



U.S. Food and Drug Administration

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## Regulatory Information

### Good Importer Practices (Draft Guidance)

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## Draft Guidance

### **This guidance document is being distributed for comment purposes only**

Although you can comment on any guidance at any time, to ensure that the agencies consider your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 12, 2009.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, U.S. Department of Health and Human Services, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that is published in the *Federal Register*. Submit electronic comments to <http://www.regulations.gov><sup>2</sup>.

For single copies of this draft guidance, please contact: Office of Policy and Planning, Food and Drug Administration, U.S. Department of Health and Human Services 10903 New Hampshire Avenue, White Oak Building 1, Silver Spring, MD 20993, (301) 796-4840.

For questions regarding this draft document, contact Jeffrey Shuren, Office of Policy and Planning, Food and Drug Administration, (301) 796-4840.

### **U.S. Department of Health and Human Services (Food and Drug Administration)**

**U.S. Department of Homeland Security**

**U.S. Consumer Product Safety Commission**

**U.S. Department of Agriculture**

**U.S. Department of Commerce**

**U.S. Department of Transportation**

**U.S. Environmental Protection Agency**

**Office of the United States Trade Representative**

**January 2009**

### **GOOD IMPORTER PRACTICES**

This draft guidance document, when finalized, will represent the current thinking of the United States Department of Agriculture, Department of Commerce, Department of Health and Human Services (Food and Drug Administration), Department of Homeland Security, Department of Transportation, Consumer Product Safety Commission, Environmental Protection Agency, and the Office of United States Trade Representative (*hereinafter* agencies) on this topic. It does not create or confer any rights for or on any person and does not operate to bind the agencies or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact the appropriate agency staff.

### **Introduction**

Helping ensure imported products are in compliance with applicable U.S. statutes and regulations is a shared responsibility between the public and private sectors. To that end, it is important that importers have practices in place that can prevent or detect potential problems at critical points along the product's life cycle to avoid placing the U.S. consumer at risk. Recognizing this, many importers have already

developed practices to prevent or detect and control problems that can occur in foreign-sourced products, ingredients and components (*hereinafter* products).

This guidance document provides general recommendations to importers on possible practices and procedures they may follow to increase the likelihood the products they import are in compliance with applicable U.S. safety and security requirements.<sup>1</sup> For example, at various points in a product's life cycle – growing, harvesting, designing, manufacturing, processing, packing, receiving, storing, transporting, importing, and distributing – it may be appropriate for companies to consider implementing preventive controls to decrease the risk of the product causing harm to people, animals, and/or the environment. The recommendations provided here are intended to promote and facilitate an assessment by importers of the product's life cycle, so the importer may make sound decisions about how best to address the product's potential to cause harm and to facilitate compliance with U.S. requirements.

Although this guidance relates to requirements and practices pertaining to product safety, importers should also take steps to help ensure that the products they bring into the United States comply with other applicable legal requirements. The recommendations in this guidance do not supersede the federal, state, and/or local statutes or regulations that apply to the product(s) being imported. The recommendations in this guidance may also assist importers in preventing unauthorized access, such as to products, facilities, and records. However, importers may need to take additional security measures. This draft guidance does not address those measures.

This draft guidance document would not establish legally enforceable rights or responsibilities. Instead, the guidance document, when finalized, would describe the current thinking of U.S. federal departments and agencies on a topic, and readers should view it only as recommendations, unless the document cites specific regulatory or statutory requirements. The use of the word "*should*" means that something is suggested or recommended, but not required. Nothing in this document is intended to affect the importer's responsibility to comply with all applicable requirements found in U.S. statutes and regulations.

### **Interagency Working Group on Import Safety**

On July 18, 2007, President Bush issued Executive Order 13439,<sup>2</sup> to establish the Interagency Working Group on Import Safety (Working Group). On September 10, 2007, the Working Group presented a report to the President entitled *Protecting Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety* (Strategic Framework).<sup>3</sup>

The Strategic Framework proposed a new approach to ensure the safety of imported products consumed and used by Americans. It noted that "[t]he challenges presented by the increasingly global economy and growing import volumes require a paradigm shift from an intervention, border-focused strategy to a life-cycle approach that stresses a risk-based approach to prevention with verification that identifies high-risk segments of the product life cycle and verifies the safety of products at those important phases. With this shift, the U.S. import process will change from viewing a 'snapshot' of the product at the border to achieving a real-time 'video' across the product's life cycle at the most appropriate points of production and distribution."

The approach outlined in the Strategic Framework is based on six building blocks,<sup>4</sup> and the three organizing principles of prevention of harm, intervention when risks are identified, and response after harm has occurred. The Strategic Framework recognized that "[t]he U.S. government must work with the private sector to adopt an approach to import safety that builds safety into manufacturing and distribution processes. Producers and the importing community will play a key role in accomplishing this objective by implementing preventive approaches and requiring these approaches from their suppliers. In addition, third-party certifications and testing requirements can play an important role in this area, as can credible manufacturer supply-chain management programs."

On November 6, 2007, the Working Group released an *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Action Plan).<sup>5</sup> The Action Plan contained 14 broad recommendations and 50 specific short- and long-term action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. The *Action Plan* stressed the importance of the private sector's responsibility for the safety of its products and compliance with U.S. standards. It also recognized the importance of private-sector mechanisms and experience and laid a foundation for ongoing substantive public-private collaboration. The public and private sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

Action Step 3.1 of the *Action Plan* recommended that "[t]he federal government should work with the importing community and other members of the public to develop Good Importer Practices and issue

guidance with respect to particular product categories. The focus of these practices will be to ensure that imported products meet U.S. safety standards, as well as to promote effective supply-chain management. The *Action Plan* recommended that "[t]hese practices be risk-based and provide concrete guidance to the importing community for evaluating imported products. This evaluation would be based on due diligence and preventive control principles." The federal government is issuing this guidance in response to the recommendation in Action Step 3.1. It provides principles and recommendations that may apply to imported products generally, and will help ensure that federal agencies and importers adopt a consistent approach. Individual agencies may issue more specific guidance directed at particular product categories to provide more targeted and detailed recommendations.

