license does not alter the responsibilities of the applicant.

Item 11. Provide a complete and detailed description for the end-use intended by the new ultimate consignee listed in Item 6. For guidance on completion of the item, refer to Supplement 1, Part 772 of the Export Administration Regulations. If additional space is needed, use Supplement Form BXA–622P–A or B.

Item 12. Complete only if end-user is not the ultimate consignee named in Item 6. If more than one end-user, insert the word "various" in the space and use Supplemental Form BXA–622P–B.

Item 13. Mark appropriate block with an (X) to identify if the commodity(ies) or technical data are to be reexported, sold or other. If "other" indicate disposition.

Item 14. When information is a continuation of a previous item(s) first state the item number(s). Do NOT put information from Item 9(a) through 9(d) in this space. Enter additional data pertinent to the transaction as required by the Export Administration Regulations. Include special certifications, names of parties in interest not disclosed elsewhere, such as foreign principal or supplier, explanation of documents attached, etc. If the application represents a transaction previously rejected, give prior case number issued by the Office of Export Licensing. Use Supplemental Form BXA–622P–A or B if additional space is needed.

Item 15. All three spaces must be completed and THE APPLICATION MUST BE MANUALLY SIGNED by the applicant or duly authorized agent of the applicant. If signed by agent of the applicant, show title and firm name or agent. (Rubber-stamped or other facsimile signatures are not acceptable.)

§ 773.2 [Amended]

13. In § 773.2, paragraph (c)(2)(ii)(B) is amended by revising the phrase "Item 7, Consignee in Country of Ultimate Destination" to read "Item 6, Ultimate Consignee" and paragraph (c)(2)(ii)(C) is amended by revising the phrase "Description of Commodity or Technical Data" to read "Commodity Manufacturer's Description of Commodity".

§ 773.7 [Amended]

14. In § 773.7, paragraph (d)(1)(iv)(B)(*2*) is amended by revising the phrase "Consignee in Country of Ultimate Destination" to read "Country of Ultimate Destination".

Supplement No. 5—[Amended]

15. Supplement No. 5 to Part 773 is amended as follows:

A. Paragraphs (b) and (c) are removed;

B. Paragraph (a) is redesignated as paragraph (b). Newly redesignated paragraph (b) is amended by revising the references to "Item 1(a)" to read "Item 3";

C. New paragraph (a) is added to read "(a) Items 1 and 2 are self explanatory.";

D. Paragraphs (d), (e), (f), (g) and (h) are redesignated as paragraphs (c), (d), (e), (f), and (g);

E. Newly redesignated paragraph (d) is amended by revising the reference to "Item 6, 8, 13, 14, 17" to read "Items 7, 8, 14, 17";

F. Newly redesignated paragraph (e) is amended by revising the reference to "Item 7" to read "Item 6" and the reference to "Attachment Item 7" to read "Attachment Item 6";

G. The phrase "Form ITA–622P" is revised to read "Form BXA–622P in the heading to Supplement No. 5 and in the newly redesignated paragraph (f), introductory text.

H. Newly redesignated paragraph (f)(1) is amended by revising the words "an attachment to the Form ITA–622P (labeled Attachment Item 9(b) product description")" to read "Form BXA–622P–A, "Commodity Description Supplement";

H. Newly redesignated paragraph (f)(2) is amended by revising the reference to "the attachment" to read "Form BXA–622P–A";

I. Newly redesignated paragraph (g) is amended by revising the words "at the bottom of the attachment to Item 9(b)" to read "in Item 15 of Form BXA–622P–A".

Dated: February 6, 1989.

Michael E. Zacharia,

Assistant Secretary for Export Administration.

[FR Doc. 89–3152 Filed 2–13–89; 8:45 am]

BILLING CODE 3510–DT–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1031 and 1032

Commission Participation and Commission Employee Involvement in Voluntary Standards

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Consumer Product Safety Commission is revising its regulations governing the Commission's participation in voluntary standards activities. The revised regulations reflect the policies set forth by Congress in the Consumer Product Safety Amendments of 1981, Pub. L. 97–35, and make several changes in the agency's policies on employee participation in voluntary standards development activities. Also, the revised regulations combine former Part 1031, Employee Membership and Participation in Voluntary Standards Organizations, and Part 1032, Commission Involvement in Voluntary Standards Activities, into a new Part 1031, Commission Participation and Commission Employee Involvement in Voluntary Standards Activities.

EFFECTIVE DATE: March 16, 1989.

FOR FURTHER INFORMATION CONTACT: Colin Church, Voluntary Standards Coordinator, Consumer Product Safety Commission, Washington, DC 20207, telephone: (301) 492–6550.

SUPPLEMENTARY INFORMATION:

Background

Congress enacted the Consumer Product Safety Act in 1972, codified at 15 U.S.C. 2051, et. seq., to protect consumers against unreasonable risks of injury associated with consumer products. In furtherance of that goal, Congress established the Consumer Product Safety Commission as an independent regulatory agency, and granted it broad authority to promulgate mandatory safety standards for consumer products as a necessary alternative to industry self-regulation. 15 U.S.C. 2056(a)(1)(A). The Commission was also given the authority to require manufacturers to provide consumer label warnings or instructions about their products, 15 U.S.C. 2056(a)(2), and to promulgate standards for products falling under the purview of the Refrigerator Safety Act, 15 U.S.C. 1211–1214, the Poison Prevention Packaging Act of 1970, 15 U.S.C. 1471–1476, the Flammable Fabrics Act, 15 U.S.C. 1191–1204, and the Federal Hazardous Substances Act, 15 U.S.C. 1261–1276. As originally enacted, neither the Consumer Product Safety Act nor the other statutes administered by the Commission contained any language referring to voluntary standards.

In 1978, the Commission issued regulations describing the extent and form of Commission involvement in the development of voluntary standards, 43 FR 19216, 16 CFR Part 1032—Commission Involvement in Voluntary Standards Activities. In the Background section, the Commission acknowledged the contribution which voluntary standards had made to reducing hazards associated with consumer products, and stated that it supported an effective voluntary standards program. Nonetheless, the Commission asserted that "While there might be circumstances in which a particular voluntary standard can substitute for a mandatory standard, the Commission generally views voluntary standards as complementary to and not a substitute

for mandatory standards". It stated, also, its belief that a proper combination of voluntary and mandatory standards can have a higher "payoff" in increased product safety than either mandatory or voluntary activities alone could have.

In 1981, Congress amended the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act, to mandate that the Commission give preference to voluntary standards over promulgating mandatory standards, if it determines that a voluntary standard will eliminate or adequately reduce an injury risk, and that there will be a likelihood of substantial compliance with the standard. 15 U.S.C. 2056(b), 15 U.S.C. 1262(g)(2), 15 U.S.C. 1193(h)(2). The amendments also require the Commission to provide administrative and technical assistance to organizations engaged in voluntary standards development. 15 U.S.C. 2054(a) (3) and (4).

Thereafter, the Commission conducted its activities in accordance with the policies of the 1981 Amendments by deferring to voluntary standards in those cases where a voluntary standard would adequately reduce an unreasonable risk of injury and there was a reasonable likelihood of substantial compliance with the standard. However, the Commission's policy statement in 16 CFR Part 1032 is inconsistent with the policy stated in the 1981 Amendments.

The Commission proposed, at 53 FR 44892, November 7, 1988, a new part 1031 to conform the Commission's policy with the 1981 Amendments. The proposed new Part 1031 also incorporated, with changes, the provisions of current 16 CFR Part 1031, the Commission's regulations governing employee membership and participation in voluntary standards organizations, which were initially promulgated on June 20, 1975, 40 FR 26023. The part specified which Commission officers and employees can be members of voluntary standards bodies or can participate in voluntary standards development activities. The comments received, and the Commission's responses, are discussed later. The substantive changes made by this final regulation are discussed below.

Explanation of Changes and Additions in Part 1031

Subpart A, General Policies, is a revision of current 16 CFR Part 1032, Commission Involvement in Voluntary Standards Activities. Subpart A is substantially the same as existing Part 1032, except as described below.

