PART 30—FOREIGN TRADE STATISTICS

1. The authority citation for 15 CFR Part 30 continues to read as follows:

Authority: 5 U.S.C. 301; 13 U.S.C. 301–307; Reorganization Plan No. 5 of 1950 (3 CFR 1949–1953 Camp., 1004); Department of Commerce Organization Order No. 35–2A. August 4, 1975, 40 CFR 42765.

Subpart D—Exemptions From the Requirements for the Filing of Shipper's Export Declarations

2. Section 30.56(b); is proposed to be revised to read as follows:

§ 30.56 Conditional exemptions.

* * * * *

(b) Tools of Trade are usual and reasonable kinds and quantities of commodities and software, and their containers, that are intended for use by individual exporters or by employees or representatives of the exporting company in furthering the enterprises and undertakings of the exporter abroad. Commodities and software eligible for this exemption are those that do not normally require an export license or that are exported without a license as specified in 15 CFR 740.9 of the EAR and are subject to the following provisions:

(1) Are owned by the individual exporter or exporting company;

(2) *Accompany* the individual exporter, employee or representative of the exporting company;

(3) Are necessary and appropriate and intended for the personal and/or business use of the individual exporter, employee or representative of the company or business;

(4) Are not for sale; and

(5) Are returned to the United States no later than one year from the date of export.

* * * * *

Dated: June 23, 1997.

Bradford R. Huther,

Deputy Director and Chief Operating Officer, Bureau of the Census.

[FR Doc. 97–17653 Filed 7–3–97; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 97N–0218]

RIN 0910–ZA01

Consideration of Codex Alimentarius Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is considering the amendment of its regulations that establish procedures for review and evaluation of standards adopted by the Codex Alimentarius Commission (Codex). Codex is an international body that establishes food standards under the joint auspices of the United Nations World Health Organization (WHO) and Food and Agriculture Organization (FAO). FDA is considering whether to establish procedures for the systematic review of standards and related texts adopted by Codex. This action has the potential to enhance consumer protection with regard to foods, to promote international harmonization, to enable FDA to better meet its public health mission, and to fulfill U.S. obligations under international agreements. The agency is soliciting comments from interested persons about whether to amend agency regulations to provide procedures for consideration of Codex standards, how to best set priorities and evaluate various Codex standards for possible acceptance by FDA, and how evaluation of each such standard could be accomplished in the most transparent, efficient, and resource-effective manner. FDA also invites comments on the agency's preliminary views on these matters.

DATES: Written comments by October 6, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John W. Jones, Office of Constituent Operations (HFS–550), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4311.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA's Policy Regarding International Standards

Codex is an international food standard-setting organization composed of national Governments that establishes ''standards'' comparable in scope and intent to certain standards established by FDA. For the purpose of this notice, the term ''standard'' refers to any numerical limit, such as a tolerance, maximum residue limit or maximum use level; a commodity or food standard of identity or composition; a code of practice; a procedure; a guideline; a labeling requirement; and a method, general recommendation, or other related text that may be adopted by Codex through its formal eight-step procedure (Ref. 1, Codex Procedural Manual, Ninth ed., FAO/WHO Rome, 1995).

In a notice published in the **Federal Register** of October 11, 1995 (60 FR 53078), FDA articulated its policy regarding the development and use of standards with respect to the harmonization of various national and international regulatory requirements and guidelines. FDA's policy addressed specifically the conditions under which FDA plans to participate in international standard-setting organizations in the development of standards applicable to products regulated by FDA and defined the conditions under which the agency intends to use the resultant standards in fulfilling its statutory mandate to safeguard the public health.

The October 11, 1995, notice stated in part:

> It is the intent of this policy to enable FDA to: (1) Continue to participate in international standards activities that assist it in implementing statutory provisions for safeguarding the public health, (2) increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve public health, and (3) respond to laws and policies such as the Trade Agreements Act and OMB Circular No. A–119 that encourage agencies to use international standards that provide the desired degree of protection.

