DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0202]

Draft Guidance on Equivalence Criteria for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing for public comment the criteria that the agency intends to use in evaluating whether the regulatory systems used by foreign countries to ensure the safety of foods exported to the United States for human consumption are equivalent to the regulatory system of the United States. Based on its evaluation, FDA will decide whether to institute the proceedings necessary to enter into an equivalence agreement with the foreign country.

DATES: Submit written comments by August 4, 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. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mary I. Snyder, Center for Food Safety and Applied Nutrition (HFS–415), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3152.

SUPPLEMENTARY INFORMATION:

I. The SPS Agreement

Under Article 4 of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (the SPS Agreement), each member nation of the WTO, including the United States, is obligated to accept as equivalent a food regulatory system of another country if it provides the same level of health protection as is provided to consumers by its own system.

Equivalent regulatory systems need not be identical. Under the concept of equivalence, the ''sanitary or phytosanitary measures'' used by an exporting country may differ from the measures applied domestically by an importing country so long as these measures ''achieve the importing Member's appropriate level of sanitary or phytosanitary protection.'' According to the SPS Agreement, ''sanitary or phytosanitary measures'' include all relevant laws, decrees, and regulations; as well as procedures relating to end-product criteria, processes and production methods, testing, and inspection. Essentially, SPS measures include virtually any measure to protect human health arising from risks in food.

Under the SPS Agreement, the burden of demonstrating that equivalence exists rests with the exporting country. The importing country has the right to decide for itself whether the regulatory system of the exporting country is equivalent to its own or is inadequate to achieve ''the importing Member's appropriate level of sanitary or phytosanitary protection,'' or that inadequate evidence has been provided to demonstrate equivalence. The SPS Agreement specifies that exporting countries allow ''reasonable access'' to the importing country to inspect or carry out other procedures for evaluating equivalence. If the exporting country can demonstrate equivalence, the importing country ''shall accept'' the exporting country's system as equivalent.

Additionally, each member country is obligated to ''enter into consultations'' with a requesting country ''with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures.'' Although the SPS Agreement does not require that every finding of equivalence of a measure or system of measures between countries should result in a bilateral or multilateral agreement, the SPS Agreement does require that members consult, if requested, with that potential goal.

A number of exporting nations have requested that the United States enter into consultations with them for the purpose of developing equivalence agreements for seafood. One reason for these requests is that FDA regulations for seafood (part 123 (21 CFR part 123)) mandate responsibilities for importers that are deemed to be met whenever an equivalence agreement exists that covers the seafood products being imported into the United States. These regulations become effective December 18, 1997 (60 FR 65096 to 65202, December 18, 1995).

Equivalence for other types of products is being discussed with exporting countries at their request. Similarly, the United States is seeking equivalence determinations from certain countries to which it exports food products.

It would be useful, therefore, for FDA to articulate how it intends to carry out equivalence determinations. FDA has decided that the best way to do so is by developing and publishing criteria that the agency intends to apply in determining whether equivalence exists between the U.S. food regulatory system and that of an international trading partner whose regulatory system is not essentially identical to the U.S. system.

FDA intends these criteria as guidelines that represent the agency's current thinking on equivalence for the SPS Agreement. The guidelines do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

II. Potential for Public Health and Other Benefits From Equivalence

FDA takes the view that equivalence in food safety measures between the United States and its international trading partners can be beneficial and should be fostered for its own sake. As countries achieve equivalence with the U.S. advanced regulatory system, consumers in this country will have greater assurance that imported foods are as safe and wholesome as domestically produced foods.

The situation with food imports into the United States provides an excellent example of the desirability of achieving equivalence between the United States and its trading partners. Food is imported into the United States from around the world and the number of formal customs entries every year is about 1.5 million.

For the most part, FDA's inspections of food processing facilities in other countries can occur only on a limited basis. Foreign inspections are extremely costly and usually are not undertaken without an invitation from the foreign country. FDA does make a consistent effort to inspect the foreign processors of some types of products, such as infant formula, but the number of such processors—and thus the number of such inspections—is relatively low.

FDA's traditional surveillance system for food imports has largely consisted of reviewing customs entries, engaging in field examinations and collecting samples for laboratory analysis, and placing products with a history of problems on detention without physical examination. While FDA performs either an electronic screening or a documentary review of virtually all customs entries with the help of automated systems, the agency can physically examine only a very small percentage of these entries. Huge sums of money would be needed to enable

FDA to increase its physical examination and sampling program.

Where equivalence has been determined to exist, however, the work of the foreign regulatory authority should serve to help ensure the safety of imports for U.S. consumers. Since the foreign inspection system will have been found to be equivalent to FDA's inspection system, FDA will be able to rely on the results of the foreign inspection system.

The possibility of equivalence agreements between and among international trading partners, with rights and benefits that accrue to the parties involved, provides an incentive for countries to improve their regulatory systems and the public health of their food exports as a means of achieving equivalence with more advanced regulatory systems. As equivalence is achieved, and agreements are reached recognizing the achievement of equivalence, trade is likely to flow more freely because of the reduced need by importing countries to engage in resource-intensive sampling and examination of products being offered for entry from countries with equivalent systems. For the United States, equivalence agreements will also mean that FDA will be able to target the limited resources it has for imports toward products from countries that have not been determined to be equivalent. Thus, FDA will be able to use its resources more efficiently and effectively. U.S. industry can also benefit from these agreements because in those cases where the U.S. system is found to be equivalent to that of its trading partners, acceptance of U.S. products by those countries is assured. The purposes and types of equivalence agreements are described later in this notice.

