

1 **GUIDANCE FOR INDUSTRY**

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3 **Good Importer Practices**

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5 **DRAFT GUIDANCE**

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13
14 Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug
15 Administration, U.S. Department of Health and Human Services, 5630 Fishers Lane, Room
16 1061, Rockville, MD 20852. All comments should be identified with the docket number listed
17 in the notice of availability that is published in the *Federal Register*. Submit electronic
18 comments to <http://www.regulations.gov>.

19
20 For single copies of this draft guidance, please contact: Office of Policy and Planning, Food and
21 Drug Administration, U.S. Department of Health and Human Services 10903 New Hampshire
22 Avenue, White Oak Building 1, Silver Spring, MD 20993, (301) 796-4840.

23
24 For questions regarding this draft document, contact Jeffrey Shuren, Office of Policy and
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29 **U.S. Department of Homeland Security**

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

31 **U.S. Department of Agriculture**

32 **U.S. Department of Commerce**

33 **U.S. Department of Transportation**

34 **U.S. Environmental Protection Agency**

35 **Office of the United States Trade Representative**

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37
38 **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This draft guidance document, when finalized, will represent the current thinking of the United States Department of Agriculture, Department of Commerce, Department of Health and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.¹ 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

¹ 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.

78 imported. The recommendations in this guidance may also assist importers in preventing
79 unauthorized access, such as to products, facilities, and records. However, importers may need
80 to take additional security measures. This draft guidance does not address those measures.

81 This draft guidance document would not establish legally enforceable rights or responsibilities.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

88 **Interagency Working Group on Import Safety**

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

93 The Strategic Framework proposed a new approach to ensure the safety of imported products
94 consumed and used by Americans. It noted that

95 [t]he challenges presented by the increasingly global economy and growing import volumes
96 require a paradigm shift from an intervention, border-focused strategy to a life-cycle
97 approach that stresses a risk-based approach to prevention with verification that identifies
98 high-risk segments of the product life cycle and verifies the safety of products at those
99 important phases. With this shift, the U.S. import process will change from viewing a
100 ‘snapshot’ of the product at the border to achieving a real-time ‘video’ across the product’s
101 life cycle at the most appropriate points of production and distribution.

102 The approach outlined in the Strategic Framework is based on six building blocks,⁴ and the three
103 organizing principles of prevention of harm, intervention when risks are identified, and response
104 after harm has occurred. The Strategic Framework recognized that

105 [t]he U.S. government must work with the private sector to adopt an approach to import
106 safety that builds safety into manufacturing and distribution processes. Producers and the
107 importing community will play a key role in accomplishing this objective by implementing
108 preventive approaches and requiring these approaches from their suppliers. In addition,
109 third-party certifications and testing requirements can play an important role in this area, as
110 can credible manufacturer supply-chain management programs.

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

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

⁴ 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.

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

121 Action Step 3.1 of the *Action Plan* recommended that “[t]he federal government should work
122 with the importing community and other members of the public to develop Good Importer
123 Practices and issue guidance with respect to particular product categories. The focus of these
124 practices will be to ensure that imported products meet U.S. safety standards, as well as to
125 promote effective supply-chain management.” The *Action Plan* recommended that “[t]hese
126 practices be risk-based and provide concrete guidance to the importing community for evaluating
127 imported products. This evaluation would be based on due diligence and preventive control
128 principles.” The federal government is issuing this guidance in response to the recommendation
129 in Action Step 3.1. It provides principles and recommendations that may apply to imported
130 products generally, and will help ensure that federal agencies and importers adopt a consistent
131 approach. Individual agencies may issue more specific guidance directed at particular product
132 categories to provide more targeted and detailed recommendations.