The policy statement concluded that the agency's primary goal in participation in such standard-setting activities and use of resultant standards is to preserve and enhance its ability to accomplish FDA's public health mission, with the aim of enhancing regulatory effectiveness, providing more consumer protection with increasingly scarce government resources, and increasing worldwide consumer access to safe, effective, and high quality products.

B. International Agreements

The U.S. Government is a party to a number of international trade agreements. FDA has participated in a number of recent international trade negotiations to ensure that under such agreements, FDA regulatory practices can remain focused on fulfilling the agency's mission to protect the public health while being supportive of emerging, broader U.S. Government trade obligations and policies.

One of the agreements that emerged from the recent General Agreement on Tariffs and Trade (GATT) Uruguay Round of Multilateral Trade Negotiations is the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS agreement, Ref. 2). This agreement governs, among other things, measures intended: (1) To protect human or animal life or health within a territory from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs; and (2) to protect human life or health within a territory from risks arising from diseases carried by animals, plants, or products thereof.

The SPS agreement requires that members of the World Trade Organization (WTO),[1] when establishing their own SPS measures, consider international standards, guidelines, or recommendations. A country is not required to use an international standard, but must have scientific justification to establish or maintain a more stringent measure to meet the country's chosen level of protection if that measure will impact on trade. As discussed in section II.B of this document, standards established by Codex regarding food and substances in food have a particular status under the SPS agreement.

A second relevant international agreement is the Agreement on Technical Barriers to Trade (TBT agreement, Ref. 3). The TBT agreement is intended to promote use by countries of standards, technical regulations, and conformity assessment procedures that are based on work done by international standard-setting bodies. In the TBT agreement, the term ''standard'' is defined as follows:

A document approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process or production method.

Thus, FDA's stated policy on international standards and the nation's obligations under the WTO provide compelling impetus for FDA to consider whether to revise its existing system for review and evaluation of international food standards, and if so, how such a revised system might be designed.

II. Codex Alimentarius Commission

A. Codex Committees and U.S. Codex

Codex was created in 1962 by two United Nations organizations, FAO and WHO. The dual purpose of Codex is to protect the health of consumers and to ensure fair international trade in food. Codex currently has over 150 members. Codex elaborates numerical standards, codes of practice, and other guidelines through its committees (which include committees related to specific commodities and committees dealing with cross-cutting general subject areas) and promotes acceptance[2] and implementation of its standards by national Governments. Each committee is chaired by a host member country.

Codex currently has 8 general subject and 15 commodity committees. The general subject committees and their host countries are: (1) Food Labelling (Canada), (2) Food Additives and Contaminants (The Netherlands), (3) Food Hygiene (The United States), (4) Pesticide Residues (The Netherlands), (5) Residues of Veterinary Drugs in Foods (The United States), (6) Methods of Analysis and Sampling (Hungary), (7) Food Import and Export Inspection and Certification Systems (Australia), and (8) General Principles (France). The General Principles Committee oversees, maintains, and manages the Codex procedural rules.

The general subject committees work closely with scientific bodies established by FAO and WHO in developing Codex recommendations and standards. For example, the Joint Expert Committee on Food Additives (JECFA) and the Joint Meeting on Pesticide Residues (JMPR) are comprised of experts selected from member countries. JECFA and JMPR provide scientific advice and consultation on matters relevant to Codex's standard-setting activities. Specifically, JECFA advises the Codex Committee on Food Additives and Contaminants and the Codex Committee on Residues of Veterinary Drugs in Foods; JMPR advises the Codex Committee on Pesticide Residues. These scientific advisory bodies do not themselves establish Codex standards, but they provide the independent scientific review and scientific judgment necessary to assist the Codex committees with development of such standards.