Finally, where equivalence exists and is acknowledged in an agreement, there will be no need under many circumstances for importing nations to continue to require certificates from the competent regulatory authority of the exporting country to accompany each shipment. (FDA does not generally require that imported products be accompanied by certificates; however, there is an increasing trend for foreign countries to require such certificates.) Where there is recognition that the exporting country's system provides an appropriate level of sanitary or phytosanitary protection, the issuance of certificates for specific products would represent a needless expenditure of public health resources with no obvious advantage to consumers or to industry. Adequate assurances may be achieved by providing lists of food processors that are in good standing with the regulatory authority of the exporting country or similar information.

III. Problem Solving Agreements vs. Equivalence Agreements

FDA has experience developing and entering into bilateral agreements with trading partners for the purpose of providing assurance that food from those countries will be safe for U.S. consumers. However, these agreements have focused on assuring compliance with U.S. requirements by the foreign regulatory authority for foods that present high risks or that have had persistent compliance problems, rather than on whether the regulatory systems were equivalent. Such agreements involve the application of virtually identical measures by the exporting and importing country to the subject commodity or compliance with specific end-product criteria to address a food safety problem.

For example, FDA has several longstanding Memoranda of Understanding (MOU's) with nations that export raw molluscan shellfish to the United States. Under these MOU's, each country has agreed to abide by the same detailed standards for regulating the growing and harvesting of raw molluscan shellfish that U.S. States have agreed to follow. These countries have entered into such MOU's in order to have access to the U.S. market. Under a Federal-State cooperative arrangement for raw molluscan shellfish, the National Shellfish Sanitation Program (NSSP), FDA lists the processors who have been found to be in compliance by States and countries that have a shellfish program that meets the NSSP standards. States decide what shipments of shellfish they will act against based on whether the processor of the shellfish is included on FDA's list. Recently, some of the countries with MOU's have expressed an interest in converting their MOU's from compliance-type agreements to equivalence agreements to permit some variations from the details of the U.S. program.

FDA has also periodically entered into MOU's or other less formal agreements with countries that have a significant volume of trade with the United States in certain products but have developed chronic, safety-related problems with these products. In these cases, the agreement is intended to correct these problems. Examples include agreements aimed at the control of excessive levels of lead and cadmium leaching from ceramicware for food use, the control of pesticide residues in certain types of fruits, and the control of pathogenic microorganisms in soft ripened cheese and certain dried milk products.

Traditionally, FDA has assigned a higher priority to agreements targeted toward solving specific problems than it has to recognizing foreign food control systems as providing the same level of protection as those in the United States. This policy of favoring problem solving agreements over others is set forth in FDA's Compliance Policy Guide (CPG) section 100.900, Attachment A, which contains the agency's criteria for how it will prioritize international MOU's.

In December 1995, FDA entered into a compliance-based Cooperative Arrangement with the New Zealand Ministries of Agriculture and Health for the purpose of ensuring the safety of fish and fishery products traded between the two countries. Significantly, it was not a problem solving agreement. Rather, it recognized that the strong regulatory systems in the United States and New Zealand enhanced the likelihood that products from each country would comply with the regulatory requirements of the other. The participants agreed to take this recognition into account in determining the frequency of border checks for fish and fishery products traded between the United States and New Zealand. While this arrangement was not intended to be an equivalence agreement, it does reflect the principle that the employment of comparable, high-standard regulatory systems by international trading partners can enable each nation to enhance the public health protection of its consumers and shift inspectional resources to other, more risky, products.

Although FDA continues to see merit in narrowly focused, problem solving MOU's, the agency also sees value in pursuing equivalence agreements. Therefore, FDA is considering revising CPG section 100.900, Attachment A, ''Food and Drug Administration Criteria for Memoranda of Understanding'' to add recognition of equivalence as a basis for entering into agreements with foreign governments. Should the agency choose to do so, it will issue a separate notice to that effect, with an opportunity for public comment.

IV. Possible Forms that Equivalence Agreements Could Take

There are several possible forms that equivalence agreements could take, depending upon the relevant circumstances.

A. ''One-Way'' Agreements vs. ''Two-Way'' Agreements

Equivalence agreements can involve simultaneous determinations by two countries that their regulatory systems are equivalent to one another (''two-way'' agreements). This is the favored type of agreement from FDA's standpoint. A determination that a trading partner's regulatory system is equivalent to the U.S. system means that imports from that country have been produced under circumstances that provide U.S. consumers with the same level of protection as domestic products. A determination by the trading partner that the U.S. system is equivalent to its system helps ensure that exports from the United States will flow freely to the country in question. It will be FDA's policy to negotiate ''two-way'' agreements whenever practicable.