Developing Good Importer Practices can assist the entire importing community in taking appropriate steps to ensure the safety of the products they bring into the United States.

## Scope

This Good Importer Practices guidance is intended for use by the importer that initiates or causes the entry or attempted entry of foreign-sourced products into the U.S. or the reimportation of U.S.-made products (American Goods Returned) for commercial purposes or distribution. However, importers who are not bringing in a product for commercial purposes or distribution should have adequate control measures to prevent the distribution of the product into U.S. markets unless the product meets all U.S. requirements.

Parties other than importers associated with import transactions might also be subject to U.S. requirements. To promote safety of imported products, these parties (e.g., retailers, manufacturers) should also carefully consider the guidance set forth in this document.

Hazards that may place consumers at risk can arise at any point during a product's life cycle. This guidance document provides recommendations concerning preventive controls firms can implement to mitigate such hazards, and to help ensure imported products are safe and are compliant with U.S. laws and regulations.

The recommendations contained in this guidance are designed to anticipate the sources of product hazard that importers may face. We recognize that different goods carry different risks and potential hazards. We encourage importers to tailor these recommendations to their specific situations by adopting the criteria that will most effectively manage the risks that they face and best protect consumers. Further, we recognize that the size and scope of importers' resources vary enormously. As such, large-scale importers may have greater challenges but also greater resources and influence to minimize risk. While some of the following recommendations may be impractical for some small-scale importers, each importer should take appropriate steps to ensure the safety of its products.

In general, we recommend that importers:

- Know the foreign firms that produce the products they purchase and any other firms with which they do business and through which such products pass (e.g., consolidators, trading companies, distributors);
- Understand the products that they import and the vulnerabilities associated with these products;
- Understand the hazards that may arise during the product life cycle, including all stages of production; and
- Ensure proper control and monitoring of these hazards.

Importers should consider instituting practices to identify and minimize risks. Determining the sources of greatest potential risk in a product's life cycle helps to direct attention to the areas where they can have the greatest positive impact to ensure the safety of the product. Importers should put into place controls for known vulnerabilities, such as microbiological contamination and product defects, and monitor for other risks, such as counterfeiting or intentional contamination.

## Good Importer Practices – Principles and Recommendations

Because of the wide variety of products and their production processes, the regulatory systems that apply to particular products, and the range of product and importer relationships, it is difficult to develop a set of detailed recommendations that fits every product. However, in developing these recommendations, members of the Working Group did consider the complexity of product life cycles and production processes, as well as the different regulatory frameworks to which various products can be subject. Not all recommendations are appropriate or feasible for every product, and for every importer, but we suggest that importers identify and understand potential risks before deciding to import a particular product. We also recognize that importers could already be using other "best practices" that provide assurance that

their products are in compliance with U.S. requirements, and thus are not advising that these importers necessarily modify their practices. However, we believe importers who follow these Good Importer Practices may be less likely to import products that may be harmful to U.S. consumers, and, as a result, may, in some cases, facilitate admissibility determinations, and, therefore, expedite the entry of their products into the United States. However, following these Good Importer Practices does not guarantee compliance with applicable U.S. requirements, or mean that the Government cannot or will not take regulatory or enforcement action regarding compliance with U.S. laws and regulations.

These Good Importer Practices are broadly organized under four guiding principles:

- Establishing a Product Safety Management Program;
- Knowing the Product and Applicable U.S. Requirements;
- Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain and Product Life Cycle; and
- Taking Corrective and Preventive Action When the Imported Product or Firm Is Not Compliant with U.S. Requirements.

### **Guiding Principle I Establishing a Product Safety Management Program**

*To ensure that the supply chain for imports receives appropriate oversight by the importer, we recommend that the importer have an organizational structure that allows it to implement the practices recommended in this guidance. That structure should have clearly defined job functions and responsibilities; established procedures, including those for oversight and quality systems; adequate training for personnel; and appropriate communication mechanisms.*

*Ensuring corporate responsibility through increased accountability, enforcement, and deterrence is one of the six building blocks of the Strategic Framework. Corporate responsibility for product safety should start at the very top of the organization. Although a product safety management program may provide the necessary organizational structure to ensure product safety, an effective program starts with management's commitment to product safety. By taking the appropriate actions to establish a product safety management plan, importers can enhance their ability to identify and minimize potential hazards to their consumers.*

*An importer should consider establishing a product safety management program that includes the following features:*

- Establish a clear management structure for product safety. Such a management structure would define and document functions, responsibilities, and reporting relationships for those individuals involved in product safety to demonstrate that management places a high degree of importance on the safety of imported products.
- Assign responsibility for product control and compliance to specific individuals, and ensure they understand their role in the organization.
- Ensure that the assigned individuals have the necessary training, knowledge, experience, skills, and competence to perform product compliance and control responsibilities, whether for finished products, raw materials, or other in-process components.
- Maintain appropriate control activities by having clearly documented policies, specifications, and procedures to ensure product safety, and maintain records to demonstrate how compliance with requirements was achieved.
- Establish a process to analyze and evaluate risks in the product life cycle, and develop an approach to control those risks appropriately. This process may include conducting risk assessments.
- Develop and maintain a system for communication and information that allows the sharing of relevant information on safety and compliance within the organization, and, where appropriate, with third parties, including federal, state, and local authorities.
- Establish a formal, documented quality-assurance program designed to control, monitor, and improve operations continually to ensure the safety of products and compliance with all applicable U.S. requirements.