In addition to the 8 general subject committees, there are 15 commodity committees,[3] of which 8 are still active. The active commodity committees and their host countries are: (1) Fish and Fishery Products (Norway), (2) Nutrition and Foods for Special Dietary Uses (Germany), (3) Fresh Fruits and Vegetables (Mexico), (4) Milk and Milk Products (New Zealand), (5) Fats and Oils (The United Kingdom), (6) Cocoa Products and Chocolate (Switzerland), (7) Natural Mineral Waters (Switzerland),[4] and (8) Processed Fruits and Vegetables (The United States).

The Codex commodity committees and general subject committees work cooperatively in that they consult one another on issues and defer particular issues to the committee with most appropriate authority and technical expertise.[5]

Since 1962, Codex has produced numerous standards, guidelines, codes of practice, and recommendations, including food commodity standards and general subject food standards. In the course of its work, Codex has evaluated the safety of over 500 food additives and contaminants and set maximum residue limits for

[1] The Final Act of the GATT Uruguay Round in 1993 and the Ministerial Meeting in Marrakesh in 1994 established the WTO. Agreements concluded during the GATT Uruguay Round Negotiations are to be administered by the WTO.

[2] Standards adopted by Codex are currently subject to various degrees of ''acceptance'' by national Governments using terms defined by Codex. Such terms as ''full acceptance'', ''non-acceptance'', and ''free distribution'' are currently employed to describe an importing country's intent to accept or reject an import shipment based on its compliance or noncompliance with applicable Codex standards. These terms of acceptance are currently under review by the Codex Committee on General Principles in order to update and refine them relative to the recent SPS and TBT agreements. The terms, *per se*, are not considered in this notice. Thus, the terms ''accept'' and ''acceptance'', as used in this document, are not intended to adhere to existing Codex definitions, practices, or procedures.

[3] Seven Codex commodity committees, having completed their current program of work, have been adjourned for the time being. One former committee, the Codex Committee on Meat, has been dissolved. The Codex commodity committees that have adjourned are: (1) Meat Hygiene; (2) Sugars; (3) Soups and Broths; (4) Edible Ices; (5) Vegetable Proteins; (6) Processed Meat and Poultry Products; and (7) Cereals, Pulses, and Legumes.

[4] This Committee was established by Codex as a Regional (European) Committee, but has since been allocated the task of elaborating world-wide standards for natural mineral waters.

[5] In addition to the committees, there are five regional coordinating committees (Africa, Asia, Europe, Latin America and the Caribbean, and North America and the Southwest Pacific). The purpose of the regional coordinating committees is to ensure that the Codex's work is responsive to regional interests, particularly to developing countries within each geographic region.

approximately 2,500 pesticide/commodity combinations. Codex has adopted maximum residue limits for 15 veterinary drugs.

The United States participates in Codex through U.S. Codex. U.S. Codex consists of Federal Government officials representing several Federal agencies, including FDA, and is assisted by representatives of industry and consumer non-government organizations (NGO's). Representatives of the United States have participated in deliberations of Codex since its inception in 1962. The United States sends delegations to participate in all Codex commodity and general subject committee meetings. FDA, through its participation on most Codex committees, provides scientific and regulatory expertise and conveys agency views on various matters concerning Codex standards, from elaboration to adoption. FDA officials also participate as independent experts on JECFA.

In a notice published in the **Federal Register** of June 4, 1996 (61 FR 28132), the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), the lead Federal agency for coordination of U.S. Codex activities,[6] published the most recent annual summary of standards under consideration or planned for consideration by Codex to solicit input from persons and organizations on these standards. This annual notice is required by the Trade Agreements Act, as amended by the Uruguay Round Agreements Act, 108 Stat. 4809 (1994).

Future annual notices by USDA/FSIS will continue to inform interested parties of matters before the various Codex committees. This mechanism provides the public with comprehensive and current information, in one place, on all Codex activities and facilitates public participation in the Codex standard-setting process. Thus, through various U.S. Codex outreach activities such as pre- and post-session briefings for the public, mailings, and the opportunity for direct participation by NGO's on U.S. Codex delegations, interested persons and organizations can contribute substantively to the elaboration and eventual adoption of Codex standards.