FDA may, however, enter into ''one-way'' agreements as appropriate. A ''one-way'' agreement would involve a finding by only one country that the regulatory system of a foreign government was equivalent to its own. A ''one-way'' agreement would be appropriate where there existed, essentially, a one way flow of trade in the commodities that were subject to the agreement. A ''one-way'' agreement might also be entered into as a temporary measure when one country was prepared to find a trading partner's system equivalent to its own, but the other country was not yet able to make a similar determination. Instead of delaying the agreement until a ''two-way'' agreement could be completed, the two countries could decide to agree in ''one-way'' stages.

B. All Products or Processors vs. Some Products or Processors

FDA may negotiate equivalence agreements that encompass some or all foods being exported to the United States from a foreign country, but will generally focus on agreements that cover one or two food categories with a high trade volume. As indicated earlier, FDA expects that many of the initial food-related equivalence evaluations will involve fish and fishery products. (The U.S. imports about 55 percent of the seafood it consumes.) Such evaluations will not consider whether the regulatory system of the foreign country is equivalent for other products.

Even within the category of products being considered for an agreement (e.g., fish and fishery products), equivalence may exist for some of those products but not for others. In those cases, FDA would enter into equivalence agreements that cover only those products. An agreement of this nature would not preclude trade in the remaining products, but such trade would be outside the scope of the agreement and thus likely subject to more intense scrutiny at ports of entry. The two most predictable situations in which a limited equivalence determination is likely are: (1) Where the regulatory system of the foreign country is designed to achieve, or is only capable of achieving, equivalence for some products but not for others; and (2) where U.S. standards for certain products are more stringent than those of the foreign country so as to rule out equivalence for those products.

The same principle should hold true for processors as well as for products. Some countries have a mix of modern, relatively advanced processing operations and other operations that are much less so, and a regulatory structure capable of achieving equivalence only with regard to the advanced processors. Other countries differentiate between food processors that are licensed to export, and processors that are not so licensed. In any case, it is important to remember that the agreement is between the United States and the government of the foreign country and not with individual processors or other private entities.

C. ''Piggy Back'' (''Triangular'') Agreements

FDA is interested in exploring the concept of ''piggy back'' equivalence agreements (also referred to as ''triangular'' agreements). Under this concept, two countries that have established an equivalence agreement would agree that additional agreements between either of the countries and a third country would be recognized by both countries. Thus, if FDA had both an equivalence agreement with Country ''A'' and a ''piggy back'' arrangement with Country ''A,'' and Country ''A'' had an equivalence agreement with Country ''B,'' FDA would recognize that Country ''B'' is equivalent to the United States in part on the basis of Country ''A's'' finding.

For such a system to work, a basis must exist for FDA to have found on its own that Country ''B's'' system was equivalent to the U.S. system. Among other things, FDA would have to have a high level of confidence in Country ''A's'' ability to make an equivalence determination, based on a detailed knowledge of Country ''A's'' verification and audit capabilities. This knowledge and confidence could be acquired through a mutual undertaking of audit responsibilities and a sharing of the results of audits. There would always have to be some form of confirmation by FDA that equivalence exists along with an adequate administrative record to support a finding of equivalence.

If such an arrangement could be established, it would provide enhanced incentives for countries to achieve equivalence with the most advanced regulatory systems because a finding of equivalence with one advanced country could hasten equivalence with other advanced countries. Obviously, a ''piggy back'' system would also permit a significant public health gains and resource savings for countries in negotiating equivalence agreements.

Some experience with equivalence agreements will be needed before FDA could enter into ''piggy back'' agreements. The agency invites public comment on this issue.

V. The Equivalence Agreement Process

FDA contemplates a process that will involve a paper review, an on-site verification review, and public notice and comment in making a determination that a foreign country's regulatory system is equivalent. The paper review would compare the U.S. system of laws, regulations, standards, regulatory practices and procedures, and all other relevant matters with those of the foreign country based on information provided by the foreign government. The review, which would be carried out by FDA in the United States, is expected to consist in part of a side-by-side comparison of the elements of the U.S. system and the elements of the foreign system to determine what similarities and differences exist between the two systems and to provide the basis for an assessment of the significance of the differences. This paper review will cover both the foreign country's requirements for industry and its inspection system.

If the paper review shows that the two systems may be equivalent, the results of this paper review will form the basis for one or more on-site visits to verify the results of the paper review and to obtain whatever additional information may be necessary. The purpose of an on-site visit would not be to inspect the processors in that country, although it is expected to include visits to some processors, but rather to verify that the foreign regulatory system, including its plant inspection system, is functioning as indicated in the paper review. The on-site visit is an audit of the system, not an audit of foreign processors.

FDA would then make a preliminary determination of whether equivalence exists and would publish this preliminary determination in a notice

for public comment in the **Federal Register**. FDA is under an obligation to do so in accordance with Pub. L. 103–465, the implementing legislation for U.S. participation in WTO agreements. This law states:

If the Commissioner [of Food and Drugs] proposes to issue a determination of the equivalency of a sanitary or phytosanitary measure of a foreign country to a sanitary or phytosanitary measure of the Food and Drug Administration that is not required to be promulgated as a rule under the Federal Food, Drug, and Cosmetic Act or other statute administered by the Food and Drug Administration, the Commissioner shall publish a notice in the **Federal Register** that identifies the basis for the determination that the measure provides at least the same level of sanitary or phytosanitary protection as the comparable Federal sanitary or phytosanitary measure. The Commissioner shall provide opportunity for interested persons to comment on the notice. The Commissioner shall not issue a final determination on the issue of equivalency without taking into account the comments received.