### **Guiding Principle II Knowing the Product and Applicable U.S. Requirements**

*To ensure imported products are in compliance with all applicable U.S. statutes and regulations, importers should have a good understanding of the products they are importing, the applicable regulatory requirements, and the compliance history of the products and the firms involved in the products' design, production and handling. The importer should have sufficient knowledge of the product, its intended use, its inherent vulnerabilities and risks, and the methods by which it is grown, harvested, manufactured, processed, packed, received, transported, stored, imported, and distributed. The importer should know the regulatory framework(s) that govern(s) the products in the country(ies) of production (if any); the compliance status of the products it imports; the foreign firms that manufacture those products; and other firms with which it conducts business involved in the product's life cycle. Actions an importer should consider taking are described below. By taking the appropriate actions to know their products and understand the applicable requirements, importers can enhance their ability to identify and minimize potential hazards to their consumers.*

- Know what you are importing.
- Know the details of the product you import, such as its use, the packaging, size, quantity, quality, product composition, specifications, safety concerns, etc. These details can make a difference as to which U.S. requirements apply, and whether the product is in compliance with all applicable U.S. statutes and regulations.
- Know whether the product is intended for commercial sale or use in the United States or for foreign markets, as this can help you to determine whether the product has been manufactured to comply with U.S. requirements, and is properly labeled. Some imported products are not intended for commercial use/distribution, or are intended solely for foreign markets and, therefore, might not need to meet U.S. requirements for commercial use/distribution in the United States. For example, some products are made in the United States for sale in other countries, and, therefore, may not meet U.S. requirements. However, if they are subsequently offered for import into the United States (commonly referred to as "American Goods Returned"), they must meet U.S. requirements to be lawfully imported.
- Know which regulatory requirements apply.
- Know which U.S. requirements apply to the imported product, and to its manufacturer. General information about these requirements typically appear on the website of the federal agency(ies) with jurisdiction over the product.<sup>6</sup>
- Become familiar with the U.S. regulatory agency's policy statements, guidance, and other available information that it publishes to assist industry and end users. These generally appear on the website(s) of the agency(ies), may answer questions about the importation process, and may provide helpful recommendations on how to comply with U.S. requirements.
- Seek assistance so you know the applicable U.S. requirements and help ensure compliance. Importers can develop internal expertise or seek outside consultants for assistance in understanding, regulatory requirements. As resources permit, agency personnel may respond to general questions, and may issue additional guidance or provide training concerning the statutes and regulations they administer.
- Know the risks and compliance history of the products you import, and of the firms that manufacture distribute, or transport those products.
- Know the potential hazards or other compliance problems associated with the product.
- Know if any of the firms or individuals involved in the product's life cycle have previously experienced product-safety problems. For example, know if agencies with jurisdiction over the foreign manufacturer or other entities in the supply chain have previously identified violations relating to product safety by searching the agencies' websites.
- Know where to find enforcement information on the agency with jurisdiction's website, if available to the public, that can aid in understanding an agency with jurisdiction's concerns related to specific products and their foreign sources, as well as problems previously found. Determine whether the firm has corrected those problems.
- Know if the manufacturer(s) and the product are compliant with applicable U.S. requirements. Ask to see official documentation of compliance.
- Know if the manufacturer and the product are compliant with, applicable requirements imposed by the country of production. Ask to see official documentation of compliance. Violations of other country's requirements can alert you to potential problems with your goods.
- Investigate a firm's reputation, and verify its legitimacy by using available public-source information (such as the Internet) or, if possible, by interviewing other customers of the firm. If the product is

sold through a trading company, distributor, or other third party, consider investigating that firm's reputation and legitimacy as well.

- Determine whether a firm is a subsidiary of a larger company, and whether the importer has recourse against the parent company if the subsidiary defaults on its obligations. Manufacturers may be more likely to comply with U.S. requirements and make a safe product if the importer has recourse against them or their parent company, if they are a subsidiary.
- Be familiar with the relevant U.S., foreign, and international organizations, such as trade associations, that can alert you to emerging problems with the imported products. Communicate with sources known to provide reliable information about compliance or quality issues relative to the products imported.
- Be alert to information that suggests the product is subject to counterfeiting or other fraudulent activities, such as an offer to sell the product at a price significantly below market value, or a history of prior counterfeiting.
- Know, if possible, whether the product was or could have been exposed to pesticides, other chemicals, or contaminants or improper storage conditions during its growth, harvesting, manufacture, processing, packing, receipt, transportation, storage, importation, or distribution and, if so, whether those circumstances could affect compliance and/or product safety. The existence of these conditions can alert you to potential safety problems.

### **Guiding Principle III**

## **Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply Chain and Product Life Cycle**

*Once importers know the regulatory requirements that apply to the imported product and its producers, importers should take care to ensure that the product and producer(s) meet these requirements. Importers should ensure that the appropriate preventive controls have been implemented throughout the supply chain and life cycle of the product, during growing, harvesting, designing, manufacturing, processing, packing, receiving, storage, transport, entry, and, if applicable, U.S. distribution. An importer should take care to ensure the product complies with all applicable U.S. requirements, that all foreign firms responsible for manufacturing/producing the product are compliant with all applicable U.S. requirements for that product and its producers, and that the foreign firms have appropriate preventive controls in place to ensure the product is safe. If there are gaps, the importer should work with the foreign firms to ensure that the foreign firms develop appropriate controls at critical points, monitor those points, and periodically evaluate them to make certain they are effective. These practices should provide confidence that products intended for sale in the United States meet regulatory requirements, such as ones that require that they be free of potentially hazardous ingredients, contaminants or defects; that they are properly labeled; and that they are the products they claim to be.*