[6] Section 491 of the Trade Agreements Act of 1979, as amended by the Uruguay Round Agreements Act, Public L. 103–465, 108 Stat. 4809 (1994) requires an annual notice of Codex activities. Presidential Proclamation No. 6780 (60 FR 15845, March 23, 1995) designates USDA/FSIS as the agency responsible for coordinating U.S. Codex activities.

B. Role of Codex Standards Under the SPS and TBT Agreements of the WTO

For the past 6 years, Codex has been engaged in a process of revising a large proportion of its standards. In March 1991, in anticipation of the changing status of Codex standards under the SPS and TBT agreements then being negotiated in the GATT Uruguay Round, WHO and FAO, in cooperation with GATT, sponsored the FAO/WHO Conference on Food Standards and Chemicals in Food and Food Trade. This 1991 Conference in Rome (Ref. 4, ALICOM 91/22, FAO, WHO, GATT, Rome 1991) made a number of recommendations on how the then-existing Codex standard-setting process could be improved to better meet the anticipated role of Codex standards under the SPS and TBT agreements. The Rome meeting anticipated the SPS agreement's reference to, and reliance upon, international standards, guidelines, and recommendations, specifically those elaborated by Codex (SPS agreement introductory statements, Art. 3.4, and Annex A, 3.a). Although the TBT agreement does not specifically refer to Codex standards, Codex does qualify as an international standard-setting body under the TBT agreement when Codex elaborates and adopts international standards not related to SPS food safety matters. Thus, the provisions of some Codex standards fall within the terms of the TBT agreement.

Among the Conference's more significant recommendations intended to position Codex to meet its anticipated role were several that addressed streamlining existing Codex standards and the process by which new standards are developed. Specifically, the Conference recommended that Codex move toward a more horizontal approach to standard-setting, i.e., away from detailed, commodity-specific standards and toward more broadly applicable, general subject standards. The Conference also recommended that standards adopted include only those provisions necessary for consumer protection, particularly those related to health and food safety.

Most recommendations made by the Conference were subsequently adopted by Codex at its 19th session in 1991. At its 20th session in 1993, Codex adopted a Medium Term Program of Work for 1993 to 1998 (Medium Term Plan, Ref. 5, ALINORM 93/38 and Addenda) which outlines the anticipated standard-setting activities of Codex (including numerical standards and related texts) over the next 5 years and incorporates the 1991 Conference recommendations.

III. Possible FDA Strategy for Review of Codex Standards

In 1973, FDA established a regulation describing the process for the review of commodity standards adopted by Codex (§§ 130.6 and 564.6 (21 CFR 130.6 and 564.5)).[7] These regulations apply only to Codex commodity standards for human and animal foods, respectively, and not to Codex general subject standards such as numerical standards for chemical contaminants in foods or codes of practice for employing food hygiene procedures. Currently, the agency has no process defined by regulation for the consideration of general subject, also known as horizontal, standards. FDA is considering revising its regulations to accommodate agency review and acceptance of Codex general subject standards. It is important to note that the Codex Committee on General Principles at its November 1996 session recognized that all Codex standards and related texts, including maximum residue limits, codes of practice, and guidelines fall under the SPS rubric of international standards, guidelines, and recommendations. Therefore, FDA has tentatively concluded that the agency should have a procedure for review of all Codex standards falling within its purview.

The agency is considering devoting substantial effort toward the review and evaluation of Codex standards, perhaps focusing on those standards adopted since 1993 and presented in the Medium Term Plan. It may, however, be appropriate to consider the review of some pre-1993 Codex standards, for example, when: (1) An interested party petitions the agency to accept a pre-1993 Codex standard and provides information to enable a review, (2) the agency plans to issue a new FDA regulation (or revise an existing regulation) and an existing Codex standard is relevant to the new regulation,[8] or (3) the United States is

[7] This regulation was originally issued as 21 CFR 10.8 and was redesignated subsequently as §§ 130.6 (Part 130--Food Standards: General) and 564.6 (Part 564--Definitions and Standards for Animal Food).