FDA is committed to this public process and intends that **Federal Register** notices published in accordance with this requirement will provide the public with a full explanation of why FDA has tentatively concluded that equivalence exists in a given situation. This explanation should cover, at a minimum, both the results of the paper review and a summary of the on-site visit. The final determination will take into account the comments received.

VI. Fundamental Principles

In determining whether equivalence exists and in entering into any agreements on equivalence, FDA intends to be guided by several basic principles. These include the following:

A. Transparency of Process and Reasoning

As indicated above, the factual basis for a determination of equivalence must be publicly available and clearly understood. To the extent that FDA is looking to foreign regulatory authorities to help to ensure the safety of food for U.S. consumers, the public has a right to review and understand the basis for FDA's action. Consumer confidence in food depends in large measure on the confidence it has in the regulatory safeguards that exist for that food.

B. No Loosening of Standards

U.S. standards will not be relaxed to facilitate a finding of equivalence. For example, products that contain unapproved additives or that contain poisonous or deleterious substances in amounts sufficient to render them adulterated under Federal law will be adulterated even if an equivalence agreement exists. Unless the foreign country can provide reasonable assurance that its products will meet these standards (i.e., will not be adulterated), equivalence will not be possible, at least for those products.

C. Fundamental Fairness and Consistency

Processing requirements that are essential for the production of safe food are germane to both domestic products and products that are imported into the United States, although, as discussed later, equivalence may permit appropriate latitude regarding the details.

D. Adequate Verification

If FDA has entered into an equivalence agreement, the agency must engage in adequate ongoing verification, including appropriate checking of imports, to ensure that equivalence continues to exist. FDA cannot rely solely on foreign regulatory authorities to ensure that equivalence is maintained. Presumably this principle will hold true for the foreign regulatory authority as well.

VII. What Is Equivalence?

A. United States Levels of Protection

As stated in section I of this document, according to the SPS Agreement, equivalence is achieved when an exporting country's measures meet an importing country's ''appropriate level of sanitary or phytosanitary protection,'' even though those measures are not the same as those of the importing country. A level of protection can be viewed in terms of the limitation on risk that a society requires relative to a particular hazard or hazards.

In the United States, the appropriate levels of sanitary or phytosanitary protection for the foods regulated by FDA are governed by the very broad, qualitative provisions of the Federal Food, Drug, and Cosmetic Act (the act), and the regulations issued under it, which state the circumstances in which a product will be deemed to present an unacceptable risk to U.S. consumers, i.e., will be deemed to be ''adulterated.'' For example, a food additive will be deemed to adulterate a food unless it is approved for use in that food (section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(c))) based on a showing that there is a ''reasonable certainty'' that no harm will result from its becoming a component of the food (section 409(a) of the act (21 U.S.C. 348(a)) and § 170.3(i) (21 CFR 170.3(i))). Food is also adulterated if it is contaminated with an added poisonous or deleterious substance ''which may render it injurious to health'' (section 402(a)(1) of the act). The act has several other adulteration provisions, including provisions that apply in specific situations, such as in the preparation of infant formula and the use of color additives. Sometimes, as with food additives, the act (a food additive must be ''safe'' under section 409) and the regulations (definition of ''safe'' in § 170.3(i)) must be read together.

These governing provisions express levels of protection in terms of overarching public health standards. However, in considering a particular risk or types of risks, these broadly stated standards need further elaboration to provide understanding of how they apply. For example, a determination of whether there is a reasonable certainty of no harm from the use of a food additive is dependant on an operational definition of that standard that facilitates its application to a specific food use of a substance. Operational definitions can be found in various places, ranging from the explanatory materials that are developed in rulemaking (i.e., preambles) to the codified text of a rule (see §§ 170.3, 170.20, and 170.22 (21 CFR 170.20 and 170.22)), to guidance materials, and even to judicial decisions.

For example, the operational definition for ''reasonable certainty of no harm'' from the use of a food additive involves determining the exposure to that additive that will not produce adverse effects in humans. This level is obtained through the application of an appropriate, scientifically based, safety factor (e.g., 100-fold, as provided in § 170.22) to the lowest no-effect level observed in a toxicological study in animals. As can be seen from this example, the level of protection afforded by the law of the United States is the protection that emerges when a broad, statutory public health standard is applied, through an operational definition, to a particular risk.

Operational definitions serve as a bridge between the underlying standard and the measures that are developed to achieve the desired level of protection. In the above example, the primary measure that the United States uses to achieve its level of protection for food additives is an approved level of the additive that is permissible in a particular food.