Section 1031.1(b) has been added to define "voluntary standards bodies" and "voluntary standards development bodies". The definitions are similar to those in OMB Circular A–119 and reflect the language Congress employed in section 5(a) (3) and (4) of the Consumer Product Safety Act as to which organizations the Commission should assist in voluntary standards activities, i.e., "public and private organizations or groups of manufacturers." The definitions are stated in broad terms so as to encompass any organization that has the capability of developing a voluntary standard.

Section 1031.2, Background, a complete revision of current § 1032.1, explains the policy of the Commission regarding voluntary standards. Section 1031.2(b) explains the statutory requirements of the 1981 Amendments regarding voluntary standards. Section 1031.2(c) describes the policies set forth in office of Management and Budget Circular No. A–119 pertaining to federal participation in the development and use of voluntary standards. The Circular encourages government participation in the standards-related activities of voluntary standards bodies and standards-developing groups when such participation is in the public interest and is compatible with the agencies, missions, authorities, priorities, and budget resources.

Section 1031.3, Consumer Product Safety Act Amendments, incorporates the text of several sections from the Act, as amended in 1981, which pertain to the Commission's participation in the development and use of voluntary standards. The provisions are provided in the text of the regulation for the reader's convenience.

Section 1031.4(a)(2) modifies current § 1032.6(a)(2), so that one of the criteria for the Commission's determination that a voluntary standard is adequate to eliminate or reduce a risk of injury associated with a consumer product is changed from the language that "there is a sufficiently high degree of conformance to the voluntary standard" to language "it is likely that there will be substantial and timely compliance with the voluntary standard." The new language reflects provisions in the 1981 Amendments that allows the Commission to defer to proposed voluntary standards under appropriate circumstances.

Section 1032.6(b) in the current regulations is deleted since it is inconsistent with the 1981 Amendments.

Section 1031.4(b) is a new provision that provides for the Commission to initiate a proceeding for the development of a mandatory standard in the event it determines there is no voluntary standard that will eliminate or adequately reduce a risk of injury.

Section 1031.4(c) revises the language in current 16 CFR 1032.6(d), which requires the Commission to consider the provisions of a voluntary standard when it initiates a development proceeding under "section 7 of the Consumer Product Safety Act." As originally enacted, section 7, referred to as the "offeror process", provided that the Commission could solicit "offers" from private sector organizations to develop a mandatory standard. However, section 7 was revised by the 1981 Amendments to abolish the "offeror process"; thus, reference to that section is inappropriate. The proposed § 1031.4(c) references, instead, the provisions of the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act which prescribe the process for issuing a mandatory consumer product safety rule.

Section 1031.5 sets forth the criteria for Commission participation in voluntary standards activities. They are substantially the same criteria set forth in the former 16 CFR 1032.5, except that two new criteria (subsections (a) and (b)) have been added to conform to criteria prescribed by the 1981 Amendments and their legislative history.

Section 1031.5(f) provides criteria superseding the criterion set forth in former 16 CFR 1032.5(e) for Commission consideration to determine whether to participate in the development of a voluntary standard. The former provision merely required that the Commission consider the degree and ascertainability of industry conformance with a voluntary standard once it is issued. The new section requires the Commission to consider any reasonable industry arrangements for achieving substantial industry compliance with a voluntary standard once it is issued and the means of ascertaining such compliance based on overall market share of product production. The latter requirement reflects the Congressional direction that, in most instances, compliance should be measured in terms of complying consumer products rather than in terms of the number of complying industry members. See the Conference Report to accompany H.R. 3982, H. R. Rep. NO. 97–208, 97th Cong., lst Sess., 871 (1981).

Section 1031.5(i) revises former 16 CFR 1032.5(a) to state that participants in a voluntary standard development have "knowledge or expertise in the

area under consideration," rather than "technical expertise," so as to encourage broader participation by those affected by the standard. See the discussion of this section in "Comments received and Commission responses" below.

Section 1031.6(c)(2) replaces and revises former 16 CFR 1032.2(b)(2), which described examples of Commission participation in voluntary standards activities, by adding language allowing the Commission to provide administrative assistance (e.g., travel costs, hosting meetings, and performing secretarial functions) in support of the development and implementation of voluntary standards. This provision is derived from section 5 of the Consumer Product Safety Act, as amended in 1981.

Section 1031.6(d) is added to conform to the policy set forth in OMB Circular A–119, that, normally, agencies should not provide greater support to a voluntary standards activity than that of all the non-federal participants.

Section 1031.7(a)(7) replaces and revises 16 CFR 1032.4(b)(7) by adding a clause that indicates that the Commission's support of voluntary standards activities may include encouraging states and local governments to participate in government or industrial model code development activities so as to develop uniformity and to minimize conflicting state and local regulations, as provided by section 2(b)(3) of the Consumer Product Safety Act.

Section 1031.7(a)(8) provides a new example of the type of support the Commission may use in assisting voluntary standards development, i.e., monitoring the number and market share of products conforming to a voluntary safety standard. This will enable the Commission to ascertain industry compliance with a voluntary standard by market share.

16 CFR 1032.4(b)(9) has been deleted.

Section 1031.7(a)(9) is a new provision. It acknowledges that one form of Commission support for voluntary standards development is providing for the involvement of agency personnel in voluntary standards activities as described in Subpart B of this part.

Sections 1031.7(a) (10) and (11) are new provisions. They indicate that the Commission may provide administrative and financial support to a voluntary standards development activity, as authorized by the 1981 Amendments.

Section 1031.8 is a new provision. It describes the functions of the Voluntary Standards Coordinator, a Commission employee responsible for coordinating agency participation in voluntary standards activities and managing the voluntary standards program.

Subpart B, Employee Involvement in Voluntary Standards Activities, supersedes the former 16 CFR Part 1031. The subpart has the same general effect as the former Part 1031 except for the changes noted below.

Section 1031.9(c)(1) revises former § 1031.1(a) to state that the Commission's participation in voluntary standards programs is consistent with the federal policy set forth in OMB Circular No. A–119, as well as the Consumer Product Safety Act and other statutes administered by the Commission.

Section 1031.9(c)(4) is a new provision. It states that Commission employee participation in voluntary standards activities should take into account Commission resources and priorities. This provision conforms to language in the legislative history of the 1981 Amendments directing the Commission to consider its resources and priorities when determining what assistance it will provide to voluntary standards development. Conference Report to H.R. 3982, p. 884.

Section 1031.10 is a new section. It defines, for the purpose of Subpart B on employee involvement in voluntary standards activities, the terms membership, participation, monitoring, observation, and communication.

Section 1031.11(b) is a new provision which requires employees, who participate in the development of a voluntary standard and then later advise the Commission regarding that standard, to advise the Commission on the extent of their involvement. Also, the provision requires that evaluations and recommendations by such employees should strive to be as objective as possible and should be reviewed by higher level Commission officials prior to submission to the Commission.

Section 1031.12(a) lists those Commission officials who may not become members of a voluntary standards group because they have the responsibility for making final decisions, or objectively advising those who make final decisions, on whether to rely on a voluntary standard, promulgate a consumer product safety standard, or to take other action to prevent or reduce an unreasonable risk of injury associated with a product. The list is the same as that in former § 1031.4, except that Program Managers in the Office of Program Management and Budget have been deleted because their work and recommendations are reviewed by supervisory officials before being given to the Commission. It has also been revised to reflect the Commission's functions regarding voluntary standards which emanate from the 1981 Amendments, i.e., to determine whether a voluntary standard will adequately address a problem involving an unreasonable risk. The predecessor provision referred to the Commission's functions relating to the "offeror process" which, as noted above, was abolished by the 1981 Amendments.

Section 1031.12(c) is a new provision. It requires employees who have obtained approval from the Executive Director to accept membership in a voluntary standards organization to so inform the General Counsel and the Voluntary Standards Coordinator prior to their acceptance. This will allow the General Counsel and the Voluntary Standards Coordinator to be aware of the membership and an opportunity for them to provide any necessary guidance to the employee.

Section 1031.12(d) is a new provision that requires employees who seek membership in a voluntary standards organization in their individual capacity to seek approval from the Commission's Ethics Official in accordance with the Commission's Employee Standards of Conduct, 16 CFR Part 1030.