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

135 **Scope**

136
137 This Good Importer Practices guidance is intended for use by the importer that initiates or causes
138 the entry or attempted entry of foreign-sourced products into the U.S. or the reimportation of
139 U.S.-made products (American Goods Returned) for commercial purposes or distribution.
140 However, importers who are not bringing in a product for commercial purposes or distribution
141 should have adequate control measures to prevent the distribution of the product into U.S.
142 markets unless the product meets all U.S. requirements.

143
144 Parties other than importers associated with import transactions might also be subject to U.S.
145 requirements. To promote safety of imported products, these parties (e.g., retailers,
146 manufacturers) should also carefully consider the guidance set forth in this document.

147
148 Hazards that may place consumers at risk can arise at any point during a product’s life cycle.
149 This guidance document provides recommendations concerning preventive controls firms can
150 implement to mitigate such hazards, and to help ensure imported products are safe and are
151 compliant with U.S. laws and regulations.

152

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

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

162

163 In general, we recommend that importers:

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

172

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

179

180 **Good Importer Practices – Principles and Recommendations**

181

182 Because of the wide variety of products and their production processes, the regulatory systems
183 that apply to particular products, and the range of product and importer relationships, it is
184 difficult to develop a set of detailed recommendations that fits every product. However, in
185 developing these recommendations, members of the Working Group did consider the complexity
186 of product life cycles and production processes, as well as the different regulatory frameworks to
187 which various products can be subject. Not all recommendations are appropriate or feasible for
188 every product, and for every importer, but we suggest that importers identify and understand
189 potential risks before deciding to import a particular product. We also recognize that importers
190 could already be using other "best practices" that provide assurance that their products are in
191 compliance with U.S. requirements, and thus are not advising that these importers necessarily
192 modify their practices. However, we believe importers who follow these Good Importer
193 Practices may be less likely to import products that may be harmful to U.S. consumers, and, as a
194 result, may, in some cases, facilitate admissibility determinations, and, therefore, expedite the
195 entry of their products into the United States. However, following these Good Importer Practices
196 does not guarantee compliance with applicable U.S. requirements, or mean that the Government
197 cannot or will not take regulatory or enforcement action regarding compliance with U.S. laws
198 and regulations.

199

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

- 201 I. Establishing a Product Safety Management Program;
- 202 II. Knowing the Product and Applicable U.S. Requirements;
- 203 III. Verifying Product and Firm Compliance with U.S. Requirements throughout the Supply
- 204 Chain and Product Life Cycle; and
- 205 IV. Taking Corrective and Preventive Action When the Imported Product or Firm Is Not
- 206 Compliant with U.S. Requirements.

207

Guiding Principle I

208

Establishing a Product Safety Management Program

209

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

215

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

224

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

227

- 228 • Establish a clear management structure for product safety. Such a management structure
- 229 would define and document functions, responsibilities, and reporting relationships for
- 230 those individuals involved in product safety to demonstrate that management places a
- 231 high degree of importance on the safety of imported products.
- 232
- 233 • Assign responsibility for product control and compliance to specific individuals, and
- 234 ensure they understand their role in the organization.
- 235
- 236 • Ensure that the assigned individuals have the necessary training, knowledge, experience,
- 237 skills, and competence to perform product compliance and control responsibilities,
- 238 whether for finished products, raw materials, or other in-process components.
- 239
- 240 • Maintain appropriate control activities by having clearly documented policies,
- 241 specifications, and procedures to ensure product safety, and maintain records to
- 242 demonstrate how compliance with requirements was achieved.

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- 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.

A. 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

288 referred to as “American Goods Returned”), they must meet U.S. requirements to be
289 lawfully imported.

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292

B. Know which regulatory requirements apply.

- 293 • Know which U.S. requirements apply to the imported product, and to its manufacturer.
294 General information about these requirements typically appear on the website of the
295 federal agency(ies) with jurisdiction over the product.⁶
296
- 297 • Become familiar with the U.S. regulatory agency’s policy statements, guidance, and other
298 available information that it publishes to assist industry and end users. These generally
299 appear on the website(s) of the agency(ies), may answer questions about the importation
300 process, and may provide helpful recommendations on how to comply with U.S.
301 requirements.
- 302
- 303 • Seek assistance so you know the applicable U.S. requirements and help ensure
304 compliance. Importers can develop internal expertise or seek outside consultants for
305 assistance in understanding, regulatory requirements. As resources permit, agency
306 personnel may respond to general questions, and may issue additional guidance or
307 provide training concerning the statutes and regulations they administer.

