



Association of Food and Drug Officials

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January 20, 2014

Department of Health and Human Services
Food and Drug Administration

RE: Comments from the Association of Food and Drug Officials
Docket No. FDA-2011-N-0143, "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals"

The Association of Food and Drug Officials (AFDO) is pleased to provide comments to the U.S. Food and Drug Administration regarding its proposed rule "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals".

AFDO is the preeminent organization of federal, state and local regulatory officials in the United States. AFDO's membership also includes non-voting representatives from industry, academia, and consumer groups who actively participate in AFDO committees, workgroups, and other organization efforts. During its 117 year history, AFDO has promoted uniform, science-based food safety laws and regulations and is well-recognized for advocating a nationally integrated food safety system that would coordinate government resources at all levels in order to reduce duplication of efforts and allow government officials to meet food safety challenges in a more strategic fashion

General Comments

AFDO recognizes that the primary purpose of the proposed regulations is to ensure that imported food is produced in a manner consistent with U.S. standards. Although FDA applies the same food safety standards to all food marketed in the United States regardless of where it was produced, FDA has taken different regulatory compliance approaches to products produced domestically and abroad.

FDA has indicated that there are more than 250,000 foreign food facilities registered to export food to the United States and it would be impractical to expect that FDA could routinely inspect all of these facilities in a comprehensive manner. AFDO supports, for this reason, FDA's effort to advance a verification system to assist in dealing with foreign manufactured foods. Whatever the form of verification that is applied to foreign manufacturers, however, must be credible in order to assure these foods have been manufactured under the same sanitary conditions to be required of domestic producers. To properly address a global food supply system and for the purpose of fairness, we believe there must be a level playing field between domestic and foreign produced food when mandating food safety controls

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Role of State and Local Agencies

AFDO believes that state and local food safety regulatory authorities can play an important role in assuring the effectiveness of this verification system through the inspection and surveillance of imported food products marketed domestically to establishments routinely inspected by state and local agencies. State and local agencies inspect food processors, warehouses, ethnic retail food stores, and restaurants where imported foods are commonly encountered. In addition, foodborne illness outbreaks are generally first reported to and investigated by state or local health agencies. We would caution FDA not to ignore state and local oversight of domestic facilities where imported products are marketed and during any illness outbreaks investigated by state or local health agencies where imported products are involved. This information that can be provided by state and local agencies can, in part, be a mechanism for measuring the effectiveness of the proposed rule.

We refer FDA to the following attachments from the New York Department of Agriculture and Markets, Division of Food Safety and Inspection:

- Attachment 1: Food Recall Summary 2000-2012
- Attachment 2: Recalls by Country

The data clearly illustrates, in our view, the critical role that state and local food safety agencies could play in the oversight of imported food and its association to a foreign verification system. It leads us to ask the following of FDA.

Does FDA have a specific vision relative to the roles state and local agencies might play with regard to imported foods?

Will FDA accept state or local food sampling analysis as grounds for taking action against a foreign manufacturer or importer?

Will FDA continue to work with states in issuing import alerts based on state food sampling analysis?

How will enforcement of violative imported food products be addressed and would there be circumstances where state and local agencies might be utilized?

FDA must recognize the value of state and local agency inspection efforts and the foodborne illness and food testing surveillance that may be conducted for imported foods. In a truly integrated food safety system, such a partnership must exist. AFDO is willing to work with FDA on training of state and local officials to expand this opportunity for partnering

Furthermore, where states are willing and have the resources to conduct surveillance on imported food products, FDA should develop a formal mechanism for the states to supply this information to FDA so that FDA may combine the state surveillance information with internal FDA information in order to better target import inspection and review of problem products, companies and countries.

FDA can expand state influence and impact with imported food issues by becoming more open and transparent with records of imported foods distributed within the states. This consideration should be made within states that are able to dedicate some of their resources to imported foods

Inspection frequency

FDA indicates that it will only be able to inspect foreign facilities at a frequency of 10 years or more, while domestic food facilities can expect an inspection rate of once every 3 to 5 years depending on the level of risk. In our view, this inspection rate is inadequate to ensure a level playing field between domestic and foreign producers.