Section 1031.13(a), like its predecessor provision § 1031.5(d), provides that Commission employees, except for those who are specifically listed, may participate in or monitor voluntary standards development. The proposed provision differs from its predecessor in that it requires approval for employee participation or monitoring by the employee's supervisor and any other person required to do so by internal agency management procedures, whereas approval under the former regulations is required to be given by the Executive Director alone.

Section 1031.14, Observation criteria, supersedes the last sentence in former § 1031.5(d). The new provision requires employees who wish to attend voluntary standards meetings for the sole purpose of observation to obtain approval from their supervisor and any other person required to approve pursuant to internal agency management procedures. Under the former provision, approval had to be provided by the Executive Director. The new provision also requires the employee to notify the Voluntary Standards Coordinator prior to observing a voluntary standard meeting.

Section 1031.15, Communication criteria, is a new provision providing the conditions for officials and employees to communicate with voluntary standards groups and representatives.

Commission officials and employees, who are authorized to be members of a voluntary standards group in their official capacity under section 1031.12(b), may communicate with a voluntary standard group or representative incidental to their membership. Likewise, those officials or employees, who are approved to participate in or monitor a voluntary standard development under § 1031.13 (a) and (b), may communicate with the voluntary standard body or its representatives as part of their approved participation in, or monitoring of, a standard under development.

Agency employees and officials who do not fall within either of the above categories, and are not prohibited from membership in a voluntary standards organization by virtue of § 1031.12(a), may be authorized to communicate with a voluntary standards group, representative, or other committee member on substantive matters, as defined in § 1031.15(a)(1). Approval must be given by the person to whom an employee would apply to obtain approval for participation or monitoring pursuant to § 1031.13. Those same employees and officials may communicate with a voluntary standards group, representative, or other committee member on non-substantive matters within the scope of their duties without specific authorization.

Substantive matters are defined in § 1031.15(a)(1) as those matters that pertain to the formulation of the technical aspects of a specific voluntary standard or the course of conduct for developing a voluntary standard. Nonsubstantive matters would include those relating to scheduling meetings, obtaining status reports, and other administrative matters.

Section 1031.15(b) is a new provision. It requires that employees communicate with voluntary standards organizations in accordance with any internal agency procedures.

Section 1031.15(c) is a new provision. It provides that the Commissioners can engage in written communications with voluntary standards bodies or representatives on voluntary standards matters providing they state that any substantive views expressed are only their individual views, and not necessarily those of the Commission acting in its collegial capacity. This provision changes the former regulation in § 1031.5—self-imposed by the Commission in 1978—that precluded the Commissioners from personally communicating with voluntary standards organizations concerning the development of voluntary standards. The new provision permits the Commissioners to actively encourage and support the development and use of voluntary standards to alleviate product hazards. The disclaimer is intended to preclude any misunderstanding on the part of a recipient of a letter as to whether the views expressed therein are those of the individual Commissioner or those of the Commission. Of course, the Commission may always communicate with parties on voluntary standards matters upon which they agree in their official collegial capacity.

Section 1031.15(d) is a new provision. It requires that Commission officials and employees furnish a copy of each written communication of a substantive nature, and a report of each substantive oral conversation with voluntary standards groups or individuals, to the Voluntary Standards Coordinator. This requirement will enable the Coordinator to monitor all the voluntary standards activities the Commission and its employees are engaged in.

Comments Received and Commission Responses

In response to the notice at 53 FR 44892, November 7, 1988, the Commission received comments from the Alliance of American Insurers, the American Gas Association Laboratories, the American Petroleum Institute, the American Society for Testing and Materials, the Consumer Federation of America, the Department of Defense, the Council of American Building Officials, the National Institute of Standards and Technology, the Whirlpool Corporation, the Underwriters Laboratories, and the ANSI Z21 Accredited Standards Committee. Several Commission staff members also made additional comments. The issues raised by these comments and the Commission's resolution of those issues are discussed below.

Section 1031.1(b)

The Consumer Federation of America recommended that § 1031.1(b) be amended to indicate the Commission's preference and support for standards development organizations that utilize a consensus process and other due process considerations. CFA cites the Conference Report on the 1981 Amendments that states that voluntary standards that the Commission rely on should have been adopted in accordance with reasonable procedures such as those utilized by groups that develop national consensus standards.

The Commission agrees with CFA's comment that preference be given to those voluntary standards that have been developed by a consensus process. This preference is expressed in § 1031.5(f) as a factor the Commission will consider in deciding whether to participate in the the development of a voluntary standard. That section requires standards development groups to establish procedures that "provide for meaningful participation" by the participants, including consumers and small business. However, there may be situations where an existing voluntary standard that was not developed by consensus procedures will, nevertheless, eliminate or adequately reduce the risk of injury presented by a hazard. Thus, the Commission has decided not to impose a consensus procedure as a mandatory requirement for Commission deferral to a standard but, instead, continue to encourage the use of consensus procedures by standards bodies.

The Alliance of American Insurers (AAI) recommends that the sentence in § 1031.1(b) that defines voluntary standards development bodies be revised to require that subgroups within the definition be "accredited subgroups" to encompass those committees whose procedures are accredited in the ANSI system of standards development.

The Commission decided not to accept this recommendation for the reason that it may be unnecessarily restrictive. The Conference Report for the 1981 Amendments indicated that Congress contemplated that voluntary standards should be developed and adopted "in accordance with reasonable procedures, such as those utilized by groups that develop national consensus standards". As stated above, the procedures that a voluntary development group will employ will be a factor in the Commission's determination whether to participate in a standard development. However, the Commission chooses not to mandate the development procedures. Likewise, it does not believe that accreditation should be a prerequisite to Commission participation in a development effort or reliance on a voluntary standard developed by a non-accredited group.

Section 1031.4(a)(2)

CFA recommends that § 1031.4(a)(2) be amended to allow deferral to a voluntary standard only where there will be compliance with the standard in a timely fashion, as was stated in the Conference Report to the 1981 Amendments.

The Commission agrees with this comment and, accordingly, has revised the subsection to require that industry compliance with a voluntary standard be "timely" as well as "substantial". As CFA noted, the Conference Report to the

1981 Amendments stated "In evaluating whether there will be substantial compliance with a voluntary standard, the Commission should determine whether or not there will be sufficient compliance to eliminate or adequately reduce an unreasonable risk of injury in a timely fashion." Conference Report, H.R. Rep. No. 97–208, July 29, 1981, at 871, 874. The timeliness language was also added to § 1031.5(f), the criterion concerning industry arrangements for achieving substantial industry compliance once a voluntary standard is issued.

Section 1031.4(a)(3)

Whirlpool Corporation commented on the language in this section that indicated the allocation of Commission staff involvement in evaluating voluntary standards as it would a mandatory standard. Whirlpool questions whether Commission involvement in voluntary standards setting is necessary or appropriate and whether Commission resources could be utilized in a better manner.

The Commission is, of course, concerned with the allocation of staff time and resources. However, the criteria for the Commission relying on a voluntary standard instead of a mandatory standard is set forth in sections 7 and 9 of the Consumer Product Safety Act, i.e., the voluntary standard must eliminate or adequately reduce the risk of injury addressed, and it is likely that there will be substantial compliance with such voluntary standard. Thus, the Commission is obligated to expend adequate staff time and resources to be able to determine whether the criteria in sections 7 and 9 is met.

Section 1031.4(a)(4)

AAI suggests that the language in the first sentence be revised to substitute the word "few" instead of "one or two" areas where a voluntary standard is considered by the Commission to be inadequate. The comment is that the words "one or two" are unnecessarily restrictive and forces the Commission to make a judgment based on numbers rather than a broader consideration of issues involved in deciding to defer to a voluntary standard modification.

The Commission agrees with the commentor and has revised the language as suggested.

In the same first sentence AAI suggests that the words "or its accredited subgroup operator" appear immediately after the words "voluntary standards groups".

The Commission does not accept this suggestion for the reason that the definitions of voluntary standards bodies or voluntary standards development bodies encompass their subgroups. Also, as stated above, the Commission chooses not to mandate that organizations or subgroups be accredited as a prerequisite to their developing or modifying a voluntary standard.