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C. Know the risks and compliance history of the products you import, and of the firms that
310 manufacture, distribute, or transport those products.

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- 314 • Know the potential hazards or other compliance problems associated with the product.
- 315 • Know if any of the firms or individuals involved in the product’s life cycle have
316 previously experienced product-safety problems. For example, know if agencies with
317 jurisdiction over the foreign manufacturer or other entities in the supply chain have
318 previously identified violations relating to product safety by searching the agencies’
319 websites.
- 320 • Know where to find enforcement information on the agency with jurisdiction’s website,
321 if available to the public, that can aid in understanding an agency with jurisdiction’s
322 concerns related to specific products and their foreign sources, as well as problems
323 previously found. Determine whether the firm has corrected those problems.
- 324
- 325 • Know if the manufacturer(s) and the product are compliant with applicable U.S.
326 requirements. Ask to see official documentation of compliance.
- 327
- 328 • Know if the manufacturer and the product are compliant with, applicable requirements
329 imposed by the country of production. Ask to see official documentation of compliance.

⁶ There are several agency websites that importers can find useful, including the following: <http://www.cpsc.gov>, <http://www.epa.gov/compliance/international/importexport.html>, <http://www.fda.gov>, <http://www.usda.gov>, <http://www.commerce.gov>, <http://www.cbp.gov>, <http://www.nhtsa.gov>. See also Appendix for agency roles and responsibilities as well as several applicable laws by product category.

330 Violations of other country's requirements can alert you to potential problems with your
331 goods.

332

333 • Investigate a firm's reputation, and verify its legitimacy by using available public-source
334 information (such as the Internet) or, if possible, by interviewing other customers of the
335 firm. If the product is sold through a trading company, distributor, or other third party,
336 consider investigating that firm's reputation and legitimacy as well.

337

338 • Determine whether a firm is a subsidiary of a larger company, and whether the importer
339 has recourse against the parent company if the subsidiary defaults on its obligations.
340 Manufacturers may be more likely to comply with U.S. requirements and make a safe
341 product if the importer has recourse against them or their parent company, if they are a
342 subsidiary.

343

344 • Be familiar with the relevant U.S., foreign, and international organizations, such as trade
345 associations, that can alert you to emerging problems with the imported products.
346 Communicate with sources known to provide reliable information about compliance or
347 quality issues relative to the products imported.

348

349 • Be alert to information that suggests the product is subject to counterfeiting or other
350 fraudulent activities, such as an offer to sell the product at a price significantly below
351 market value, or a history of prior counterfeiting.

352

353 • Know, if possible, whether the product was or could have been exposed to pesticides,
354 other chemicals, or contaminants or improper storage conditions during its growth,
355 harvesting, manufacture, processing, packing, receipt, transportation, storage,
356 importation, or distribution and, if so, whether those circumstances could affect
357 compliance and/or product safety. The existence of these conditions can alert you to
358 potential safety problems.