Recognizing the work of the states enrolled in the Manufactured Food Regulatory Program Standards can help FDA meet its inspection obligations internationally while relying on equivalent state inspections performed domestically. In order for FSMA to be successful, FDA needs to pursue funds to invest in state agencies that can assist them in meeting inspection mandates. Congress did not provide all necessary funds when it passed FSMA, and FDA needs to position itself to get the proper funds. FSMA cannot be an unfunded mandate.

Definitions

Proposed § 1.500 would define qualified individual as a person who has the necessary education, training, and experience to perform the activities needed to meet the requirements of this subpart; this person may be, but is not required to be, an employee of the importer. FDA is directed to establish a system for determining whether an individual is qualified and whether the education and training provided to a qualified individual is from an accredited source. In our opinion, whatever system is established, it should include a set of minimum qualifications approved by FDA for determining what a qualified individual is.

AFDO is a strong supporter of the various Alliances that have been formed within the seafood, juice, produce, and food manufacturing industries to provide necessary food safety assurance training for individuals working in these industries. We believe similar Alliances could be formed to develop and deliver standardized training for auditors conducting foreign verifications. We further believe that foreign manufacturers should not be permitted to rely on third-party auditors who have not received food safety preventive control training that is from an accredited source using a standardized training program. Importers can verify that individuals have received this necessary training through a data management system which identifies approved courses and individuals that have successfully completed the training course. This is precisely how this matter is addressed in the Seafood HACCP Alliance. The approval and numbering of courses is most useful in controlling issues associated with fraudulent certificates.

Proposed § 1.500 would define very small importer as an importer, including any subsidiary, affiliate, or subsidiaries or affiliates, collectively, of any entity of which the importer is a subsidiary or affiliate, whose average annual monetary value of sales of food during the previous 3-year period (on a rolling basis) is no more than \$500,000, adjusted for inflation. AFDO generally opposes the use of monetary values in regulations for the purpose of determining the size of an establishment or determining the importance or significance of circumstances there. In our view they are generally unenforceable. Will there be a need to determine the monetary value of an importer, and if so, who will make this determination?

Applicability and Exemptions

Proposed § 1.501(b) through (e) set forth exemptions and exceptions from subpart L for several types of foods: food from juice and seafood HACCP facilities that are in compliance with the HACCP regulations; food imported for research or evaluation purposes; food for personal consumption; alcoholic beverages; and food that is transshipped or imported for further processing and export. This is another area that AFDO traditionally opposes as exemptions and exceptions are usually unenforceable, as well. While we understand the logic in providing exemption and exception for juice and seafood facilities, food imported for research or evaluation, food for

personal consumption, and alcoholic beverages, we would caution exempting food to be transshipped or imported for further processing. This, in our view, shifts the burden of food safety assurance of an imported ingredient to a domestic manufacturer. While the domestic manufacturer will be required to develop a food safety plan, they will be denied assurance that an imported product used in their product has been safely produced. This seems unwise to us and we ask that FDA clarify its reasoning here.

The proposed rule would require food for research or evaluation be labeled with the statement "Food for research or evaluation use". Furthermore, when entry for the food is made with U.S. Customs and Border Protection [CBP], the importer of record must provide an electronic declaration that the food will be used for research or evaluation purposes only and will not be sold or distributed to the public. Our only suggestion here would be to require the labeling to be permanent and affixed to the product to eliminate any misgivings.

Under proposed § 1.501(d), the regulations in subpart L would not apply to food that is imported for personal consumption, provided that such food is not intended for retail sale and is not sold or distributed to the public. This is an area where we believe problems can occur. As representatives of the state and local officials who conduct the overwhelming majority of retail food establishment inspections, we are well aware of the numerous issues and infractions which occur at retail with imported foods. Proposed § 1.501(d) states that food is considered to be imported for personal consumption when it is purchased or otherwise acquired by a person in a small quantity for a non-commercial purpose and is not sold or distributed to the public. Our experiences have shown that small ethnic food stores have offered for sale food from their native countries that they have shipped or smuggled in for personal use. Identifying a quantity of product for controlling this is very difficult, in our view. Controlling this at the retail establishment is difficult as well, since the establishments that violate this rule generally do not maintain any shipment records or invoices. AFDO believes the best way for controlling this is for state and local agencies to better coordinate with FDA Import Operations and U.S. Customs and Border Patrol [CBP] and share information where violations occur domestically. AFDO members especially from border states and states that receive high volumes of imported foods may have a good perspective on how this matter could be best handled and we encourage FDA to discuss this with those state and local regulators. AFDO is willing to assist in advancing this discussion. Sanctions against violating individuals and establishments should be strong and integrated.