CFA stated its belief that § 1031.4(a)(4), a provision which allows the Commission to extend the deferral period, contradicts the requirement that a voluntary standard be promulgated in a timely fashion. It recommends that the section be revised to say that if a voluntary standard is not developed or modified in an expeditious manner, then the Commission will immediately commence to develop a mandatory standard.

The Commission agrees that the development or modification of a voluntary standard to address a product hazard should always be done as expeditiously as possible and that is a consideration in its decision whether to defer to the voluntary standard development or to commence a mandatory rulemaking immediately. However, the Commission does not believe that the language of this section has to be changed since it is implicit in the Commission's decision whether to defer mandatory standards development or to commence it immediately. The Commission will consider whether the initial deferral period was adequate or whether additional time is reasonable under the circumstances.

Section 1031.5(f)

As CFA commented on § 1031.4(a)(2), discussed above, it suggests the language in this section be revised to require that substantial compliance be reached in a "timely" fashion.

The Commission agrees with the commentor and has revised the language to revise the criteria for Commission participation to require Commission consideration of "timely," as well as "substantial" compliance.

Section 1031.5(g)

AAI suggests that this section be made more specific as to what types of marking requirements should be included in a voluntary standard to permit Commission investigation of such products at a later time. The commentor suggested several examples.

Although the examples given by the commentor would be appropriate, the Commission does not cite specific examples since they may not be appropriate to every voluntary standard. Accordingly, the Commission prefers to state the marking requirement in broad terms.

Section 1031.5(i)

CFA expressed its concern that the last sentence in § 1031.5(i) could be interpreted to mean that representatives of consumers and small business in a voluntary standard development have technical expertise in the areas under consideration.

The Commission agrees that the sentence could be misread and thus has revised it to make it clear that technical expertise, as that term is commonly used, should not be a prerequisite for consumer and small business participation in a voluntary standard development process. There may be situations where the voluntary standard development group would want non-technical input from consumer and small business representatives, e.g., on frequency of use of a product, consumer awareness of the meaning of proposed labels, etc. Likewise, as CFA suggests, these representatives can play an important role in questioning the rationale for a standard without having technical expertise. Accordingly, the Commission has replaced the expression "technical expertise" with the expression "knowledge or expertise."

Whirlpool inquired whether the listing of the representatives in this section means that, unless all the groups are included in each voluntary standards proceeding, the Commission will expand its involvement. The commentor suggests that participation by so many groups could be counterproductive and could impede the voluntary standards setting process.

The purpose of this provision is to encourage voluntary standards groups to conduct their activities openly and to include in their development activities those parties who will be affected by the voluntary standard under development. The Commission does not expect that each and every entity listed in this provision be represented on every voluntary standard development group; the composition of each development group will necessarily depend on the nature of the subject matter.

Whirlpool also suggested that some groups may not have the technical expertise to participate in voluntary standards development.

The Commission does not believe that participation is appropriate only for persons or groups with purely technical expertise. In accordance with its discussion of CFA's comments on § 1031.5(i), it has broadened the definition of "openness" by calling for participation of parties having "knowledge or expertise."

Section 1031.7(a)(4)

AAI recommended that the term "technical support" be broadened by including the words "engineering support such as innovative product design", and the words "safety and" immediately before the words "health science data."

The Commission believes that the section, as written, adequately describes the type of assistance the Commission may provide to support a voluntary standard development activity. Also, the Commission's use of the term "health science data" includes safety data. Thus, it prefers to leave the section unchanged.

Section 1031.7(a)(6)

AAI suggests that the phrase "including labels/markings" be added at the end of the sentence to permit the Commission staff to not only evaluate the technical adequacy of a standard in reducing injuries, but also to evaluate the labels and markings that must be included in the standard as part of the safety strategy.

The Commission believes that this addition is unnecessary because it is understood that the staff will evaluate all relevant aspects of a standard, including labels and markings. Thus, the Commission decided to leave this section unchanged.

Section 1031.7(a)(9)

Representatives of the Commission staff recommended that this section (formerly 16 CFR 1032.4(b)(9)) be deleted since the Commission will not approve the preparation of a listing of voluntary standards that adequately address specific hazards in view of a previous Commission decision regarding the recognition of voluntary standards. See Minutes of Commission Action dated January 16, 1985. The Commission agrees with the staff's recommendation and, therefore, has deleted this section. Accordingly, proposed §§ 1031.7(a)(10) through 1031.7(a)(13) have been renumbered as §§ 1031.7(a)(9) through 1031.7(a)(12).

Section 1031.10(a)

AAI suggests that the language in the last sentence, stating that membership includes all oral and written communications "which are incidental to such membership" may not be sufficiently clear, and recommends that the last sentence in subparagraph (b) be substituted in (a).

The Commission believes the language in this section is sufficiently clear that the definition of "membership" encompasses communications relating to a membership. Also, the suggested substitute language from subparagraph (b) would be inappropriate since it pertains to communications relating to active participation in a voluntary standard activity. Membership, as used in this section, could be passive membership. Thus, the Commission has decided to leave this section unchanged.

Section 1031.11(d)

Several commentors criticized the Commission policy in this section which prohibits Commission employees from voting or otherwise formally indicating approval or disapproval of a voluntary standard during its development and adoption. They suggested that the no-voting policy is inconsistent with active participation of Commission employees in standards development activities. Also, several commentors pointed out that the OMB Circular A–119 encourages agencies to actively participate in the development of voluntary standards, including voting on issues in the course of the development process. On the other hand, several other commentors applauded the Commission policy.

The Commission's no-voting policy is premised on the Commission's status as a regulatory agency and on the role of the Commission staff in ultimately recommending whether the Commission should defer setting a mandatory standard because a voluntary standard addresses the hazard in question. Additionally, the Commission is able to provide technical and administrative assistance to those organizations and groups developing standards. The Commission, through its employees, have been able to provide that assistance to many voluntary standard development activities over the course of years without formally voting. Also, the no-voting policy is intended to preclude any appearance that the Commission, through its representative, is endorsing a particular standard or is committing it to supporting that standard to the exclusion of alternative regulatory actions. Although the OMB Circular encourages active participation and voting by agency representatives, it recognizes that agencies may prohibit such voting. See Circular, section 7.b.(5). For the reasons stated, the Commission continues to believe the no-voting policy is a prudent and well-considered one. Thus, the Commission has decided to leave this section unchanged.

Section 1032.12(b)

The Associate Director for Industry and Standards, National Institute of Standards and Technology, commented that the no-voting policy should apply to employees serving on voluntary standards development groups or committees, but not to employees serving on standards advisory groups that are not responsible for the development and approval of standards. The Associate Director suggested several such groups.

Although the advisory groups referred to in this section may not directly engage in the development of voluntary standards, they frequently establish policies that could impact on voluntary standard activities of the particular organization. As with voluntary standards development groups, the Commission does not want its employees formally participating in the policy decisions of a voluntary standards board or advisory group for the reason that an employee's formal vote may give the appearance of Commission action or the Commission's position on the matter. The policy also precludes a possible conflict of interest situation where an employee who voted on a matter is later required to address the same matter in his or her capacity as a Commission employee. Further, the Commission believes it can provide information and assistance to these policy committees without having to vote on particular issues or policy matters. In this regard, the Commissioners and Commission staff may freely communicate with voluntary standards groups or representative in accordance with § 1032.15. For these reasons, the Commission has decided not to change this section.

Sections 1031.13(a) and 1031.15(b)

A staff member commented that the last sentence in these two paragraphs could be understood that an employee who is participating in or monitoring a voluntary standard development would have to obtain consensus review and approval of Commission officials at every stage of the development process, and that voluntary standards groups would be reluctant to have a Commission employee as a member on that basis.

The Commission did not intend to imply that staff review and consensus of an employee's participation or monitoring is required at each and every stage of a voluntary standard development process. Instead, the statement was intended to state an employee's participation or monitoring shall be in accordance with any internal Commission procedures that the Commission or Commission management may have established. However, to avoid any

misunderstanding, the last sentence in both these paragraphs have been revised to delete the phrase "designed to assure staff review and consensus".

Section 1031.13(c)

CFA commented that § 1031.13(c), which allows Commission employees to participate in closed meetings of voluntary standards development groups under extraordinary circumstances, be amended to require that meeting logs from such closed meeting be made available to the public upon request.

