in intervention effect among subgroups (gender and/or racial/ethnic subgroups), the primary question(s) to be addressed by the proposed Phase III trial and the design of that trial must specifically accommodate this. For example, if men and women are thought to respond differently to an intervention, then the Phase III trial must be designed to answer two separate primary questions, one for men and the other for women, with adequate sample size for each.

- If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect between subgroups, then gender or race/ethnicity will not be required as subject selection criteria. However, the inclusion of gender or racial/ethnic subgroups is still strongly encouraged.

- If the data from prior studies neither support strongly nor negate strongly the existence of significant differences of clinical or public health importance in intervention effect between subgroups, then the Phase III trial will be required to include sufficient and appropriate entry of gender and racial/ethnic subgroups, so that valid analysis of the intervention effect in subgroups can be performed.

However, the trial will not be required to provide high statistical power for each subgroup.

Cost is not an acceptable reason for exclusion of women and minorities from clinical trials.

C. Funding

NIH funding components will not award any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which does not comply with this policy. For research awards that are covered by this policy, awardees will report annually on enrollment of women and men, and on the race and ethnicity of research participants.

IV. Implementation

A. Date of Implementation

This policy applies to all applications/proposals and intramural projects to be submitted on and after June 1, 1994 (the date of full implementation) seeking Fiscal Year 1995 support. Projects funded prior to June 10, 1993, must still comply with the 1990 policy and report annually on enrollment of subjects using gender and racial/ethnic categories as required in the Application for Continuation of a Public Health Service Grant (PHS Form 2590), in contracts and in intramural projects.

B. Transition Policy

NIH-supported biomedical and behavioral research projects involving human subjects, with the exception of Phase III clinical trial projects as discussed below, that are awarded between June 10, 1993, the date of enactment, and September 30, 1994, the end of Fiscal Year 1994, shall be subject to the requirements of the 1990 policy and the annual reporting requirements on enrollment using gender and racial/ethnic categories.

For all Phase III clinical trial projects proposed between June 10, 1993 and June 1, 1994, and those awarded between June 10, 1993 and September 30, 1994, Institute/Center staff will examine the applications/proposals, pending awards, awards and intramural projects to determine if the study was developed in a manner consistent with the new guidelines. If it is deemed inconsistent, NIH staff will contact investigators to discuss approaches to accommodate the new policy. Administrative actions may be needed to accommodate or revise the pending trials. Institutes/Centers may need to consider initiating a complementary activity to address any gender or minority representation concerns.

The NIH Director will determine whether the Phase III clinical trial being considered during this transition is in compliance with this policy, whether acceptable modifications have been made, or whether the Institute/Center will initiate a complementary activity that addresses the gender or minority representation concerns. Pending awards will not be funded without this determination.

Solicitations issued by the NIH planned for release after the date of publication of the guidelines in the *Federal Register* will include the new requirements.

C. Roles and Responsibilities

While this policy applies to all applicants for NIH-supported biomedical and behavioral research involving human subjects, certain individuals and groups have special roles and responsibilities with regard to the adoption and implementation of these guidelines.

The NIH staff will provide educational opportunities for the extramural and intramural community concerning this policy; monitor its implementation during the development, review, award and conduct of research; and manage the NIH research portfolio to address the policy.

1. Principal Investigators

Principal investigators should assess the theoretical and/or scientific linkages between gender, race/ethnicity, and their topic of study. Following this assessment, the principal investigator and the applicant institution will address the policy in each application and proposal, providing the required information on inclusion of women and minorities and their subpopulations in research projects, and any required justifications for exceptions to the policy. Depending on the purpose of the study, NIH recognizes that a single study may not include all minority groups.

2. Institutional Review Boards (IRBs)

As the IRBs implement the guidelines, described herein, for the inclusion of women and minorities and their subpopulations, they must also implement the regulations for the protection of human subjects as described in title 45 CFR part 46, "Protection of Human Subjects." They should take into account the Food and Drug Administration's "Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs," Vol. 58 *Federal Register* 39406.

3. Peer Review Groups

In conducting peer review for scientific and technical merit, appropriately constituted initial review groups (including study sections), technical evaluation groups, and intramural review panels will be instructed, as follows:

- To evaluate the proposed plan for the inclusion of minorities and both genders for appropriate representation or to evaluate the proposed justification when representation is limited or absent,
- To evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the health of the subjects,
- To evaluate the proposed exclusion of minorities and women on the basis that a requirement for inclusion is inappropriate with respect to the purpose of the research,
- To determine whether the design of clinical trials is adequate to measure differences when warranted,
- To evaluate the plans for recruitment/outreach for study, participants, and
- To include these criteria as part of the scientific assessment and assigned score.

4. NIH Advisory Councils

In addition to its current responsibilities for review of projects where the peer review groups have raised questions about the appropriate inclusion of women and minorities, the Advisory Council/Board of each Institute/Center shall prepare biennial reports, for inclusion in the overall NIH Director's biennial report, describing the manner in which the Institute/Center has complied with the provisions of the statute.

5. Institute/Center Directors

Institute/Center Directors and their staff shall determine whether: (a) The research involving human subjects, (b) the Phase III clinical trials, and (c) the exclusions meet the requirements of the statute and these guidelines.

6. NIH Director

The NIH Director may approve, on a case-by-case basis, the exclusion of projects, as recommended by the Institute/Center Director, that may be inappropriate to include within the requirements of these guidelines on the basis of circumstances other than the health of the subjects, the purpose of the research, or costs.

7. Recruitment Outreach by Extramural and Intramural Investigators

Investigators and their staff(s) are urged to develop appropriate and culturally sensitive outreach programs and activities commensurate with the goals of the study. The objective should be to actively recruit the most diverse study population consistent with the purposes of the research project. Indeed, the purpose should be to establish a relationship between the investigator(s) and staff(s) and populations and community(ies) of interest such that mutual benefit is derived for participants in the study. Investigator(s) and staff(s) should take precautionary measures to ensure that ethical concerns are clearly noted, such that there is minimal possibility of coercion or undue influence in the incentives or rewards offered in recruiting into or retaining participants in studies. It is also the responsibility of the IRBs to address these ethical concerns.

Furthermore, while the statute focuses on recruitment outreach, NIH staff underscore the need to appropriately retain participants in clinical studies, and thus, the outreach programs and activities should address both recruitment and retention.

To assist investigators and potential study participants, NIH staff have prepared a notebook, "NIH Outreach Notebook On the Inclusion of Women and Minorities in Biomedical and Behavioral Research." The notebook addresses both recruitment and retention of women and minorities in clinical studies, provides relevant references and case studies, and discusses ethical issues. It is not intended as a definitive text on this subject, but should assist investigators in their consideration of an appropriate plan for recruiting and retaining participants in clinical studies. The notebook is expected to be available early in 1994.

8. Educational Outreach by NIH to Inform the Professional Community

NIH staff will present the new guidelines to investigators, IRB members, peer review groups, and Advisory Councils in a variety of public educational forums.

9. Applicability to Foreign Research Involving Human Subjects

For foreign awards, the NIH policy on inclusion of women in research conducted outside the U.S. is the same as that for research conducted in the U.S.

However, with regard to the population of the foreign country, the

definition of the minority groups may be different than in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

V. Definitions

Throughout the section of the statute pertaining to the inclusion of women and minorities, terms are used which require definition for the purpose of implementing these guidelines. These terms, drawn directly from the statute, are defined below.

A. Clinical Trial

For the purpose of these guidelines, a "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

B. Research Involving Human Subjects

All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research under this policy. Under this policy, the definition of human subjects in title 45 CFR part 46, the Department of Health and Human Services regulations for the protection of human subjects applies: "Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) identifiable private information." These regulations specifically address the protection of human subjects from research risks. It should be noted that there are research areas (Exemptions 1-6) that are exempt from these regulations. However, under these guidelines, NIH-supported biomedical and behavioral research projects involving human subjects which are exempt from the human subjects regulations should still address the inclusion of women and minorities in their study design. Therefore, all biomedical and behavioral research

projects involving human subjects will be evaluated for compliance with this policy.

C. Valid Analysis

The term "valid analysis" means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- Allocation of study participants of both genders and from different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the gender and racial/ethnic groups.

D. Significant Difference

For purposes of this policy, a "significant difference" is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used "statistically significant difference," which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

E. Racial and Ethnic Categories

1. Minority Groups

A minority group is a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic racial and ethnic categories, which are used below. NIH has chosen to continue the use of these definitions because they allow comparisons to many national data bases, especially national health data bases. Therefore, the racial and ethnic

categories described below should be used as basic guidance, cognizant of the distinction based on cultural heritage.

American Indian or Alaskan Native:

A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

2. Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

3. Subpopulations

Each minority group contains subpopulations which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

F. Outreach Strategies

These are outreach efforts by investigators and their staff(s) to appropriately recruit and retain populations of interest into research studies. Such efforts should represent a thoughtful and culturally sensitive plan of outreach and generally include involvement of other individuals and organizations relevant to the

populations and communities of interest, e.g., family, religious organizations, community leaders and informal gatekeepers, and public and private institutions and organizations. The objective is to establish appropriate lines of communication and cooperation to build mutual trust and cooperation such that both the study and the participants benefit from such collaboration.

G. Research Portfolio

Each Institute and Center at the NIH has its own research portfolio, i.e., its "holdings" in research grants, cooperative agreements, contracts and intramural studies. The Institute or Center evaluates the research awards in its portfolio to identify those areas where there are knowledge gaps or which need special attention to advance the science involved. NIH may consider funding projects to achieve a research portfolio reflecting diverse study populations. With the implementation of this new policy, there will be a need to ensure that sufficient resources are provided within a program to allow for data to be developed for a smooth transition from basic research to Phase III clinical trials that meet the policy requirements.

VI. Discussion—Issues in Scientific Plans and Study Designs

A. Issues in Research Involving Human Subjects

The biomedical and behavioral research process can be viewed as a stepwise process progressing from discovery of new knowledge through research in the laboratory, research involving animals, research involving human subjects, validation of interventions through clinical trials, and broad application to improve the health of the public.

All NIH-supported biomedical and behavioral research involving human subjects is defined broadly in this guidance as clinical research. This is broader than the definition provided in the 1990 NIH Guidance and in many program announcements, requests for applications, and requests for proposals since 1990.

The definition was broadened because of the need to obtain data about minorities and both genders early in the research process when hypotheses are being formulated, baseline data are being collected, and various measurement instruments and intervention strategies are being developed. Broad inclusion at these early stages of research provides valuable information for designing

broadly based clinical trials, which are a subset of studies under the broad category of research studies.

The policy on inclusion of minorities and both genders applies to all NIH-supported biomedical and behavioral research involving human subjects so that the maximum information may be obtained to understand the implications of the research findings on the gender or minority group.

Investigators should consider the types of information concerning gender and minority groups which will be required when designing future Phase III clinical trials, and try to obtain it in their earlier stages of research involving human subjects. NIH recognizes that the understanding of health problems and conditions of different U.S. populations may require attention to socioeconomic differences involving occupation, education, and income gradients.

B. Issues in Clinical Trials

The statute requires appropriate representation of subjects of different gender and race/ethnicity in clinical trials so as to provide the opportunity for detecting major qualitative differences (if they exist) among gender and racial/ethnic subgroups and to identify more subtle differences that might, if warranted, be explored in further specifically targeted studies. Other interpretations may not serve as well the health needs of women, minorities, and all other constituencies.

Preparatory to any Phase III clinical trial, certain data are typically obtained. Such data are necessary for the design of an appropriate Phase III trial and include observational clinical study data, basic laboratory (i.e. *in vitro* and animal) data, and clinical, physiologic, pharmacokinetic, or biochemical data from Phase I and Phase II studies. Genetic studies, behavioral studies, and observational, natural history, and epidemiological studies may also contribute data.

It is essential that data be reviewed from prior studies on a diverse population, that is, in subjects of both genders and from different racial/ethnic groups. These data must be examined to determine if there are significant differences of clinical or public health importance observed between the subgroups.

While data from prior studies relating to possible differences among intervention effects in different subgroups must be reviewed, evidence of this nature is likely to be less convincing than that deriving from the subgroup analyses that can be performed in usual-sized Phase III trials. This is because the evidence from

preliminary studies is likely to be of a more indirect nature (e.g. based on surrogate endpoints), deriving from uncontrolled studies (e.g. non-randomized Phase II trials), and based on smaller numbers of subjects than in Phase III secondary analyses. For this reason, it is likely that data from preliminary studies will, in the majority of cases, neither clearly reveal significant differences of clinical or public health importance between subgroups of patients, nor strongly negate them.

In these cases, Phase III trials should still have appropriate gender and racial/ethnic representation, but they would not need to have the large sample sizes necessary to provide a high statistical power for detecting differences in intervention effects among subgroups. Nevertheless, analyses of subgroup effects must be conducted and comparisons between the subgroups must be made. Depending on the results of these analyses, the results of other relevant research, and the results of meta-analyses of clinical trials, one might initiate subsequent trials to examine more fully these subgroup differences.

C. Issues Concerning Appropriate Gender Representation

The "population at risk" may refer to only one gender where the disease, disorders, or conditions are gender specific. In all other cases, there should be approximately equal numbers of both sexes in studies of populations or subpopulations at risk, unless different proportions are appropriate because of the known prevalence, incidence, morbidity, mortality rates, or expected intervention effect.

D. Issues Concerning Appropriate Representation of Minority Groups and Subpopulations in All Research Involving Human Subjects Including Phase III Clinical Trials

While the inclusion of minority subpopulations in research is a complex and challenging issue, it nonetheless provides the opportunity for researchers to collect data on subpopulations where knowledge gaps exist. Researchers must consider the inclusion of subpopulations in all stages of research design. In meeting this objective, they should be aware of concurrent research that addresses specific subpopulations, and consider potential collaborations which may result in complementary subpopulation data.

At the present time, there are gaps in baseline and other types of data necessary for research involving certain minority groups and/or subpopulations

of minority groups. In these areas, it would be appropriate for researchers to obtain such data, including baseline data, by studying a single minority group.

It would also be appropriate for researchers to test survey instruments, recruitment procedures, and other methodologies used in the majority or other population(s) with the objective of assessing their feasibility, applicability, and cultural competence/relevance to a particular minority group or subpopulation. This testing may provide data on the validity of the methodologies across groups. Likewise, if an intervention has been tried in the majority population and not in certain minority groups, it would be appropriate to assess the intervention effect on a single minority group and compare the effect to that obtained in the majority population. These types of studies will advance scientific research and assist in closing knowledge gaps.

A complex issue arises over how broad or narrow the division into different subgroups should be, given the purpose of the research. Division into many racial/ethnic subgroups is tempting in view of the cultural and biological differences that exist among these groups and the possibility that some of these differences may in fact impact in some way upon the scientific question. Alternatively, from a practical perspective, a limit has to be placed on the number of such subgroups that can realistically be studied in detail for each intervention that is researched. The investigator should clearly address the rationale for inclusion or exclusion of subgroups in terms of the purpose of the research. Emphasis should be placed upon inclusion of subpopulations in which the disease manifests itself or the intervention operates in an appreciable different way. Investigators should report the subpopulations included in the study.

An important issue is the appropriate representation of minority groups in research, especially in geographical locations which may have limited numbers of racial/ethnic population groups available for study. The investigator must address this issue in terms of the purpose of the research, and other factors, such as the size of the study, relevant characteristics of the disease, disorder or condition, and the feasibility of making a collaboration or consortium or other arrangements to include minority groups. A justification

is required if there is limited representation. Peer reviewers and NIH staff will consider the justification in their evaluations of the project.

NIH interprets the statute in a manner that leads to feasible and real improvements in the representativeness of different racial/ethnic groups in research and places emphasis on research in those subpopulations that are disproportionately affected by certain diseases or disorders.

VII. NIH Contacts for More Information

The following senior extramural staff from the NIH Institutes and Centers may be contacted for further information about the policy and relevant Institute/Center programs:

- Dr. Marvin Kalt, National Cancer Institute, 6130 Executive Boulevard, Executive Plaza North, room 600A, Bethesda, Maryland 20892, Tel: (301) 496-5147.
- Dr. Richard Mowery, National Eye Institute, 6120 Executive Boulevard, Executive Plaza South, room 350, Rockville, Maryland 20892, Tel: (301) 496-5301.
- Dr. Lawrence Friedman, National Heart, Lung and Blood Institute, 7550 Wisconsin Avenue, Federal Building, room 212, Bethesda, Maryland 20892, Tel: (301) 496-2533.
- Dr. Miriam Kelty, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Building, room 2C218, Bethesda, Maryland 20892, Tel: (301) 496-9322.
- Dr. Cherry Lowman, National Institute on Alcohol Abuse and Alcoholism, 6000 Executive Boulevard, Rockville, Maryland 20892, Tel: (301) 443-0796.
- Dr. George Counts, National Institute of Allergy and Infectious Diseases, 6003 Executive Boulevard, Solar Building, room 207P, Bethesda, Maryland 20892, Tel: (301) 496-8214.
- Dr. Michael Lockshin, National Institute of Arthritis and Musculoskeletal and Skin Diseases, 9000 Rockville Pike, Building 31, room 4C32, Bethesda, Maryland 20892, Tel: (301) 496-0802.
- Ms. Hildegard Topper, Bethesda, National Institute of Child Health and Human Development, 9000 Rockville Pike, Building 31, room 2A-03, Bethesda, Maryland 20892, Tel: (301) 496-0104.
- Dr. Earleen Elkins, National Institute of Deafness and Other Communication Disorders, 6120 Executive Boulevard, Executive Plaza South, room 400,

Rockville, Maryland 20892, Tel: (301) 496-8683.