*At or before entry, importers are required to file information with the U.S. Government about the product. Importers can file this information themselves or may use the services of a licensed customhouse broker to facilitate submission of the required documentation including product coding. Firms usually provide the information electronically to Customs and Border Protection (CBP), and in some cases to other agencies with jurisdiction, through a broker/filer. Accurate identification of the facility, product-coding information, product description, as well as the Harmonized Tariff Schedule Classification can facilitate the government's review and assessment, and, therefore, expedite the entry process. The importer might be responsible for providing other documentation relevant to the U.S. Government's review, such as prior notice for some products, advance manifest information, product registration, information on process, affirmation of compliance or the import declaration form and accession number of the reports required to show compliance with federal performance standards.*

*An importer's responsibility could continue after the product has moved into distribution within the United States. Problems could surface after the product has changed ownership or form, or has reached the consumer or other end user. Depending on several factors, the importer might need to remove the product from the marketplace, and/or notify the public and the government agency(ies) with regulatory authority. The importer should take responsibility for evaluating problems that develop with its imported products prior to importation, while under its control, or while under the control of domestic parties with whom it conducts business, and for determining the appropriate course of action. The agency(ies) with regulatory authority can assist in notifying the public, and assist the importer or manufacturer to conduct a safety recall, if necessary. Both the agency(ies) and the company can use the information to determine if other products are affected, to increase surveillance, and to modify control practices. When the importer uncovers a problem, it is important that the importer share this information, where appropriate, to inform*

*others, and enhance future performance of both private and public entities. By taking the appropriate actions to verify product and firm compliance with U.S. requirements, importers can enhance their ability to identify and minimize potential hazards to their consumers.*

*This section makes several specific recommendations that should generally apply, although appropriate actions for each importer to take may vary with the circumstances.*

A. Control, Monitor, and Verify Product and Producer Compliance Prior to the Arrival of the Product in the United States.

- Have knowledge of the firms/persons in the foreign supply chain (e.g., name, address, type of business, etc.), to the extent feasible, from the production or growing of raw materials to manufacturing/processing, packaging, storage, and transportation of products destined for import into the United States.
- Know what preventive controls, if any, firms must institute at each critical point in the product's life cycle, and the steps firms need to take to ensure that those controls are being appropriately applied so that the product is safe for end users, such as consumers or healthcare professionals. The presence of inadequate preventive controls can alert you to potential safety risks.
- Prior to doing business with a supplier, perform an assessment of the supplier to determine whether it has implemented an effective product safety program to help ensure you receive a product that meets applicable U.S. requirements. The assessment may include a review of documents, an on-site audit, or both.
- Resolve any potentially significant or questionable information gaps about the firms involved in the product life cycle prior to importing their products, because the lack of information can raise concerns about the safety and security of the product.
- Obtain a written guarantee of product compliance from company representatives, if appropriate, based on a consideration of the risks associated with non-compliance and other conformity-assessment procedures employed. Insist on compliance with U.S. requirements in the purchasing contract, and impose remedies if the firm sells you non-compliant products for export to the U.S. Be as specific as possible about safety requirements. This can help ensure you receive a product that complies with applicable U.S. requirements. Firms can establish additional measures to ensure product safety through contracts or agreements with other participants in the supply chain, such as shippers.
- When possible, deal directly with the supplier, or its authorized agent, to avoid fraudulent schemes. Avoid dealing with entities that claim to represent a supplier but cannot demonstrate they are the supplier's authorized agent or refuse to provide information other than a certification about the supplier.
- When appropriate, require all those in the supply chain to have evidence of compliance with applicable U.S. requirements. Such evidence might include certification, licensing, certificates of analysis, and/or letters of guarantee.
- When appropriate, require foreign firms to train their employees on U.S. requirements applicable to their products when imported into the United States.
- Establish mechanisms to verify compliance with U.S. requirements. Possible mechanisms include the following acts by the importer:
  - Periodically inspect the foreign firm where appropriate and feasible. The importer could conduct inspections either through periodic visits or by placing personnel in critical, foreign production facilities. Alternatively, the importer could hire qualified third parties to perform inspections. The inspections should verify that preventive controls (e.g., Hazard Analysis and Critical Control Point) are in place, review records, review sampling results of both finished products and raw materials and ingredients of those finished products, and perform independent analysis of representative product samples. Third party auditors should be independent of the foreign firm, with no conflict of interest. They should have adequate training and expertise, and be accredited by a nationally or internationally recognized accrediting body.
  - Consider purchasing from certified firms. If the U.S. Government agency(ies) with jurisdiction over the product has established or recognized a certification program for foreign producers of the imported product, the importer should consider purchasing solely from those firms. In such instances, the frequency of inspections by the importer or an independent third party on behalf of the importer might be reduced.
  - Determine if the source country has laws that regulate the product, if the foreign regulatory scheme applies to exports and covers U.S. requirements, if there is a competent regulatory authority that regularly inspects the facility for compliance with the source country's requirements, and whether the source country's oversight includes any sampling and analysis.

The importer should assess whether the foreign firm has complied with, or is complying with the source country's regulations, if applicable and not inconsistent with U.S. requirements, by monitoring the foreign government's oversight results. These results can assist an importer to assess the source, quality, and compliance status of products they plan to purchase and import into the United States. If the foreign government issues any type of "export" certificate for the product, or requires that the product's manufacturer be certified or licensed, be aware of the meaning of the certificate or license, including whether it covers the appropriate safety, effectiveness, labeling or other factors relative to applicable U.S. requirements.

- Conduct paper audits. The importer should consider performing or consider having an appropriate third party perform periodic reviews of production/processing records. These records should document compliance, including procedures for all processes and operations relating to compliance with U.S. requirements, control of measuring and monitoring devices, sampling and testing, corrective action plans, and steps the foreign firm takes to verify compliance with U.S. requirements.
- Periodically reassess monitoring mechanisms, and modify them, as appropriate, to ensure they are working as designed.
- Be alert to evidence that casts suspicion on the product. Ask appropriate questions if there are unusual aspects of the product's history or transportation route to its final destination, such as: Did the product take an atypical route to get to the United States? Is it from a country that does not ordinarily supply that product? Is the price for the product much lower than expected? Is there evidence another country or firm rejected it? Is it entering through a port through which it does not ordinarily enter? Were there events, natural or otherwise, that could have led to problems with the imported product?
- Obtain guarantees or certifications subject to substantiation, if appropriate, that products vulnerable to moisture, contaminants, temperature, or other environmental conditions have been maintained under acceptable conditions during transit.