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360

Guiding Principle III

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

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364 *Once importers know the regulatory requirements that apply to the imported product and its*
365 *producers, importers should take care to ensure that the product and producer (s) meet these*
366 *requirements. Importers should ensure that the appropriate preventive controls have been*
367 *implemented throughout the supply chain and life cycle of the product, during growing,*
368 *harvesting, designing, manufacturing, processing, packing, receiving, storage, transport, entry,*
369 *and, if applicable, U.S. distribution. An importer should take care to ensure the product*
370 *complies with all applicable U.S. requirements, that all foreign firms responsible for*
371 *manufacturing/producing the product are compliant with all applicable U.S. requirements for*
372 *that product and its producers, and that the foreign firms have appropriate preventive controls*
373 *in place to ensure the product is safe. If there are gaps, the importer should work with the*
374 *foreign firms to ensure that the foreign firms develop appropriate controls at critical points,*
375 *monitor those points, and periodically evaluate them to make certain they are effective. These*

376 *practices should provide confidence that products intended for sale in the United States meet*
377 *regulatory requirements, such as ones that require that they be free of potentially hazardous*
378 *ingredients, contaminants or defects; that they are properly labeled; and that they are the*
379 *products they claim to be .*

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

392
393 *An importer's responsibility could continue after the product has moved into distribution within*
394 *the United States. Problems could surface after the product has changed ownership or form, or*
395 *has reached the consumer or other end user. Depending on several factors, the importer might*
396 *need to remove the product from the marketplace, and/or notify the public and the government*
397 *agency(ies) with regulatory authority. The importer should take responsibility for evaluating*
398 *problems that develop with its imported products prior to importation, while under its control, or*
399 *while under the control of domestic parties with whom it conducts business, and for determining*
400 *the appropriate course of action. The agency(ies) with regulatory authority can assist in*
401 *notifying the public, and assist the importer or manufacturer to conduct a safety recall, if*
402 *necessary. Both the agency(ies) and the company can use the information to determine if other*
403 *products are affected, to increase surveillance, and to modify control practices. When the*
404 *importer uncovers a problem, it is important that the importer share this information, where*
405 *appropriate, to inform others, and enhance future performance of both private and public*
406 *entities. By taking the appropriate actions to verify product and firm compliance with*
407 *U.S. requirements, importers can enhance their ability to identify and minimize potential hazards*
408 *to their consumers.*

409
410 *This section makes several specific recommendations that should generally apply, although*
411 *appropriate actions for each importer to take may vary with the circumstances.*

- 412
413 A. Control, Monitor, and Verify Product and Producer Compliance Prior to the Arrival of the
414 Product in the United States.
415
416 • Have knowledge of the firms/persons in the foreign supply chain (e.g., name, address,
417 type of business, etc.), to the extent feasible, from the production or growing of raw
418 materials to manufacturing/processing, packaging, storage, and transportation of products
419 destined for import into the United States.
420

- 421 • Know what preventive controls, if any, firms must institute at each critical point in the
422 product's life cycle, and the steps firms need to take to ensure that those controls are
423 being appropriately applied so that the product is safe for end users, such as consumers or
424 healthcare professionals. The presence of inadequate preventive controls can alert you to
425 potential safety risks.
426
- 427 • Prior to doing business with a supplier, perform an assessment of the supplier to
428 determine whether it has implemented an effective product safety program to help ensure
429 you receive a product that meets applicable U.S. requirements. The assessment may
430 include a review of documents, an on-site audit, or both.
431
- 432 • Resolve any potentially significant or questionable information gaps about the firm s
433 involved in the product life cycle prior to importing their products, because the lack of
434 information can raise concerns about the safety and security of the product.
435
- 436 • Obtain a written guarantee of product compliance from company representatives, if
437 appropriate, based on a consideration of the risks associated with non-compliance and
438 other conformity-assessment procedures employed. Insist on compliance with U.S.
439 requirements in the purchasing contract, and impose remedies if the firm sells you non-
440 compliant products for export to the U.S. Be as specific as possible about safety
441 requirements. This can help ensure you receive a product that complies with applicable
442 U.S. requirements. Firms can establish additional measures to ensure product safety
443 through contracts or agreements with other participants in the supply chain, such as
444 shippers.
445
- 446 • When possible, deal directly with the supplier, or its authorized agent, to avoid fraudulent
447 schemes. Avoid dealing with entities that claim to represent a supplier but cannot
448 demonstrate they are the supplier's authorized agent or refuse to provide information
449 other than a certification about the supplier.
450
- 451 • When appropriate, require all those in the supply chain to have evidence of compliance
452 with applicable U.S. requirements. Such evidence might include certification, licensing,
453 certificates of analysis, and/or letters of guarantee.
454
- 455 • When appropriate, require foreign firms to train their employees on U.S. requirements
456 applicable to their products when imported into the United States.
457
- 458 • Establish mechanisms to verify compliance with U.S. requirements. Possible
459 mechanisms include the following acts by the importer:
460
 - 461 ○ Periodically inspect the foreign firm where appropriate and feasible. The importer
462 could conduct inspections either through periodic visits or by placing personnel in
463 critical, foreign production facilities. Alternatively, the importer could hire qualified
464 third parties to perform inspections. The inspections should verify that preventive
465 controls (e.g., Hazard Analysis and Critical Control Point) are in place, review
466 records, review sampling results of both finished products and raw materials and