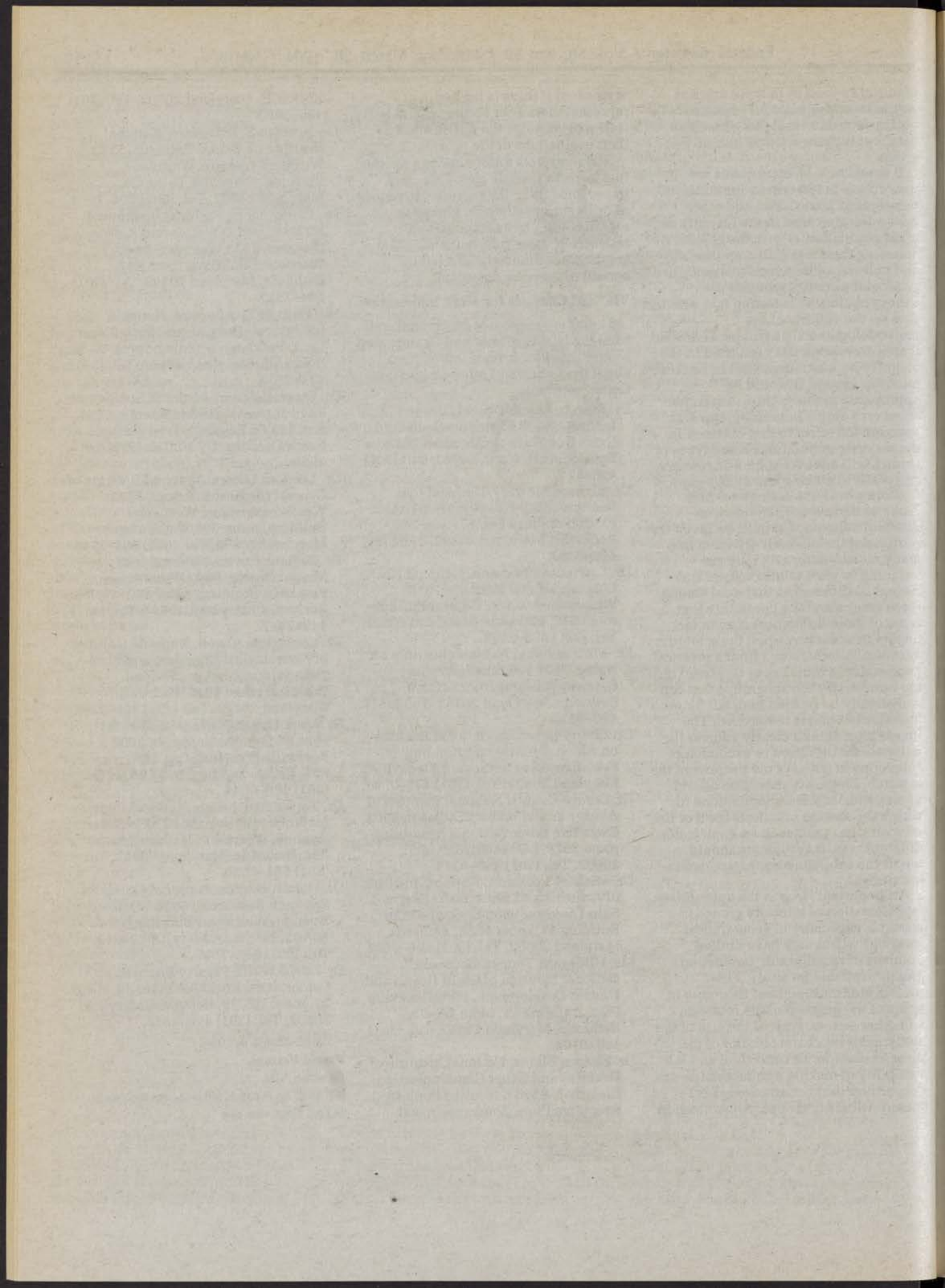
- Dr. Norman S. Braveman, National Institute on Dental Research, 5333 Westbard Avenue, Westwood Building, room 509, Bethesda, Maryland 20892, Tel: (301) 594-7648.
- Dr. Walter Stolz, National Institute of Diabetes and Digestive and Kidney Diseases, 5333 Westbard Avenue, Westwood Building, room 657, Bethesda, Maryland 20892, Tel: (301) 594-7527.
- Ms. Eleanor Friedenberg, National Institute on Drug Abuse, 5600 Fishers Lane, Parklawn Building, room 10-42, Rockville, Maryland 20857, Tel: (301) 434-2755.
- Dr. Gwen Collman, National Institute of Environmental Health Sciences, P.O. Box 12233, Research Triangle Park, North Carolina 27709, Tel: (919) 541-4980.
- Dr. Lee Van Lenten, National Institute of General Medical Sciences, 5333 Westbard Avenue, Westwood Building, room 905, Bethesda, Maryland 20892, Tel: (301) 594-7744.
- Dr. Dolores Parron, National Institute of Mental Health, 5600 Fishers Lane, Parklawn Building, room 17C-14, Rockville, Maryland 20857, Tel: (301) 443-2847.
- Dr. Constance Atwell, National Institute of Neurological Disorders and Stroke, 7550 Wisconsin Ave., Federal Building, room 1016, Bethesda, Maryland 20892, Tel: (301) 496-9248.
- Dr. Mark Guyer, National Center for Human Genome Research, 9000 Rockville Pike, Building 38A, room 605, Bethesda, Maryland 20892, Tel: (301) 496-0844.
- Dr. Teresa Radebaugh, National Center for Nursing Research, 5333 Westbard Avenue, Westwood Building, room 754, Bethesda, Maryland 20892, Tel: (301) 594-7590.
- Dr. Harriet Gordon, National Center for Research Resources, 5333 Westbard Avenue, Westwood Building, room 10A03, Bethesda, Maryland 20892, Tel: (301) 594-7945.
- Dr. David Wolff, Fogarty International Center, 9000 Rockville Pike, Building 31, room B2C39, Bethesda, Maryland 20892, Tel: (301) 496-1653.

Dated: March 3, 1994.

Harold Varmus,
Director, NIH.

[FR Doc. 94-5435 Filed 3-8-94; 8:45 am]

BILLING CODE 1505-01-D



Federal Register

Monday
March 28, 1994

Part IX

Corporation for National and Community Service

Availability of Funds for Training and
Technical Service; Notice

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Availability of Funds for Training and Technical Assistance

AGENCY: Corporation for National and Community Service.

ACTION: Notice of availability of funds.

SUMMARY: The Corporation for National and Community Service announces the availability of approximately \$5.1 million to provide training and technical assistance to State Commissions or alternative entities, AmeriCorps grantees (except where otherwise stated for Learn and Serve grantees) and those interested in becoming AmeriCorps grantees. The Corporation seeks proposals and concept papers describing activities to meet the technical assistance and training needs outlined in this Notice. The Corporation also invites concept papers proposing additional or alternative technical assistance and training activities.

DATES: Deadlines for submission of technical assistance and training (T/TA) proposals are 6 pm Eastern Standard Time on the following dates:

T/TA for the National Leadership Corps.....	May 3, 1994
Maintaining a Strong Organization.....	May 18, 1994
National Priority Skills Development Centers.....	June 1, 1994

The deadlines for submission of concept papers are 6 pm Eastern Standard Time May 27, 1994, and September 13, 1994. Following the May deadline, the Corporation expects to invite potential applicants to submit a detailed proposal by July 15, 1994.

ADDRESSES: All proposals and concept papers should be submitted to the Corporation for National and Community Service, 1100 Vermont Avenue NW., Washington, DC 20525. Attn.: T/TA Proposal or Concept Paper Review. Applicants are requested to include four copies of proposals or concept papers to facilitate the review processes.

FOR FURTHER INFORMATION CONTACT: Kathryn Frucher or Tracy Gray at the Corporation for National and Community Service, (202)606-5000 ext. 106. Questions about this Notice will be answered during technical assistance and training conference calls which are scheduled to take place on March 31, April 7, April 14, and April 21, 1994 from 2:00 pm-3:00 pm. To reserve a place on a conference call, please call the Corporation at (202)606-5000 ext. 432 or fax a request to (202)606-4816.

SUPPLEMENTARY INFORMATION:

Outline

Summary—Training and Technical Assistance Activities

- (I) Application by Proposal
 - (A) Training and Technical Assistance for the National Leadership Corps
 - (B) Maintaining a Strong Organization—Fundraising, Program Management, Evaluation, Fiscal Management, and Grievance Procedures
 - (C) National Priority Skills Development Centers
- (II) Application by Concept Paper
 - (A) National Service Resource Center
 - (B) Strengthening the Basics of National Service Programs
 - (C) Service and Citizenship
 - (D) Strengthening Program Diversity
 - (E) Peer Exchange Visitation Program
 - (F) Learn and Serve America K-12—Resource Publications
 - (G) Training Initiatives on Service-Learning
 - (H) Learn and Serve America Higher Education—Higher Education Service Resource Center Institutionalizing Service-Learning Infrastructure and Capacity-Building
 - (I) Training and Technical Assistance for State Commissions
- (III) Invitation for Original Concept Papers Proposing Additional or Alternative Training and Technical Assistance Activities

Summary

Background

On September 21, 1993, the President signed into law the National and Community Service Trust Act, which created the Corporation for National and Community Service (the Corporation). The Corporation's mission is to engage Americans of all ages and backgrounds in service that addresses the nation's education, public safety, health, and environmental needs to achieve direct and demonstrable results. In doing so, the Corporation will foster civic responsibility, strengthen the ties that bind us together as a people, and provide educational opportunity for those who make a substantial commitment to service.

The Corporation is a new government corporation that encompasses the work and staff of two existing independent agencies, the Commission on National and Community Service and ACTION. The Corporation will fund a new national service initiative called AmeriCorps. AmeriCorps includes a wide variety of programs operated by grantees (including local non-profits), the National Civilian Community Corps, and the Volunteers in Service to America (VISTA) program. The Corporation will also support service-learning initiatives for elementary and secondary schools and institutions of

higher education called Learn and Serve America, and operate the senior volunteer programs previously operated by ACTION.

The Act authorizes the Corporation to support and improve Summer of Service programs, AmeriCorps grants programs, and Learn and Serve programs through a variety of training and technical assistance (T/TA) activities. These activities should build on the AmeriCorps regulations and the "Principles for High Quality National Service Programs" document which lay out the Corporation's vision and expectations for AmeriCorps programs. The regulations and "Principles" document should be read by all potential T/TA providers. Copies may be obtained by calling the Corporation at 202-606-4949 or writing the Corporation at 1100 Vermont Avenue NW., Washington, DC, 20525. To receive information on getting the "Principles" or regulations on Internet, please send a blank electronic mail message to: cnscs@ace.esusda.gov. There should be no text in the body of the message. An automatic response will be sent back to you with information on how to retrieve the regulations.

Overview

The Corporation announces the availability of approximately \$5.1 million in fiscal year 1994 for training and technical assistance initiatives. Under each fundable activity, estimated levels of funding are listed. Most grants or cooperative agreements will be made for a term of one year, unless specified otherwise. The Corporation requests proposals, and, in some cases, concept papers for the specific activities described herein. This Notice lists applications requiring full proposals and areas in which concept papers are requested. In most cases, applicants are not required to cover all of the needs in a given area; for example, an organization can apply to train grantees in fundraising skills only in the "Maintaining a Strong Organization" section.

Concept papers may also be submitted describing activities that meet needs of AmeriCorps or Learn and Serve programs not described in this Notice. Guidelines are described in the "Invitation for Original Concept Papers" section.

In all cases, applicants should demonstrate an understanding of and commitment to the Corporation's mission and goals, a need that relates to that mission and goals, a sound plan for accomplishing the activity, and a fulfillment of the selection criteria listed below.

Eligibility

Public agencies (including federal, state, and local agencies and other units of government), non-profit organizations (including youth-serving groups, community-based organizations, service organizations, etc.), institutions of higher education, Indian tribes, and for-profit companies are eligible to apply. State and federal agencies and non-governmental organizations that intend to operate AmeriCorps or Learn and Serve programs are also eligible. Organizations may apply to provide T/TA in partnership with organizations seeking other Corporation funds.

Applications for Continuation of Assistance for Current Technical Assistance Grantees

The former Commission on National and Community Service issued a number of technical assistance grants to organizations in fiscal years 1992 and 1993. Pursuant to the National and Community Service Trust act of 1993, the administration of these grants transferred to the Corporation for National and Community Service. Existing technical assistance grantees interested in the continuation of funding or undertaking new technical assistance activities may submit competitive applications in accordance with the applicable due dates and activities described in this Notice.

Objectives of the Training and Technical Assistance Activities

The goal of training and technical assistance is to improve the ability of AmeriCorps programs and participants to "get things done" by achieving direct and demonstrable results in communities, fostering civic responsibility, and strengthening the ties that bind communities together. To best support programs, the Corporation will fund technical assistance that strengthens program performance and effectiveness in the short term and builds leadership and permanent resources in the long term. Technical assistance must be relevant to program needs, responsive to changing needs, and easily accessed by states and grantees. Training and technical assistance providers will build a strong infrastructure by—

- Increasing the effectiveness and capacity of programs and states;
- Increasing the resources available to support high quality work; and
- Developing leaders at all levels.

Training and technical assistance providers will also foster a national identity and common understanding of the goals and mission of national service

among AmeriCorps participants, programs, and states.

In addition, the Corporation is committed to strengthening service nationwide. Although technical assistance providers should show preference to AmeriCorps program grantees (except where activities pertain to Learn and Serve grantees), T/TA providers may be expected to serve those who wish to become grantees as well. (For more on this, see "Requirements" section below).

These principles guide the Corporation's technical assistance strategy:

—Treat technical assistance as a full partnership among the Corporation, states, and programs, with roles for all in designing and delivering technical assistance.

—Encourage collaboration among partners, especially efforts that team service programs and those experienced in working in the issue areas.

—"Train the trainers"—focus on developing resource capacity in local areas.

—Instead of repeating the excellent work of others, build on existing training, materials, and expertise.

—Focus on the most pressing needs to have the greatest impact.

—Invest sufficiently to provide adequate technical assistance support in the first years.

Application Guidelines

Applications can be of two kinds as specified: full proposals and concept papers. While many of the same elements will be addressed in these two types of applications, proposals ask applicants to give a much more comprehensive and detailed overview of planned activities, organizational capacity, budget, and workplan than do concept papers. After reviewing concept papers, the Corporation may ask for full proposals from a select number of applicants based on program need, availability of funds, and the strength of concept paper ideas received by the Corporation.

Where specified, a full proposal should be submitted for each activity, unless the proposal thoughtfully combines activities into a single coordinated initiative. A full proposal must include:

- A cover page listing: the title of the organization applying; the amount of funds requested; a brief summary of the proposed T/TA program or activity; the name, address, phone number, and fax number of the organization; and the name and title of a contact person.

—A narrative of no more than 10 double-spaced typed pages in 12-point font, describing—

- (a) The scope of activity being proposed, e.g., number of trainers hired and programs served by them, relative to the amount of the grant requested;
- (b) the organization's plan and ability to meet compelling and ongoing needs, in collaboration with others where possible and appropriate;
- (c) the organization's capacity, including staff strengths and backgrounds, resumes of key people, and the organization's track record;
- (d) the innovation and replicability of the proposed T/TA activity; and
- (e) outcome objectives and indicators to be used to assess success.

—A detailed budget, including an estimate of travel costs for delivery of T/TA services, with a supporting narrative explaining how costs are calculated and information on funding from other sources.

—A detailed workplan for accomplishing the specific objectives including a timeline showing when each step toward the objectives will be accomplished.

Where specified, a concept paper must include:

—A cover page listing the title of the organization applying; the amount of funds requested; a brief summary of the proposed T/TA program or activity; the name, address, phone number, and fax number of the organization; and the name and title of a contact person.

—A brief narrative of no more than 5 double-spaced typed pages in 12-point font describing proposed T/TA activity.

—A brief budget, with major expense line items, which may include a supporting narrative.

—A preliminary workplan for accomplishing the specific objectives.

