



AMERICAN FEED INDUSTRY ASSOCIATION

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April 4, 2003

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Prior Notice of Imported Food; Docket No. 02N-0278

Dear Sir/Madam:

The American Feed Industry Association (AFIA) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on prior notice of imported food. 68 Fed. Reg. 5428 (Feb. 3, 2003).

AFIA is the national, not-for-profit trade association for feed and pet food manufacturers, ingredient manufacturers and suppliers, equipment manufacturers, and other firms that supply goods and services to the feed industry. AFIA's nearly 600 corporate members manufacture 75 percent of the nation's primary commercial feed. Because AFIA members would be subject to the proposed rule, AFIA offers these comments on their behalf.

AFIA strongly supports the purpose of ensuring the safety of imported foods, the goal of the proposed rule and of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). However, by proposing to require far more information than was required by Congress in the Bioterrorism Act, the proposed rule takes the wrong approach. FDA appears to take the position that it should require every item of information that might be useful in determining whether to inspect imported food. In doing so, FDA runs the risk of requiring information that may later prove unnecessary. AFIA believes it would make far more sense to begin by requiring only that information that FDA is certain will be needed in making its inspection determination. The information requirements can always be expanded at a later date.

AFIA suggests the following changes in the proposed rule:

- 1. The final rule should clarify a shipment of food from multiple growers may still constitute one "article of food" requiring one prior notice.**

Under the proposed rule, a separate prior notice would be required for each article of food. Although not defined in the proposed rule, the preamble defines "each article of food" as "any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number)." 68 Fed. Reg. at 5425.

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AFIA requests clarification of how this definition would apply to fungible, commingled products like oats, fish meal, or canola meal that may contain product from many different sources. In our view, a shipment of oats, whether shipped in bulk or in bags, should be considered one article of food, even if the oats were grown by multiple growers. However, the definition quoted above might be interpreted to mean that food must be from a single grower to be considered one article of food. AFIA believes that FDA did not intend this result. We note that such an interpretation would be inconsistent with the proposed Prior Notice Submission, which includes room for up to three growers for each article of food. We request that FDA confirm that commingled foods may constitute a single article of food, even though they come from multiple growers.

**2. AFIA sees problems with several items of information required by the proposed rule.**

**a. Grower information.**

Consistent with the Bioterrorism Act, the proposed rule would require that the prior notice include the identity of all growers "if known." Grower information must include the grower's name, address, telephone number, fax number, email address, and (if the grower is required to register with FDA) its facility registration number. If the grower does not have a fax number or email address, "the prior notice submission should declare this." 68 Fed. Reg. at 5436. The grower's location must also be provided if different from the grower's business address. According to the preamble to the proposed rule, "this information is not optional; if it is known, it must be submitted." 68 Fed. Reg. at 5437. However, FDA requests comments on whether the Bioterrorism Act permits the agency to exempt processed foods and wild products (*e.g.*, fish, botanicals) from the requirement to provide grower information.

The requirement to provide grower information could pose serious problems if it is not limited:

- **A requirement to provide grower information for processed foods would be extremely burdensome.**

Requiring grower information for processed foods would be very burdensome and would lead to absurd results. For example, it would mean that the prior notice for a vitamin and mineral supplement for mixing with animal feed must identify the growers of the plants or animals from which the vitamins were derived, the harvester of the fish from which any vitamin or protein sources were derived, and so on. Such detailed information is not known by feed ingredient manufacturers, and it is certainly not known by importers.

Moreover, if Congress had intended to require grower identification beyond the common sense definition of those who cultivate plants and crops, it would have so stated. There is no support for extending grower identification to reach processed foods.

To the extent that FDA is concerned with the ability to identify sources of food product ingredients and components, traceback to source suppliers is presumably to be addressed in the regulations implementing the recordkeeping provisions of the Bioterrorism Act. It is not appropriate to try to achieve through the prior notice provision of the Bioterrorism Act what Congress intended to address in the recordkeeping requirements.