- 467 ingredients of those finished products, and perform independent analysis of
468 representative product samples. Third party auditors should be independent of the
469 foreign firm, with no conflict of interest. They should have adequate training and
470 expertise, and be accredited by a nationally or internationally recognized accrediting
471 body.
- 472
- 473 ○ Consider purchasing from certified firms. If the U.S. Government agency(ies) with
474 jurisdiction over the product has established or recognized a certification program for
475 foreign producers of the imported product, the importer should consider purchasing
476 solely from those firms. In such instances, the frequency of inspections by the
477 importer or an independent third party on behalf of the importer might be reduced.
 - 478
 - 479 ○ Determine if the source country has laws that regulate the product, if the foreign
480 regulatory scheme applies to exports and covers U.S. requirements, if there is a
481 competent regulatory authority that regularly inspects the facility for compliance with
482 the source country's requirements, and whether the source country's oversight
483 includes any sampling and analysis. The importer should assess whether the foreign
484 firm has complied with, or is complying with the source country's regulations, if
485 applicable and not inconsistent with U.S. requirements, by monitoring the foreign
486 government's oversight results. These results can assist an importer to assess the
487 source, quality, and compliance status of products they plan to purchase and import
488 into the United States. If the foreign government issues any type of "export"
489 certificate for the product, or requires that the product's manufacturer be certified or
490 licensed, be aware of the meaning of the certificate or license, including whether it
491 covers the appropriate safety, effectiveness, labeling or other factors relative to
492 applicable U.S. requirements.
 - 493
 - 494 ○ Conduct paper audits. The importer should consider performing or consider having
495 an appropriate third party perform periodic reviews of production/processing records.
496 These records should document compliance, including procedures for all processes
497 and operations relating to compliance with U.S. requirements, control of measuring
498 and monitoring devices, sampling and testing, corrective action plans, and steps the
499 foreign firm takes to verify compliance with U.S. requirements.
 - 500
 - 501 ● Periodically reassess monitoring mechanisms, and modify them, as appropriate, to ensure
502 they are working as designed.
 - 503
 - 504 ● Be alert to evidence that casts suspicion on the product. Ask appropriate questions if
505 there are unusual aspects of the product's history or transportation route to its final
506 destination, such as: Did the product take an atypical route to get to the United States? Is
507 it from a country that does not ordinarily supply that product? Is the price for the product
508 much lower than expected? Is there evidence another country or firm rejected it? Is it
509 entering through a port through which it does not ordinarily enter? Were there events,
510 natural or otherwise, that could have led to problems with the imported product?
 - 511

- 512 • Obtain guarantees or certifications subject to substantiation, if appropriate, that products
513 vulnerable to moisture, contaminants, temperature, or other environmental conditions
514 have been maintained under acceptable conditions during transit.
515