—A preliminary timeline.

Selection Criteria

The Corporation will assess applications based on the criteria listed below. The percentage weight of each criterion in the assessment is given.

Quality (45%). The Corporation will consider the quality of the proposed activities, based on—

—Scope of proposed T/TA activity relative to the amount of the grant requested, the number of people, programs, and/or State Commissions proposed T/TA activities are expected to reach;

—Demonstration that the proposed activities meet clear compelling program and/or state needs related to the Corporation's mission and goals for national service;

—Description of proposed T/TA techniques, including opportunities for

peer exchange and peer training, experiential learning, and individual assistance tailored to meet specific program or state needs; also description of plans to use tested methods or ways to test training activities or curricula on a small scale and refine them before offering them on a large scale;

—Plan for implementing mechanisms continually to assess and improve value and impact of T/TA services. This may include providing opportunities for customer(s) participation in design of activity and opportunities for ongoing training and feedback from AmeriCorps or Learn and Serve participants and programs, community partners of AmeriCorps or Learn and Serve programs, State Commissions, Corporation staff, and others;

—Commitment to build on existing resources and collaborate with other technical assistance providers; ability to coordinate planning, development, and execution with other providers; efforts to prevent duplication of work or inefficient use of resources; and ways to establish networks with other T/TA providers to ensure coordination among providers and presentation of a clear, coherent set of assistance activities to programs, states, and the Corporation; and

—Cost-effectiveness of proposed activity, the degree to which the T/TA provider proposes a reasonable estimate of the amount of services the organization will be able to provide given the requested amount of funds and the organization's existing resources.

Organizational Capacity (45%). Applicants should demonstrate evidence of either organizational experience and success in delivering high-quality technical assistance and training, particularly in the specific area under consideration, or the similar experience of identified staff retained for the T/TA project. Backgrounds of key staff, leadership, and other individuals proposed to contribute to the proposed program will be considered in assessing organizational capacity.

In some cases, the capacity to begin providing training and/or technical assistance quickly will be required. In certain instances, noted in the description of applicable activities, services will be needed as early as summer 1994. The applicant must demonstrate the ability to provide high quality services in the desired time frame.

Innovation and Replicability (10%). The Corporation will assess the extent to which the T/TA activity, or its

elements, are creative or distinctive in approach or in the need that is met.

The Corporation will assess the degree to which the proposed T/TA activity could serve as a long-term resource by identifying other sources of funding and the extent to which the activity or its elements are applicable or adaptable to various program types, locations, or approaches to service.

In addition, the Corporation will assess the use of innovative technology in providing training or technical assistance, where appropriate. This criterion includes use of technology to increase access to training and technical assistance activities and convenience for users. For example, an information session might be conducted by video conference, allowing users to participate from a local facility and avoid travel costs. The Corporation expects that all of its program grantees will be connected through on-line networks. Training and technical assistance providers will be expected to be connected to electronic networks as well and should be prepared to use technology and to distribute information through on-line networks when appropriate.

Requirements

There are certain requirements that every recipient of a T/TA grant or cooperative agreement must fulfill. They include the following provisions:

(a) T/TA providers must work closely with Corporation staff and other T/TA providers, especially the "National Service Resource Center" described in the "Concept Paper" section below. Providers must be willing to receive input from Corporation staff during development and delivery of T/TA activities; periodically attend meetings and conferences at the Corporation's request; inform other T/TA providers of plans and progress and coordinate efforts when appropriate; and work with Corporation staff to assess the direction and value of each T/TA activity every six months and modify T/TA activity to better serve the users of T/TA and adapt to changing needs.

(b) T/TA grantees must develop and continually apply mechanisms for assessing the value and impact of their T/TA activities and show evidence of continuous program improvement resulting from the application of such mechanisms.

(c) While the Corporation has a vested interest in promoting best practices throughout the field, to grantee and potential grantees alike, grantees will be given preference when resources are limited.

(d) Databases or other on-line materials should be created in Foxpro or Oracle software. This will allow easy data transfer both to the Corporation and among T/TA grantees. Assistance may be available to convert existing databases to Foxpro or Oracle if necessary.

TRAINING AND TECHNICAL ASSISTANCE ACTIVITIES

The Corporation expects to give grants to or enter into cooperative agreements with organizations to accomplish the following activities.

(I) Application by Proposal

Proposed T/TA activities in this category include:

(A) Technical Assistance and Training for the National Leadership Corps.

(B) Maintaining a Strong Organization.

(C) National Priority Skills Development Centers.

(A) Technical Assistance and Training for the National Leadership Corps

—Proposals due May 3, 1994.

—Must be able to deliver services by July 1, 1994.

Summary

The National Leadership Corps will create a diverse cadre of emerging service leaders to help build the highest quality AmeriCorps programs and strengthen the national service infrastructure and identity. In the first year, the Corporation will recruit up to 50 members from programs such as Peace Corps, VISTA, the Armed Forces, youth corps, and other full-time service programs. T/TA providers will help design and carry out initial training for the Corps which will last two to five weeks and begin in mid-July or early August, 1994. Providers will also help with ongoing training which will occur at least three times during the year. Leadership Corps (LC) members will bring skills and expertise to new AmeriCorps programs in year-long assignments starting September, 1994.

Amount and Duration of Funding

The Corporation expects to issue one or more grants or cooperative agreements totaling approximately \$100,000 to accomplish the tasks listed below. Funding would be for one year, with possibility of renewal subject to performance, continuing need, and availability of funds.

Description of T/TA Activities Desired

The Corporation seeks T/TA providers who will work with Corporation staff and other T/TA

providers to design and deliver training for the Leadership Corps.

Proposals may address one or all of the activities outlined below, or may suggest additional activities. These include:

—*Team building* among Leadership Corps members. Since LC members will be placed in separate AmeriCorps programs around the country, it is important that members develop strong bonds with each other during training so that they are able to provide support to each other and share resources, ideas, and lessons learned throughout their experience.

—*Specialty skills*. This component of training will give LC members an understanding of how to organize and carry out projects that meet community needs in one or more of the Corporation's national priority areas. (The national priorities areas are discussed more fully in the "National Priority Skills Development" section below). This element of training will ensure that members know how to make demonstrable impacts on specific community problems and bring resources to programs that do not already exist.

—*Leadership skills*. Training that helps LC members master the main tasks required of front-line supervisors such as group facilitation, organizing and managing service projects, team building, handling conflict, community relations, working with diverse peoples and organizations, and others.

—*Communication skills*. Training that teaches LC members how to communicate effectively, including public speaking and media training.

Proposals should include a plan to train leaders in any or all of the activities mentioned above over a 2–5 week period during the initial training in July, 1994, as well as periodically throughout the year. The Corporation intends to involve leaders in curriculum design for ongoing training, so applicant plans should be flexible enough to accommodate their input.

Encouraged Approaches

While the Corporation will consider any proposal that accomplishes one or more of the activities listed above, it especially encourages the following approaches:

(a) A proposal by an organization that has experience and expertise in one or more of the components listed above and can arrange to have expert resources and information available starting in mid-May to provide assistance to the Corporation in designing and delivering training.

(b) A proposal by a consortium of organizations whose members collectively have the expertise to work with the Corporation to provide all of the training components listed above. This sort of proposal should clearly describe the specific responsibilities of each provider, the amount of funds to be allocated to each, the amount of staff time devoted by each, and the mechanisms for cooperation and coordination among members and the Corporation. If possible, the consortium should have experts available to work with the Corporation starting in mid-May as discussed above. For more information on the leadership pool, please contact Jane Marsh at (202) 606–5000, extension 173.

(B) Maintaining a Strong Organization: Fundraising, Program Management, Evaluation, Fiscal Administration, and Grievance Procedures

—Proposals due May 18, 1994.

—Preference will be given to organizations which can have the majority of services available by August 1994.

Summary

Strong management, well-planned and well-executed fundraising, evaluation, and careful, appropriate administration of funds are critical to the success of AmeriCorps programs. The Corporation will fund activities that provide information, training, and technical assistance to State Commissions and AmeriCorps programs to strengthen the ability of programs to manage, fundraise, and leverage community resources, design and perform program evaluation, administer funds effectively, establish grievance procedures, and perform other critical functions.

Amount and Duration of Funding

The Corporation expects to make up to five grants or cooperative agreements in this area. Together, grants will total approximately \$1,000,000. Grants will be for one year, with the possibility of renewal based on performance, need, and availability of funds.

Description of T/TA Activity Desired

Specific tasks include but are not limited to providing, arranging for, or connecting programs to information, training, and technical assistance on the factors involved in establishing and maintaining a strong organization, including:

(a) *Fundraising*: Building on existing Corporation materials, assist grantees in developing comprehensive fundraising strategies. Proposals may also describe

ways in which technical assistance can help organizations put fundraising plans into action. The Corporation has an interest, as manifested through the match requirement, to encourage grantees not to rely solely on Corporation funds, but rather to solicit a broad range of financial and in-kind resources from foundations, corporations, individuals, and other governmental agencies. As the match increases, grantees will need to raise additional funds, create more partnerships, build larger constituencies, and leverage additional resources. Technical assistance should be designed with this mission in mind.

(b) *Program Management*: Help programs build a strong leadership team as well as feedback mechanisms such as participant advisory councils or other vehicles which allow for regular input from participants and/or community members and involve them in program design, operation, and evaluation.

(c) *Evaluation and organizational development*: Help programs use evaluation as a tool for program improvement. Aid them in developing a mission statement, goals, and annual objectives, concrete operating plans, and tailored evaluation strategies. As needed, work with Corporation evaluation staff to create materials, develop and conduct trainings, and/or offer technical assistance to State Commissions and AmeriCorps programs related to setting direct and demonstrable objectives and performing program monitoring and evaluation functions.

(d) *Fiscal Management*: Building on Corporation materials, help establish appropriate and effective fiscal management and accounting processes, including compliance with all federal laws and regulations.

(e) *Grievance Procedures*: Help grantees develop grievance procedures that give programs systems in which to resolve disputes with staff members, program participants, community residents, and others. These procedures should comply with the requirements for grievance procedures described in the National and Community Service Trust Act of 1993.

In each case, providers are expected to:

—Bring to bear existing training and subject expertise. Efforts will focus on arranging or providing assistance, rather than developing new training and resources using Corporation funds;

—Comply with federal requirements for administering federal funds. The T/TA provider will work with Corporation staff as needed to develop training on this topic;

—Demonstrate a commitment to and experience in evaluation that examines outcomes and uses its findings as tools for redesigning and improving program activities and approaches; and

—Assist Corporation evaluation and T/TA staff in providing other training or technical assistance, as requested.

Encouraged Approaches

While the Corporation will consider any proposal that accomplishes the activities listed above, it encourages the following approaches:

(a) A proposal that includes a partnership among providers who together can offer training and technical assistance in the areas listed above and who together have a presence across the country that enables them to provide training and assistance regionally. Such a proposal must clearly describe the specific responsibilities of each partner, the amount of funds to be allocated to each, the amount of staff time dedicated by each, and the mechanisms for cooperation and coordination among partners and the Corporation.

(b) A proposal that includes a partnership of which at least one member has experience providing training and technical assistance in complying with federal requirements for administering federal funds.

(C) National Priority Skills Development Centers

—Proposals due June 1, 1994.

—Preference will be given to applicants that can begin delivering assistance by August 1994.

Summary

National Priority Skills Development Centers will help meet the short-term, immediate training and technical assistance needs of the Corporation, states, and AmeriCorps programs in their efforts to make direct and demonstrable impacts in the areas of need the Corporation has identified as "national priorities." The Centers will provide information and hands-on support, create networks and expert groups, and carry out other activities as needed.

National Priority Skills Development Centers also provide an opportunity to begin developing resources to serve the service field over the long-run. Based on the lessons learned and foundations laid by the Skills Development Centers, grantees may begin to develop "Centers of Excellence." Centers of Excellence will serve as more permanent resources for the service field and as such, will receive a much more significant investment of funds from the Corporation. These Centers will be

much larger than the Skills Development Centers. Over time, they will develop more extensive expertise in the practices that make for high-quality, effective service programs in various priority area fields.

At present, funding is only available for the Skills Development Centers. The Corporation encourages providers to devote some of their resources to developing plans to expand their Skills Development Center(s) into more comprehensive and permanent Center(s) of Excellence.

Need

AmeriCorps programs must achieve direct and demonstrable results in the areas of education, public safety, health, human needs, and the environment. Programs funded through the AmeriCorps direct competition must achieve the results in more specific national priority areas. The national priority areas are as follows:

In Education:

—*School Readiness*: furthering early childhood development.

—*School Success*: improving the educational achievement of school-age children and adults who lack basic academic skills.

In Public Safety:

—*Crime Control*: improving criminal justice services, law enforcement, and victim services.

—*Crime Prevention*: reducing the incidence of violence.

In Human Needs:

—*Health*: providing independent living assistance and home- and community-based health care.

—*Home*: rebuilding neighborhoods and helping people who are homeless or hungry.

In Environment:

—*Neighborhood Environment*: reducing community environmental hazards.

—*Natural Environment*: conserving, restoring, and sustaining natural habitats.

The Corporation will fund Skills Development Centers to help programs and participants achieve demonstrable results in these areas by providing them with training, information, technical support, and other resources. T/TA providers will be expected to work closely with service programs so that providers' expertise in how to make impacts in certain needs areas is complemented by an understanding of service programs, regardless of the area of need addressed. The "Principles of High Quality National Service Programs" document mentioned in the Background section more extensively describes the Corporation's current

thinking in these areas. Applicants should have the expertise to expand the Corporation's thinking and the ability to help make programs working in each area more effective.

Amount and Duration of Funding

The Corporation will make available approximately \$1,500,000 for all activities. Up to eight Skills Development Centers may be funded to provide the T/TA activities described below. Grants will range from \$50,000 to approximately \$300,000, with most awards between \$100,000 and \$150,000. Up to \$25,000 of each award can be used in planning for a future "Center of Excellence" in the priority area addressed. Grants or cooperative agreements will be for up to one year, with the possibility of renewal or of an award to implement a "Center of Excellence," subject to performance, need, and availability of funds. There is no guarantee of renewal or implementation award.

Description of T/TA Activity Desired

The Corporation will fund Skills Development Centers to help programs and participants meet needs in the areas listed below. Applicants may propose to provide T/TA in one or more areas. Applicants may also combine areas rather than running two distinct Centers, for example, as long as the applicant's proposal provides an explanation of the manner in which the needs of each area can be addressed when combined with others.

Skills Development Centers will be developed in the following areas:

Crime Control: T/TA activities to help programs improve criminal justice services, enforcement, and victim services.

Crime Prevention: T/TA activities to help programs and participants reduce the incidence of violence.

Early Childhood Development: (including the Corporation's School Success priority) T/TA activities to help programs and participants further early childhood development.

School Success: T/TA activities to help programs and participants improve educational achievement.

Comprehensive Services: (including the Corporation's Home and Neighborhood Environment priorities) T/TA activities to help programs and participants link community resources together to provide for disadvantaged residents' basic needs.

Preventive Health Care: T/TA activities to help programs and participants successfully carry out health outreach, education, and prevention campaigns.

Independent Living: T/TA activities to help programs and participants provide independent living assistance and home-based health care.

Natural Environment: T/TA activities to help programs and participants conserve, restore, and sustain natural habitats.

In each case, Skills Development Centers are expected to:

(a) *Develop and/or maintain a network of geographically dispersed expert resource people and organizations around the country and maintain a database of these resources.* Providers should identify expert resources from the specific field—organizations and individuals—that the Corporation, state commissions, and programs can access when needed. A database, developed in Foxpro or Oracle software, with pertinent information about these expert resources should be maintained and linked to the National Service Resource Center database (described below) so that capacity building is ensured. The provider should train resource people as needed to make sure that they provide useful assistance; receive regular feedback from T/TA customer's on resource peoples' performance; and work with Resource Center staff to make recommendations on how to "certify" trainers and other T/TA providers should the Corporation decide that this is necessary. The provider should also gather information from Corporation staff, state commissions, programs, and other T/TA grantees in order to expand the pool of resources in the database.

(b) *Provide hands-on support to programs using the network of expert trainers and other resource people.* Working with the National Service Resource Center, National Service Skills Development Centers should respond to individual requests for assistance from the Corporation, state commissions, or programs to provide help with project design and implementation, specific project improvement issues, or other forms of training and technical assistance. Applicants should estimate how many person days they expect to devote to this and how many people and/or programs they think they have the capacity to serve. Whenever possible, T/TA providers should use local resource people to carry out these tasks. This way, T/TA efforts will help build capacity and relationships on the local level.