In fact, the Commission's regulations setting forth its meetings policy (16 CFR Part 1012) already requires employees to prepare and submit a meeting summary to the Office of the Secretary within twenty calendar days after a meeting for which a summary is required to be made. These summaries are available to the public as permitted by law. The Commission agrees that the section should be revised to reference the meeting summary requirement.

CFA recommends that the last sentence in § 1031.13(c), requiring Commission employees to provide notice of their attendance at a voluntary standard development meeting in the public calendar, also be included in § 1031.11, the section setting forth the procedural safeguards to assure employee objectivity and for avoiding conflict of interest situations.

The Commission agrees that the meetings policy requirements are procedural safeguards that permit public monitoring of Commission involvement of voluntary standards activities. Thus, a new subsection, similar to the last sentence in § 1031.13(c), has been added as § 1031.11(f) to reference the Commission's meetings policy requirement.

Section 1031.15(a)

AAI commented that this section may be unclear as to whether the term "representative" is restricted to an official of the voluntary standard organization or whether it could pertain to another member of a voluntary standard development group who is not an official of the sponsoring voluntary standard organization.

The Commission agrees that the paragraph, as written, could be read as restricting communications to representatives of the sponsoring voluntary standard organization. The Commission did not intend to restrict communications between its employees and other members who may both be serving together on a voluntary standard committee. Thus, the language in this section is revised to add "or other committee member" immediately after the phrase "voluntary standard group or representative".

Section 1031.15(a)(2)

AAI states that it cannot understand the need for communication which is nonsubstantive in nature and requests a clarification.

The Commission distinguishes between substantive and nonsubstantive communications because substantive communications require supervisory approval whereas nonsubstantive communications do not. Nonsubstantive communications would cover administrative matters such as the date and place of the next meeting of the voluntary standard group, travel arrangements, etc. With these examples, and the definition of substantive matters in § 1032.15(a)(1) as "matters that pertain to the formulation of the technical aspects of a voluntary standard or the course of conduct for developing a standard", the meaning of anything else, i.e., "non-substantive" matters, is sufficiently clear. Thus, the Commission decided not to revise the section.

Certification of No Significant Economic Impact on Small Entities

The Regulatory Flexibility Act (5 U.S.C. 601, et seq.) requires that whenever a federal agency publishes a proposal under the Administrative Procedure Act (5 U.S.C. 553), it must give particular consideration to small businesses, small non-profit organizations, and small local governments (collectively called "small entities"). The proposed regulations are only for the information of the public and industry. They will not have the force of law, and will not impose any substantive obligation or duty on any person or firm, including any small firm. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, the Commission certifies that the proposed regulations will not have a significant economic impact on a substantial number of small entities.

Environmental Considerations

The proposal published below will have little or no potential for affecting the human environment. For this reason, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

16 CFR Part 1031

Business and industry, Conflict of interest, Consumer protection, Voluntary standards.

16 CFR Part 1032

Business and industry, Consumer protection, Voluntary standards.

For the reasons set out in the preamble, Title 16, Chapter II of the Code of Federal Regulations is amended as follows:

PART 1032—[REMOVED]

1. Part 1032 is removed.

2. Part 1031 is revised to read as follows:

PART 1031—COMMISSION PARTICIPATION AND COMMISSION EMPLOYEE INVOLVEMENT IN VOLUNTARY STANDARDS ACTIVITIES

Subpart A—General Policies

Sec.

Subpart B—Employee Involvement

Authority: 15 U.S.C. 2051–2083, 15 U.S.C. 1261–1276, 15 U.S.C. 1191–1204.

Subpart A—General Policies

§ 1031.1 Purpose and scope.

(a) This Part 1031 sets forth the Consumer Product Safety Commission's guidelines and requirements on participating in the activities of voluntary standards bodies. Subpart A sets forth general policies on Commission participation, and Subpart B sets forth policies and guidelines on employee involvement in voluntary standards activities.

(b) For purposes of both Subpart A and Subpart B of this Part 1031, voluntary standards bodies are private sector domestic or multinational organizations or groups, or combinations thereof, such as, but not limited to, all non-profit organizations, industry associations, professional and technical societies, institutes, and test laboratories, that are involved in the planning, development, establishment,

revision, review or coordination of voluntary standards. Voluntary standards development bodies are voluntary standards bodies, or their subgroups, that are devoted to developing or establishing voluntary standards.

§ 1031.2 Background.

(a) Congress enacted the Consumer Product Safety Act in 1972 to protect consumers against unreasonable risks of injury associated with consumer products. In order to achieve that goal, Congress established the Consumer Product Safety Commission as an independent regulatory agency and granted it broad authority to promulgate mandatory safety standards for consumer products as a necessary alternative to industry self regulation.

(b) In 1981, the Congress amended the Consumer Product Safety Act, The Federal Hazardous Substances Act, and the Flammable Fabrics Act, to require the Commission to rely on voluntary standards rather than promulgate a mandatory standard when voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with the voluntary standards. (15 U.S.C. 2056(b), 15 U.S.C. 1262(g)(2), 15 U.S.C. 1193(h)(2)). The 1981 Amendments also require the Commission, after any notice or advance notice of proposed rulemaking, to provide technical and administrative assistance to persons or groups who propose to develop or modify an appropriate voluntary standard. (15 U.S.C. 2054(a)(3)). Additionally, the amendments encourage the Commission to provide technical and administrative assistance to groups developing product safety standards and test methods, taking into account Commission resources and priorities (15 U.S.C. 2054(a)(4)). Although the Commission is required to provide assistance to such groups, it may determine the level of assistance in accordance with the level of its own administrative and technical resources and in accordance with its assessment of the likelihood that the groups being assisted will successfully develop a voluntary standard that will preclude the need for a mandatory standard.

(c) In 1982, the Office of Management and Budget revised Circular No. A–119, Federal Participation in the Development and Use of Voluntary Standards. The Circular establishes the policy to be followed by executive agencies, including the Commission, in working with voluntary standards bodies and in adopting and using voluntary standards. The Circular encourages government participation in the standards-related activities of voluntary standards bodies and standards-developing groups when such participation is in the public interest and is compatible with the agencies, missions, authorities, priorities, and budget resources. The Circular recognizes, however, that voluntary standards activities, if improperly conducted, can suppress free and fair competition, impede innovation and technical progress, exclude safer and less expensive products, or otherwise adversely affect trade, commerce, health, or safety. Thus, agencies are urged to take full account of the impact on the economy, applicable Federal laws, policies and national objectives, including, for example, laws and regulations relating to antitrust, national security, small business, product safety, environment, technological development, and conflicts of interest.

§ 1031.3 Consumer Product Safety Act Amendments.

The Consumer Product Safety Act, as amended, contains several sections pertaining to the Commission's participation in the development and use of voluntary standards.

(a) Section 7(b) provides that the Commission shall rely on voluntary consumer product safety standards prescribing requirements described in subsection (a) whenever compliance with such voluntary standards would eliminate or adequately reduce the risk of injury addressed and it is likely that there will be substantial compliance with such voluntary standards. (15 U.S.C. 2056(b)).

(b) Section 5(a)(3) provides that the Commission shall, following publication of an advance notice of proposed rulemaking or a notice of proposed rulemaking for a product safety rule under any rulemaking authority administered by the Commission, assist public and private organizations or groups of manufacturers, administratively and technically, in the development of safety standards addressing the risk of injury identified in such notice. (15 U.S.C. 2054(a)(3)).

(c) Section 5(a)(4) provides that the Commission shall, to the extent practicable and appropriate (taking into account the resources and priorities of the Commission), assist public and private organizations or groups of manufacturers, administratively and technically, in the development of product safety standards and test methods. (15 U.S.C. 2054(a)(4)).

§ 1031.4 Effect of voluntary standards activities on Commission activities.

(a)(1) The Commission, in determining whether to begin proceedings to develop mandatory standards under the acts it administers, considers whether mandatory regulation is necessary or whether there is an existing voluntary standard that adequately addresses the problem and the extent to which that voluntary standard is complied with by the affected industry.