[8] As an example of this type of situation, current FDA standards of identity regulations are often very specific for particular foods. Virtually all of these standards of identity regulations were established prior to the passage of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535, November 8, 1990) (the 1990 NLEA amendments) and thus, were developed without reference to the significant informational function that a food label can play. For example, prior to the 1990 amendments, standarized foods were not required to bear complete ingredient labeling. In light of this and other factors, FDA published an Advance Notice of Proposed Rulemaking (60 FR 67492, December 29, 1995) announcing that the agency intends to review its regulations pertaining to identity, quality, and

Continued

challenged in an international trade situation where another country cites as supporting information an existing Codex standard.

IV. Request for Information

A. FDA's Possible Strategy for Consideration of Codex Standards

FDA notes that, faced with competing food safety priorities, it may not be able to devote the resources necessary to fulfill all of its responsibilities in an efficient and timely manner. In light of this, FDA invites general comment on the relative importance of its Codex activities in comparison to its other food safety and regulatory responsibilities. In particular, FDA requests comments on the following questions:

1. What is the appropriate priority of the agency's activities in Codex in light of U.S. obligations under the WTO?
2. How might FDA enhance its ability to fulfill its broad public health mandate through judicious acceptance and use of Codex standards?
3. Are there reasons that the agency should not expend resources in the review and consideration of Codex standards?
4. If there are reasons that FDA should not expend resources on the review of Codex standards, are these reasons compelling considering U.S. obligations under the WTO?
5. How can review of Codex standards be incorporated efficiently into current FDA standard setting processes?
6. Can resource savings be achieved without compromising consumer protection?

If the agency concludes that it is appropriate to propose to revise its regulations to accommodate consideration of Codex standards, FDA plans to develop and publish a proposal outlining specific revisions. To facilitate the agency's consideration of possible alternative approaches, FDA requests comments on the following questions:

1. What revisions to existing FDA regulations or what new regulations are appropriate?
2. If the agency eventually does undertake systematic review of Codex standards, FDA is faced with deciding on how best to proceed with review and evaluation of many newly adopted and some existing Codex standards with regard to the acceptability of such standards relative to existing FDA standards. What factors should the agency consider to guide its priority setting and the efficient review and evaluation of these Codex standards during any such review?

Codex standards adopted since 1993 reflect strengthening of the standard setting process to enhance consumer protection and to accommodate the more prominent role of Codex standards under the SPS and TBT agreements. Because Codex standards adopted from 1993 forward are intended to reflect the new role of Codex standards under the WTO trade agreements, FDA is considering focusing its resources for review of Codex standards on those standards adopted since 1993 as articulated in the Codex Medium Term Plan and in its future updates. In this context, FDA requests comments on the following questions:

1. Should FDA give priority to those Codex standards adopted since 1993?
2. Alternatively, should FDA attempt systematic review of all existing Codex standards?
3. What are the resource implications of an approach requiring review of all existing Codex standards?
4. Are there cost-efficient means for FDA to review all Codex standards?
5. If only certain pre-1993 Codex standards merit consideration for review by FDA, what circumstances would warrant FDA consideration of a pre-1993 Codex standard?
6. How do existing Codex standards currently affect U.S. imports and exports?
7. Are there specific Codex standards that have significant trade impacts?
8. Are there specific Codex standards that are of particular importance due to safety or other concerns?
9. In the case of a person or organization that specifically petitions FDA to review a particular Codex standard, how might FDA best guide the petitioner to submit appropriate background information? Should FDA encourage the submission of draft language that could be used as a basis for a proposed FDA regulation governing the particular issue?
10. What are the potential benefits and costs to U.S. consumers and businesses of FDA consideration, acceptance and use of some specific Codex standards?
11. What costs are associated with researching and summarizing information necessary to compare a Codex standard with an FDA standard? How do these costs vary according to the complexity of the standard?