(c) *Demonstrate an understanding of the central characteristics of successful service programs.* T/TA providers are expected to have expertise in the specific fields their T/TA will cover (e.g. crime prevention) so that they can help

service programs produce direct and demonstrable results in those areas. Providers must also understand the more generic, common components of successful service programs, regardless of what needs service programs address. For suggestions on how to gain this knowledge, see "Encouraged approaches" below. Providers will be expected to collaborate with other Corporation T/TA providers, particularly those working to "Strengthen the Basics of National Service Programs" (as described in section below).

(d) *Gather and provide critical information on at least one of the priority areas.* T/TA providers should identify the most important information and resources (including databases) from the specific field(s) addressed. This might include training curricula, standards of best practice, examples of effective practices in service and community work, and in project planning, and participant training and support specific to the needs of that field. Providers should focus their efforts by gathering the 50 or so "best" resources. The resource materials should be made available to the National Service Resource Center and should be adapted to meet the needs of Corporation staff, state commissions, and AmeriCorps programs where necessary. (Reproduction and distribution issues will be negotiated in the terms of the grant.)

(e) *Convene an expert group.* With input from the Corporation, regularly convene a sounding board of leading individuals from the priority area field, the service community, and other areas to develop an agenda for T/TA activity in each priority area.

(f) *Plan for a "Center of Excellence."* T/TA providers should lay the groundwork for more established future "Centers of Excellence," focusing on particular priority areas. Providers are encouraged to develop a plan to submit to the Corporation by January, 1995, for a potential "Center of Excellence" in a specific area. A maximum of \$25,000 may be expended for this planning activity, and there is no guarantee of future funding from the Corporation.

(g) *Assist in applicant outreach.* Providers may be asked to assist the Corporation in reaching out to potential AmeriCorps program applicants in the priority area(s) addressed.

Encouraged Approaches

While the Corporation will consider any proposal that accomplishes the activities listed above, it encourages the following approaches:

—Proposals by a small consortium of organizations that include at least one organization with expertise in each national priority area being addressed, and at least one organization with experience in the operation of service programs. Service programs will help organizations with issue-area expertise better understand issues such as participant recruitment, selection, training and preparation, management, and support; and project issues including project conception and selection, formation of working relationships with service sponsors, orientation of service sponsors, and project management and evaluation.

—Proposals in which the organization(s) providing expertise in specific priority area(s) has a partnership with a service program or operates a service program, and where it tests project models and T/TA models directly in the program as it develops them for national use.

For example, a proposal in the area of school readiness might include a national center that does program development and assistance in the early childhood area, and which operates its own pre-school program. The center would test certain service projects in its program, and test training for participants who work in the program. These activities would help refine and improve the training and technical assistance it offers to national service programs funded by the Corporation.

(II) Application by Concept Paper

Proposed activities in this category include:

- (A) National Service Resource Center
- (B) Strengthening the Basics of National Service Programs
- (C) Service and Citizenship
- (D) Strengthening Program Diversity
- (E) Peer Exchange Visitation Program
- (F) Learn and Serve America K-12—Resource Publications
Training Initiatives on Service-Learning
- (G) Learn and Serve America Higher Education—
Higher Education Service Resource Center
Institutionalizing Service-Learning Infrastructure and Capacity-Building
- (H) Training and Technical Assistance for State Commissions

Concept papers will be accepted on May 27, 1994 and September 13, 1994. Following the May deadline, the Corporation expects to invite likely applicants to submit a detailed proposal by June 30, 1994.

(A) National Service Resource Center

—Preference will be given to applicants which can begin delivering assistance by August, 1994.

Summary

The Corporation seeks to provide a National Service Resource Center to compile, store, and retrieve the T/TA resources provided by the Corporation and other T/TA providers. Rather than producing materials and resources, the resource center will ensure that State Commissions and AmeriCorps programs have easy access to the T/TA services and resources other T/TA providers produce.

The Resource Center will develop and manage the following:

—A *resource library* that gathers training curricula, effective strategies for program planning and management, and other information and materials from Corporation T/TA providers and the service field. The Resource Center will also develop means of dissemination, both in print and through electronic outlets.

—A *start-up survey* of T/TA providers around the nation who can meet needs of State Commissions and AmeriCorps programs. This survey should be done as quickly as possible, to provide an immediate resource for Corporation grantees, and to establish the foundation for the long-term project of creating and developing a comprehensive database for the directory service.

—A *T/TA directory service* that draws on the start-up survey and subsequent database to respond to queries for information from state commissions and national service programs in search of trainers, consultants, and other resources. On a toll-free assistance line, trained information specialist(s) will respond to day-to-day questions and inquiries from grantees, state commissions, and Corporation staff, matching their needs with T/TA services whenever possible. The Resource Center will be responsible for marketing the directory service to AmeriCorps programs and State Commissions in order to make its services as accessible as possible and may make the directory service database available to them through print and/or electronic means.

AmeriCorps program grantees will be required to assess the T/TA they use and report back to the Corporation program staff and the Resource Center with their evaluations. This information will inform Resource Center listings and eventually may serve as the foundation for a system of consumer-based T/TA service provider ratings. The Resource

Center will be expected to make recommendations to the Corporation on how to certify T/TA providers should the Corporation decide that this is necessary.

Grantee evaluations are especially important in the case of T/TA purchased with the up to \$5,000 of discretionary T/TA money each AmeriCorps program grantee will be allotted. The purpose of these funds is to flexibly meet immediate program needs not met by other Corporation- or state-funded T/TA services, tap grantee-based networks, and help to establish a consumer-driven marketplace. The Resource Center, working closely with Corporation staff, will be the repository for all grantee evaluations of T/TA and will incorporate those evaluations into the resource library and directory service.

Amount and Duration of Funding

The Corporation will make available one grant totaling approximately \$500,000. The grant or cooperative agreement will be issued for 18 months, with no guarantee of renewal but possibility of renewal based on performance, need, and availability of funds.

Requirements

—The resource library staff must work closely with Corporation staff to make sure that the Corporation's own internal resource room is kept up to date with important materials and other pieces of information.

—The Commission on National and Community Service, predecessor to the Corporation, awarded funds to a consortium of organizations led by the National Youth Leadership Council to establish a clearinghouse for information and technical assistance on service-learning primarily for K-12. To avoid duplication of effort and unnecessary costs, will be expected to refer interested parties to the Service-Learning Cooperative and coordinate other efforts with them whenever possible.

—Providers must use Foxpro or Oracle software when establishing any databases.

(B) Strengthening the Basics of National Service Programs

—Preference will be given to applicants who can begin delivering assistance August 1994.

Summary

The Corporation will fund T/TA activities that help programs strengthen the basic components that enable programs to implement excellent service

projects and engage participants in addressing vital community needs. The Corporation hopes that many seasoned service providers will share their expertise with others in the service field through these activities.

The Corporation describes many of these components in the second half of its "Principles of High Quality National Service Programs." Opportunities to provide technical assistance supporting several of these components—building a strong organization, evaluation procedures, and developing fundraising expertise—are listed in the "Maintaining a Strong Organization" section of this Notice. Here, the Corporation encourages potential grantees to provide assistance in—

- Designing excellent service projects;
- Providing a high quality participant experience through participant preparation and support;
- Front-line supervisor training;
- Training in mediation and conflict resolution; and
- Creating strong community partnerships.

Amount and Duration of Funding

The Corporation expects to make available approximately \$500,000 total for up to 10 grants or cooperative agreements with 18 month durations. The possibility of renewal is subject to performance, continuing need, and availability of funds.

Description of T/TA Activities Desired

The Corporation would like T/TA providers to provide trainings and/or develop resource materials in the following areas:

Excellent service projects: Develop strategies and provide trainings to increase the effectiveness of national service programs at conceiving, planning, and executing excellent service projects, regardless of the area of need addressed by them.

Participant training and support: Develop strategies and provide trainings to program staff on the key elements of orienting and training program participants in all types of service programs.

Front-line supervisor training: Develop strategies and provide trainings on ways to train and support front-line supervisors—whether team leaders or coordinators of individually-placed participants—to supervise and support participants in all types of national service programs. Activities could include developing ways to help program directors and/or other program supervisors address the professional development needs of their front-line supervisors; designing support

structures for front-line supervisors such as peer networks, on-call resources, or resource lists; or preparing flexible designs for training modules for regional conferences or trainings.

By July 1995, the Corporation would also like the T/TA provider(s) in this area to train approximately 30-35 groups of supervisors in key tasks including but not limited to:

- Planning and managing service projects or internship placements;
- Management and development of participants;
- Creating good working relationships with service sponsors, and other community members and organizations;
- Teambuilding at various levels among participants, with community partners, and among staff;
- Communication at all levels, within the program, with media, with community through other vehicles
- Facilitation of service-learning among participants that encourages their development into engaged, active citizens.

Conflict resolution and mediation: developing strategies and providing trainings to program staff and participants on how to deal effectively with conflicts through conflict resolution and mediation techniques.

Community Partnerships: developing strategies and providing trainings on ways to help programs build and maintain strong partnerships and engage in collaborative efforts with a broad range of organizations and individuals working to solve community problems.

For each activity listed above, T/TA providers will be expected to:—Coordinate efforts with other T/TA providers, especially the "National Priority Skills Development Centers" and the "National Service Resource Center";

- Provide hands-on training, consulting and other services on the subject;
- Identify best practices in accomplishing these tasks, adapt as necessary and package for program use. Material might include management tools, training curricula, or other useful items; and
- In the long term, lead the development and refinement of best practices in accomplishing high quality service projects.

(C) Service and Citizenship

Summary

The Corporation will fund T/TA activities that help programs develop participants' understanding of the relationship between service and the rights and responsibilities that citizenship entails.

Amount and Duration of Funding

The Corporation expects to make approximately \$100,000 total available for up to two grants or cooperative agreements. Grantees will develop and pilot a variety of training curricula with several AmeriCorps programs, with the aim of developing trainings that can meet the needs of many different participants and program types. The possibility of renewal is subject to performance, continuing need, and availability of funds.

Description of T/TA Activities Desired

Whether addressing immediate community problems or examining broader social needs, AmeriCorps participants take on a variety of civic responsibilities. The Corporation will fund the provision of technical assistance and training to enable AmeriCorps participants to constructively examine and explore larger issues associated with their service work and strengthen their understanding of their engagement in public life.

(D) Strengthening Program Diversity Summary

The Corporation will fund the development and implementation of a strategy to provide technical assistance and training to AmeriCorps programs and State Commissions on how to enhance their work, build stronger communities, and draw strength from diversity through full inclusion of diverse populations of participants in programs. This will include developing strategies which encourage mutual respect and cooperation among citizens of different races, ethnicities, socioeconomic backgrounds, educational levels, ages, and sexual orientations, including both men and women and individuals with both physical and cognitive disabilities.

Amount and Duration of Funding

The Corporation expects to make three or more grants or cooperative agreements in the first year. The amount of funds will be determined in light of need. The possibility of renewal is subject to performance, continuing need, and availability of funds. In its concept paper the applicant should present a proposed budget for the first and second years of activity.

Description of T/TA Activities Desired

The Corporation will fund the provision of technical assistance and training and development of resource materials for State Commissions and AmeriCorps programs to give them

practical guidance on how to build diversity into programs and identify resources, especially local and regional resources, which they can tap for these purposes when needed.

Possible activities include—

- Strategies to improve recruitment, retention, and training of diverse staff and program participants;
- Strategies to find appropriate participant placements;
- Ways to ensure that programs are sensitive to the specific cultural needs of the community in which the service is being performed;
- Strategies specifically aimed at recruiting and ensuring full inclusion of people with physical and cognitive disabilities as participants in AmeriCorps programs;
- Ways to help AmeriCorps programs comply with laws regarding accommodation of people with disabilities; and
- Other strategies to assist programs in building diversity into their programs.

T/TA providers will be expected to work closely with the National Service Resource Center.

(E) Peer Exchange Visitation Program Summary

The Corporation seeks to enhance the opportunities for program planners, staff and participants of AmeriCorps programs, and State Commission members to visit existing service programs in order to learn more about different approaches to accomplishing high quality service. To this end, the Corporation is making funds available to existing service programs to prepare for and host such visits.

Eligible Applicants

Only existing service programs may apply. While an applicant does not have to be a former or current grantee of the Corporation or the Commission on National and Community Service, the applicant should demonstrate that the program activities it will exhibit to visitors are consistent with the Corporation program requirements and "Principles for High Quality Programs."

Amount and Duration of Funding

The Corporation expects to make up to ten grants totaling approximately \$200,000. Grants will be for one year, with possibility of renewal subject to performance, continuing need, and availability of funds.

Description of T/TA Activities Desired

The applicant should accomplish activities including but not limited to—

—Making Corporation grantees aware of the opportunity to visit by being included in Corporation communications that list T/TA opportunities;

—Helping potential visitors determine if a visit would be of use to them, and helping them select an appropriate delegation to visit;

—Preparing a visit schedule for each group of visitors that includes relevant aspects of the program they should see. Possible activities should include observing project work, talking with participants, staff and/or service sponsors and other community partners, attending program meeting or educational activities, etc.;

—Facilitating a debriefing session or discussion in which the visitors may discuss questions or concerns regarding what they have seen and learned; and

—Providing a small amount of follow-up contact with visitors, especially in cases where the visitor wishes to adopt a practice observed during the visit. Note that the host organization will not be expected to pay for the travel costs of the visitors.

Requirements

—Program activities to be exhibited to visitors must be consistent with the Corporation's program requirements and "Principles for High Quality Programs."

—The grantee must report regularly to the Corporation on visits: number of visits, who visited, what was presented, some assessment of the value gained by visitors, and any improvements planned for the visitation program.

(F) Learn and Serve America K-12

Resource Publications

The Corporation will fund development and publication of materials on critical subjects to the field.

Amount and Duration of Funding

Up to three grants totaling approximately \$50,000 will be made available. Funding is for one year, with possibility of renewal subject to performance, continuing need, and availability of funds.

Description of T/TA Activities Desired

Focus areas may include service-learning evaluation models, case studies, linking service-learning to education reform or school restructuring efforts, integrating service-learning into school-to-work transition initiatives, integrating service-learning into academic curricula, and other topics that would be useful in advancing the service-learning field.

T/TA providers will be expected to coordinate resources and activities with

the National Service Learning Cooperative funded by the Commission on National and Community Service whenever possible.

Training Initiatives on Service-Learning

The Corporation will fund training in service-learning methodology for teachers, administrators, community-based organization personnel, potential trainers and other appropriate individuals.

Amount and Duration of Funding

Up to four grants totaling approximately \$480,000 will be made available. Funding will be for one year, with possibility of renewal subject to performance, continuing need, and availability of funds.

Description of Program Desired

The Corporation is interested in a broad range of training opportunities that include regional seminars, introductory workshops, institutes with specific focus areas (i.e. engaging youth with disabilities in service-learning, linking service-learning to education reform or school-to-work transition initiatives, or service-learning as a vehicle for addressing specific educational, public safety, human, or environmental needs).

(G) Learn and Serve America: Higher Education

Summary

The Corporation seeks to enhance the quality and sustainability of higher education service-learning programs, through T/TA activities that offer ready resources for effectively integrating service and education, that help strengthen institutional commitment to service-learning, that develop the ability of grantees to support one another, and that build capacity at state, regional, and national levels to support campus-based service-learning.

The Corporation will make grants or cooperative agreements for the following activities:

Higher Education Service Resource Center

Summary

The Corporation will fund T/TA activities that provide detailed, user-friendly resources and consultation to meet the needs of individual programs, Corporation staff, and State Commissions. This resource center should focus on service-learning in higher education, and should be flexible in its design so that its resources may be integrated eventually with the National Service Resource Center and/or the

National Service Learning Cooperative funded by the Commission on National and Community Service.

Amount and Duration of Funding

One grant or cooperative agreement of approximately \$100,000 will be made, with the possibility of renewal.

Description of T/TA Activities Desired

Specific tasks include but are not limited to—

—Actively collecting, selecting, organizing, and disseminating information on model programs, best practices, and innovations in the higher education service-learning field;

—Developing resources on various subject areas, including service integrated with academic disciplines, service-learning programs addressing community needs in the national priorities, critical reflection, co-curricular service-learning, and evaluation of service-learning programs;

—Regularly providing grantees, Corporation staff, and State Commissions with an updated inventory of resources, and responding to their questions and requests for information; and

—Working with Corporation staff and grantees to identify areas requiring resource development.

Providers will be expected to:

—Have experience in collecting and disseminating information that is relevant to the higher education service-learning field;

—Demonstrate an ability to set and adhere to high standards of quality in collecting and reviewing resources;

—Apply in partnership with one or more organizations in order to broaden the scope of information and constituencies connected to the resource center;

—Have adequate electronic capacity and staff to manage efficiently a high volume of incoming and outgoing information;

—Be equipped to participate in a phone system, on-line computer network, or other technological systems, as instructed by the Corporation; and

—Be prepared to work closely with the K-12 service-learning clearinghouse funded by the Commission on National and Community Service, toward the goal of integrating all the resource matching and clearinghouse efforts funded by the Corporation.