Quantification is not the only way to provide a level of protection, and in many situations quantification is not practical. An excellent example of a

level of protection that is qualitative rather than quantitative is that provided by the food safety processing system known as Hazard Analysis Critical Control Point (HACCP), which FDA has mandated for the processing of seafood. The statutory standard from which this protection derives states that food should not be prepared, packed, or held under conditions ''whereby it may have been rendered injurious to health'' (section 402(a)(4) of the act). Concerns about the conditions under which seafood is processed led FDA to conclude that to give this standard meaning in the circumstances under which seafood is processed, it would be necessary to impose a prevention-oriented system of food safety controls which would operate to define the statutory standard by ensuring that hazards are identified in advance and then prevented or reduced to an acceptable level through the application of several specific principles (see the preamble to FDA's seafood regulations (60 FR 65096). The primary measure by which this level of protection is achieved is a regulation that requires that food processors establish and operate under such a system (21 CFR part 123).

B. Measures for Achieving U.S. Levels of Protection

As the previous examples demonstrate, the United States provides protections both through outcome (whether the food contains an unapproved substance or an undesirable substance in sufficient quantity to adulterate it) and method of production (i.e., whether the conditions under which a food is prepared, packed, or held are conducive to producing a safe product). It is important to recognize that food is adulterated under U.S. law unless there is adherence to all applicable protections. A food might be free of contaminants, and thus be consistent with the protections extended by law in that respect, but still be adulterated under section 402(A)(4) of the act because it was processed under insanitary conditions whereby it may have become contaminated.

Thus, the U.S. regulatory system for food addresses both outcome and processing. As a practical matter, therefore, FDA would expect that another country's SPS measures must also address both outcome and processing if those measures are to provide assurance that food offered for export to the United States meets the U.S. level of protection.

1. Outcome

In establishing and enforcing tolerances, or maximum residue levels (MRL's), for food contaminants or residues of pesticides or veterinary drugs in foods as risk management measures, the United States ensures that its levels of protection are met. MRL's are based on assessments of the risks to human health and specifically to the health of U.S. consumers. These assessments take into account factors such as toxicity, expected residue levels based on labeled use of the product, and expected dietary exposures based on the U.S. diet.

As these factors suggest, the U.S. MRL's are based in part on domestic circumstances. It is not clear how a less stringent MRL could, alone, address these factors in a way that achieves the same level of protection for U.S. consumers as the U.S. MRL. Further, food containing contaminants or residues in excess of U.S. MRL's are deemed to be adulterated under U.S. law. Therefore, as a practical matter, as part of evaluating whether a foreign regulatory system can be judged equivalent, the agency would expect adequate assurances that U.S. MRL's will not be exceeded in those foods being exported to the United States.

It may be possible for a country with a less stringent MRL, or no MRL, to achieve equivalence, however, if it can demonstrate that the products that it exports to the U.S. will not contain contaminants in excess of the U.S. MRL. If, for example, the United States has established level ''L'' for a particular contaminant in a food, an exporting country could demonstrate that the food that it exports to the United States will not contain the contaminant because conditions do not exist there whereby the food would be exposed to the contaminant or contain levels in excess of the U.S. MRL.

An exporting country could also seek to present scientific evidence to demonstrate that the United States could meet its own level of protection with a less stringent MRL. While importing countries may occasionally revise older MRL's on the basis of such demonstrations, FDA expects that these revisions will occur only in limited situations if the importing country already bases its SPS measures on science, as does the United States.

In addition to tolerances, or MRL's, which are considered binding under U.S. law, FDA has provided ''action levels'' for contaminants as nonbinding guidance for FDA, industry, and the public about the level at which the contaminants in question may pose a health risk, based on available science. In providing nonbinding regulatory guidance, FDA may choose to take regulatory action when it finds that an action level has been exceeded or decide to exercise discretion based on the circumstances and risks posed by the particular case. Nevertheless, the manner in which the action level is applied to domestic products and to imports should be the same, and action levels should be taken into account when determining equivalence.

2. Conditions of Production

How a product is prepared, packed, or held can be of great importance to the safety of the product. As with the issuance of tolerances or MRL's, FDA periodically issues regulations on how certain foods must be processed to ensure that the foods are safe, and that U.S. levels of protection are met. The agency engages in inspections of processing establishments to determine whether these processing requirements are being carried out.

Attention to processing helps ensure that food is safe by preventing potential food safety problems and by ensuring that processors are aware of problems that may develop, and that they address those problems when they do occur. Sanitary and phytosanitary measures are credible to the extent that they decrease the likelihood that problems will occur, or increase the likelihood that problems will be discovered and corrected quickly, even when the regulatory inspector is not present.

End-product testing, which measures outcome, cannot generally be relied upon exclusively to provide an adequate level of protection because it only tests for a specific risk or group of risks on a particular day. The results of end-product sampling may or may not be representative of the actual, continuing risk, depending upon product uniformity, the amount of sampling, and other factors. Processing controls coupled with adequate verification by a regulatory authority provide an essential assurance that food will not present unacceptable risks. Processing controls can assure that the level of protection is met in many circumstances where end-product testing alone realistically cannot.

FDA, therefore, has issued several regulations that focus on how food is to be processed. The overall purpose of these regulations is to require that processing methods and equipment be appropriate to control potential risks. The regulations take into account available scientific evidence on food safety hazards and controls, relevant processes and production methods, and relevant economic factors, including costs and benefits. One of these regulations establishes basic sanitation principles and good manufacturing practices for all foods (''Current Good

Manufacturing Practice in Manufacturing, Packing, or Holding Food,'' (part 110 (21 CFR part 110)). Others require a specific processing regimen to control a particular problem or problems in certain types of foods. These regulations are key elements in FDA's regulatory system.