#### B. Control, Monitor, and Verify Product Compliance during Entry.

- Conduct a risk-based monitoring program of incoming products to target your resources where they will likely have the greatest positive impact on product safety. Such a program could include the following:
  - Examination of shipping records;
  - Examination of certifications, certificates of analysis, letters of guarantee, etc.;
  - Physical examination of the product, packaging, and labeling; and
  - Risk-based product sampling and testing by the importer or an independent third party, to ensure the product is authentic, and meets company specifications and U.S. requirements. Importers should use appropriately accredited laboratories.
- Consider using a licensed customhouse broker who is knowledgeable, trained, and understands the critical nature of accurate filing information to help ensure the accuracy and timeliness of your import filing. Know the correct harmonized tariff schedule number, as well as the correct commodity and product codes, and provide them to the broker/filer.
- Conduct or have an appropriate third party conduct licensed customhouse broker audits to ensure the transmission of accurate and legitimate information to appropriate Federal agencies.
- Refrain from using the services of any broker/filer that you believe repeatedly provides incorrect information to the U.S. Government.
- Encourage the participation of eligible entities in widely recognized industry-partnership programs that promote additional security measures. This provides a higher level of assurance that firms do not simply have security protocols in place, but are actually following them.

#### C. Control, Monitor, and Verify Product Compliance in U.S. Distribution.

- Establish procedures for the routine review and handling of safety complaints from consumers and customers to help ensure that safety problems are identified and addressed quickly. These procedures should include an analysis to determine if any patterns of problems are developing.
- Establish procedures for identifying non-compliant products, and for communicating information and problems regarding non-compliant products within the organization, and, where appropriate, to third parties, including Federal, State, and local authorities.
- In order to identify the source and destination of a potentially violative product, the importer should consider whether it should be able to trace the product from its origin to its destination. This would facilitate the removal of the violative product from the marketplace, as well as identify other



implicated products. Importers should consider using contract provisions that require the use of "track and trace" technologies to accomplish these objectives.

- Establish procedures to isolate and hold the product to prevent its distribution in the United States until all applicable agencies have issued the relevant releases. If the U.S. Government denies entry, establish procedures to export or destroy the product, or take other action consistent with applicable U.S. laws and regulations. These actions can help ensure an unsafe product does not reach consumers.
- Establish, in advance, procedures for the recall of imported products from distribution channels in the United States to limit consumer exposure to unsafe products should they come into the United States. Firms should periodically evaluate and modify these procedures, as appropriate. Develop a plan to notify appropriate Federal agencies of the product recall, which may be required by U.S. statute or regulations.
- Establish procedures to notify distributors, retailers, consumers and other end users of unsafe imported products to minimize the exposure of consumers to unsafe products, and to facilitate their timely recall.

### **Guiding Principle IV Taking Corrective and Preventive Action When the Imported Product or Firm Is Not Compliant with U.S. Requirements**

*As stated above, procedures should identify problems before a product reaches consumers. After firms have detected a problem, and have managed the process to minimize harm, the importer should take corrective and preventive action to ensure similar problems do not recur. By taking the appropriate corrective and preventive action when an imported product or firm is not compliant with U.S. requirements, importers can enhance their ability to minimize potential hazards to their consumers.*

*We recommend importers undertake the following actions:*

- Establish procedures for developing corrective action plans, and for taking corrective and preventive actions if non-compliance with a U.S. requirement or a safety concern should arise. Address the potential need for disposal/destruction or export of non-compliant products, consistent with applicable U.S. statutes and regulations.
- Identify and investigate the root cause of non-compliance with U.S. requirements for products they import, or by foreign firms with which they do business.
- Take steps to remediate and prevent harm from present and future shipments, and to ensure non-compliance and safety problems do not recur. These corrective action plans must, of course, be consistent with the appropriate U.S. agency's regulations. They could, for instance, include product re-labeling, product re-working or further processing, product export or destruction (if the violative product is already at a U.S. port-of-entry or in U.S. commerce), or a decision not to offer the product for entry into the United States. Proper corrective action plans are based on practices that either ensure the product is in compliance when offered for entry into the United States, or that will correct any problems prior to marketing in the United States.
- Work with the non-compliant firm to meet U.S. requirements, or stop conducting business with that firm.

## **Footnotes**

<sup>1</sup>While this guidance document sets out principles and recommendations for helping to ensure the safety and security of imported products, the principles and the non-customs related recommendations are also applicable to helping ensure the safety and security of products that are domestically produced.

<sup>2</sup> <http://www.whitehouse.gov/news/releases/2007/07/20070718-4.html><sup>3</sup>

<sup>3</sup> <http://www.importsafety.gov/report/strategicframework/index.html><sup>4</sup>

<sup>4</sup> The six building blocks are (1) Advance a Common Vision, (2) Increase Accountability, Enforcement, and Deterrence, (3) Focus on Risks Over the Life Cycle of an Imported Product, (4) Build Interoperable Systems, (5) Foster a Culture of Collaboration, and (6) Promote Technological Innovation and New Science

<sup>5</sup> <http://www.importsafety.gov/report/actionplan.pdf><sup>5</sup>

<sup>6</sup> There are several agency websites that importers can find useful, including the following:

<http://www.cpsc.gov><sup>6</sup>, <http://www.epa.gov/compliance/international/importexport.html><sup>7</sup>,  
<http://www.fda.gov><sup>8</sup>, <http://www.usda.gov><sup>9</sup>, <http://www.commerce.gov><sup>10</sup>, <http://www.cbp.gov><sup>11</sup>,  
<http://www.nhtsa.gov><sup>12</sup>. See also [Appendix](#) for agency roles and responsibilities as well as several applicable laws by product category.