Institutionalizing Service-Learning

Summary

The Corporation will fund T/TA activities that help bring sustainability to programs in institutions of higher education.

Amount and Duration of Funding

One or two grants or cooperative agreements of approximately \$150,000 will be made, with the possibility of renewal.

Description of T/TA Activities Desired

Specific tasks include but are not limited to—

- Engaging faculty, administrators, students, and/or community partners from funded programs in intensive strategic planning, tailored to the needs of each program, on how to make the program a permanent part of the institution;

- Creating mechanisms that enable faculty members with expertise in service-learning to provide ongoing, hands-on support to their peers on integrating service with specific academic disciplines and expanding faculty interest and involvement in service-learning within institutions;

- Providing ongoing consultation to programs on effective strategies for securing support from the institution's top administrative and academic leadership;

- Developing resource materials that present "case studies" describing the evolution and institutionalization of high-quality service-learning programs, courses, and centers on a diverse array of college and university campuses.

Providers will be expected to:

- Have experience in guiding service-learning programs beyond the start-up phase and into a stage of stability and institutionalization;

- Have sufficient organizational resources and stature in the higher education service-learning field to work effectively with faculty members and top administrative and academic officials; and

- Coordinate the distribution of resource materials and the implementation of workshops or institutes with the Corporation staff.

Infrastructure- and Capacity-Building Summary

The Corporation will fund T/TA activities that develop the ability of grantees to support one another, and that build capacity at state, regional, and national levels to support campus-based service-learning.

Amount and Duration of Funding

One or two grant(s) or cooperative agreement(s) of approximately \$200,000 will be made, with the possibility of renewal.

Description of T/TA Activities Desired

Specific tasks include but are not limited to—

- Organizing regional conferences that convene grantees in early 1995 (after the first quarter or semester of activity) and that address T/TA needs identified by the Corporation staff;

- Developing from the regional conferences a variety of facilitated mechanisms—utilizing electronic networks and other technology—that enable grantees to build and sustain supportive relationships with one another;

- Working closely with Corporation staff to conduct outreach to State Commissions and higher education organizations and associations to encourage their attendance at the regional conferences, to orient them to higher education service-learning programs and build their capacity to support service-learning at state, regional, or national levels; and

- Developing and implementing a strategic follow-up plan that sustains and strengthens relationships and initiatives catalyzed by the regional conferences.

Providers will be expected to:

- Have sufficient expertise, contacts, and organizational capacity to plan regional conferences for up to 150 higher education service-learning grantees;

- Work in partnership with organizations or individuals with expertise in structuring sustainable peer networks that facilitate lateral knowledge transfer (i.e., peer-to-peer technical assistance);

- Have at least some experience in working with state commissions and higher education organizations and associations;

- Have adequate capacity, creativity, and flexibility to channel the momentum developed at the regional conferences toward longer-term efforts and objectives, and to identify and respond actively to needs for on-going follow-up.

(H) Training and Technical Assistance to State Commissions**Summary**

The Corporation will fund provision of information, training, and support to all State Commissions involved in AmeriCorps, as provided by the National and Community Service Trust Act of 1993. This can be provided by independent organizations or by the States themselves, acting as peer trainers.

Amount and Duration of Funding

Up to three grants or cooperative agreements totaling approximately \$400,000. Funding would be for one

year, with possibility of renewal subject to performance, continuing need, and availability of funds.

Description of Program Desired

T/TA activities may address one or more of the following issues, or may address other issues as proposed by the applicant:

- Help states develop a technical assistance strategy and network of possible T/TA providers within their states;

- Assist states in setting objectives and designing and implementing an evaluation plan;

- Help states develop specific state-wide recruitment strategies that are consistent with the Corporation's national recruitment plan;

- Help states design peer review panels;

- Help states design participant advisory groups and other vehicles through which they can engage participants in decision-making processes and feedback mechanisms;

- Provide orientation or training to State Commission members and staffs about national service and the role of State Commissioners; and

- Provide other training or assistance to State Commissions as needed.

(III) Invitation for Original Concept Papers Proposing Additional or Alternative T/TA Activities

The Corporation has created a National Program Innovation Fund, through which it will support innovative training and technical assistance that helps make programs more effective.

The Corporation requests concept papers which suggest ways in which it might best support its goals through T/TA activities. Concept papers may expand on the activities specified in this Notice, improve on them, or suggest original approaches.

In proposing an original activity, the applicant must demonstrate a need for it that relates to the goals of AmeriCorps, present a sound plan for accomplishing the activity, and otherwise satisfy the quality criteria listed in this Notice.

An applicant may propose an original concept under this section and apply at the same time to undertake one or more of the activities listed in another section.

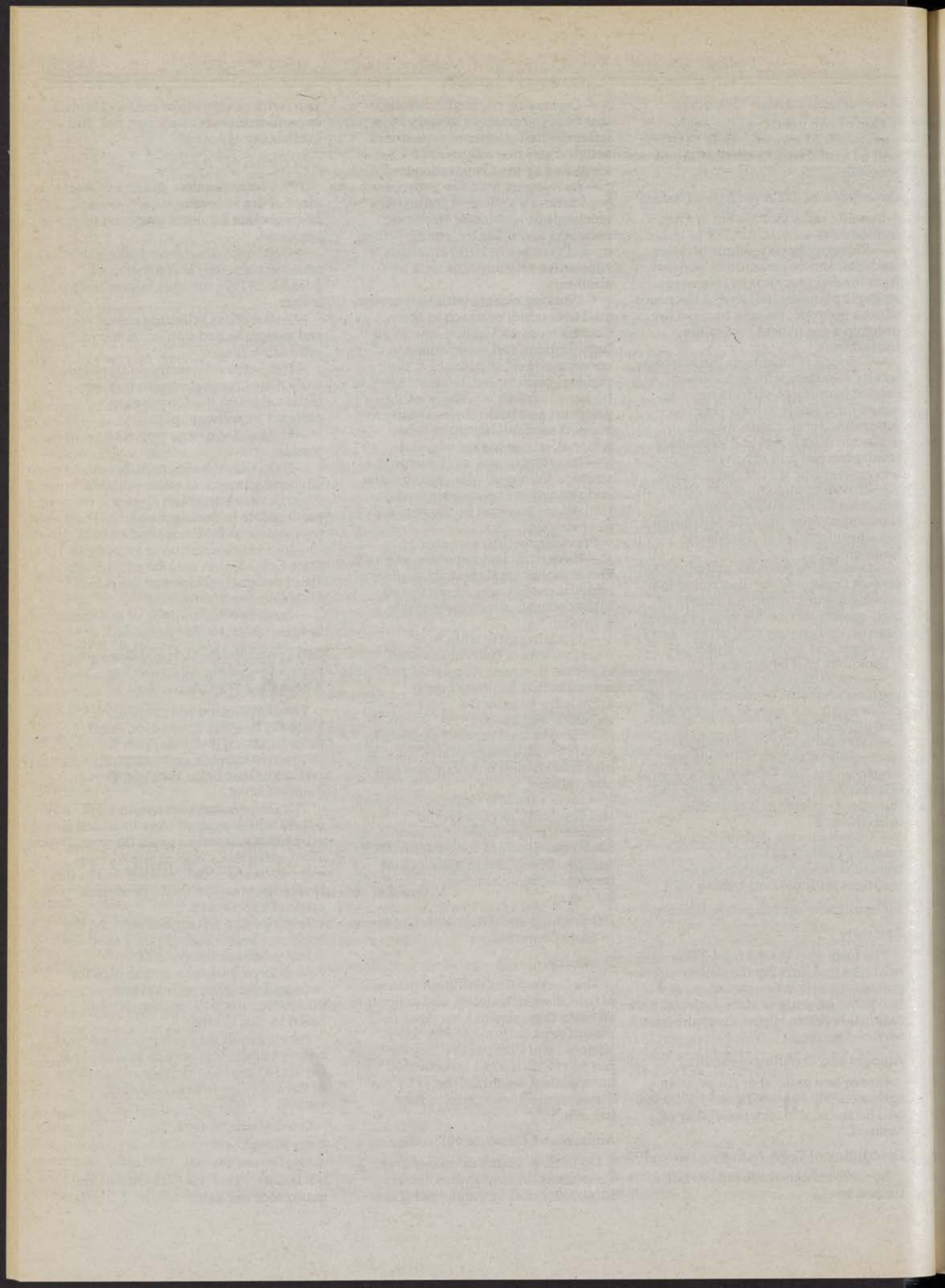
Dated: March 22, 1994.

Terry Russell,

Acting General Counsel.

[FR Doc. 94-7146 Filed 3-25-94; 8:45 am]

BILLING CODE 6820-BA-P



Registered Federal Food

Monday
March 28, 1994

Part X

**Department of
Agriculture**

Food Safety and Inspection Service

9 CFR 317 and 381

**Mandatory Safe Handling Statements on
Labeling of Raw Meat and Poultry
Products; Final Rule**

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 93-026F]

RIN 0583-AB67

Mandatory Safe Handling Statements on Labeling of Raw Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to make safe handling instructions mandatory on all raw meat and poultry product labeling. The handling instructions include a rationale statement and address safe storage of raw product, prevention of cross-contamination, cooking of raw product, and handling of leftovers. The rule provides additional safeguards to protect consumers from exposure to possible bacterial contaminants found in raw meat and poultry products. This action is being taken in an effort to reduce the risk of foodborne illness.

DATES: This regulation is effective May 27, 1994. The compliance date for comminuted meat and poultry products is May 27, 1994, and the compliance date for all other meat and poultry products is July 6, 1994.

FOR FURTHER INFORMATION CONTACT: Patrick J. Clerkin, Director, Evaluation and Enforcement Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 254-2537.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

In publishing the proposal on November 4, 1993 (58 FR 58922), the Agency stated that it had determined that the proposed rule was a significant regulatory action under Executive Order 12866 because the action would likely raise policy issues arising out of the principles set forth in the Executive Order. The proposal advocated a significant new policy direction that would require safe handling instructions on raw and partially cooked meat and poultry products to further combat foodborne illness.

The Agency published an economic analysis for comment in the preamble to the proposed rule. That analysis incorporated comments received in response to an earlier interim rule (58 FR 43478). As discussed in the

proposal, a preliminary economic analysis was published for comment in the preamble of that interim rule. Most comments addressed the cost of the rule.

In contrast to the earlier interim rule, the proposal generated relatively few comments that criticized the analysis and the assumptions behind the analysis. Presumably, the fewer critical comments reflected the modifications that were made in response to data supplied in comments on the preliminary analysis published with the interim rule. Comments on the modified analysis published with the proposal are discussed in the following paragraphs.

At least one commenter misunderstood the statement that: "The Department also anticipates that stores will utilize point-of-purchase materials that will minimize any labor costs." The commenter stated that the assertion was inaccurate because the proposed rule does not allow for point-of-purchase information except as a supplement to the label on each package. This statement was referring to the period after the effective date and before April 15, 1994. Under the proposal, before April 15, 1994, official establishments and retailers would be allowed alternative approaches, such as point-of-purchase materials, for affected products other than comminuted products. The Agency included the above statement to acknowledge that there would be some labor costs associated with point-of-purchase materials, but that such costs could easily be minimized.

The same commenter pointed out that many stores, especially smaller ones, do not have label application guns and questioned basing the estimate for labor costs on the use of label application guns. The Agency was not implying that it believes that most retail stores currently have label guns. However, since hand-held label application guns are low cost option for applying safe handling instructions, the Department would expect to see widespread use of such equipment.

One commenter stated that USDA has dismissed, based upon non-public information, the cost estimates provided by the regulated industry regarding label costs. The reference to non-public information is related to the statement in the proposal that "Discussions with label manufacturers indicate that the lower prices are available for even small quantities."

The proposal points out that the preliminary analysis (published with the interim rule) estimated that the cost of an additional pressure-sensitive label would range from \$.01 to \$.025. That

estimate was based on discussions with label manufacturers and/or wholesale distributors. Most of the comments on the interim rule suggest that the preliminary estimate was accurate. In fact, the most frequent response was that the labels would cost \$.01 each. The proposal acknowledged that some comments including one from the U.S. Small Business Administration suggested that some retail firms were paying more. Because the comments on the interim rule are more compelling evidence than provided by the earlier discussions with label manufacturers, the quoted sentence would have been better stated as "Comments on the interim rule support the preliminary estimate that the lower prices are available for even small quantities."

With respect to the comment on non-public information, the process of conducting a preliminary regulatory cost analysis involves a wide mix of formal surveys and informal information gathering. In this case the preliminary estimate was based on informal discussions with 4 or 5 manufacturers and/or wholesale distributors of pressure-sensitive labels and the fact that pressure-sensitive address labels are widely advertised at costs ranging from \$.01 to \$.025. Because the details of the specific label were not available the discussions were limited to general questions concerning the range of costs and the relationship between label size and cost. The information collected was not recorded by name of firm. Individual firm confidentiality is also a standard practice for more formal cost surveys. For example, in conducting the regulatory impact analysis for the nutrition labeling rule, a survey was mailed to 650 meat and poultry firms. Confidentiality of individual responses was assured.

A comment from a meat industry trade association noted the lack of "hard numbers" used in the cost-vs-benefit section. This commenter specifically questioned why the Department estimated that annual deaths attributable to *Escherichia coli* 0157:H7 could range from 146 to 389.

The estimate referred to was published in Agricultural Outlook, Economic Research Service, USDA, AO-197, June 1993. The discussion in the preamble stated that "the estimates in Table 1 were developed after the epidemic outbreak of foodborne illness attributed to *E. coli* 0157:H7 in undercooked hamburgers from a fast-food chain in 1993. Although the States have voted to make foodborne illness from *E. coli* 0157:H7, a disease that must be reported to the Center for Disease

Control and Prevention (CDC), such reporting will not be effective for some time. Thus, cost estimates for *E. coli*

should be reviewed as preliminary." Table 1 from the proposal is repeated here also as Table 1.

TABLE 1.—ESTIMATED ANNUAL COSTS FOR SELECTED FOODBORNE PATHOGENS, 1992

Pathogen ¹	Cases	Deaths	Annual medical & productivity costs	Attributable to meat and poultry	Costs ²
				Percent of cases	
	Number	Number	\$ million	Percent	\$ million
Bacteria:					
<i>Salmonella</i>	1,920,000	960–1,920	1,188–1,588	50	600–800
<i>Campylobacter jejuni</i> or <i>coli</i>	2,100,000	120–360	907–1,016	50	450–500
<i>Escherichia coli</i> 0157:H7	7,668–20,448	146–389	229–610	50	100–300
<i>Listeria monocytogenes</i>	1,526–1,581	378–433	209–233	50	100
Parasites:					
<i>Toxoplasma gondii</i> ³	2,090	42	2,628	100	2,630
<i>Trichinella spiralis</i>	131	0	0.8	100	0
<i>Taenia saginata</i>	894	0	0.2	100	0
<i>Taenia solium</i> ⁴	210	0	0.1	100	0
Total			5,162–6,076		3,880–4,330

¹ Analysis assumes 100% of human illnesses are foodborne for *Campylobacter*, *Escherichia coli*, *Trichinella*, and the *Taenias* and assumes 96% of *Salmonella* cases, 85% of *Listeria* cases, and 50% of *Toxoplasma* cases are foodborne. Meat and poultry are assumed to be responsible for 100% of foodborne parasitic diseases and 50% of foodborne bacterial diseases.

² Estimates rounded.

³ Productivity losses are high for survivors who develop mental retardation or blindness as a result of toxoplasmosis. These costs exclude toxoplasmic encephalitis infections in 2,250 to 10,200 AIDS patients annually which are a significant cause of premature death (50% of cases may also have a foodborne origin).

⁴ Costs are estimated at less than \$0.1 million, although estimates do not include costs for cysticercosis which may have an indirect foodborne transmission.

Reference: Agricultural Outlook, Economic Research Service, USDA, AO-197 (June 1993), pp 32–36.

The Agricultural Outlook publication (which was available in the FSIS Hearing Clerk's office) states that "CDC researchers estimate that between 7,668 and 20,448 persons became ill from exposure to *E. coli* 0157:H7 annually in the U.S." The range in estimated deaths is directly related to the range in the CDC estimate for number of cases. CDC researchers have estimated that 1.9 percent of the 7,668 to 20,448 cases result in death.

Several comments point out that costs are affected by the effective date, especially in view of the upcoming implementation date for nutrition labeling. The Department agrees that costs are affected by the implementation schedule. However, it is beyond the scope of the cost analysis to be able to differentiate or estimate the cost savings that would be attributable to processors and retailers having an additional 30 or 60 days to comply. The issue of effective date is discussed elsewhere under comments related to the implementation schedule.