For purposes of equivalence, therefore, FDA will be looking for SPS measures established by an exporting country that fully address the objectives and purposes of applicable FDA regulations. FDA's examination may occur on a provision-by-provision basis, or on some other basis, as the agency deems necessary. To the extent possible, for example, differences in requirements affecting the actual physical dimensions or components of equipment (e.g., hand washing equipment for employees) will generally be less important than whether the broader public health purposes or objectives to which the equipment relates (i.e., personnel hygiene) are being adequately addressed. In any event, FDA will be prepared to articulate the objectives or purposes of its regulatory provisions during consultations on equivalence with foreign governments.

3. Labeling and Other Special Considerations

FDA notes that the SPS Agreement includes labeling within its definition of sanitary or phytosanitary measures. Not all labeling falls within this definition, however. Regarding labeling that does meet the definition, it is not clear to FDA how labeling that fails to meet U.S. requirements could be equivalent to these requirements. Therefore, the agency is not offering criteria at this time on how such labeling could be found to be equivalent and invites comment on whether differing SPS labeling requirements can be equivalent, and how determinations of equivalence should be made.

Similar difficulties may be presented by particular types of foods (e.g., infant formula and medical foods), which are subject to special statutory requirements (see section 412 of the act (21 U.S.C. 350a)). Therefore, FDA also requests comment about how it should handle equivalence determinations for those types of products.

4. Elements of the U.S. Regulatory System

As indicated previously, SPS measures include laws, decrees, regulations, and related matters. Clearly, the operations and functions of a country's regulatory system, which implements laws and issues decrees and regulations, constitute SPS measures. It is thus necessary to identify the elements of the U.S. regulatory system and the purposes that these elements serve in order that foreign regulatory systems can be compared against these measures and purposes.

For foods regulated by FDA, there are essentially two layers of regulatory authority: Federal or national authority, represented primarily by FDA, with regulatory jurisdiction over food in interstate commerce, as broadly defined in relevant case law, and individual State and local regulatory systems, with regulatory jurisdiction over food within their boundaries. The State systems are germane for purposes of ''two way'' equivalence primarily because States engage in regulatory inspections of food processors in addition to those conducted by FDA. Inspections, as discussed below, are a key element of the U.S. regulatory system.

The elements of the U.S. regulatory system may be thought of as falling into two broad categories. The first is infrastructure, which includes applicable law and the government bodies charged with implementing the law. The second category is implementation, or performance, which relates to how the infrastructure actually operates to prevent and control food-related risks. It is worth pointing out that, under the U.S. system, private food producers are responsible for producing safe food, while government is essentially responsible for verifying that producers are meeting their obligations and for taking remedial action when they fail to do so.

a. *Infrastructure*.

1. *Law*. The United States has national law that includes the following purposes:

- To prohibit the introduction of adulterated or misbranded food into commerce;
- To broadly establish what constitutes adulteration and misbranding;
- To authorize national regulatory agencies with the power to establish standards for foods (including how it is prepared, packed, and held), to conduct mandatory inspections of food processors, to issue processing requirements for food, and to take enforcement action to prevent adulterated or misbranded food from entering commerce and to remove it from any stage of interstate commerce if found.

In order for equivalence to be achieved, a foreign country needs to have laws applicable to food to be exported to the United States that achieve essentially the same objectives and will meet U.S. levels of protection. In addition, as discussed below, the foreign country must have the authority to implement the law in an appropriate way and must be, in fact, doing so.

2. *Regulatory authority*. The United States has national regulatory agencies that implement Federal food safety law applicable to all food in interstate commerce in the United States, including food to be exported. Essential characteristics of these agencies include, but are not limited to, the following:

- A regulatory infrastructure capable of, and engaged in, identifying existing and potential public health problems associated with food and capable of establishing appropriate regulatory policy with regard to such problems, including, but not limited to, the establishment of scientifically-based regulatory standards, processing requirements, and guidelines. This capability includes the ability, either within the agency or through contact with other agencies, to determine the causes of illness from foods that may be consumed domestically or shipped for export.
- An inspection infrastructure capable of, through appropriate training and experience, and engaged in conducting mandatory inspections of commercial entities that prepare, pack, and handle food to determine whether these entities are meeting their responsibility to produce food that is not adulterated. Inspections should include both observation and the taking of product samples for laboratory or organoleptic examination.
- A laboratory infrastructure that is capable of, and engaged in, analyzing samples to determine the presence and quantity of adulterants that are reasonably likely to affect food, including but not limited to pathogens, chemicals, toxins, and parasites. The methodologies used should have, in most cases, been approved or validated by recognized entities that are competent to evaluate such methods. The competency of the laboratories to use these methods has been appropriately evaluated and maintained through extensive quality assurance programs.
- An enforcement infrastructure that is capable of, and engaged in, reviewing the findings from inspections and making rapid determinations as to whether regulatory action is necessary to resolve existing or potential public health problems. Where regulatory action is necessary, the enforcement infrastructure has available to it a range of actions designed to remove violative product from distribution and prevent a recurrence of the problem.
- An internal monitoring infrastructure to preserve the integrity and credibility of the agency's food

protection system. The infrastructure must be able to issue and enforce rules and procedures to promote ethical behavior, and to protect against conflict of interest, among its employees.