516 B. Control, Monitor, and Verify Product Compliance during Entry.
517

- 518 • Conduct a risk-based monitoring program of incoming products to target your resources
519 where they will likely have the greatest positive impact on product safety. Such a
520 program could include the following:
521
- 522 ○ Examination of shipping records;
 - 523 ○ Examination of certifications, certificates of analysis, letters of guarantee, etc.;
 - 524 ○ Physical examination of the product, packaging, and labeling; and
 - 525 ○ Risk-based product sampling and testing by the importer or an independent third
526 party, to ensure the product is authentic, and meets company specifications and
527 U.S. requirements. Importers should use appropriately accredited laboratories.
528
- 529 • Consider using a licensed customs broker who is knowledgeable, trained, and
530 understands the critical nature of accurate filing information to help ensure the accuracy
531 and timeliness of your import filing. Know the correct harmonized tariff schedule
532 number, as well as the correct commodity and product codes, and provide them to the
533 broker/filer.
534
- 535 • Conduct or have an appropriate third party conduct licensed customs broker audits to
536 ensure the transmission of accurate and legitimate information to appropriate Federal
537 agencies.
538
- 539 • Refrain from using the services of any broker/filer that you believe repeatedly provides
540 incorrect information to the U.S. Government.
541
- 542 • Encourage the participation of eligible entities in widely recognized industry-partnership
543 programs that promote additional security measures. This provides a higher level of
544 assurance that firms do not simply have security protocols in place, but are actually
545 following them.
546

547 C. Control, Monitor, and Verify Product Compliance in U.S. Distribution.
548

- 549 • Establish procedures for the routine review and handling of safety complaints from
550 consumers and customers to help ensure that safety problems are identified and addressed
551 quickly. These procedures should include an analysis to determine if any patterns of
552 problems are developing.
553
- 554 • Establish procedures for identifying non-compliant products, and for communicating
555 information and problems regarding non-compliant products within the organization, and,
556 where appropriate, to third parties, including Federal, State, and local authorities.
557

- 558 • In order to identify the source and destination of a potentially violative product, the
559 importer should consider whether it should be able to trace the product from its origin to
560 its destination. This would facilitate the removal of the violative product from the
561 marketplace, as well as identify other implicated products. Importers should consider
562 using contract provisions that require the use of “track and trace” technologies to
563 accomplish these objectives.
564
- 565 • Establish procedures to isolate and hold the product to prevent its distribution in the
566 United States until all applicable agencies have issued the relevant releases. If the U.S.
567 Government denies entry, establish procedures to export or destroy the product, or take
568 other action consistent with applicable U.S. laws and regulations. These actions can help
569 ensure an unsafe product does not reach consumers.
570
- 571 • Establish, in advance, procedures for the recall of imported products from distribution
572 channels in the United States to limit consumer exposure to unsafe products should they
573 come into the United States. Firms should periodically evaluate and modify these
574 procedures, as appropriate. Develop a plan to notify appropriate Federal agencies of the
575 product recall, which may be required by U.S. statute or regulations.
576
- 577 • Establish procedures to notify distributors, retailers, consumers and other end users of
578 unsafe imported products to minimize the exposure of consumers to unsafe products, and
579 to facilitate their timely recall.
580

581 **Guiding Principle IV**

582 **Taking Corrective and Preventive Action When the Imported Product or Firm Is Not** 583 **Compliant with U.S. Requirements** 584

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

591 *We recommend importers undertake the following actions:*
592

- 593
- 594 • Establish procedures for developing corrective action plans, and for taking corrective and
595 preventive actions if non-compliance with a U.S. requirement or a safety concern should
596 arise. Address the potential need for disposal/destruction or export of non-compliant
597 products, consistent with applicable U.S. statutes and regulations.
598
- 599 • Identify and investigate the root cause of non-compliance with U.S. requirements for
600 products they import, or by foreign firms with which they do business.
601
- 602 • Take steps to remediate and prevent harm from present and future shipments, and to
603 ensure non-compliance and safety problems do not recur. These corrective action plans

604 must, of course, be consistent with the appropriate U.S. agency's regulations. They
605 could, for instance, include product re-labeling, product re-working or further processing,
606 product export or destruction (if the violative product is already at a U.S. port-of-entry or
607 in U.S. commerce), or a decision not to offer the product for entry into the United States.
608 Proper corrective action plans are based on practices that either ensure the product is in
609 compliance when offered for entry into the United States, or that will correct any
610 problems prior to marketing in the United States.