One comment alleged that the Department did not make sufficient supporting material available to the public, particularly in the area of the cost and benefit analysis. The data from Table 1 represents the latest and best estimates of the cost of foodborne illness prepared by the Department's Economic

Research Service (ERS). ERS has been publishing articles on their cost of foodborne illness research for more than a decade. The methodology has been refined and updated over time. From the perspective of Executive Order 12866, the relevant information is the available data on costs and benefits that is based on the latest methodology. The Department is not obligated to identify all the materials that have been published during the development and refinement of these methods.

Another comment stated that USDA failed to place on the record any studies or other information relied upon by USDA regarding foodborne illnesses other than *E. coli* 0157:H7. The Agricultural Outlook article summarizes CDC findings for all foodborne diseases caused by bacterial and parasitic agents.

While recognizing that in the majority of cases, the cause is unknown, CDC has found that when a source or likely source is identified, approximately 50 percent of cases of all foodborne diseases are associated with meat or poultry products. The CDC analysis supports the ERS estimates that meat and poultry are associated with approximately 50 percent of foodborne bacterial diseases.

A supermarket chain commented that scale upgrades would cost almost \$500,000, or approximately \$9,700 per

store. While this cost is slightly outside the estimate of \$6,000 to \$9,000 used in the analysis, changing the range from \$6,000 to \$10,000 would not have an effect on the net benefit conclusions.

The same commenter pointed out that upgrading equipment does not eliminate labor costs, since there would always be some items that were not compatible with automated equipment and would have to be done by hand. The Department agrees, but accounting for this in the analytical model would have minimal effect on net benefits.

A large processor commented that the Agency did not include in its cost estimate many of the significant costs associated with label redesign. The analysis did recognize that the cost of revising a label varies widely and that variation is included in the estimate of a one-time cost for processors of \$50 to \$100 million. The Agency is aware that some firms spend several thousand dollars on label revisions. Other firms spend far less. The Department considers an average cost of \$1,000 per label to be a reasonable estimate for an average cost for a label revision of this type.

A supermarket chain from a large urban area submitted a detailed estimate of its costs using a labor rate of \$24.00 per hour. The cost analysis used a labor rate of approximately \$10.00 per hour.

The Department recognizes that wages will vary widely. Aggregate cost and benefit analyses must, however, be based on national averages.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirement on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR 335 and 381, Subpart W, must be exhausted prior to any judicial challenge of the application of the provisions of this rule with respect to labeling decisions.

Effect on Small Entities

The Administrator has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The rule will affect a substantial number of small entities, but the economic impact on such small entities will not be significant.

The final rule affects both retail stores and inspected establishments. In 1991, USDA estimated there were 253,000 foodstores in the United States. These stores are categorized as follows:

(Sales >\$2.5 million each)	
Superettes	94,647
(Sales <\$2.5 million each)	
Convenience Stores	51,700
Specialty stores	82,895
Total	253,055

Most of the small businesses affected would be superettes and specialty stores, such as meat markets, butcher shops, and locker plants. The specialty store category includes a large number of small businesses that do not sell meat and poultry products, e.g., confectionery stores. Most convenience stores do not sell raw or partially cooked meat and poultry products.

The Department recognizes that small retail firms would experience the greatest relative ongoing costs because they may not be able to afford new or modified equipment that can minimize costs. However, the public health risks do not allow for alternative small business considerations. At least one of the recent foodborne illness incidents described in the interim rule referred to earlier involved ground beef sold through a small market in a small community.

Background

Introduction

The Secretary of Agriculture has statutory authority to require meat and poultry products to bear labels including such "information as the Secretary may require * * * to assure that * * * the public will be informed of the manner of handling required to maintain the article in a wholesome condition." Federal Meat Inspection Act, 21 U.S.C. 601 (n) (12); Poultry Products Inspection Act, 21 U.S.C. 453 (h) (12). The Secretary issued an interim final rule on August 16, 1993, requiring raw and partially cooked meat and poultry products to carry safe handling instructions, effective October 15, 1993 (58 FR 43478), and solicited comments for 30 days. In light of these comments, the Secretary issued a final rule on October 12, 1993, which made significant changes in response to the comments (58 FR 52856). Due to continued outbreaks of foodborne illness involving meat and poultry products which resulted in serious illness and death, the Secretary invoked the "good cause" exception to the notice and comment requirement of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(13)(B)).

On September 23, 1993, the Texas Food Industry Association, the National American Wholesale Grocers' Association, the International Foodservice Distributors Association, and the National Grocers Association

filed a complaint in the United States District Court for the Western District of Texas (District Court) alleging that the issuance of the interim rule violated the APA and requested that the Court issue a preliminary injunction.

On October 14, the District Court granted plaintiffs' request for a preliminary injunction and enjoined the Department from enforcing or implementing the interim or final regulations against the plaintiffs or any other affected entities or individuals. The Department filed a motion with the United States Court of Appeals for the Fifth Circuit on October 15 to stay the preliminary injunction and allow the safe handling regulations to take effect. This motion was denied on October 19, 1993.

While the Department believed it would prevail on the APA issue in further litigation, it recognized that a notice and comment rulemaking would take less time than further litigating the APA issue with the plaintiffs. Due to the importance of protecting public health and the related need to provide this crucial information to consumers as quickly as possible, the Department published simultaneously on November 4, 1993, a proposal to amend the regulations to require safe handling instructions on raw and partially cooked meat and poultry products, and a final rule withdrawing the provisions of the interim and final rules (58 FR 43478 and 58 FR 52856).

Authority

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are wholesome, not adulterated, and properly marked, labeled, and packaged.

Section 2 of the FMIA (21 U.S.C. 602) and section 2 of the PPIA (21 U.S.C. 451) state that unwholesome, adulterated, or misbranded meat or meat food products and poultry products are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly marked, labeled, and packaged products, and result in sundry losses to producers and processors of meat and poultry products, as well as injury to consumers. Therefore, Congress has granted the Secretary authority to regulate meat, meat food products, and poultry products to protect consumers' health and welfare. Subsection 1(n)(12) of the FMIA (21 U.S.C. 601(n)(12)) and subsection 4

Supermarkets 23,813

(h)(12) of the PPIA (21 U.S.C. 453(h)(12)) state that the term "misbranded" applies to any product if it fails to bear, directly thereon or on its container, as the Secretary may be regulations prescribe, the inspection legend, and unrestricted by any of the foregoing, such information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition. Section 7(d) of the FMIA (21 U.S.C. 607(d)) states: "No article subject to this title shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted." The PPIA contains similar language in section 8(c) (21 U.S.C. 457(c)).

Safe Handling Labeling Instructions

In 1972, the American Public Health Association, individual consumers, and six other public health and consumer interest groups brought suit in the U.S. District Court for the District of Columbia against the U.S. Department of Agriculture alleging that labels placed on meat and poultry products were false and misleading because they failed to warn consumers against the dangers of foodborne illness caused by Salmonella and other bacteria in such products. The Court of Appeals affirmed the District Court's order dismissing the action, and ruled that the Secretary of Agriculture did not abuse his discretion by choosing to undertake a consumer education program instead of requiring labeling instructions for meat and poultry products. Since that ruling, USDA has conducted a massive and increasingly targeted food safety campaign to inform consumers about safe handling and cooking of meat and poultry products. FSIS has offered a toll-free nationwide hotline, staffed by food safety specialists, and conducted campaigns, directed at such specialized audiences as food handlers, institutions, health professionals, and at-risk populations, as well as food handlers in the home. Additionally, FSIS has permitted the voluntary labeling of poultry products with safe handling instructions since 1987. FSIS does not monitor participation in voluntary labeling; however, one trade association has said

that 75 percent of its members offer handling instructions on their labels.

New Policy Direction

In recent years, FSIS has been aware that a growing percentage of the U.S. population consists of persons lacking experience in food preparation and knowledge of safe food handling and storage methods. Studies of foodborne illness outbreaks have repeatedly shown improper food handling to be the frequent cause of foodborne illnesses. Improper cooling of cooked foods has been ranked as the leading factor. Other factors cited included inadequate cooking, cross-contamination, and inadequate reheating.

Studies of consumer knowledge and practices indicate that a significant number lack basic food safety information and skills, particularly with respect to the relationship between temperature and foodborne illness.

Information from the CDC revealed that: (1) Undercooking was a factor in 108 of 345 (31.3 percent) home outbreaks of foodborne illness that occurred between 1973 and 1982 (data include all foods); and (2) cooking foods ahead, i.e., 12 hours or more before serving, was a factor in 12.8 percent of the home outbreaks.

While the Agency has long been committed to a program of consumer education to help prevent foodborne illness, as exemplified by its distribution of publications for consumers and its Meat and Poultry Hotline, it has become convinced of the need for more direct methods of placing food safety information in the hands of consumers. Thus, Agency officials in early January 1993 began to advocate in their speeches and writings that the mandatory safe handling instructions on the labeling of meat and poultry products was a necessary component of a program to combat foodborne illness.

The Agency's new policy direction gained additional impetus following the January 1993 outbreaks of a severe foodborne illness that led to four deaths among approximately 500 confirmed cases in Washington, Idaho, California, and Nevada. The outbreaks were linked to the pathogenic bacterial strain *E. coli* 0157:H7. Because most of the cases were attributed to undercooked hamburgers served at a fast-food restaurant chain, Federal and local authorities have intensified their regulatory activities. In June and July of 1993, the Department became aware of nine separate incidents where *E. coli* 0157:H7 was the direct or suspected cause of illness or death. The incidents led the Department to conclude that it was time to immediately require safe handling

information on raw and partially cooked meat and poultry products. On August 16, 1993, FSIS published in the *Federal Register* an interim rule (58 FR 43478) mandating safe handling instructions on all raw and partially cooked meat and poultry product labeling. Also, FSIS established a permanent liaison position with the CDC. The responsibilities of this position include monitoring and tracking all *E. coli* epidemics reported to the CDC. Preliminary data for 1993 from CDC indicates 17 reported clusters of *E. coli* 0157:H7 infections. Many of these cases occurred after publication of the interim rule.

Several noteworthy developments in previously cited cases of foodborne illness and new incidents, not reported in the prior rulemaking publication, which reinforce the exigent need for safe handling instructions are summarized below:

Reading, CT

The Connecticut Department of Health investigated an outbreak of *E. coli* 0157:H7 that appeared to be linked to a country club. Four cases of *E. coli* 0157:H7 were positively linked to undercooked hamburger patties served at the Reading Country Club. *E. coli* 0157:H7 was isolated by the Connecticut State Lab and the FSIS Beltsville Lab.

Ft. Bragg, CA

The Mendocino County Health Department reported confirmed cases of *E. coli* 0157:H7 in a 13 year old girl and an 84 year old woman in Ft. Bragg. The two cases appeared unrelated except that both victims consumed home-cooked hamburgers which may have been made from ground beef purchased at the same supermarket during the same time period. FSIS isolated *E. coli* 0157:H7 from ground beef returned to the market as well as a patty from the residence where the 13 year old girl had eaten.

Texas

A total of 10 separate cases *E. coli* 0157:H7 occurring over a 6-week period in the autumn of 1993 are being investigated by the Texas Health Department. These included three cases that resulted in hemolytic uremic syndrome and one death. No common source has been identified.

Parameters of Good Safety

After reviewing available information, FSIS in conjunction with the Food and Drug Administration (FDA) identified the following parameters of safe handling by consumers: How to safely store raw product and thaw frozen

product; how to avoid cross-contamination during preparation; how to cook for optimal safety and palatability; and, how to store leftovers after preparation. For institutions, hot holding of prepared food is an additional parameter. (The term institutions as used throughout this preamble includes hotels, restaurants, or similar institutions.) In addition, the Agency proposed that the safe handling instructions include a rationale statement specifying the reason why it is important to follow such instructions. The Agency believes that consumers will pay more attention to the safe handling instructions if they understand that mishandling will lead to the growth of bacteria and possibly to illness.

Labeling

Various methods have been used in the past to inform consumers of handling instructions. Such methods have included putting the instructions on the product label, on inserts, on tags attached to the product, and on point-of-purchase materials displayed near the product at the point of sale. FSIS has concluded that the outside label is the most appropriate location for safe handling instructions.

The Agency considered three options for presenting safe handling information on the label. These options included long word messages, short word messages, and short word messages with symbols or graphic representations to accompany the message. To collect information on which format would most effectively influence consumer behavior, FSIS initiated consumer focus-study research.

In the FSIS initiated consumer focus-study, most participants wanted to see safe handling instructions on raw meat and poultry products. Consumers in the study expressed a preference for the safe handling instructions to be on the package label and felt that other labeling, such as pamphlets or in-store signs, should only be used to supplement package labels. Instructions with graphic illustrations were generally preferred to those without graphic illustrations and the short word messages were preferred to the long word messages. Also, most participants of the focus-study research felt that the rationale statement was a necessary part of the safe handling instructions.

Current Regulations

The Federal meat and poultry products inspection regulations currently require the placement of safe handling statements on packaged products that require special handling to maintain their wholesome condition.

Sections 317.2 and 381.125 of the Federal meat and poultry products inspection regulations (9 CFR 317.2(k) and 9 CFR 381.125, respectively) provide that packaged products which require special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or such similar statement as the Administrator may approve in specific cases.

Proposal

FSIS proposed to amend the Federal meat and poultry products inspection regulations to mandate the inclusion of safe handling instructions on the labeling of raw and partially cooked meat and poultry products along with a rationale statement to indicate the reason why it is important to follow such handling instructions. The Department has established required cooking temperatures for certain beef, poultry, and patty products. These requirements are set forth at 9 CFR 318.17, 381.150, and 318.23, respectively. The proposed rule applied the beef temperature requirements to beef, swine, sheep, goat, horse, and other equine. The Department has also established processing requirements for the curing or other treatment of certain meat products to control microbial activity. Some of these products are identified in part 319 of the meat inspection regulations. These cooked products, e.g., cooked sausage, and some products that have been otherwise further processed so as to render them ready-to-eat, e.g., dry fermented sausage, are not considered to be at sufficient risk of microbial contamination to warrant the application of safe handling labels. However, some products that are traditionally considered ready-to-eat receive no lethal heat treatment and may not be pathogen free. FSIS is reevaluating its policies and regulations governing these products and plans to propose a regulation requiring that these products either bear the safe handling instructions or be processed in such a manner as to assure the destruction of pathogens.

FSIS proposed to permit official establishment and retailers to use alternate approaches to deliver the safe handling instructions until April 15, 1994, except for comminuted products. For comminuted products, FSIS proposed to require that safe handling instructions be included on the label within 30 days after publication of the final rule.

The alternate approaches presented in the proposed rule are: (1) Official establishments may include in the shipping container either pressure-sensitive labels containing the safe handling instructions for retailers to apply to packages or leaflets containing a facsimile of the safe handling instructions in lettering no smaller than one one-sixteenth of an inch for retailers to place in close proximity to the packages to ensure that leaflets are likely to be seen and taken home by consumers; and (2) retailers may distribute leaflets containing the facsimile described above.

In some cases, it was expected that retailers might prefer pressure-sensitive labels or leaflets of their own design and manufacture to those that an official establishment would provide under the permitted alternative. FSIS proposed that if a retailer notifies an official establishment in writing that it intends to supply its own labels or labeling, the official establishment would not be required to supply the materials in the shipping container.

The following rationale statement was proposed for products prepared from inspected and passed meat and/or poultry: This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

FSIS proposed the following rationale statement for poultry slaughtered under exemptions specified in 9 CFR 381.10: Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.

FSIS proposed the following four safe handling statements for use on the label of both red meat and poultry products distributed to both household consumers and institutions: (1) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted.) (A graphic illustration of a refrigerator shall be displayed next to the statement.); (2) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.); (3) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and (4) Keep hot foods hot. Refrigerate leftovers immediately or

discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

The label for safe handling instructions is shown in Exhibit 1.

BILLING CODE 3410-DM-M

EXHIBIT 1

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.



Keep refrigerated or frozen.
Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods.
Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers immediately or discard.

BILLING CODE 3410-DM-C

FSIS proposed that safe handling instructions may appear anywhere on the label where they would likely to be read. The proposal also required the safe handling instructions to be set off by a border and to one color type printed on a single color contrasting background.

FSIS proposed to exempt products intended for further processing by an inspected establishment from mandatory safe handling labeling requirements. Since products for further processing by another Federal or State establishment will not be available to consumers or food service institutions, FSIS did not believe that it was necessary to require safe handling instructions on such packaging.

FSIS proposed to allow safe handling instructions to be added to labels by the manufacturer and to be approved under the provisions of generic label approval since the regulations prescribe the exact language of the safe handling instructions.

Discussion of Comments

The FSIS Hearing Clerk received 60 comments on the proposed rule. Commenters included consumers, representatives of consumer and other interest groups, State meat and poultry inspection officials, representatives and associations of retail stores, representatives and associations of official meat and poultry establishments, two U.S. Department of Agriculture Agencies, and others.