Upon consideration of a Codex standard, FDA believes that it will be faced with the following four situations with regard to standards that the agency believes to be suitable for FDA acceptance: (1) The standard is substantively identical to FDA's regulations; (2) the standard is similar but not identical to FDA's regulations; (3) although the standard is not identical or similar to FDA's regulations, FDA wishes to propose to accept the Codex standard to further its public health mission and such acceptance will require rulemaking under the Federal Food, Drug, and Cosmetic Act (the act); (4) or the standard is not identical to or similar to any FDA regulation, and the adoption of the Codex standard is not subject to rulemaking under the act. In addition to these four situations where the agency might wish to accept a Codex standard, FDA might wish, instead, to reject a particular Codex standard because the standard fails to provide the appropriate level of protection for U.S. consumers.

There are various procedural approaches that the agency might use to address these situations. In a case where a Codex standard is essentially identical to an FDA regulation, the agency might elect only to publish a **Federal Register** notice recognizing the substantive equivalence of the Codex standard to FDA's standard. Where a Codex standard is very similar, but not identical, to an FDA standard, the agency might publish a proposal for comment to amend FDA's regulations slightly to bring the agency's regulations into conformity with the Codex standard. More complex proposals and associated rulemaking would likely be required when FDA wishes to accept a Codex standard that is substantively different from an FDA regulation, but that the agency believes would provide a greater degree of public health protection than an existing FDA standard. Such a situation would likely entail significant revision to the existing FDA regulation with corresponding greater opportunities for public comment on the proposed, substantive revisions.

In light of the need for FDA to accomplish any review, consideration, and determination of acceptability of Codex standards in as efficient a manner as possible, and recognizing that there

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fill of container for standardized foods with the intent of simplifying the regulations where practicable and taking into account the impact of the 1990 NLEA amendments.

As part of any rulemaking growing out of the December 1995 ANPR, and in keeping with FDA's obligations under international trade agreements to consider Codex standards whenever the agency develops or revises regulations, FDA intends to review corresponding Codex commodity standards (including those adopted before 1993) concurrently with its planned review and evaluation of FDA standards pertaining to identity, quality, and fill of container and to determine whether the corresponding provisions in the Codex standard should be incorporated entirely or partially into any revised FDA standard. In this context, it should be noted that FDA has not yet determined the best means for streamlining domestic commodity standards and the eventual approach chosen for evaluation of relevant Codex standards will depend significantly on this determination.

are a large number of Codex standards that may vary greatly in their complexity and their actual impact on U.S. public health protection, FDA invites comments on approaches the agency might employ to achieve the most resource-efficient reviews.

FDA is considering amending its current regulations by removing §§ 130.6 and 564.6 and establishing a new section to describe procedures that the agency would use when it considers Codex standards for acceptance. To date, FDA has identified the following goals for the proposed amendments it is considering: (1) To be certain that any process used by FDA for reviewing standards adopted by Codex ensures that food conforming to a Codex standard is safe within the meaning of the act, (2) to ensure that FDA's review and consideration of Codex standards is transparent and science-based, (3) to clarify the procedures for FDA's consideration of commodity and general subject standards adopted by Codex, (4) to clarify when rulemaking is necessary as part of the agency's consideration of a standard adopted by Codex, and (5) to ensure that FDA's regulations for consideration of Codex standards are appropriate for all Codex standards and related texts.

The agency seeks comment on whether to proceed with a proposal to establish new regulations governing agency consideration of Codex standards. What goals, in addition to those listed previously, should be considered by the agency in developing any new regulations governing consideration of Codex standards?