Review of Compliance Status

Proposed § 1.504 would require an importer, before importing a food from a foreign supplier, to assess the compliance status of the food and the foreign supplier, including whether either is the subject of an FDA warning letter, import alert, or requirement for certification relating to the safety of the food, for determination of whether it would be appropriate to import the food from the foreign supplier. AFDO again references data Attachments 1 and 2 from New York Agriculture & Markets; Division of Food Safety & Inspection. This enforcement data and any other from state and local regulatory agencies should not be neglected, but integrated into any compliance information to be made available to importers. FDA should consider working with AFDO to identify methods for collecting and recording state and local data that may exist pertaining to imported food products for this purpose. We believe this is an area that has been sorely lacking and must be improved upon. If FDA is committed to integration, AFDO believes this is an area that must be included.

FDA has requested comment on what compliance information an importer should be required to obtain and consider regarding a food or foreign supplier as part of its food/supplier compliance status review. At a minimum, AFDO believes the following information should be considered:

Recent inspection reports

Sample testing results [food product and environmental]

Adverse finding reports including those from all domestic and foreign government agencies. This information should include information about a foreign supplier's compliance standing with the food safety authority of the country in which it is located.

Records that indicate how recognized food safety hazards are controlled

FDA has requested comments on whether to include potential hazards that may be intentionally introduced for economic reasons. AFDO believes a review of data from FDA and state surveillance data could identify specific areas of concern. For instance, in New York State there have been documented issues of species substitution in imported ground fish found to contain raw pork and raw poultry. Raw poultry from SE Asia was recently banned from import into the U.S. because of concern for the spread of avian influenza. These matters were referred to FDA and USDA/FSIS and are an example of an economically motivated adulterant.

AFDO believes other circumstances including "knock off products" could be identified with a closer working relationship between FDA and state agencies. AFDO is willing to assist FDA in building closer relationships with state agencies that are active in imported food surveillance.

Verification Activities

Proposed § 1.506(d) states that if an importer conducts a hazard analysis in accordance with § 1.505 and determines that there are no hazards that are reasonably likely to occur with a food, the only requirement in § 1.506 with which the importer must comply with respect to that food is to maintain a list of its suppliers of this food in accordance with § 1.506(a). The importer would also need to reassess this determination at least every 3 years in accordance with proposed § 1.508. AFDO believes importers should be required to document, at least annually, their control of these hazards whenever a compliance event occurs with the product. . This should also be required for imported foods that are controlled through procedures implemented by the importer's U.S. customer.

Furthermore, an importer should be required to obtain, at least annually, written assurance from its customer that the customer is following procedures to adequately control a food safety hazard following a compliance event which occurs with the product.

AFDO supports the proposed Option 1 requirement to conduct or obtain documentation of onsite audits of foreign suppliers with respect to those hazards designated as "serious adverse health consequences or death to humans or animals" [SAHCODHA]. In our view, Option 1 creates more stringent auditing requirements on high risk foods and less stringent requirements on low risk foods while Option 2 creates less stringent requirements on all foods. Our preference is clearly Option1.

Many in the food industry already rely on third-party auditors to accomplish verification of food safety controls and we expect that they will continue to do so. AFDO agrees there is considerable variance in the quality of auditing services and the nature of audit criteria. There is also a great lack of uniformity and we are well aware of the difficulty this can cause industry. Good Agricultural Practices [GAPs] audits provided by federal and state government can be much different from those provided by the private sector. In many cases producers are being required to obtain several food safety audits in order to market their product more broadly. AFDO

supports the concept of a standardized audit by a competent auditor that has the education/experience from a standardized advanced HACCP training and a minimum amount of auditing expertise.

AFDO does not support allowing the importer to use other procedures that it may have established unless those procedures have been approved by FDA or a recognized authority as being appropriately based on the risk associated with the hazard.

Any audit performed as a result of this proposed rule should include a review and approval of all supplier food safety and quality programs.

AFDO believes importers should be permitted to rely on an inspection of a foreign supplier by FDA or an officially recognized or equivalent food safety authority in substitution of an onsite audit. It is doubtful, however, that FDA will be in these foreign firms on a routine basis unless there is a significant reason to do so. Therefore, if the importer is allowed to rely on an FDA inspection as “verification” of compliance, it should be time limited, but not more than 2 years. We further believe these inspections should be limited to specific products or activities that concern the same hazard(s) as the food for which the onsite audit would have been required.

Complaints, Investigations, and Corrective Actions

An importer might learn that a food it imported is adulterated or misbranded as a result of investigating a complaint (such as a consumer reporting becoming ill after eating an imported food), being notified by FDA (such as during an Agency investigation of possible contamination), through media reports, or by other means. This is another area where state and local food safety regulatory agencies must play an important role given the local intelligence they maintain and their work with consumer complaints and food product investigations.

Does FDA plan to capture and utilize complaint and investigation data on imported foods developed by state and local agencies? We strongly suggest they do.

Food from Countries with Officially Recognized or Equivalent Food Safety Systems

FDA indicates it is developing an approach for systems recognition of food safety systems of foreign countries and determining whether their systems may be deemed comparable to that of the United States. AFDO believes the Manufactured Food Regulatory Program Standards are one acceptable model that can be used and recommend they be considered.

Consequences of Failure to Comply

AFDO believes the consequence of a failure to comply with the FSVP is grounds for refusal of entry of the food product into the U.S. from the supplier or importer that has failed to comply. Products which may have been marketed from these foreign suppliers should be found and placed under embargo or stop sale. FDA should work with state and local government authorities whenever possible.

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AFDO has long believed that greater emphasis for regulating imported foods should be placed at the source of manufacturing and not solely at the domestic point of entry. In addition, these efforts should be harmonized with routine domestic surveillance of imported foods from federal and willing state agencies to form a more integrated oversight approach. This proposed rule is a strong and necessary step for fulfilling this objective

Respectfully submitted,

A handwritten signature in black ink that reads "David Read". The signature is written in a cursive, flowing style.

David Read
AFDO President

Enclosures (2): Food Recall Summary 2000-2012
Recalls by Country

New York State Department of Agriculture and Markets
 Division of Food Safety and Inspection

ATTACHMENT 1 - Food Recall Summary 2000-2012

Year	Class I	Class II	Class III	Totals
2000	46 33 Imported 13 Domestic	58 43 Imported 15 Domestic	20 14 Imported 6 Domestic	124 80 Imported 44 Domestic
2001	61 39 Imported 22 Domestic	104 73 Imported 31 Domestic	13 11 Imported 2 Domestic	178 123 Imported 55 Domestic
2002	129 101 Imported 28 Domestic	187 141 Imported 46 Domestic	42 38 Imported 4 Domestic	358 280 Imported 78 Domestic
2003	101 54 Imported 47 Domestic	187 122 Imported 65 Domestic	65 52 Imported 13 Domestic	353 228 Imported 125 Domestic
2004	73 55 Imported 18 Domestic	183 123 Imported 60 Domestic	102 67 Imported 35 Domestic	358 245 Imported 113 Domestic
2005	70 46 Imported 24 Domestic	192 164 Imported 28 Domestic	72 44 Imported 28 Domestic	334 254 Imported 80 Domestic
2006	22 14 Imported 8 Domestic	223 192 Imported 31 Domestic	106 65 Imported 41 Domestic	351 271 Imported 80 Domestic
2007	41 31 Imported 10 Domestic	187 160 Imported 27 Domestic	83 40 Imported 43 Domestic	311 231 Imported 80 Domestic
2008	45 38 Imported 7 Domestic	201 165 Imported 36 Domestic	59 3 Imported 21 Domestic	305 241 Imported 64 Domestic
2009	32 20 Imported 12 Domestic	127 84 Imported 43 Domestic	43 25 Imported 18 Domestic	202 129 Imported 73 Domestic
2010	52 27 Imported 25 Domestic	151 128 Imported 23 Domestic	36 20 Imported 16 Domestic	239 175 Imported 64 Domestic
2011	57 29 Imported 28 Domestic	161 123 Imported 38 Domestic	48 26 Imported 22 Domestic	266 178 Imported 88 Domestic
2012	45 23 Imported 22 Domestic	228 167 Imported 61 Domestic	28 19 Imported 9 Domestic	301 209 Imported 92 Domestic
TOTAL 2000 - 2012	774 510 Imported 264 Domestic	2,189 1,685 Imported 504 Domestic	682 424 Imported 258 Domestic	3,645 2,619 Imported 1,026 Domestic

ATTACHMENT TWO

Recalls by Country
2003-2009

(data through October 2009)

ATTACHMENT 2 - Country	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Africa						1						1
Afghanistan								1				1
Albania										1		1
Argentina	3						1			2		6
Australia				1								1
Austria						1						1
Azerbaijan				2	9	2			2	1		16
Bangladesh			3	2	4				2	6		17
Belarus			1	3			1					5
Bosnia		1		1		1		1				4
Bulgaria			1	5	2		1		1			10
Canada	3	4	4	1	1				8	3		24
Chile		1	2	1						1		5
China (includes Taiwan & Hong Kong)	32	38	69	102	65	127	55	67	68	59		682
Columbia				1		1						2
Costa Rica			2									2
Dominican Republic	2				1		1	1				5
Ecuador	12	2		8					2			24
Egypt						1		5	2			8
El Salvador				1	2				2	4		9
England						1						1
European Union						1						1
France	4	1	11				1	1				18
Fuji					1							1
Georgia		1		1			2	3	1			8
Germany	2							1				3
Ghana				1		2						3
Greece		1			1	2				2		6
Guatemala	1				1			2				4
Guyana					1							1
Haiti				1								1
Holland			2									2
Hungary				1	2							3
India			6	8	10	10	4	11	12	15		76
Indonesia	1	1	1							1		4

(partial data - origin of many foods unknown)

ATTACHMENT TWO

Recalls by Country
2003-2009
(data through October 2009)

ATTACHMENT 2 - Country	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Iran		1										1
Israel	1	7	2	3	6	1	2	3	2	4		31
Italy	1	6	6	13	2	1	4	1	1	1		36
Jamaica	1	3	1	4	1		2			2		14
Japan	7	2	3	3	4	1			3	2		25
Korea	4	1	1	4	1	5	5	1	3	2		27
Latvia				1	1			2				4
Lebanon			1					1	2			4
Lithuania		1		1				1				3
Macedonia			1					1				2
Malaysia	1		2	2	5	1		5	3	4		23
Maldova				3						3		6
Mexico	1	3		12	19	2	1	4	1	3		46
Nepal									1	8		9
New Zealand	1									1		2
Nigeria		1										1
Norway								1				1
Pakistan			1	5	8	6	7	4	1	6		38
Peru						1	1			2		4
Phillipines	1	1		3	2	4		1	1	4		17
Poland	7	7	6		7		3	3	3	1		37
Portugal		1							1			2
Russia	4	4	23	30	19	15	4	20	35	20		174
Saudi Arabia					2		1	1				4
Slovakia				2								2
Slovenia			2	2								4
Spain		1										1
Sri Lanka				1			1					2
St. Lucia				1								1
Switzerland			1									1
Syria									1			1
Thailand	8	12	18	21	15	13	4	4	3	14		112
Trinidad				2	6	1		3	2	1		15
Turkey	2	6	9	2	7	3	1	11	2	5		48
Ukraine		4	1		4	1	5	1	2	8		26
Uraquay				1					1			2

(partial data - origin of many foods unknown)

ATTACHMENT TWO

Recalls by Country
 2003-2009
 (data through October 2009)

ATTACHMENT 2 - Country	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
Vietnam	8	10	3	5	8	14	3	5	4	20		80
TOTAL	107	121	183	261	217	219	110	166	172	206		1762