In order to be equivalent to the United States, a foreign country should have a regulatory infrastructure with jurisdiction over food to be exported to the United States that, at a minimum, possesses these characteristics. It is not necessary that these characteristics reside solely within a single government agency. They may be performed by multiple agencies at a national level or, under a Federal-type system, by a combination of national and local government agencies, as long as there is adequate assurance that the functions are being carried out adequately and in a reasonably consistent and coordinated manner.

Also, FDA does not rule out the possibility that nongovernment entities might be able to perform some regulatory functions under strictly controlled circumstances. When any function is performed by a nongovernment entity, such as a private inspection organization, there must be sufficient government oversight of the private organization to ensure that the relevant regulatory functions are being carried out adequately and in a manner that preserves the integrity and credibility of the functions. Ultimate regulatory responsibility must continue to rest with the government. In determining whether equivalence exists under such circumstances, FDA would expect the foreign government to be engaged in rigorous oversight over the nongovernment entity.

b. *Implementation.*

Equivalent implementation is achieved when the foreign regulatory infrastructure is carrying out its functions in a manner that provides a reasonable assurance that the products being offered for import into the United States meet our country's levels of protection and thus are not adulterated under U.S. law. While FDA will examine each function separately, the decision as to whether equivalence exists will be based on a consideration of whether the foreign country's system as a whole in some way provides the assurances that are provided by the U.S. system. As indicated previously, the whole system must be able to provide assurances beyond those that would be provided solely through end-product testing.

This examination may also take into account relevant conditions in the foreign country. For example, in considering whether inspections occur with sufficient frequency, FDA may consider sanitary and other conditions in that country, and particularly in processing plants, that bear on how much on-site presence and intervention by regulatory authorities is necessary to provide adequate assurance that adulterated products are not being exported. Furthermore, the degree to which industry uses appropriate processing controls can influence the methods and procedures by which government verifies compliance.

When considering the performance of the country's regulatory infrastructure, FDA intends to take into account experience already acquired with that country, including historical data from FDA monitoring of its products that are exported to the United States.

APPENDIX

Equivalence for Seafood

Because FDA has already received requests for consultations on seafood from a number of countries, the agency is including in this Appendix specific guidance on determining equivalence with its seafood HACCP regulations and with other features of its regulatory program for seafood. FDA may choose to issue specific additional guidance for other types of food at a later date.

A. HACCP and the Prerequisites

FDA's seafood HACCP regulations declare that fish and fishery products in interstate commerce are adulterated if they are not processed in accordance with the principles of HACCP and prerequisite requirements for sanitation provided for therein (§ 123.6(g)), regardless of whether the products may be otherwise adulterated. As with other regulations, the FDA seafood HACCP regulations have the force and effect of law. The regulations apply to imports into the United States as well as to products produced domestically.

In the absence of a determination of equivalence, imports must be processed in compliance with the regulations. In any consultations relating to equivalence, an exporting nation will be given the opportunity to demonstrate that its own measures for the seafood that is being exported from it to the United States are adequate to ensure that the objectives and purposes of each provision of the U.S. regulations will be met.

The seafood HACCP regulations require that fish and fishery products be processed under a system of preventive controls to ensure the safety of the food for human consumption. As part of this system, commercial processors must demonstrate the following: (1) A knowledge of safety hazards to which their products are subject; and (2) the ability to identify and apply controls that eliminate or minimize the likelihood of the occurrence of those hazards in the products. HACCP is essentially the opposite of end-product testing, which attempts to detect problems after they have occurred. As a scientifically-based processing control system, HACCP is able to achieve the level of protection deemed appropriate for the risks posed by seafood. End-product testing or other types of process controls that do not involve systematic, daily monitoring in conjunction with hazard analysis, cannot achieve this level of protection.

The preventive controls of HACCP are applied through the application of seven internationally recognized principles, all of which are required of seafood processors in the FDA regulations. These are:

(1) Conduct a hazard analysis.

(2) Identify the critical control points (CCP) in the process. A CCP is a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can, as a result, be prevented, eliminated, or reduced to acceptable levels.

(3) Establish critical limits for preventive measures associated with each identified CCP. A critical limit is the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

(4) Establish CCP monitoring requirements.

(5) Establish corrective action to be taken when monitoring indicates that there is a deviation from an established critical limit.

(6) Establish effective recordkeeping procedures that document the HACCP system.

(7) Establish procedures for verification that the HACCP system is working correctly.

These principles have been recognized in a Codex Alimentarious Code of Practice for Food Hygiene guide. Countries seeking a determination of equivalence regarding seafood should have measures involving a system of preventive controls that honors these seven principles. There is latitude regarding how countries mandate and operate such a system. For example, FDA regulations contemplate a mix of processor and government activities to fulfill the seventh principle, verification. Hypothetically, however, a country electing to have its regulatory agency conduct all verification activities would be given the opportunity to

demonstrate that its verification procedures meet the purposes and objectives of the U.S. requirement. It is worth noting that the purposes and objectives of each provision of the seafood HACCP regulations are addressed in the preambles to the regulations when issued as a proposal (59 FR 4142, January 28, 1994) and as a final rule (December 18, 1995).