(2) The Commission acknowledges that there are situations in which adequate voluntary standards, in combination with appropriate certification programs, may be appropriate to support a conclusion that a mandatory standard is not necessary. The Commission may find that a mandatory standard is not necessary where compliance with an existing voluntary standard would eliminate or adequately reduce the risk of injury associated with the product, contains requirements and test methods that have been evaluated and found acceptable by the Commission, and it is likely that there will be substantial and timely compliance with the voluntary standard. Under such circumstances, the Commission may agree to encourage industry compliance with the voluntary standard and subsequently evaluate the effectiveness of the standard in terms of accident and injury reduction for products produced in compliance with the standard.

(3) In evaluating voluntary standards, the Commission will relate the requirements of the standard to the identified risks of injury and evaluate the requirements in terms of their effectiveness in eliminating or reducing the risks of injury. The evaluation of voluntary standards will be conducted by Commission staff members, including representatives of legal, economics, engineering, epidemiological, health sciences, human factors, other appropriate interests, and the Voluntary Standards Coordinator. The staff evaluation will be conducted in a manner similar to evaluations of standards being considered for promulgation as mandatory standards.

(4) In the event that the Commission has evaluated an existing voluntary standard and found it to be adequate in all but a few areas, the Commission may defer the initiation of a mandatory rulemaking proceeding and request the voluntary standards organization to revise the standard to address the identified inadequacies expeditiously. In such cases, the Commission may monitor or participate in the development of these revisions.

(b) In the event the Commission determines that there is no existing voluntary standard that will eliminate or adequately reduce a risk of injury the Commission may commence a proceeding for the development of a consumer product safety rule or a regulation in accordance with section 9 of the Consumer Product Safety Act, 15 U.S.C. 2058, section 3(f) of the Federal Hazardous Substances Act, 15 U.S.C. 1262(f), or section 4(a) of the Flammable Fabrics Act, 15 U.S.C. 1193(g), as may be applicable. In commencing such a proceeding, the Commission will publish an advance notice of proposed rulemaking which shall, among other things, invite any person to submit to the Commission an existing standard or portion of an existing standard, or to submit a statement of intention to modify or develop, within a reasonable period of time, a voluntary standard to address the risk of injury.

(c) The Commission will consider those provisions of a voluntary standard that have been reviewed, evaluated, and deemed to be adequate in addressing the specified risks of injury when initiating a mandatory consumer product safety rule or regulation under the Consumer Product Safety Act, the Federal Hazardous Substances Act, or the Flammable Fabrics Act, as may be applicable. Comments will be requested in the advance notice of proposed rulemaking on the adequacy of such voluntary standard provisions.

§ 1031.5 Criteria for Commission participation in voluntary standards activities.

The Commission will consider the extent to which the following criteria are met in considering Commission participation in the development of voluntary safety standards for consumer products:

(a) The likelihood the voluntary standard will eliminate or adequately reduce the risk of injury addressed and that there will be substantial and timely compliance with the voluntary standard.

(b) The likelihood that the voluntary standard will be developed within a reasonable period of time.

(c) Exclusion, to the maximum extent possible, from the voluntary standard being developed, of requirements which will create anticompetitive effects or promote restraint of trade.

(d) Provisions for periodic and timely review of the standard, including review for anticompetitive effects, and revision or amendment as the need arises.

(e) Performance-oriented and not design-restrictive requirements, to the maximum practical extent, in any standard developed.

(f) Industry arrangements for achieving substantial and timely industry compliance with the voluntary standard once it is issued, and the means of ascertaining such compliance based on overall market share of product production.

(g) Provisions in the standard for marking products conforming to the standard so that future Commission investigation can indicate the involvement of such products in accidents and patterns of injury.

(h) Provisions for insuring that products identified as conforming to such standards will be subjected to a testing and certification (including self-certification) procedure, which will provide assurance that the products comply with the standard.

(i) The openness to all interested parties, and the establishment of procedures which will provide for meaningful participation in the development of such standards by representatives of producers, suppliers, distributors, retailers, consumers, small business, public interests and other individuals having knowledge or expertise in the areas under consideration, and procedures for affording other due process considerations.

§ 1031.6 Extent and form of Commission involvement in the development of voluntary standards.

(a) The Commission shall approve agency "participation", as defined below, in the development and support of voluntary safety standards for consumer products. The Executive Director shall approve Commission activities that are defined below as "monitoring." The extent of Commission involvement will be dependent upon the Commission's interest in the particular standards development activity and the commission's priorities and resources.

(b) The Commission's interest in a specific voluntary standards activity will be based in part on the frequency and severity of injuries associated with the product, the involvement of the product in accidents, the susceptibility of the hazard to correction through standards, and the overall resources and priorities of the Commission. Commission involvement in voluntary standards activities generally will also be guided by the Commission's operating plan and budget.

(c) There are two levels of Commission involvement in voluntary standards activities, each of which reflects a different level of Commission involvement as set forth below:

(1) *Monitoring.* Monitoring involves maintaining an awareness of the voluntary standards development process through oral or written inquiries, receiving and reviewing minutes of meetings and copies of draft standards, or attending meetings for the purpose of observing and commenting during the standards development process in accordance with Subpart B of this part. For example, monitoring may involve responding to requests from voluntary standards organizations, standards development committees, trade associations and consumer organizations; by providing information concerning the risks of injury associated with particular products, NEISS data, summaries and analyses of in-depth investigation reports; discussing Commission goals and objectives with regard to voluntary standards and improved consumer product safety; responding to requests for information concerning Commission programs; and initiating contacts with voluntary standards organizations to discuss cooperative voluntary standards activities.

(2) *Participating.* Participating involves regularly attending meetings of a standard development committee or group and taking an active part in the discussions of the committee and in developing the standard, in accordance with Subpart B of this part. Under certain conditions, the Commission will contribute to the deliberations of the committee by expending resources to provide technical assistance (e.g., research, engineering support, and information and education programs) and administrative assistance (e.g., travel costs, hosting meetings, and secretarial functions) which would support the development and implementation of voluntary standards. Participating may also include Commission support of voluntary standards activities as described in § 1031.7.

(d) Normally, the total amount of Commission support given to a voluntary standards activity shall be no greater than that of all non-Federal participants in that activity, except where it is in the public interest to do so.

(e) In the event of duplication of effort by two or more groups (either inside or outside the Commission) in developing a voluntary standard for the same product or class of products, the Commission shall encourage the several groups to cooperate in the development of a single voluntary standard.

§ 1031.7 Commission support of voluntary standards activities.

(a) The Commission's support of voluntary safety standards development

activities may include any one or a combination of the following actions:

(1) Providing epidemiological and health science information and explanations of hazards for consumer products.

(2) Encouraging the initiation of the development of voluntary standards for specific consumer products.

(3) Identifying specific risks of injury to be addressed in a voluntary standard.

(4) Performing or subsidizing technical assistance, including research, health science data, and engineering support, in the development of a voluntary standard activity in which the Commission is participating.

(5) Providing assistance on methods of disseminating information and education about the voluntary standard or its use.

(6) Performing a staff evaluation of a voluntary standard to determine its adequacy and efficacy in reducing the risks of injury that have been identified by the Commission as being associated with the use of the product.

(7) Encouraging state and local governments to reference or incorporate the provisions of a voluntary standard in their regulations or ordinances and to participate in government or industrial model code development activities, so as to develop uniformity and minimize conflicting State and local regulations.

(8) Monitoring the number and market share of products conforming to a voluntary safety standard.

(9) Providing for the involvement of agency personnel in voluntary standards activities as described in Subpart B of this Part.

(10) Providing administrative assistance, such as hosting meetings and secretarial assistance.

(11) Providing funding support for voluntary standards development, as permitted by the agency budget.

(12) Taking other actions that the Commission believes appropriate in a particular situation.

(b) [Reserved.]

§ 1031.8 Voluntary Standards Coordinator.

(a) The Executive Director shall appoint a Voluntary Standards Coordinator to coordinate agency participation in voluntary standards bodies so that:

(1) The most effective use is made of agency personnel and resources, and

(2) The views expressed by such personnel are in the public interest and, at a minimum, do not conflict with the interests and established views of the agency.