## Appendix: Agency Roles and Responsibilities

*(The information below pertains to some but not all agencies who play a role in product safety, and to some but not necessarily all information that may be of interest to importers)*

<b>Product Category</b>	<b>Relevant Agency</b>	<b>Applicable Law</b>	<b>Roles &amp; Responsibilities</b>	<b>Websites</b>
All Products	Customs and Border Protection (CBP)	Tariff Act of 1930, Trade Act of 2002, and Security and Accountability for Every (SAFE) Port Act of 2006	<p>CBP exercises its regulatory authority to require detailed advance electronic cargo information on arriving goods.</p> <p>Pursuant to its authority to enforce the legal requirements for the entry of merchandise into the U.S. under 19 USC 1484, coupled with its general inspection and examination authorities, e.g., 19 USC 1499, CBP is to sample and hold merchandise on behalf of other government agencies (for example, the Food &amp; Drug Administration and the Consumer Product Safety Commission) that have specific authority to determine the admissibility of these products.</p> <p>CBP exercises enforcement authority using bonding procedures as permitted by the general authority under 19 USC 1623.</p> <p>CBP also has authority under the Tariff Act, particularly 19 USC 1595a(c) to seize merchandise that is imported in violation of any health, safety or conservation prohibition.</p>	<a href="http://www.cbp.gov">http://www.cbp.gov</a> <sup>13</sup>

Engines and Vehicles (highway and off-road)	<i>Environmental Protection Agency (EPA)</i>	<i>Clean Air Act (CAA)</i>	EPA establishes and enforces regulations that set air pollution emission standards. Vehicles and engines must be certified to meet these standards. Importation of uncertified vehicles or engine-driven equipment without a valid exemption or exclusion is prohibited.	<a href="http://www.epa.gov/compliance/international/importexport.html">http:// www.epa.gov/compliance/international/importexport.html</a> <sup>14</sup> <sup>15</sup>
Motor Vehicles (on-road) and Motor Vehicle Equipment	<i>National Highway Traffic Safety Administration (NHTSA)/U.S. Department of Transportation (DOT)</i>	<i>National Traffic and Motor Vehicle Safety Act</i>	NHTSA issues and enforces the Federal motor vehicle safety standards (FMVSS), which establish minimum performance requirements for the safety systems and components on vehicles that are primarily manufactured for use on public roads (motor vehicles) and for certain items of motor vehicle equipment (such as tires, automotive lighting equipment, motorcycle helmets, and child restraints). NHTSA regulates the importation of motor vehicles and regulated items of motor vehicle equipment to ensure compliance with the FMVSS. NHTSA also investigates suspected safety-related defects and noncompliance with the FMVSS. If a motor vehicle or item of motor vehicle equipment contains such a defect or noncompliance, the manufacturer must notify affected owners of the defect or noncompliance and remedy the defect or noncompliance without charge. Manufacturers who fail to furnish notification and remedy may be ordered by NHTSA to do so, and be subject to civil penalties.	<a href="http://www.nhtsa.gov">http://www.nhtsa.gov</a> <sup>16</sup> <a href="http://www.nhtsa.gov/cars/rules/import">http://www.nhtsa.gov/cars/rules/import</a> <sup>17</sup> (for information in importing motor vehicles and equipment) <a href="http://www.odi.gov">http://www.odi.gov</a> <sup>18</sup> (for information on defect investigations and recalls)

Fuels and EPA  
Fuel  
Additives

CAA

EPA establishes and enforces regulations requiring that each manufacturer or importer of gasoline, diesel fuel, or a fuel additive for use in motor vehicles, must have its product registered by EPA prior to its introduction into commerce. Registration involves providing a chemical description of the product and certain technical, marketing and health-effects information. This allows EPA to identify the likely combustion and evaporative emissions.

<http://www.epa.gov/compliance/international/importexport.html><sup>19</sup>  
<sup>20</sup>

EPA also has established and enforces regulations associated with the composition and physical properties of finished gasoline, and onroad and offroad diesel fuel such as sulfur and benzene content. Importers must be registered with EPA and meet these requirements. Importers of renewable fuels must also be registered with EPA and meet specific reporting requirements.

Ozone- EPA  
Depleting  
Substances

CAA

EPA regulates the import of controlled ozone depleting substances. EPA bans the sale and distribution of certain products that contain or that were manufactured with controlled ozone depleting substances. FIFRA requires all pesticide products (with limited exceptions) to be registered by the United States, and in compliance with FIFRA including requirements

<http://www.epa.gov/compliance/international/importexport.html><sup>21</sup>  
<sup>22</sup>

Pesticides EPA

*Federal  
Insecticide,  
Fungicide,  
and  
Rodenticide  
Act (FIFRA)*

<http://www.epa.gov/compliance/international/importexport.html><sup>23</sup>  
<sup>24</sup>

for bearing labels/labeling approved by EPA and product composition requirements. Unregistered products and products determined not to meet EPA requirements may be denied entry. Any product being sold or distributed in the United States must be in compliance with these requirements. If not, they may be subject to penalties, Stop Sale, Use, or Removal Orders, and seizure.