B. Public Participation

1. FDA Notice of Newly Adopted Codex Standards

In the event that FDA proposes to establish a systematic review and evaluation procedure for Codex standards, the agency has tentatively concluded that it would be important to establish a mechanism to solicit active public participation in its consideration of such standards. Therefore, the agency is considering what procedures, including notice and comment procedures, could be utilized that would be appropriate, efficient, and would facilitate review, evaluation, and public notification of agency determinations regarding Codex standards. One approach under consideration is to have FDA, after each meeting of the Codex Alimentarius Commission, announce publicly those standards, codes of practice, guidelines, and related texts adopted by Codex at that session that fall within FDA's jurisdictional areas. This could be accomplished through notice in the **Federal Register** announcing adoption by Codex of the standard(s) and requesting interested parties to provide FDA with pertinent information and comments concerning the particular Codex standard(s).

Under such an approach, the **Federal Register** notice could:

1. Describe the nature of the Codex standard and its comparability to an FDA regulation or another measure;

2. Provide FDA's preliminary views on the Codex standard's provisions, including its potential for acceptance by FDA, and whether rulemaking would be necessary;

3. Describe information the agency would need for adequate evaluation of the standard;

4. Invite interested persons to provide information relevant to the evaluation of the standard and to the assessment of the relative importance of the particular Codex standard(s) to public health protection and international trade; and

5. State the agency's preliminary plans to perform substantive review of the standard.

In light of any comments received in response to such a notice and other available information bearing on the potential of the new Codex standard to further FDA's public health mission, FDA would be better positioned to determine the priority to attach to review and evaluation of the standard(s) and would have sufficient information on which to base an initial determination of whether to accept the new Codex standard.

The agency seeks comment on whether a notice such as suggested in this section is an appropriate means to notify the public initially of the adoption of a standard by Codex. If not, what alternative approach should be considered? Are any supplemental notification methods appropriate and, if so, what methods? For example, should the agency consider complementary notification mechanisms such as use of internet sites or public meetings? Is there information (in addition to that identified previously) that an initial public notice should contain?

2. Enlisting Assistance of Expertise Outside of FDA

The potentially large number of standards that may emerge from the Codex process requires the agency to consider alternatives for providing adequate resources for the review of Codex standards, particularly in identifying expertise in a specific subject or commodity area.

One possible approach to facilitate the review process is to enlist expertise outside of FDA to participate actively in the technical examination of Codex standards for the purpose of determining similarities and differences between the Codex standards and FDA standards. The agency has tentatively concluded that actively soliciting outside technical assistance from industry, academia, consumer representatives, and other interested persons with knowledge and expertise in a given subject or product area should be considered as an approach to cataloguing, performing technical comparisons, setting priorities for review of new Codex standards, and perhaps preparing draft documents that might serve as the basis for eventual FDA regulations. FDA's current view is that such non-FDA expertise would be used primarily for comparing the technical aspects of a Codex standard and an FDA regulation, such as a side-by-side comparison.

To what extent, and how, should FDA utilize outside expertise such as that which exists in the affected industries to assist with the task of setting priorities for review of Codex standards and otherwise facilitating agency evaluation of Codex standards? For example, both the Codex commodity standards and FDA's food standards established under section 401 of the act (21 U.S.C. 341) are currently being reviewed and revised (60 FR 67492). Should FDA consider a process that draws upon non-FDA expertise to assist with review of FDA standards of identity regulations and Codex commodity standards? If so, how might expertise outside of FDA be utilized to review existing Codex and FDA standards, to assist FDA in establishing priorities for review of such Codex standards relative to their importance in consumer protection and the international trade for the particular commodity, and to prepare detailed technical reports comparing the Codex and FDA standards? Are there any limitations - legal, practical, or otherwise - on FDA's utilization of such experts as part of any agency process established to review and evaluate Codex standards? If so, what are those limitations?

Are there any other circumstances besides the previous example in which the utilization of non-FDA expertise could facilitate FDA's review, evaluation, and acceptance of Codex standards? How can FDA increase general participation of outside experts, including consumers, industry representatives and others, in facilitating the agency's setting of priorities and review of Codex

standards? What are the benefits and costs of participation by non-FDA experts in the review and evaluation of Codex standards? Are there any drawbacks to such participation by non-FDA experts in agency review of Codex standards?