(b) The Voluntary Standards Coordinator is responsible for managing the Commission's voluntary standards program, as well as preparing and submitting to the Commission a semiannual summary of its voluntary standards activities. The summary shall set forth, among other things, the goals of each voluntary standard under development, the extent of CPSC activity (monitoring or participation; the current status of standards development and implementation) and, if any, recommendations for additional Commission action. The Voluntary Standards Coordinator shall also compile information on the Commission's voluntary standards activities for the Commission's annual report.

Subpart B—Employee Involvement

§ 1031.9 Purpose and scope.

(a) This subpart sets forth the Consumer Product Safety Commission's criteria and requirements governing membership and involvement by Commission officials and employees in the activities of voluntary standards development bodies.

(b) The Commission realizes there are advantages and benefits afforded by greater involvement of Commission personnel in the standards activities of domestic and international voluntary standards organizations. However, such involvement might present an appearance or possibility of the Commission giving preferential treatment to an organization or group or of the Commission losing its independence or impartiality. Also, such participation may present real or apparent conflict of interest situations.

(c) The purpose of this subpart is to further the objectives and programs of the Commission and to do so in a manner that ensures that such membership and participation:

(1) Is consistent with the intent of the Consumer Product Safety Act and the other acts administered by the Commission, as well as with federal policy as set forth in the current version of OMB Circular No. A–119, Federal Participation in the Development and Use of Voluntary Standards;

(2) Is not contrary to the public interest;

(3) Presents no real or apparent conflict of interest, and does not result in or create the appearance of the Commission giving preferential treatment to an organization or group or the Commission compromising its independence or impartiality; and

(4) Takes into account Commission resources and priorities.

(d) In general, Commission employees must obtain approval from their supervisor and appropriate agency management to be involved in voluntary standards activities. They should also strive to apprise the Voluntary Standards Coordinator, where practicable, as to their involvement in voluntary standards activities.

(e) All Commission employees involved in voluntary standards activities are subject to any restrictions for avoiding conflicts of interest and for avoiding situations that would present an appearance of bias.

§ 1031.10 Definitions.

For purposes of describing the level of involvement in voluntary standards activities for which Commission employees may be authorized, the following definitions apply:

(a) *Membership.* Membership is the status of an employee who joins a voluntary standards development or advisory organization or subgroup and is listed as a member. It includes all oral and written communications which are incidental to such membership.

(b) *Participation.* Participation is the active, ongoing involvement of an official or employee in the development of a new or revised voluntary standard pertaining to a particular consumer product or to a group of products that is the subject of a Commission hazard project. These projects should be one of those that are approved by the Commission, either by virtue of the agency's annual budget or operating plan, or by other specific agency authorization or decision, and are in accord with Subpart A. Participation includes regularly attending meetings of a standards development committee or group, taking an active part in discussions and technical debates, registering opinions and expending other resources in support of a voluntary standard development activity. It includes all oral and written communications which are part of the participation process.

(c) *Monitoring.* Monitoring is involvement by an official or employee in maintaining an awareness of the voluntary standards development process by attendance at meetings, receiving and reviewing minutes of standards development meetings and copies of draft standards, and commenting during the standards development process. It involves all oral and written communications which are part of the monitoring process. These monitoring activities must be related to general voluntary standards projects set forth in the agency's annual budget or operating plan or otherwise approved by the agency.

(d) *Observation.* Observation is the attendance by an official or employee at a meeting of a voluntary standards development group for the purpose of observing and gathering information.

(e) *Communication.* Communication is the oral or written contact by an official or employee with a representative or committee of a voluntary standards organization or advisory group.

§ 1031.11 Procedural safeguards.

(a) Subject to the provisions of this subpart and budgetary and time constraints, Commission employees may be involved in voluntary standards activities that will further the objectives and programs of the Commission, are consistent with ongoing and anticipated Commission regulatory programs as set forth in the agency's operating plan, and are in accord with the Commission's policy statement on participation in voluntary standards activities set forth in Subpart A of this part.

(b) Commission employees who are involved in the development of a voluntary standard and who later participate in an official evaluation of that standard for the Commission shall describe in any information, oral or written, presented to the Commission, the extent of their involvement in the development of the standard. Any evaluation or recommendation for Commission actions by such employee shall strive to be as objective as possible and be reviewed by higher-level Commission officials or employees prior to submission to the Commission.

(c) Involvement of a Commission official or employee in a voluntary standards committee shall be predicated on an understanding by the voluntary standards group that participation by Commission officials and employees is on a non-voting basis.

(d) In no case shall Commission employees or officials vote or otherwise formally indicate approval or disapproval of a voluntary standard during the course of a voluntary standard development process.

(e) Commission employees and officials who are involved in the development of voluntary standards may not accept voluntary standards committee leadership positions, e.g., committee chairman or secretary. Subject to prior approval by the Executive Director, a Commission employee or official may accept other committee positions only if it appears to be clearly in the public interest for the employee to carry out the functions of that specific position.

(f) Attendance of Commission personnel at voluntary standards meetings shall be noted in the public calendar and meeting summaries shall be submitted to the Office of the Secretary as required by the Commission's meetings policy, 16 CFR Part 1012.

§ 1031.12 Membership criteria.

(a) The Commissioners, their special assistants, and Commission officials and employees holding the positions listed below, may not become members of a voluntary standards group because they either have the responsibility for making final decisions, or advise those who make final decisions, on whether to rely on a voluntary standard, promulgate a consumer product safety standard, or to take other action to prevent or reduce an unreasonable risk of injury associated with a product.

(1) The Commissioners;

(2) The Commissioners' Special Assistants;

(3) The General Counsel and General Counsel Staff;

(4) The Executive Director, the Deputy Executive Director, and special assistants to the Executive Director;

(5) The Associate Executive Directors and Office Directors;

(6) The Director of the Office of Program Management and Budget and any Special Assistants to the Director.

(b) All other officials and employees not covered under § 1031.12(a) may be advisory, non-voting members of voluntary standards development and advisory groups with the advance approval of the Executive Director. In particular, the Commission's Voluntary Standards Coordinator may accept such membership.

(c) Commission employees or officials who have the approval of the Executive Director to accept membership in a voluntary standards organization or group pursuant to paragraph (b) of this section shall apprise the General Counsel and the Voluntary Standards Coordinator prior to their acceptance.

(d) Commission officials or employees who desire to become a member of a voluntary standards body or group in their individual capacity must obtain prior approval of the Commission's Ethics Counselor for an outside activity pursuant to the Commission's Employee Standards of Conduct, 16 CFR Part 1030.

§ 1031.13 Participation and monitoring criteria.

(a) Commission officials, other than those positions listed in § 1031.12(a), may participate in or monitor the development of voluntary safety standards for consumer products, but only in their official capacity as employees of the Commission and if permitted to do so by their supervisor and any other person designated by agency management procedures. Such participation or monitoring shall be in accordance with Commission procedures.

(b) Employees in positions listed in § 1031.12(a) (4), (5), and (6) may, on a case-by-case basis, participate in or monitor the development of a voluntary standard provided that they have the specific advance approval of the Commission.

(c) Except in extraordinary circumstances and when approved in advance by the Executive Director in accordance with the provisions of the Commission's meetings policy, 16 CFR Part 1012, Commission personnel shall not become involved in meetings concerning the development of voluntary standards that are not open to the public for attendance and observation. Attendance of Commission personnel at a voluntary standard meeting shall be noted in the public calendar and meeting logs filed with the Office of the Secretary in accordance with the Commission's meetings policy.

(d) Generally, Commission employees may become involved in the development of voluntary standards only if they are made available for comment by all interested parties prior to their use or adoption.

(e) Involvement by Commission officials and employees in voluntary standards bodies or standards-developing groups does not, of itself, connote Commission agreement with, or endorsement of, decisions reached, approved or published by such bodies or groups.

§ 1031.14 Observation criteria.

A Commission official or employee may, on occasion, attend voluntary standards meetings for the sole purpose of observation, with the advance approval of his or her supervisor and any other person designated by agency management procedures. Commission officials and employees shall notify the Voluntary Standard Coordinator, for information purposes, prior to observing a voluntary standards meeting.

§ 1031.15 Communication criteria.