The following discussion of comments follows the general structure of the proposed rule. General concerns are addressed in the context of specific features of the rule. Where the concerns cannot be logically addressed in the context of specific sections of the rule, they are presented under a "Miscellaneous Issues" section. Changes made in the final rule are described so that it is apparent how they address the concerns of commenters. Where the Agency addresses the meat regulations, conforming changes are also made in the poultry regulations. Any

changes unique to either the meat or poultry regulations are identified.

Miscellaneous Issues

One commenter suggested that the comment period should be extended and that additional information that FSIS used in formulating and supporting the regulation should be placed on the regulatory record. We disagree with this comment and note that FSIS had made publicly available, as part of this rulemaking proceeding, all relevant data upon which the regulation is based, including: the August 16, 1993 interim rule and all comments received in response thereto; the studies referenced in the interim rule; the October 12, 1993 final rule; questions and answer papers formulated in response to questions raised by the interim rule; the November 4, 1993 Notice of Proposed Rulemaking and all comments received in response thereto; all studies referenced in the Notice of Proposed Rulemaking, including the Focus-Study Research and Agricultural Outlook (June, 1993); and

documentation of oral presentations made in the course of the rulemaking proceeding.

The majority of commenters supported the labeling of products with safe handling instructions. Several commenters objected to mandatory labeling stating either that other methods of educating consumers would be more appropriate, that the required labeling would be ineffective, that labeling is not a substitute for proper training of safe food handling, that requiring a simple label can not guarantee any consumer will follow that label, or that some products currently include sufficient safe handling instructions which make the proposed safe handling label unnecessary. Seven commenters stated that many existing products contain much more helpful and meaningful handling and preparation information than that required by the proposed regulation. One also questioned whether the information contained in the proposed statements is so demonstrably more effective than the safe handling instructions currently in use on meat and poultry so as to justify the millions of dollars in conversion costs. They also suggest that to prohibit alternative language is unnecessarily restrictive and may preclude a more effective way of conveying the message intended. Five commenters suggested that labeling is only one option and point-of-purchase materials or other types of signs may be equally effective or more effective in instructing the consumer about safe food handling.

FSIS does not agree with these comments. The focus-study research asked participants about other alternatives for safe handling instructions. Participants in the focus-study research expressed a preference for safe handling instructions to be on the package label and felt other labeling, such as pamphlets or in-store signs, should only be used to supplement package labels, but not replace the package labels. The safe handling instructions are not meant to substitute for comprehensive training of safe handling procedures either in the home or food service setting. The instructions primarily alert food preparers that there is a risk of illness if products are mishandled or improperly cooked, and it addresses four broad parameters of food safety. Finally, FSIS does not believe that current handling instructions on labels will make safe handling instructions unnecessary. The safe handling instructions are not meant to replace more comprehensive cooking instructions found on products. In addition, current labeling may cover the

four broad parameters of food safety, but does not include a rationale statement explaining to food preparers why it is important to follow the instructions. The focus-study research found that the rationale statement was an essential feature of the label.

Officials from two retail stores and two retail associations suggested that the regulations have a sunset provision and that the effectiveness of the regulation be studied periodically. Five additional commenters suggested that the effectiveness of the regulation be evaluated. Several suggested annual reports be sent to the Secretary of Agriculture for review and one requested that FSIS publish a method to measure the effectiveness of the regulation as part of the final rule. There are no changes in the final rule in response to these comments. The Regulatory Flexibility Act already provides that Agencies will periodically review regulations. While this does not have the same effect as a sunset provision, it does insure that the continuing appropriateness of regulations will be assessed. Further, there is no way to quantify the effectiveness of the regulation. It is impossible to determine how many cases of foodborne illness were prevented by the inclusion of these instructions on the labels of raw and partially cooked meat and poultry products.

Twelve commenters addressed the four sets of "Questions and Answers (Q&A's)" that FSIS disseminated between August 20 and September 15, 1993. Suggestions included codifying the Q&A's as part of the final rule, adding the Q&A's to the proposal and reopening the comment period to allow all interested parties an opportunity to comment on the Q&A's, and including specific responses either in the regulatory language or the preamble of the final rule. Four issues specifically cited were the status of export products, retroactive labeling of products, placement of information on hang tags and on the bottom of trays, and safe handling information requirements for multi-component products which include a meat or poultry portion that is fully cooked or otherwise processed so as to render it ready-to-eat. FSIS does not believe that these Q&A's need to be part of the regulatory language of the final rule. The Q&A's either cited other regulations within Title 9 or provided interpretations of how the safe handling regulation would be applied in specific situations.

In addition, the Q&A's, in large part, related to the interim rule, which was withdrawn. However, we will address

the specific questions raised by the commenters. Regarding the need for export products to carry safe handling instructions, the condition under which deviations from labeling requirements are permitted are already set out in 9 CFR 317.7 and 9 CFR 381.128. FSIS will not require retroactive labeling of products, products labeled on or after the effective date will be required to carry safe handling instruction on the label. Products labeled prior to the effective date will not require the addition of safe handling instructions. For example, products in frozen storage, labeled prior to the effective date but shipped afterwards, will not be required to add the safe handling instructions. Regarding the placement of safe handling instructions on hang tags or the bottom of trays, FSIS has considered hang tags to be an extension of the label and consequently they may contain required label features such as safe handling instructions. Also, the instructions may be placed on the bottom of trays as long as they are visible at time of purchase. This is evident in the language of the proposed and final rules that state the safe handling instructions, "shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary consumer under customary conditions of purchase and use." Finally, as to whether safe handling instructions need to be on products that include a fully cooked meat filling but where the total product requires cooking, e.g., a fully cooked meat filling in uncooked dough: the rule does not require safe handling instructions on products where the meat or poultry portion is fully cooked or otherwise processed to render that portion ready-to-eat. However, while such products do not require safe handling instructions they are not considered ready-to-eat products.

One commenter suggested that FSIS implement appropriate compliance procedures for safe handling labels, stating the hope that "after all the commotion and rhetoric accompanying this present rule that more effort will be made to assure not only compliance with it but with all the other regulatory initiatives that are sorely in need of the Department's attention." FSIS appreciates the concern of this commenter. It is envisioned that the monitoring of compliance with these requirements will follow the current model of enforcement of misbranding of products at the retail level. Jurisdiction

is primarily exercised by State and local food regulatory agencies. Local codes generally require that food be fully labeled in conformance with requirements of agencies having jurisdiction over the product. FSIS and State meat and poultry inspection programs also monitor meat and poultry products in commerce. If products are found out of compliance with these requirements, they generally require that the specific product be brought into compliance or other appropriate action is taken. FSIS anticipates that initial compliance monitoring of this labeling requirement will have an educational focus. Where noncompliance is found, FSIS Compliance and other enforcement officials will provide guidance on these labeling requirements. Where it is apparent that businesses are making a good faith effort to comply with these requirements, they will not be subject to enforcement action.

One commenter suggested that FSIS replace the term "comminuted" with a different term such as "non-whole muscle" products because historically, "comminuted" has been used to include only very finely ground meat and poultry products produced from by-products of other whole muscle operations. FSIS does not agree with this comment. Other FSIS regulations, including the August 2, 1993, pattie regulation (58 FR 41138), have defined "comminuted" as a processing term used to describe the reduction in size of pieces of meat or poultry, and includes chopping, flaking, grinding, and mincing.

One commenter was concerned that styrofoam trays are sometimes reused in children's crafts and that such a use poses risks. The commenter suggested that these trays should include a message saying to discard them. Meat packed in styrofoam trays could pose a potential health risk if ready-to-eat food products are stored in an unwashed tray. Use of these materials by school children has not resulted in any reported foodborne illness. FSIS believes that most consumers either discard the trays or wash them before giving them to their children to use. On this basis, FSIS does not believe a message is needed to address this concern.

One commenter suggested that the Department introduce two new categories of product that could be sold in addition to the current products that are labeled "USDA Inspected and Passed (or For Wholesomeness)." The first category would be "USDA Inspected for Cosmetics and Marketing Defects Only—Not Health Hazards," and the second category would be

"Uninspected." Both of the new categories would be required to include safe handling information on the label. Products meeting the criteria to be labeled "USDA Inspected and Passed (or For Wholesomeness)" would not be required to include safe handling information.

The Agency does not agree with this commenter. The "USDA Inspected and Passed" logo represents an assurance that products are derived only from animals slaughtered under inspection; contain only ingredients from approved sources; are processed in a sanitary environment; and, are processed in accordance with accepted Good Manufacturing Practices. All these assurances are of health and safety concern. The Agency does not agree with an assertion that failure to assure that raw meat and poultry products are sterile reduces inspectional efficacy to assuring only the absence of cosmetic and marketing defects. Inspection of the processing of cooked products is designed to assure a commercially sterile product. Requiring safe handling instructions on the labels of raw and partially cooked meat and poultry products is the appropriate step to alert consumers to the practical limits of the assurance represented by the "USDA Inspected and Passed" logo.

Some commenters suggested that the focus-study research results were misused. Specifically, they state that FSIS is mandating a nationwide labeling plan based on the input of 86 individuals. They also cited a statement in the final report on the focus-study research that cautioned that the findings of focus-study research should not be generalized to a larger population in any statistical sense. FSIS does not believe that its use of the focus-study research findings was inappropriate. Consumers have an important role in assuring meat and poultry are safe to eat. Safe handling labels are a part of the Agency's consumer education campaign. The focus-study research was used to obtain consumer feedback on three label formats proposed by FSIS. The process used was consistent with generally recognized focus group methodology. Focus-study research provides a richness of detail not possible in more structured quantitative research. Focus groups are highly effective for developing understanding and insight into consumer behavior and thinking. The Agency was responsive to focus-study research suggestions as well as public comments in formulating the previous final regulation on safe handling instructions. As previously cited, participants in the focus-study research expressed a preference for safe

handling instructions to be on the package label and felt other labeling, such as pamphlets or in-store signs, should only be used to supplement package labels, but not replace the package labels.

Implementation Date

Representatives from many official establishments and their associations, retail stores and their associations, as well as officials of State meat and poultry inspection programs strongly recommended that the effective date of the rule be extended. The most frequently mentioned date was July 6, 1994, to coincide with the effective date for nutrition labeling. Many noted that a 30 day implementation time was not feasible. Retailers state that it will take a minimum of 60 days to either receive and install new equipment or receive new labels, taking into account the lag time from publication of a final rule to receiving the new regulation, and ordering and delivery of equipment or labels. Federally inspected establishments and trade associations commenting on the 30-day implementation timeframe offered varied estimates of the time required to make label changes. These ranged from 4 weeks to 4 months. In addition, several commenters stated that pressure-sensitive stickers pose feasibility problems, including inability of the stickers to remain on the product through processing, lack of adequate space on the current label to place the sticker without obscuring other mandatory features, and extremely high labor costs due to the need to add a labor intensive manual process step where businesses currently use high speed equipment that cannot be easily or economically retrofitted to apply the stickers.

The National Association of State Departments of Agriculture states that "FSIS should consider delaying the implementation to July 6, 1994, to provide an opportunity to educate not only the public, but also those who must enforce the requirement and encourage the public to follow the guidelines. It is essential that FSIS provide a lead time to furnish state officials with accurate and reliable information before the regulation is implemented." One retail store also stated that 30 days did not provide the time necessary to properly train employees.

Regarding FSIS's suggestion that companies revise their nutrition labeling timetable to coincide with safe handling, one official establishment wrote, "it is not practical to simply 'revise our timetable for nutrition

labeling' as FSIS has stated. There is a great deal of analysis, planning, and designing that goes into each nutrition panel. It is simply not a case of printing information that is already dictated as is the case for the handling instructions." Additionally, one commenter questioned whether the incremental cost of complying with the label requirement versus the pamphletting option during the April 15 and July 6 period for noncommuted products could be justified by any demonstrable benefit. However, one consumer group requested that implementation of these requirements not be delayed for any reason, because of the risks of foodborne illness associated with raw meat and poultry.

FSIS has been persuaded by the comments that in some cases it might be impractical to achieve compliance with a 30-day implementation requirement for comminuted products and an April 15 requirement for other products. However, the Agency does not agree that businesses will require 4 months to comply. A commenter that calculated 4 months as a minimum included time for sketch approval by FSIS in its calculation. That step is not required for these generically approved labels. They also included a period of time to exhaust preexisting label inventories. This is not a factor that impacts on the feasibility of obtaining complying labels. Additionally, they did not consider such alternatives to complete label redesign as pressure-sensitive labels. The latter approach could obviate both time concerns and concerns over utilization of existing label inventories. Finally, many firms demonstrated the ability to make the required label changes within the 2 months following the publication of the interim rule on August 16, 1993. Their performance certainly belies the notion that 4 months is a minimum required to achieve compliance.

FSIS will extend the implementation requirement for the labeling of comminuted products to 60 days after publication and the labeling of other products to July 6, 1994. The Agency believes that the high level of voluntary compliance before these required dates will minimize the impact of extending the timeframes for implementation and eliminating the pamphletting requirement. The Agency believes that these extended timelines will provide retailers as well as establishments the needed time for those companies having difficulty obtaining the necessary labeling. Additionally, it will allow some businesses to make one label change to incorporate both safe handling instructions and nutrition

labeling at a cost savings. Many retailers as well as official establishments have already voluntarily complied with this regulation by providing safe handling labels, brochures and other point of sale information. In addition, the Department's educational efforts to inform the public of the need to safely handle and prepare meat and poultry as well as other food products along with publicity surrounding the rule has increased the public's awareness of the necessity and requirements of safe food handling. A major joint voluntary effort to educate consumers began last year. The Food Marketing Institute, the American Meat Institute and the National Livestock and Meat Board, in cooperation with the USDA and FDA, developed "A Consumer Guide to Safe Handling and Preparation of Ground Meat and Ground Poultry." The brochures are for consumers and for food service operators. Each brochure discusses proper handling, preparation and storage methods for ground meat and ground poultry and emphasizes three key points (the three C's): keep it cold; keep it clean; and cook it. These interim measures should minimize the impact of extending the timelines for implementation of these labeling requirements.

Three commenters suggested that FSIS permit companies up to 18 months to exhaust supplies of labels that do not include the safe handling instructions since it would be an economic and environmental burden to discard packaging materials. One commenter cited the nutrition regulation which gave an 18 month implementation time and suggested a similar implementation time. Three additional commenters requested that FSIS permit companies up to 1 year after the effective date of the regulation to use labels with safe handling instructions required by the interim rule. They state that materials were ordered in good faith to comply with the interim rule and it would be an economic burden to destroy such materials. Commenters stated that due to low volume sales of certain products, they expect to have over a year's supply of labels with the original safe handling instructions.

FSIS does not believe that 18 months or even 1 year should be given to exhaust packaging materials that do not include the safe handling instructions. Implementation time required for the nutrition regulations cannot be compared to the safe handling regulations since the two are very different. The safe handling regulations prescribe the exact language required on the label and do not require time consuming laboratory analysis or

interpretation of extensive rules regarding formats, serving sizes, claims, etc. However, FSIS has been persuaded by the comments to permit safe handling instructions provided in both the August 16, 1993, interim rule and the October 12, 1993, final rule to be used for 1 year past the effective date of this final rule. The label required under this final rule is unchanged from the label required in the October 12, 1993, final rule.

Product Appropriateness and Inclusiveness

Eleven commenters suggested that we narrow the focus of the regulation making safe handling instructions mandatory on ground meat and poultry products and voluntary on all other meat and poultry products. Many stated that the proposed rule was overly broad and that no evidence was presented to support the requirement of safe handling instructions on products other than ground products. They suggested the labeling effort would be more effective if ground products were targeted so that the information would have a proper impact with consumers. In addition, they stated that to blanket every package in the meat case with the same message would in effect make the message invisible because it would be so repetitive.

Several commenters questioning the scope of the regulation cited information from the preamble of the August 2, 1993, Uncured Meat Pattie regulation which stated "The likelihood of foodborne illness is not the same in all beef products or all hamburger-type products. Ground meat presents a different risk than whole muscle cuts such as steaks, roasts, or chops * * * the production process for ground meat assures that any present pathogens will be distributed throughout the product, including the interior, while bacteria tend to remain on the surface of steaks, roasts, and chops. This factor has major implications for the cooking process. Because a rare steak is thoroughly cooked at the surface, one can presume that pathogenic bacteria present are killed." They proposed limiting this labeling to ground products. One additional commenter objected to pork products in 9 CFR 318.10(a) being suddenly drawn into the proposed regulation.

FSIS agrees that comminuted products present a greater potential threat to public health than whole muscle cuts. For this reason, FSIS is requiring that comminuted products be labeled with safe handling instructions within 60 days after publication of this final rule. As cited elsewhere in this

preamble, many outbreaks of *E. coli* 0157:H7 food poisoning in the past year have been epidemiologically linked to the consumption of comminuted products. However, *E. coli* 0157:H7 is not the only pathogen targeted in this rulemaking proceeding. The proposed rule also cited statistics relating to illness, death, and medical and productivity cost due to other bacteria, including *Salmonella*, *Campylobacter jejuni* or *coli*, *Listeria monocytogenes*, and parasites, including *Toxoplasma gondii*, *Trichinella spiralis*, *Taenia saginata*, and *Taenia solium*.