- **Grower information should not be required for commingled foods.**

The proposed rule does not explain how the requirement of grower information applies to products like oats or canola meal that consist of commingled product from many different growers. One shipment of oats may contain product from many different farms. Requiring the submitter to collect and supply grower information for so many growers would impose an impossible burden. Even if the submitter were able to obtain this information, it is not clear how reporting this information to FDA would further the purposes of the Bioterrorism Act. If the purpose of the prior notice requirement is to help FDA determine whether to inspect a particular imported food product, requiring grower information does not serve that purpose unless that food product can be identified as having come from the grower whose information is provided. In the case of commingled products like grains, that cannot be done. Therefore, for commingled products like grains, AFIA submits that the contributing growers cannot be known, and that therefore, grower information need not be provided.

- **The final rule should make clear that there is no affirmative duty to ascertain grower information.**

The Bioterrorism Act requires grower information “if known within the specified period of time that notice is required to be provided.” 21 U.S.C. § 381(m)(1). The proposed rule would require the identity of all growers “if known.” Neither the Bioterrorism Act nor the proposed rule requires the submitter to take any affirmative steps to obtain grower information if not known. AFIA requests that the final rule clarify that the submitter has no legal duty to ascertain grower information if not known at the time the prior notice is submitted.

- b. Customs entry number, Customs entry type, and date of Customs entry**

The proposed rule would require that the prior notice include the U.S. Customs entry number, Customs entry type, and the anticipated date of Customs entry. All three items pose significant problems. The customs broker, not the importer, generates the Customs entry number. While the importer can request the number from the broker, the importer cannot force the broker to provide it

or verify that the number provided is accurate. The Customs entry type may change. For example, if a food product is subject to an import quota and that quota has been exceeded, the importer may have to change a consumption entry to a warehouse entry. The date of Customs entry is also difficult to predict. As FDA notes, the port where entry will be made for U.S. Customs purposes may be a great distance from the actual port of entry, and the Customs date of entry may be several days after the date of arrival at the port of entry. Consequently, the submitter cannot always be expected to know the date of Customs entry with certainty at the time the prior notice is submitted.

**c. Quantity information**

Quantity information frequently changes for a wide variety of reasons (*e.g.*, fluctuations in supply, changes in weather, production problems, personnel problems). In fact, for many animal feed ingredients, the products absorb or shed moisture during transit. Also, the weight measurement taken at a foreign source is often not deemed to be reliable – the scales may not be calibrated to the exact standards required by State weights and measures laws. For these reasons, it is customary in the feed industry to take a final weight of the product at point of delivery, in the United States, and to calculate payment based upon that weight at delivery, not weight at the foreign point of shipment.

Precise quantity information should not be necessary for FDA to determine whether a particular article of food needs to be inspected. Quantity information is not required at all by the Bioterrorism Act. AFIA requests that the final rule provide that relatively minor changes in quantity do not require amendment of the prior notice. Alternatively, the final rule should require only an estimate of quantity.

**d. Arrival information**

It is extremely difficult to predict the arrival time for a shipment. While the proposed rule would allow a four-hour window within which changes in arrival time will be allowed, this is not sufficient. If a shipment is coming overland by truck, waits of several hours at border crossings are not unusual. If a truck is in a long line at the border crossing, it may not be feasible for the truck driver to know how long the delay will be or to notify the submitter of the delayed arrival time. Air cargo is subject to the same delays. For food imports by ship, it is very difficult to know the precise hour (or four-hour period) within which the vessel will arrive in port. Shippers generally only notify the importer of the day of arrival, not the arrival time, and even this frequently changes.

AFIA recommends that FDA eliminate the requirement that the filer provide (and then be required to update if it changes), the time of arrival. Alternatively, the filer should be able to provide an estimated time, with no requirement to update that information. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. To be able to update arrival information as the proposed rule contemplates will require filers to provide 24 hour a day, 7 days a week filing operations.