- 611
- 612 • Work with the non-compliant firm to meet U.S. requirements, or stop conducting
- 613 business with that firm .

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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)

<u>Product Category</u>	<u>Relevant Agency</u>	<u>Applicable Law</u>	<u>Roles & Responsibilities</u>	<u>Websites</u>
All Products	<i>Customs and Border Protection (CBP)</i>	<i>Tariff Act of 1930, Trade Act of 2002, and Security and Accountability for Every (SAFE) Port Act of 2006</i>	<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 & 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>	http://www.cbp.gov

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.	http://www.epa.gov/compliance/international/importexport.html
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.	http://www.nhtsa.gov http://www.nhtsa.gov/cars/les/import (for information importing motor vehicles and equipment) http://www.odj.gov (for information on defect investigations and recalls)
Fuels and	EPA	CAA	EPA establishes and enforces	http://www.epa.gov/com

Fuel Additives

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>

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-Depleting Substances

EPA

CAA

EPA regulates the import of controlled ozone depleting substances.

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

EPA bans the sale and distribution of certain products that contain or that were manufactured with controlled ozone depleting substances.

Pesticides

EPA

Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA requires all pesticide products (with limited exceptions) to be registered by the United States, and in

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

		(FIFRA)	<p>compliance with FIFRA including requirements 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.</p>	
Food	EPA	<i>Federal Food, Drug, and Cosmetic Act (FFDCA)</i>	<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>	http://www.epa.gov/compliance/international/importexport.html
	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</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</p>	http://www.cfsan.fda.gov/html

and Labeling Act (FPLA)

approved by FDA before marketing, as must use of health and nutrient content claims. Further, infant formula, food contact 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)*

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.

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

*Poultry Products
Inspection Act (PPIA)*

*Egg Products
Inspection Act (EPIA)*

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). 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 issued by USDC officers and inspectors are legal documents recognized in U.S. courts.

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

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

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

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>

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
Substance CPSC

*Federal
Hazardous
Substances Act
(FHSA)*

The FHSA requires that certain <http://www.cpsc.gov> 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 deliver 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
Fabrics CPSC

*Flammable
Fabrics Act
(FFA)*

The FFA regulates the manufacture of highly flammable clothing, such as brushed rayon 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.

<http://www.cpsc.gov>

Certain
Household
Substances CPSC

*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

<http://www.cpsc.gov>

regulations defining 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.

Cosmetics FDA

FFDCA

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.

<http://www.cfsan.fda.gov/ms/cos-toc.html>

Drugs FDA

FFDCA

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

<http://www.fda.gov/cder/ix.html>

requirements.

Medical
Devices
And
Radiation-
Emitting
Electronic
Products

FDA

FFDCA

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.

<http://www.fda.gov/cdrh/index.html>

Biologics,
Blood, and
Vaccines

FDA

FFDCA

PHS Act

FDA regulates biological products, such as blood and blood products, vaccines, allergens, 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 definition of “drug” or “device” under the FFDCA, they are also subject to certain FFDCA 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.

<http://www.fda.gov/cber/ix.html>

Animal Feed/Feed Ingredients	FDA	<i>FFDCA</i> <i>PHS Act</i>	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/cult.html
Plumbing Products	EPA	<i>Safe Drinking Water Act (SDWA)</i>	SDWA prohibits the use of any pipe, plumbing fitting, solder, flux, or plumbing fixture used in plumbing that provides water for human consumption 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.	http://www.epa.gov/compliance/international/importexport.html

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