FDA's seafood HACCP requirements do not replace or supersede the Good Manufacturing Practices regulations for all foods in part 110 (see section VII.B.2 of this document). These provisions provide basic good manufacturing practices for all foods. Countries seeking a determination of equivalence must always demonstrate SPS measures that meet the objectives and purposes of part 110, regardless of the types of food that are to be the subject of the equivalence determination.

In addition to the seven principles cited above, FDA's seafood HACCP regulations require processors to engage in a sanitation program as a prerequisite to HACCP (§ 123.11). The importance of good sanitation as a prerequisite to HACCP is internationally recognized, as exemplified by the discussions on this subject at the most recent meeting of the Codex Alimentarious Committee on Fish and Fishery Products. The FDA prerequisite program requires processors to monitor and keep records of how, on a daily basis, they are meeting the conditions and practices specified in part 110 relating to eight fundamental areas of sanitation. Countries seeking equivalence should have in place measures that meet the purposes and objectives of the U.S. prerequisite requirements for sanitation.

B. FDA's Seafood HACCP Guidelines

FDA's seafood HACCP regulations provide the basic ground rules and principles for establishing HACCP systems. For example, processors must conduct a hazard analysis to determine what hazards must be controlled through the seven principles of HACCP. The regulations themselves contain little detailed guidance, however, regarding what the result of that hazard analysis should be in a given situation.

It would not be sufficient for a seafood processor to implement a HACCP system that failed to properly identify all specific hazards that should be identified during the hazard analysis process or that failed to establish appropriate controls for those hazards. Therefore, to provide guidance on what FDA would consider adequate in implementing the regulations, FDA has issued guidelines entitled the ''Fish and Fishery Products Hazards and Controls Guide.''

A country seeking a determination of equivalence for seafood should be able to demonstrate that hazards identified by its system, and the controls applied to those hazards, are appropriate to the purposes and objectives of the seven principles of HACCP. When making the determination for seafood, FDA will use the ''Fish and Fishery Products Hazards and Controls Guide'' in evaluating the exporting country's measures relating to the identification of hazards and the implementation of controls for those hazards.

As with a domestic processor, the exporting country has the opportunity to demonstrate that hazards are being adequately addressed through controls other than those described in the guidelines. Moreover, during consultations with that country, FDA would be willing to consider arguments that it is mistaken in its judgment regarding hazards and controls (just as FDA is willing to listen to arguments of this nature from domestic processors). In any event, there must ultimately be agreement between the two countries on the outcome of hazard analysis as well as on appropriateness of the other elements of the program (e.g., the adequacy of controls for the identified hazards).

At the outset, FDA plans to conduct its reviews on a product-by-product basis, until such time as the agency has sufficient confidence that it is no longer necessary to demonstrate adequate hazard analysis and controls for each product to be exported from a particular country.

C. Raw Molluscan Shellfish

The safety of molluscan shellfish for human consumption raw or partially cooked involves special considerations that must be taken into account when determining equivalence. Because they are sedentary, filter-feeding animals, molluscan shellfish can accumulate pathogens and other types of contaminants that are harmful to humans. For example, the positive relationship between harvesting areas contaminated by sewage pollution and shellfish-borne enteric disease is well established. Consequently, the condition of the water from which they are harvested is critical to the safety of molluscan shellfish, especially those that are intended to be consumed raw or partially cooked.

The U.S. program to ensure the safety of raw molluscan shellfish centers around a classification system for opening and closing molluscan shellfish harvesting waters. This aspect of the program is run by the governments of U.S. States that possess shellfish harvesting waters. FDA audits and evaluates these State programs. The procedures and standards for classifying waters, and for conducting other aspects of the program, are in a document known as the Manual of Operations of the National Shellfish Sanitation Program. From FDA's perspective, the Manual of Operations has the status of a guideline. Each State in the program, however, has agreed to strictly adhere to it. Moreover, each State in the program has agreed to reject shellfish that have not been grown, harvested, or otherwise processed in accordance with the Manual of Operations.

Several countries have entered into MOU's with FDA for the export of raw molluscan shellfish to the United States. (See FDA, International Cooperative Agreements (November 1996); available from National Technical Information Service.) Under these MOU's, the exporting countries have agreed to comply with the Manual of Operations, as if each were a U.S. State. Some of these countries have expressed an interest in renegotiating these agreements as equivalence agreements rather than compliance agreements.

The Manual of Operations is comprehensive and highly detailed. Where differences exist between an exporting country's program and details in the Manual of Operations, judgments must be made about the significance of the differences. Equivalence determinations should focus on matters of significance. A country seeking a determination of equivalence with the United States for raw molluscan shellfish needs to demonstrate that its program meets the purposes and objectives of the Manual of Operations wherever a significant difference exists between its program and the provisions of the Manual.

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William B. Schultz,

Deputy Commissioner for Policy.

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