3. Assessing Impact on Small Business

The Regulatory Flexibility Act (Pub. L. 105–121 (5 U.S.C. 601–612)) requires agencies to analyze the impact of regulations on small entities. How can FDA take into account the special concerns of small businesses in FDA's consideration of Codex standards? What is the likely impact on small entities of a program of formal review and acceptance of Codex standards? What issues, if any, would have a disproportionately large impact on small entities or would place small entities at a disadvantage relative to large entities? Are there particular features to a system for review and acceptance of Codex standards that would minimize the impact on small entities?

C. Maintenance of Public File of FDA Determinations Regarding Codex Standards

The agency anticipates that if a process for reviewing Codex standards is adopted, FDA determinations in response to standards adopted by Codex will be published in the **Federal Register** either by notice or by rulemaking. The agency currently plans to maintain a public docket pertinent to each such **Federal Register** publication. In addition, FDA believes that it may be appropriate to provide copies of all final FDA determinations regarding Codex standards to the Office of the U.S Codex (FSIS/USDA) for maintenance in a public file. FDA believes that the Office of the U.S. Codex is positioned to maintain this information, along with Codex-related documents from other U.S. Federal agencies, as a comprehensive record readily accessible by the public. The agency specifically requests comments on this approach. In addition, FDA requests comments on alternative approaches.

V. References

The following references have been placed on public display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Procedural Manual, Codex Alimentarius Commission, Ninth Ed., Food and Agriculture Organization/World Health Organization, Rome 1995.

2. Agreement on the Application of Sanitary and Phytosanitary Measures, in *The Results of the Uruguay Round of Multilateral Trade Negotiations--The Legal Texts*, p. 69, World Trade Organization, Geneva 1995.

3. Agreement on Technical Barriers to Trade, in *The Results of the Uruguay Round of Multilateral Trade Negotiations--The Legal Texts*, p. 138, World Trade Organization, Geneva 1995.

4. FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade (in cooperation with GATT), vol. 1, Report of Conference, ALICOM 91–22, FAO/WHO/GATT, Rome 1991.

5. Proposed Medium Term Plan for the Codex Alimentarius Commission 1993–1998, ALINORM 93/38, Codex Alimentarius Commission Twentieth Session, Geneva 1993.

Dated: June 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–17515 Filed 7–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–242–FOR]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Ohio regulatory program (hereinafter the ''Ohio program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to provisions of the Ohio rules pertaining to attorney fees. The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations and was submitted in response to a required amendment at 30 CFR 935.16.

DATES: Written comments must be received by 4:00 p.m., [E.D.T.], August 6, 1997. If requested, a public hearing on the proposed amendment will be held on August 1, 1997. Requests to speak at the hearing must be received by 4:00 p.m., [E.D.T.], on July 22, 1997.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Field Branch Chief, at the address listed below.

Copies of the Ohio program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937–2153.

Ohio Division of Mines and Reclamation, 1855 Fountain Square Court, Columbus, Ohio 43224, Telephone: (614) 265–1076

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the August 10, 1982, **Federal Register** (42 FR 34688). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Description of the Proposed Amendment

By letter dated June 24, 1997, (Administrative Record No. OH–2173–00) Ohio submitted a proposed amendment to its program pursuant to SMCRA and in response to a required amendment at 30 CFR 935.16. The provision of the Ohio Revised Code (ORC) that Ohio proposes to amend is: ORC 1531:13—Appeal of Violation. Specifically, Ohio is proposing that a permittee may file a request for an award to the permittee of the costs and expenses, including attorney's fees, reasonably incurred by the permittee in connection with an appeal. Ohio may assess those costs and expenses against a party who initiated, or participated in, the appeal if the permittee demonstrates that the party initiated or participated in the appeal in bad faith and for the purpose of harassing or embarrassing the permittee. The Division of Mines and Reclamation may file with the Commission a request for an award of the attorney's fees.