(a) Commission officials and employees, who are not in the positions listed in § 1031.12(a), or who are not already authorized to communicate with a voluntary standards group or representative incidental to their approved membership in a voluntary standard organization or group or as part of their participation or monitoring of a voluntary standard, may:

(1) Communicate, within the scope of their duties, with a voluntary standard group, representative, or other committee member, on voluntary standards matters which are substantive in nature, i.e., matters that pertain to the formulation of the technical aspects of a specific voluntary standard or the course of conduct for developing the standard, only with the specific advance approval from the person or persons to whom they apply to obtain approval for participation or monitoring pursuant to § 1031.13. The approval may indicate the duration of the approval and any other conditions.

(2) Communicate, within the scope of their duties, with a voluntary standard group, representative, or other committee member, concerning voluntary standards activities which are not substantive in nature.

(b) Commission employees may communicate with voluntary standards organizations only in accordance with Commission procedures.

(c) Commissioners can engage in substantive and non-substantive written communications with voluntary standards bodies or representatives, provided a disclaimer in such communications indicates that any substantive views expressed are only their individual views and are not necessarily those of the Commission. Where a previous official Commission vote has taken place, that vote should also be noted in any such communication. Copies of such communications shall thereafter be provided to the other Commissioners, the Office of the Secretary, and the Voluntary Standards Coordinator.

(d) The Voluntary Standards Coordinator shall be furnished a copy of each written communication of a substantive nature and a report of each oral communication of a substantive nature between a Commission official or employee and a voluntary standards organization or representative which pertains to a voluntary standards activity. The information shall be provided to the Voluntary Standards Coordinator as soon as practicable after the communication has taken place.

Dated: February 8, 1989.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 89-3342 Filed 2-13-89; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 87F-0309]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a mixture of dodecyltin S,S',S"-tris (isooctylmercaptoacetate) and di(*n*-dodecyl)tin S,S'-di(isooctylmercaptoacetate) as a thermal stabilizer for vinyl chloride homopolymers and copolymers intended for use in contact with food. This action responds to a petition filed by Sherex Chemical Co., Inc.

DATES: Effective February 14, 1989; written objections and requests for a hearing by March 16, 1989.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 7, 1987 (52 FR 37525), FDA announced that a petition (FAP 5B3873) had been filed by Sherex Chemical Co., Inc., P.O. Box 646, Dublin, OH 43017, proposing that § 178.2650 *Organotin stabilizers in vinyl chloride plastics* (21 CFR 178.2650) be amended to provide for the safe use of a mixture of dodecyltin tri(isooctylmercaptoacetate) and di(dodecyl)tin di(isooctylmercaptoacetate) as a stabilizer in polyvinyl cloride and vinyl chloride copolymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, and that the regulations should be amended in 21 CFR 178.2650 by revising the introductory paragraph, by adding new paragraph (a)(7), and by adding new paragraph (b)(1)(iii). The agency is also modifying the nomenclature for the two organotin chemicals in this additive. The agency is listing them as "dodecyltin S,S',S"-tris(isooctylmercaptoacetate)" and "di(*n*-dodecyl)tin S,S'-di(isooctylmercaptoacetate)." The agency concludes that this nomenclature is more descriptive than that set out in the filing notice and is also more consistent with the nomenclature used for other chemicals appearing in 21 CFR 178.2650.

Additionally, the agency is making editorial changes in the introductory text and in the introductory text of paragraph (a) of § 178.2650. It is changing the term "octyltin," used to describe tin compounds in these paragraphs, to read "organotin." This term more accurately describes the tin compounds in the referenced paragraphs. It is also changing the reference to "polyvinyl chloride and vinyl chloride copolymers" to read "vinyl chloride homopolymers and copolymers" to reflect the terminology used in the agency's proposal on these substances. See 51 FR 4177, February 3, 1986.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact, including a determination that this action will have no effect on the market for vinyl chloride, and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. This action was considered under FDA's final rule implementing the National Environmental Policy Act (21 CFR Part 25).

Any person who will be adversely affected by this regulation may at any time on or before March 16, 1989 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made

and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, Part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR Part 178 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61.

2. Section 178.2650 is amended by revising the introductory text and the introductory text of paragraph (a), by adding new paragraph (a)(7), and by adding new paragraph (b)(1)(iii), to read as follows:

§ 178.2650 Organotin stabilizers in vinyl chloride plastics.

The organotin chemicals identified in paragraph (a) of this section may be safety used alone or in combination, at levels not to exceed a total of 3 parts per hundred of resin, as stabilizers in vinyl chloride homopolymers and copolymers complying with the provisions of § 177.1950 or § 177.1980 of this chapter and that are identified for use in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter, except for the organotin chemical identified in paragraph (a)(3) of this section, which may be used in contact with food of types I through IX at temperatures not exceeding 75 °C (167 °F), and further that the organotin chemicals identified in paragraphs (a)(5) and (6) of this section may be used in contact with food of types I through IX at temperatures not exceeding 66 °C (150 °F), conditions of use D through G described in table 2 of § 176.170(c) of this chapter, and further that dodecyltin chemicals identified in paragraph (a)(7) of this section which may be used in contact with food of types I, II, III, IV (except liquid milk), V, VI (except malt beverages and carbonated nonalcoholic beverages), VII, VIII, and IX described in table 1 of § 176.170(c) of this chapter at temperatures not exceeding 71 °C (160 °F), in accordance with the following prescribed conditions:

(a) For the purpose of this section, the organotin chemicals are those listed in paragraphs (a) (1), (2), (3), (4), (5), (6), and (7) of this section.

* * * * *

(7) The dodecyltin stabilizer is a mixture of 50 to 60 percent by weight of *n*-dodecyltin S,S',S''-tris(isooctylmercaptoacetate) (CAS Reg. No. 67649–65–4) and 40 to 50 percent by weight of di(*n*-dodecyl)tin S,S'-di(isooctylmercaptoacetate) (CAS Reg. No. 84030–61–5) having 13 to 14 percent by weight of tin (Sn) and having 8 to 9 percent by weight of mercapto sulfur. It is made from a mixture of dodecyltin trichloride and di(dodecyl)tin dichloride which has not more than 0.2 percent by weight of dodecyltin trichloride, not more than 2 percent by weight of dodecylbutyltin dichloride and not more than 3 percent by weight of tri(dodecyl) tin chloride. The isooctyl radical in the mercaptoacetate is derived from oxo process primary octyl alcohols.

(b) * * *

(1) * * *

(iii) Subsequent determinations for the dodecyltin mixture described in paragraph (a)(7) of this section shall be at a minimum of 24-hour intervals for aqueous solvents and 2-hour intervals for heptane. These tests shall yield di(*n*-octyl)tin S,S'-bis(isooctylmercaptoacetate), or di(*n*-octyl)tin maleate polymer, or (C_{10}-C_{16})-alkylmercaptoacetate reaction products with dichlorodioctylstannane and trichlorooctylstannane, or *n*-octyltin S,S',S''-tris(isooctylmercaptoacetate), tris(isooctylmercaptoacetate) and di(*n*-dodecyl)tin bis(isooctylmercaptoacetate) or any combination thereof, not to exceed 0.5 parts per million as determined by an analytical method entitled "Atomic Absorption Spectrophotometric Determination of Sub-part-per-Million Quantities of Tin in Extracts and Biological Materials with Graphite Furnace," *Analytical Chemistry*, Vol. 49, pp. 1090-1093 (1977), which is incorporated by reference in accordance with 5 U.S.C. 552(a). The availability of this incorporation by reference is given in paragraph (b)(1)(ii) of this section.

* * * * *

Dated: February 1, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–3383 Filed 2–13–89; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Dichlorophene and Toluene Capsules

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elite Chemical Corp., Inc., providing for safe and effective use of dichlorophene/toluene capsules in treating dogs and cats for certain helminth infections.

EFFECTIVE DATE: February 14, 1989.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3430.

SUPPLEMENTARY INFORMATION: Elite Chemical Corp., Inc., P.O. Box 1947, Norcross, GA 30091, filed NADA 140–850, providing for the use of a capsule containing dichlorophene and toluene for single dose administration to dogs and cats for removal of certain ascarids and hookworms and as an aid in the removal of certain tapeworms. The NADA is approved and 21 CFR 250.580(b)(1) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. The regulations are further amended in 21 CFR 510.600(c) (1) and (2) to add the firm to the list of sponsors of approved NADA's.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen