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BY ELECTRONIC AND FIRST CLASS MAIL

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: **Docket No. FDA-2011-N-0920; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**

Docket No. FDA-2011-N-0143; Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

The Association of Food Industries, Inc. (AFI) and the Cheese Importers Association of America (CIAA) appreciate the opportunity to submit comments regarding the Food and Drug Administration's (FDA) supplemental proposed rules on Preventive Controls for Human Food and Foreign Supplier Verification Programs.

AFI is an international trade association which fosters international trade in food products, with its primary focus on U.S. food imports. The association has approximately 1,000 member companies throughout the world, though its core members are approximately 400 U.S. companies importing food products from companies located across the globe.

The CIAA is a non-profit trade association comprised of the vast majority of firms engaged in the business of importing, selling, promoting, and distributing cheese, cheese products, and butter in the United States.

AFI and CIAA appreciate the effort FDA has made to make the two proposed rules more flexible. However, we think further modifications are needed, especially regarding some of the new requirements that have been added in the supplemental proposed rules. Most importantly, we urge FDA to allow importers greater flexibility in selecting appropriate verification activities in the Foreign Supplier Verification Programs rule. Locking in or mandating one specific method of verifying foreign suppliers (*i.e.*, annual onsite audits) is not the best approach.

We have the following specific comments on the supplemental proposed rules:

Preventive Controls for Human Food

1. AFI and CIAA support FDA's expansion of the definition of "farm."

The supplemental proposed rule would expand the definition of "farm" in several respects. It would expand the definitions of "holding" and "packing," and it would provide that farms may engage in limited manufacturing/processing activities. For example, a farm may engage in drying/dehydrating of raw agricultural commodities to create a distinct commodity when such drying/dehydrating is akin to harvesting. Drying of fruits and vegetables using natural sunlight to create a distinct commodity (e.g., drying grapes to make raisins) therefore would be considered a farming activity; a farm engaging in that activity would not be required to register with FDA or comply with preventive controls.

AFI and CIAA strongly support the proposed expanded definition of "farm." Drying fruits and vegetables using natural sunlight is an activity that has always been considered to be a traditional farming activity and it should not trigger registration or other regulatory requirements.

2. AFI and CIAA appreciate FDA's expansion of the exemptions for storage facilities but request the final rule clarify that importers' offices that store packaged foods are also exempt.

In the supplemental proposed rule, FDA expands the definitions of "packing" and "holding" to include activities incidental to the packing and storage of food. FDA recognizes that no facility engages solely in the storage of food and that, without these expanded definitions, the proposed exemptions for certain storage facilities would be meaningless. Those exemptions are for: (a) facilities engaged solely in the storage of raw agricultural commodities (other than fruits and vegetables) for further distribution or processing and (b) facilities engaged solely in the storage of packaged foods that are not exposed to the environment.

We strongly support the expanded definitions of "packing" and "holding." However, we still would like FDA to clarify, perhaps in preamble language or in guidance documents, that exempt storage facilities may, of course, engage in other business activities without losing their exemption. FDA should clarify that the words "solely engaged" in these exemptions refers only to a facility's activities on the food it holds. For example, the offices of food importers typically store packaged foods that are not exposed to the environment but they are not solely engaged in the storage of food (*i.e.*, because they also engage in the business activities associated with running an import business). FDA should clarify that importers' offices will not lose their exemption from preventive controls by virtue of engaging in those business activities.

3. FDA should give further thought to how best to address economically motivated adulteration (EMA).

FDA should take a "wait and see" approach and decide if EMA hazards are still a concern after the preventive controls rule has been implemented. AFI and CIAA would like to see FDA address EMA aggressively. However, we believe that a stand-alone, targeted approach is preferable.

4. AFI and CIAA have significant concerns about the proposed supplier controls requirements.

The supplemental proposed rule would require receiving facilities to implement supplier controls for raw materials and ingredients that contain significant hazards that are controlled before the raw material or ingredient reaches the receiving facility. We have several concerns with this proposal:

a. The final rule should clarify that there is only one supplier for each raw material or ingredient.

Because the "supplier" may be either the farm that harvested the food or the last facility that manufactured/processed the food in more than a *de minimis* way, there is a potential that a single article of food could have multiple suppliers. FDA should make clear that there is only one supplier for each raw material or ingredient, as it stated that there can be only one foreign supplier for each imported food in the proposed rule on Foreign Supplier Verification Programs.

b. The definition of "supplier" should include a requirement that the supplier be the establishment that controls the significant hazard in question.

Under the proposed definition of "supplier," the supplier may not always be the establishment that controls the hazard in question. For example, a significant hazard in a food may be a chemical hazard that is controlled on the farm, but the supplier may be a later facility that processes the food. It makes no sense to require a receiving facility to verify a supplier that does not control the hazard. Therefore, the definition of "supplier" should be modified to provide that the supplier must be the establishment that controls the hazard in question.

c. FDA must recognize the very limited ability of receiving facilities to verify suppliers with which they have no commercial relationship.

Under the proposed definition of "supplier," the supplier may be an establishment with which the receiving facility has no direct commercial relationship. For example, the supplier may be the farm that harvested a food that passes through the hands of packers and distributors before it reaches the receiving facility. Where the receiving facility has no commercial relationship with the supplier, the receiving facility lacks the leverage to require the supplier to accept an on-site audit or to provide its confidential food safety records for review. In situations where there is no relationship between receiving facility and supplier, FDA must recognize that the verification activities available to the receiving facility will be very limited (*e.g.*, sampling and testing the food).

5. If product testing and environmental testing are required for certain types of facilities, FDA needs to give affected facilities detailed guidance regarding when these verification measures will be required.

As currently written, the supplemental proposed rule does not clearly state when a covered facility would be required to conduct product testing or environmental monitoring. AFI and CIAA appreciate the flexibility FDA is proposing to give facilities to determine whether environmental monitoring and product testing are appropriate and how sampling/testing should be done (*e.g.*, frequency of sampling, number of samples, organism to be tested for).

While we support the flexibility in the supplemental proposed rule, we are also concerned about the possibility that facilities and FDA field inspectors may have very differing interpretations of when environmental monitoring and product testing are appropriate. For that reason, we request that FDA provide detailed guidance, in the form of guidance documents, regarding the situations in which it believes environmental monitoring and product testing are appropriate.

6. Any testing required under the final rule should be exempt from the requirement to use an accredited laboratory under FD&C Act Section 422.

AFI and CIAA request that FDA clarify that any laboratory testing required under the Preventive Controls for Human Food rule (such as environmental monitoring, product testing, or testing of raw materials and ingredients as part of supplier controls) is not subject to the requirement to use an accredited laboratory under FD&C Act Section 422.

Section 422 requires that "food testing" for certain purposes, including food testing to address an identified or suspected "food safety problem," must be performed by an accredited laboratory and the test results must be sent directly to FDA. Although FDA has not yet established a laboratory accreditation system, we think it is still important that FDA make clear that the testing that food facilities would do as part of their preventive controls plans is not subject to Section 422.

We think it is clear that Section 422 was not intended to apply to routine testing done under a facility's food safety plan. First, environmental monitoring is not "food testing," so it can be excluded from Section 422 coverage. Second, routine product testing by a food facility to verify the effectiveness of preventive controls is not testing to address a specific "food safety problem." Rather, it is testing to confirm that no food safety problem exists. The same is true of testing of raw materials and ingredients by a receiving facility as part of a supplier control program. Third, we note the many practical problems if such routine testing were to be subject to Section 422. It might discourage some facilities from conducting aggressive environmental monitoring and could result in FDA being inundated with lab test reports. It is sufficient that FDA would have the authority to review such lab test reports during facility inspections.

7. Given the expansion of recordkeeping in the supplemental proposed rule, it is all the more important that preventive controls records be exempt from public disclosure and that electronic records be exempt from Part 11 requirements.

The supplemental proposed rule would significantly expand the number of records that covered facilities are required to maintain and that FDA inspectors would have authority to inspect and copy. This further expansion in recordkeeping and FDA records access makes it all the more important that such records be protected from public disclosure under the Freedom of Information Act. Preventive controls records should be given the same protection that FDA currently gives to HACCP records under its HACCP regulations for juice and seafood products.

It is also important that preventive controls records in electronic form be exempt from Part 11. If all of the new records that covered facilities are required to keep are subject to Part 11 requirements, many facilities may be reluctant to transition from paper to electronic records.

8. FDA should not issue regulations governing diversion of adulterated human food to animal feed.

In the preamble to the supplemental proposed rule on Preventive Controls for Animal Food, FDA requested comments on whether the agency should issue regulations governing the diversion of adulterated human food to animal food. Currently, FDA has two guidance documents that outline the policy for diversion of human food to animal food.[1] We believe the current system is working well and that additional regulations, which would likely impose recordkeeping and other burdens that might discourage the productive use of adulterated food products, are unnecessary and potentially counterproductive.

9. AFI and CIAA support the proposed exemption of hulling, shelling and drying of nuts.

In the preamble, FDA is proposing to exempt hulling, shelling, and drying of nuts (without further manufacturing/processing) from the Current Good Manufacturing Practice requirements (CGMPs). Given further manufacturing/processing will take place, we support this exemption.

Foreign Supplier Verification Programs

1. FDA should wait to address economically motivated adulteration.

AFI and CIAA would very much like FDA to address EMA aggressively, but we do not think it should be addressed in the FSVP rule. Instead, we think that a stand-alone, targeted approach to EMA is preferable.

2. Importers should be given more flexibility to select the appropriate mix of verification activities for a foreign supplier.

[1] FDA Compliance Policy Guides, Sections 675.100 (Diversion of Contaminated Food for Animal Use) and 675.200 (Diversion of Adulterated Food to Acceptable Animal Feed Use).

FDA is proposing to require that importers conduct verification activities using a "hybrid" of the two options in the original proposed rule. Importers would be able to choose from four verification activities: onsite audits of foreign suppliers, sampling and testing of food from foreign suppliers, review of foreign suppliers' food safety records or other appropriate verification activities. However, where there is a reasonable probability that the imported food contains a hazard that would cause serious adverse health consequences or death to humans or animals (SAHCODHA), the importer would be required to conduct (or have conducted) an annual onsite audit of the foreign supplier, unless it can show that other verification activities or less frequent audits would adequately control the SAHCODHA hazard.

AFI and CIAA believe that this proposal is too restrictive and that importers should be given greater flexibility in selecting appropriate verification activities. The importer is in the best position to determine which verification activities will most effectively assure the safety of imported food, and onsite audits may not always be the best choice. For example, there are new technologies that may provide more effective oversight than onsite audits. At least one company is offering video monitoring of manufacturing/processing facilities 24 hours a day, 7 days a week. Such monitoring, combined with other verification activities such as review of food safety records, may provide a more effective method of verifying a foreign supplier's food safety practices than an onsite audit, which only looks at the foreign supplier's compliance on the day of the audit and which the foreign supplier can prepare for.

We strongly recommend that the final rule avoid mandating any specific verification activities, even in the case of SAHCODHA hazards, and instead allow importers to choose the verification activities that it believes will provide the best assurance of food safety.

3. <u>There needs to be a mechanism that will enable an importer to import food where all of the significant hazards in the imported food are controlled by a subsequent facility that is not the importer's customer.</u>

There are situations in which all of the significant hazards in an imported food are controlled not by the foreign supplier, the importer, or the importer's customer, but by a facility much later in the supply chain. For example, an importer may import tree nuts that will be roasted not by the importer's customer, but rather by the importer's customer's customers' (and so on) customer. The supplemental proposed rule does not address these situations.

Where the importer is removed from the facility that will ultimately control all significant hazards in the imported food, the importer cannot obtain written assurance that such facility is controlling those hazards. FDA needs to provide a mechanism whereby the importer can import such foods while meeting its FSVP obligations.

We propose that FDA allow an importer to certify that it will either control all significant hazards in the imported food or will ensure that any contract for sale of the food will require the ultimate purchaser to control all significant hazards prior to distributing the food to consumers. This mechanism has already been employed by FDA in a similar situation. To allow release of imported cocoa beans detained due to the presence of live

insects, FDA accepts a certification by the importer that it will fumigate and clean the cocoa beans itself or will "ensure that any contract for sale of the goods will require such cleaning by the ultimate purchaser." Form FD-766. We believe a similar solution should be used for all imported foods where the importer is unable to identify to subsequent facility that will control all significant hazards in the imported food.

4. A requirement that importers have procedures to ensure they only import food from approved foreign suppliers is reasonable, but FDA should give importers considerable flexibility to import food on a temporary basis from unapproved foreign suppliers, provided appropriate verification measures are used.

The supplemental proposed rule would require importers to implement procedures to ensure they import food only from approved foreign suppliers. The supplemental rule would, however, allow importers to import food from unapproved foreign suppliers on a temporary basis when necessary, provided that the importer verifies the safety of such food before using it.

While AFI and CIAA support this requirement, we request that FDA give importers considerable flexibility to import food from unapproved foreign suppliers on a temporary basis. There are many circumstances in which an importer loses an approved foreign supplier unexpectedly and is forced to turn to an unapproved foreign supplier. This can happen, for example, when a foreign supplier experiences a natural disaster, goes out of business or breaks its contract. The importer has its own contracts with U.S. customers to supply the imported food and must scramble to find substitute product. Here is just one scenario: an importer has a contract to import a product; the price of product goes up and the foreign supplier breaks the contract and refuses to ship the product. The importer nevertheless must honor its contracts with its U.S. customers. The importer contacts another importer and the second importer sells a shipment of the product that is en route to the United States or already in the United States to the first importer; the first importer relies on food safety testing performed by the second importer. While it is reasonable to require procedures to ensure that importation from approved foreign suppliers is the rule, FDA needs to allow considerable flexibility for importers to import food from unapproved foreign suppliers when commercial realities demand such action.

5. Given the expansion of recordkeeping in the supplemental proposed rule, it is all the more important that FSVP records be exempt from public disclosure and that electronic records be exempt from Part 11 requirements.

The supplemental proposed rule would significantly expand the number of FSVP records that covered facilities are required to maintain and that FDA inspectors would have authority to inspect and copy. This further expansion in recordkeeping and FDA records access makes it all the more important that such records be protected from public disclosure under the Freedom of Information Act. FSVP records should be given the same protection that FDA currently gives to HACCP records under its HACCP regulations for juice and seafood products.

It is also important that FSVP records in electronic form be exempt from Part 11. If all of the new records that covered facilities are required to keep are subject to Part 11

requirements, many facilities may be reluctant to transition from paper to electronic records.

6. AFI and CIAA strongly support the clarification that importers in compliance with the supplier controls requirements in the Preventive Controls rules will be deemed to be in compliance with the FSVP rule.

To avoid redundant requirements, FDA is proposing that, where an importer is also a covered facility subject to the Preventive Controls for Human Food rule and is in compliance with the supplier controls requirements in that rule, the importer will be deemed to be in compliance with the FSVP rule. Similarly, if an importer's customer is a receiving facility and is in compliance with the supplier control requirements with respect to an imported raw material or ingredient, the importer would be deemed to be in compliance with the FSVP rule, provided the importer annually obtains written assurance from the customer that it is in compliance with its supplier control obligations.

AFI and CIAA strongly support these common sense provisions in the supplemental proposed rule.

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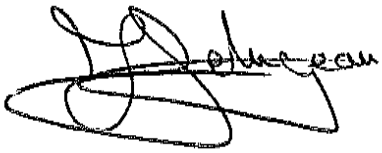
AFI and CIAA stand ready to assist FDA in any way we can with implementation of these regulations.

Respectfully submitted,

Robert Bauer
President
Association of Food Industries, Inc.



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