Food	EPA	<p><i>Federal Food, Drug, and Cosmetic Act (FFDCA)</i></p> <p>Under the FFDCA EPA sets "tolerances" (maximum residue limits) for pesticides in both domestic and imported food, to ensure the levels of pesticides in food are safe. U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) are responsible for enforcing EPA established pesticide tolerances on domestic and imported food to ensure any residues detected are within these tolerances.</p>	<p><a href="http://www.epa.gov/compliance/international/importexport.html">http://www.epa.gov/compliance/international/importexport.html</a><sup>25</sup><sup>26</sup></p>
	FDA	<p><i>Federal Food, Drug, and Cosmetic Act (FFDCA)</i></p> <p><i>Public Health Service Act (PHS Act)</i></p> <p><i>Fair Packaging and Labeling Act (FPLA)</i></p> <p>FDA regulates all food products (except meat, poultry, and processed egg products), including dietary supplements. In general, FDA regulates these products using a post-market system to help ensure that food is not adulterated or misbranded. In addition, food and color additives must be approved by FDA before marketing, as must use of health and nutrient content claims. Further, infant formula, food contact</p>	<p><a href="http://www.cfsan.fda.gov/list.html">http://www.cfsan.fda.gov/list.html</a></p>

substances, and certain new dietary ingredients used in dietary supplements are subject to premarket notification requirements, and low acid canned foods and acidified foods are subject to requirements to file with FDA.

*USDA  
Food Safety  
and Inspection  
Service (FSIS)*

*Federal Meat  
Inspection  
Act (FMIA)*

*Poultry  
Products  
Inspection  
Act (PPIA)*

*Egg Products  
Inspection  
Act (EPIA)*

FSIS regulates imported meat, poultry, and egg products. Imported products are subject to the same food safety and processing standards applied to U.S. domestic products. These standards ensure that meat, poultry, and egg products in U.S. commerce are safe, wholesome, unadulterated, properly labeled, and correctly packaged. FSIS evaluates the meat, poultry and egg product food regulatory system in each exporting country that applies for equivalence eligibility. These evaluations must verify system equivalence before FSIS will accept an exporting country as eligible for trade with the U.S. Eligible exporting countries may then certify establishments that will be permitted to process FSIS-regulated products for entry into the U.S. The food importation process begins with filing an import application with CBP, which enforces essential U.S. entry requirements for all food commodities. These include animal health restrictions set by the Animal and Plant Health Inspection Service (APHIS).

<http://www.fsis.usda.gov><sup>27</sup>

Imported meat, poultry, and processed egg products must also be presented to FSIS for reinspection at an official import establishment.

Imported products that pass FSIS reinspection are permitted entry into U.S. commerce.

Failed products are refused entry and must be removed from U.S. soil, converted to non-human food use (with FDA approval), or destroyed.

*U.S. Department of Commerce (DOC)/National Oceanic and Atmospheric Administration (NOAA) National Marine Fisheries Service (NMFS)*

*Agricultural Marketing Act*

The U.S. Department of Commerce (NOAA/NMFS) provides a voluntary inspection program to the seafood industry to assist in the assurance of compliance with food regulations. All types of establishments may receive these services (e.g., processing plants, vessels, retail, and foreign facilities) ranging from product inspection and grading to system audits to consultative and training services. The official government forms and certificates issues by USDC officers and inspectors are legal documents recognized in U.S. courts.

<http://seafood.nmfs.noaa.gov><sup>28</sup>

Chemical Substances *EPA*

*Toxic Substances Control Act (TSCA)*

EPA is responsible for regulating the safety of chemical substances manufactured, imported, processed, distributed, used, and disposed in the United States. EPA (1) reviews new chemicals before manufacture; (2) requires necessary testing of chemicals by manufacturers, importers, and processors where risks or exposures of concern are found; (3) may restrict

<http://www.epa.gov/compliance/international/importexport.html><sup>29</sup><sup>30</sup>

manufacture, import, processing, use, distribution, or disposal of chemicals to mitigate unreasonable risks; and (4) works to ensure that imported chemicals are in compliance.

Consumer Products

*Consumer Product Safety Commission (CPSC)*

*Consumer Product Safety Act (CPSA)*

CPSC has jurisdiction over approximately 15,000 types of consumer products. The CPSA defines consumer product broadly to include any article or component part thereof, sold to consumers or for personal use by consumers, in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. (Generally excluded from CPSC's jurisdiction are food, drugs, cosmetics, medical devices, tobacco products, firearms and ammunition, motor vehicles, pesticides, aircraft, boats and fixed site amusement rides.) Several other Acts provide authority for CPSC to regulate specific products such as gasoline cans and pool drain covers under the CPSA.

<http://www.cpsc.gov><sup>31</sup>

Under the CPSA, when the CPSC finds an unreasonable risk of injury associated with a consumer product it can develop a standard to reduce or eliminate the risk. The CPSA also provides the authority to ban a product if there is no feasible standard, and it gives CPSC authority to pursue recalls for products that present a substantial product hazard. The CPSA



contains several provisions impacting imports. Among others, it is unlawful for any person to manufacture for sale, offer for sale, distribute in commerce or import into the United States any consumer product not in conformity with an applicable consumer product safety standard. Imports as well as domestically produced products must be accompanied by certifications of compliance with applicable CPSC consumer product safety requirements under the CPSA and other laws administered by the CPSC.

Hazardous CPSC  
Substance

*Federal  
Hazardous  
Substances  
Act (FHSA)*

The FHSA requires that <http://www.cpsc.gov><sup>32</sup> certain hazardous household products ("hazardous substances") bear cautionary labeling to alert consumers to the potential hazards that those products present and to inform them of the measures they need to protect themselves from those hazards. Any product that is toxic, corrosive, flammable or combustible, an irritant, a strong sensitizer, or that generates pressure through decomposition, heat, or other means requires labeling, if the product may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonable foreseeable handling or use, including

reasonable  
foreseeable ingestion  
by children.