The safe handling instructions were designed to cover the four broad parameters of food safety and to prevent outbreaks of foodborne illness resulting from all sources, not just *E. coli* 0157:H7 in ground beef. Meat and poultry products are known carriers of the pathogenic bacteria and parasites identified in the proposed rule and compliance with the safe handling instructions will prevent some foodborne illnesses and deaths. To require safe handling instructions exclusively on ground meat and poultry might lead consumers to mistakenly believe that other raw or partially cooked meat and poultry products are without risk, and ignores the concern for public health arising from the presence of pathogenic organisms on all types of raw and partially cooked meat and poultry products. It is important to remember that the safe handling instructions include parameters of safe handling beyond cooking instructions. In addition, the scope of the proposed regulation is supported by one official establishment which stated that all types of meat and poultry products should be required to have safe handling instructions since bacterial contamination can take place on any cut or type of meat and one meat trade association which stated that even products traditionally well cooked in the home need to carry safe handling instructions due to the possibility of cross contamination.

Regarding the inclusion of certain pork products in 9 CFR 318.10(a), these products have not suddenly been drawn into the safe handling regulation. These products were included in the interim rule as products needing safe handling instructions. The commenter misinterpreted this section.

One meat trade association questioned the fact that FSIS has taken no initiative to seek FDA efforts to have foods under FDA jurisdiction similarly labeled. FSIS will advise the Food and Drug Administration of the concerns expressed by commenters.

Nine commenters recommended that safe handling instructions not be required for products such as frozen dinners and entrees. Several reasons were given as to why such products do not need safe handling instructions. Commenters stated that FSIS has provided no evidence that such products present a meaningful health risk to consumers. In addition, they state that the four safe handling instructions either appear on the labels already or are unnecessary for frozen dinners and entrees. The commenters state that other regulations require a handling statement on the label, thus the refrigeration statement is redundant and unnecessary. Most of the products are not handled directly by consumers and there is no contact between the products and working surfaces, making the cross contamination statement unnecessary. Frozen dinners and entrees already contain very specific cooking instructions which are far superior to "cook thoroughly." Lastly, most products are single serve items making the statement on leftovers inapplicable, however, many manufacturers currently include statements such as "Promptly refrigerate any unused portion" on their labels.

FSIS disagrees with these comments. While frozen dinners and entrees probably pose a relatively lower risk of foodborne illness than fresh meat and poultry products, these products are vulnerable to the same mishandling risks associated with fresh product. Freezing is not considered a pathogen destruction step, but will only slow their growth. The Agency believes it is prudent to require the safe handling instructions on these types of frozen products if the meat portion is either uncooked or partially cooked. Since current instructions for handling frozen dinners and entrees varies from manufacturer to manufacturer the safe handling instructions will provide a consistent and uniform message. In addition, none of the current handling instructions include a rationale statement which explains to consumers why it is important to follow the prescribed instructions and the focus-study research indicated that the rationale statement was an integral part of the safe handling instructions.

The Texas Department of Health recommended that the exemption for custom slaughter products be eliminated. They state that these products are as likely to contain harmful or pathogenic bacteria that could cause illness if mishandled. However, they suggest that labeling each individual package is not necessary since the product goes back to the owner for use.

One meat trade association suggested that we retain the custom exemption since elimination of the exemption could cause more owners to do their own farm slaughter and processing which would result in a greater danger of meat and poultry contamination.

FSIS is not persuaded by the comments to eliminate the exemption of custom slaughtered products. While the Agency encourages the distribution of safe handling information with products slaughtered under the exemption, labeling is not required for such products if they are marked "not for sale."

Location of Information on Label

One official establishment and two meat trade associations misread the proposal as requiring that the labels be placed on either the principal display panel or the information panel. One poultry trade association on behalf of an official establishment requested FSIS to permit the safe handling instructions to appear on the back of an insert label with a referral statement on the front informing consumers that the instructions were on the back.

One consumer group stated that placement of the safe handling instructions anywhere on the label as to render it likely to be read is ambiguous and will likely result in lengthy disputes regarding its meaning. They recommended that FSIS revert to the original requirement from the interim regulation on the placement, i.e., on the principal display panel or information panel, which will have the same result while avoiding unnecessary disputes and litigation.

FSIS is not persuaded by the comments to make any changes in the placement of the safe handling instructions. The instructions may be placed anywhere on the outside label where they will be visible at the time of purchase. Several of the commenters must have misread the proposal when they objected to placement of the instructions on the principal display panel or the information panel. The interim rule required such placement but comments persuaded FSIS to allow flexibility in the placement of the safe handling instructions. We do not believe that the current language is ambiguous or will lead to lengthy disputes.

Several commenters stated that FSIS ignored the previous comments that packages would be too small to carry all mandatory information. As stated in the previous final regulation, FSIS is not aware of labels smaller than those on 12 ounce chubs that would likely require safe handling instructions. FSIS believes

that labels will be large enough to accommodate all mandatory information due to the flexibility provided by the safe handling and nutrition regulations. FSIS received no comments which provided examples of packages that could not accommodate both features.

Rationale Statement

Five commenters suggested changes to the rationale statement. One retail store, one grocers association and one meat association recommended that since all meat and poultry sold in commerce was inspected and passed by either Federal or State authorities, FSIS should permit the following on all products, "This product was inspected for your safety." These groups suggested the second sentence be changed to "Food products must be handled and prepared properly to prevent potential illness." This would emphasize the positive rather than negative aspects of proper food handling. In addition one commenter suggested the option of a singular "meat" or "Poultry" label. Two consumer groups suggested that the rationale statement did not appraise consumers of the true threat bacterial contamination poses and may even give consumers a false sense of confidence about the safety of the product. Suggested change included eliminating the first sentence of the rationale, the use of a "warning," mentioning the possibility of death, and adding descriptions of the symptoms of foodborne illness. FSIS concluded that the proposed rationale statement strikes a good balance that will neither scare consumers away from meat and poultry products nor cause them to ignore risks of foodborne illness. Given that, and the overwhelming acceptance of the single label message which will reduce the likelihood of errors, no changes are made or further flexibility permitted in the final rule.

Additionally, one commenter stated that a different rationale statement should be permitted for irradiated product. They suggested that a reference should be made to the reductions in bacterial counts that irradiation produces. While FSIS does not agree with this comment, it anticipates addressing the issue of label claims related to emerging pathogen reduction treatments in the future. However, these statements should not be a substitute for the required safe handling instructions since the handling statements also apply to treated products.

Handling Statements

Some commenters suggested allowing flexibility on the cross contamination,

cooking, and leftover statements similar to the flexibility permitted in the proposal for the refrigeration statement. Three commenters suggested that deviations in the statements could be approved through the prior approval system.

FSIS does not agree with these comments. In the long term, differences between label messages would work against consumer recognition of the one label message. In addition, this is supported by five commenters who recommended that FSIS make no changes in the text of the safe handling statements and one commenter that stated that it was in the best interest of both consumers and the industry to have only one set of safe handling instructions since the existence of more than one statement would only contribute to consumer and industry confusion.

One commenter suggested that we require the FSIS Hotline number with the label. The Meat and Poultry Hotline telephone number may be included on other parts of the label. FSIS does not have enough information about the impact of including this phone number on the label. Requiring it on 15 billion packages of product per year might easily overwhelm the Hotline resources.

One fast-food restaurant chain suggested that FSIS permit deviations in the refrigeration statement, as well as in other statements, if they conflicted with company policy or other printed company materials including operating manuals. FSIS is not persuaded by this comment to make any changes in the regulation. FSIS believes that the flexibility provided for the refrigeration statement is adequate to accommodate the only significant area of concern identified.

Two commenters suggested that FSIS add a recommendation for disinfecting or sanitizing hard surfaces because washing cutting boards with soap and water will not guarantee elimination of pathogens. One of the commenters suggested that this be included in leaflets containing other expanded information, such as cooking temperatures. They recommend that the leaflets be required to be available at the point-of-sale in addition to the safe handling labels on the products.

Washing of working surfaces has been found to be an effective means of reducing pathogens on cutting boards, utensils, etc. Use of a sanitizing agent would add another margin of safety, however, FSIS believes that the current message conveys the importance of washing working surfaces that have contacted raw product. This was further supported by the focus-study research.

Participants preferred short word messages, and indicated that the longer the messages, the less likely consumers would be to read them. While FSIS encourages programs to provide additional information on safe handling at the point-of-sales, it believes that additional verbiage might detract from the efficacy of the label.

One commenter suggested that the cross contamination statement be revised to include washing before and after contact with raw meat and poultry. While FSIS agrees that this is a good practice, the focus of these statements is avoidance of contamination of other ready-to-eat foods with raw meat and poultry products. This change will not be incorporated.

Six commenters stated that more explicit cooking instructions were necessary. The commenters suggested that visual signs of doneness and/or internal temperatures be required or at least allow the flexibility in the cooking statement to include such information. One commenter recommended that FSIS provide the proscribed internal cooking temperatures for each type of raw meat and poultry that would be labeled as well as a descriptive statement to accompany the internal cooking temperature. One suggested that a descriptive visual definition will provide safeguards for any consumer who is unable or unwilling to measure the internal temperature of their meat. One consumer group suggested that visual keys were preferable to the use of internal temperatures, as consumers may misunderstand the internal temperature to be a cooking temperature. They stated that it is critical to provide more specific cooking instructions since there is no single definition of "thoroughly cooked" among consumers. One meat trade association stated that the cooking instructions were adequate for the safe handling label because consumers want simple accurate information. In addition, they stated that it would be more appropriate to include more detailed handling information in a brochure or pamphlet which could be distributed at the point-of-purchase.

FSIS does not believe it would be appropriate to add either an endpoint temperature or more comprehensive cooking directions because cooking temperatures and other visual indications of doneness vary by product. As stated above, this labeling is not intended to replace comprehensive cooking statements that accompany many products. Additionally, as cited earlier, more complex messages might reduce the likelihood of consumer use of the label.

A consumer group suggested that FSIS include a time limit with the leftover statement, such as the two hours mentioned in the interim regulation. Another commenter representing a restaurant chain suggested that the leftover statement be eliminated in situations where company policy strictly controls holding time for products and the sale of leftover meat and poultry products is not permitted.

FSIS is not persuaded by these comments to make any changes in the leftover statement. The Agency believes that current language conveys appropriate information on the importance of prompt refrigeration of leftovers. In addition, the leftover statement is broad enough so as not to conflict with the described company policy.

Symbols

Six retailers and their associations commented on the symbols required by the proposed regulation. They stated the symbols were possibly misleading, do not effectively enhance the message and are meaningless without the word message. In addition, the commenters stated that the symbols were likely to confuse those who can read the label as well as those who cannot read. A specific example cited was that the frying pan may suggest that frying is the preferred method of cooking. In addition, the use of symbols also substantially increases costs to retailers. The commenters recommended that the symbols be eliminated.

One consumer group and one meat trade association supported the use of the symbols. The consumer group stated that the symbols provide important information to those who cannot read English and serve as a reminder of the written instructions to those who have read them. The symbols also draw attention to the labels and convey the instructions to the consumers instantaneously. However, they do not believe the symbol for the cross contamination message is clear or effectively illustrated the need to keep raw meat and poultry separate from other foods.

One USDA Agency suggested that the frying pan be replaced by a pot. This Agency believes that the skillet might be interpreted as a suggestion that the meat be fried, which is inconsistent with nutritional recommendations of the Department. Our focus-study research on labels has indicated that short messages with visual symbols are more acceptable to consumers as a means of alerting them to actions they should take. Symbols convey messages to individuals who have difficulty reading

English. The symbols provide visual reminders of actions consumers should take to handle food safely. The symbols were modified from those originally considered to reflect suggestions from participants of the focus-study research and public comments. Regarding the cross contamination symbol, FSIS agrees that the symbol addresses the cleaning portion of the message. However, since no feasible alternatives were offered for the symbol of the soapy hands under a faucet, FSIS will not make any changes in the symbol. Finally, regarding the objections to the skillet symbol, FSIS believes that the skillet is a more recognizable symbol than a pot, given the scale of its representation. Additionally, the Agency considers the likelihood of resulting confusion over preferred cooking method to be low. Therefore, FSIS is retaining the skillet symbol as proposed.

FSIS is adopting the proposed rule as a final rule with the changes as discussed above. Labels prepared in accordance with the August 16, 1993, interim rule may be used for 1 year past the effective date of this final rule.

List of Subjects

9 CFR 317

Food labeling, Meat inspection.

9 CFR 381

Food labeling, Poultry inspection.

Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 317 and 381 of the Federal meat and poultry products inspection regulations to read as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 317.2 is amended by adding a new paragraph (1) to read as follows:

§ 317.2 Labels; definition; required features.

* * * * *

(1) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, or other equine not heat processed in a manner that conforms to the time and temperature combinations in the Table for Time/Temperature Combination For Cooked Beef, Roast Beef, and Cooked Corned Beef in § 318.17, or that have not undergone

other further processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations For Fully-Cooked Patties in § 318.23; except as exempted under paragraph (1)(4) of this section.

(1)(i) Safe handling instructions shall accompany every meat or meat product, specified in this paragraph (1) destined for household consumers, hotels, restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading "Safe Handling Instructions" which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (1)(2) and (1)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) The labels of the meat and meat products specified in this paragraph (1) shall include the following rationale statement as part of the safe handling instructions, "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Meat and meat products, specified in this paragraph (1), shall bear the labeling statements:

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions, may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after

touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Meat or meat products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (l)(1) through (l)(3) of this section.

3. Section 317.5 is amended by deleting the word "or" following the semicolon at the end of paragraph (b)(12), replacing the period at the end of paragraph (b)(13) with a semicolon followed by the word "or", and adding a new paragraph (b)(14) to read as follows:

§ 317.5 Generically approved labeling.

* * *

(b) * * *

(14) The addition of safe handling instructions as required by § 317.2 of this subchapter.

4. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451-470; 7 CFR 2.17, 2.55.

5. Section 381.125 is amended by designating the current paragraph as (a) and adding a new paragraph (b) to read as follows:

§ 381.125 Special handling label requirements.

* * *

(b) Safe handling instructions shall be provided for all poultry products not heat processed in accordance with the provisions of § 381.150(b) or that have not undergone other further processing that would render them ready-to-eat, except as exempted under paragraph (b)(4) of this section.

(1) (i) Safe handling instructions shall accompany the poultry products, specified in this paragraph (b), destined for household consumers, hotels,

restaurants, or similar institutions and shall appear on the label. The information shall be in lettering no smaller than one-sixteenth of an inch in size and shall be prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) The safe handling information shall be presented on the label under the heading "Safe Handling Instructions" which shall be set in type size larger than the print size of the rationale statement and handling statements as discussed in paragraphs (b)(2) and (b)(3) of this section. The safe handling information shall be set off by a border and shall be one color type printed on a single color contrasting background whenever practical.

(2) (i) The labels of the poultry products, specified in this paragraph (b) and prepared from inspected and passed poultry, shall include the following rationale statement as part of the safe handling instructions, "This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

(ii) The labels of the poultry products, specified in this paragraph (b) and prepared pursuant to § 381.10(a) (2), (5), (6), and (7), shall include the following rationale statement as part of the safe handling instructions, "Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

(3) Poultry products, specified in this paragraph (b), shall bear the labeling statements.

(i) Keep refrigerated or frozen. Thaw in refrigerator or microwave. (Any portion of this statement that is in conflict with the product's specific handling instructions may be omitted, e.g., instructions to cook without thawing.) (A graphic illustration of a refrigerator shall be displayed next to the statement.);

(ii) Keep raw meat and poultry separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw meat or poultry. (A graphic illustration of soapy hands under a faucet shall be displayed next to the statement.);

(iii) Cook thoroughly. (A graphic illustration of a skillet shall be displayed next to the statement.); and

(iv) Keep hot foods hot. Refrigerate leftovers immediately or discard. (A graphic illustration of a thermometer shall be displayed next to the statement.)

(4) Poultry products intended for further processing at another official establishment are exempt from the requirements prescribed in paragraphs (b)(1) through (b)(3) of this section.

6. Section 381.134 is amended by deleting the word "or" following the semicolon at the end of paragraph (b)(12), replacing the period at the end of paragraph (b)(13) with a semicolon followed by the word "or", and adding a new paragraph (b)(14) to read as follows:

§ 381.134 Generically approved labeling.

* * *

(b) * * *

(14) The addition of safe handling instructions as required by § 381.125 of this subchapter.

Done at Washington, DC, on March 23, 1994.

Patricia Jensen,
Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 94-7217 Filed 3-25-94; 8:45 am]

BILLING CODE 3410-01-M