The FHSA gives the CPSC authority to ban by regulation a hazardous substance if it determines that the product is so hazardous that the cautionary labeling required by the act is inadequate to protect the public. Any toy or other article that is intended for use by children and that contains a hazardous substance is also banned under the FHSA if a child can gain access to the substance. In addition, the act gives the CPSC authority to ban by regulation any toy, or other article intended for use by children which presents a mechanical, electrical or thermal hazard. The Commission has issued regulations under this provision relating to specific products such as electrically operated toys, cribs, rattles, pacifiers, bicycles, and children's bunk beds. The FHSA includes several provisions related to imports and it is prohibited to introduce or delivery for introduction into interstate commerce any misbranded hazardous substance or banned hazardous substance. The product certification requirements noted above in the discussion of the CPSA also apply to products regulated under the FHSA.

Flammable CPSC  
Fabrics

*Flammable  
Fabrics Act  
(FFA)*

The FFA regulates the manufacture of highly flammable clothing, such as brushed rayon <http://www.cpsc.gov><sup>33</sup>

sweaters and children's cowboy chaps as well as interior furnishings, paper, plastic, foam and other materials used in wearing apparel and interior furnishings. Under the FFA, CPSC can issue mandatory flammability standards. Standards have been established for the flammability of clothing textiles, vinyl plastic film (used in clothing), carpets and rugs, children's sleepwear and mattresses and mattress pads. It is unlawful to manufacture for sale or import into the United States any product, fabric, or related material that fails to conform to an applicable standard issued under the FFA. The product certification requirements noted above in the discussion of the CPSA also apply to products regulated under the FHSA.

Certain CPSC Household Substances

*The Poison Prevention Packaging Act (PPPA)*

The PPPA requires a number of household substances to be packaged in child-resistant packaging. These include certain types of chemical and cosmetic products; mouthwash products and drugs and dietary supplements. The packaging required by the PPPA must be designed or constructed to be significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. The CPSC has issued regulations defining

<http://www.cpsc.gov><sup>34</sup>

Cosmetics	FDA	FFDCA	<p>which products require child resistant packaging as well as testing protocols to verify the effectiveness of the child-resistant packaging feature. The product certification requirements noted above in the discussion of the CPSA also apply to products required by CPSC regulations to be packaged in child-resistant packaging. FDA regulates cosmetics to help ensure that they are not adulterated or misbranded. In general, FDA's regulation of cosmetics is post-market, except that color additives used in cosmetics require pre-approval. With the exception of a few prohibited or restricted ingredients, cosmetic manufacturers may use any raw material as a cosmetic ingredient, as long as the ingredient does not adulterate the product.</p>	<a href="http://www.cfsan.fda.gov/~dms/cos-toc.html">http://www.cfsan.fda.gov/~dms/cos-toc.html</a>
Drugs	FDA	FFDCA	<p>FDA has the responsibility to ensure that human and animal drugs are safe, effective, and properly labeled. All drugs sold in the United States must meet various requirements of the FFDCA, including registration and listing, new drug approval, misbranding, and adulteration provisions, where applicable. FDA performs both pre-market approval inspections and Good Manufacturing Practices (GMPs) inspections to assess compliance with applicable</p>	<a href="http://www.fda.gov/cder/index.html">http://www.fda.gov/cder/index.html</a>

Medical Devices And Radiation-Emitting Electronic Products	FDA	<i>FFDCA</i>	<p>requirements.</p> <p>FDA's regulation of medical devices includes registration of establishments, listing of devices, the requirement that devices be manufactured in accordance with the quality system regulation, reporting of adverse events, and premarket notification (510(k)) or premarket approval (PMA), if applicable. As with drugs, FDA performs both pre-market approval inspections and Quality Systems Regulations (QSRs) inspections to assess compliance. In addition, FDA regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. Regulatory requirements for these products include performance standards, labeling, and submission of radiation safety product reports.</p>	<a href="http://www.fda.gov/cdrh/index.html">http://www.fda.gov/cdrh/index.html</a>
Biologics, Blood, and Vaccines	FDA	<i>FFDCA</i> <i>PHS Act</i>	<p>FDA regulates biological products, such as blood and blood products, vaccines, allergenics, and cellular and gene therapies. Such biological products must be approved, which requires that the products are demonstrated to be "safe, pure, and potent" and the facilities involved in production meet applicable standards. In addition, because biological products also meet the</p>	<a href="http://www.fda.gov/cber/index.html">http://www.fda.gov/cber/index.html</a>

definition of "drug" or "device" under the FDCA, they are also subject to certain FDCA provisions. Biological product standards regulations include specific standards for blood and blood components and general biological product standards for other products. General standards include requirements for lot release and standards regarding potency, general safety testing, sterility testing, purity testing, as well as standards related to testing for communicable disease agents. FDA's human tissue regulations address registration of manufacturers, donor eligibility, current good tissue practices, reporting adverse reactions and manufacturing deviations, product labeling, imports, and inspection and enforcement.

Animal Feed/Feed Ingredients FDA

*FFDCA*  
*PHS Act*

FDA regulates animal feeds/food in a manner similar to human foods. Non-medicated animal feeds/food are not subject to premarket approval or licensing. Food and color additives require FDA premarket approval. Facilities that manufacture medicated feed must have a FDA approved medicated feed mill license.

<http://www.fda.gov/cvm/default.html>

Plumbing Products EPA

*Safe Drinking Water Act (SDWA)*

SDWA prohibits the use of any pipe, plumbing fitting, solder, flux, or plumbing fixture used in plumbing that provides water for human consumption

<http://www.epa.gov/compliance/international/importexport.html><sup>35</sup>  
<sup>36</sup>

that is not "lead free."  
SDWA defines lead free for solders and flux as not more than 0.2 percent lead and for pipes, pipe fittings, and well pumps as not more than 8 percent lead. SDWA also requires EPA to work with third party certifiers to develop a testing protocol for leaching of lead from new plumbing fittings and fixtures. In 1994, EPA identified American National Standards Institute (ANSI)/NSF Standard 61 Section 9.

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U.S. Department of **Health & Human Services**

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