Greater flexibility in port arrival information is warranted in the final rule. The Bioterrorism Act states that “Nothing in this section may be construed as a limitation on the port of entry for an article of food.” § 307, 21 U.S.C. § 381(m)(1). Congressman Shimkus stated:

Section [307] is not intended as a limitation on the port of entry for an article of food. In some instances, such as inclement weather, routine shipping delays, or natural disasters, a shipment of food may arrive at a port of entry other than the anticipated port of entry provided in the notice. When such situations arise, arrival at a port other than the anticipated port should not be the sole basis for invalidating a notice that is otherwise in accordance with the regulations.

Remarks of Hon. John Shimkus, Dec. 20, 2001, Cong. Rec. E2389. Thus, FDA may not refuse to admit imported product solely because port of entry information changes due to shipping delays, weather, and the other routine matters. As Congress and the Act mandate flexibility where the port changes, certainly, similar flexibility is warranted when the time of the product’s entry changes. The final rule should reflect this flexibility.

AFIA suggests that FDA look to the Customs Service for arrival information. Customs has direct communications with vessels, port authorities, airlines, and airports. As a result, it is more likely to have reliable arrival time information than importers. Yet another alternative would be to allow carriers to provide updates of arrival information.

AFIA assumes further that FDA must also be able to man all ports of entry on a 24/7 basis to review the prior notice submissions, or alternatively, that the failure of an FDA inspector to appear and object to a shipment is sufficient to allow the shipment to proceed. The proposed rule does not address such procedures. Inspector availability, or some clear procedure for when product may and may not proceed is necessary to continue the smooth flow of safe product into the United States, without causing massive backlog at ports of entry. AFIA looks forward to continuing to work with FDA to resolve resource allocation and staffing issues.

We also request that FDA clarify the term “arrival.” For example, does food coming by sea arrive when the vessel enters a U.S. port, when the vessel docks in a U.S. port of entry, or when the vessel is unloaded?

- e. **FDA’s Prior Notice System must be designed so that it does not reject prior notices that omit information that is not required.**

In the preamble to the proposed rule on prior notice, FDA states that “a prior notice that does not contain all of the information listed in proposed § 1.288 will be considered inadequate.” 68 Fed.

Reg. 5428, 5435 (Feb. 3, 2003). However, the proposed rule does not seem to recognize that many of the items of information listed in proposed § 1.288 would not be required for all articles of food.

Many items of information listed in proposed § 1.288 will not be required in all cases, for example:

- If the article of food is a raw agricultural commodity, it likely will not have a trade or brand name.
- Many foods, including raw agricultural commodities, will not have a lot or code number.
- If the article of food is a raw agricultural commodity, it will not have a manufacturer.
- Grower information is not required if not known.

AFIA believes it is critical that the Prior Notice System be designed so that it does not automatically reject a prior notice as incomplete if it lacks non-required information.

**3. The final rule should provide more flexible rules for amending a prior notice.**

The proposed rule would allow submitters to amend a prior notice previously submitted, but this right of amendment is very narrow: (a) only one amendment is permitted; (b) only product identity information may be amended; (c) the amendment may provide more detailed information about the product identity, but may not change the “general identity” of the article of food, (d) such information may be amended only if complete information did not exist by noon of the calendar day before the day of arrival, and only if the prior notice indicated an intention to amend, and (e) the amendment must be submitted no later than two hours prior to the time of arrival. Otherwise, the submitter must cancel the prior notice and submit a new one, thereby delaying admission.

AFIA believes these limitations are unnecessarily restrictive. A more flexible right of amendment can serve the purposes of the prior notice requirement without unduly burdening international trade. We propose the following changes:

- **FDA should permit correction of minor, inadvertent errors at any time prior to arrival.**

The prior notice calls for entry of many multi-digit alpha and numeric codes (*e.g.*, telephone numbers, fax numbers, email addresses, zip codes, Customs entry numbers). Under the proposed rule, even a minor error in entering one item of information may result in refusal of admission. The submitter would be required to cancel the prior notice and submit a new one. A submitter should be permitted to correct such minor, inadvertent errors at any time prior to arrival.

- **The right to amend product identity information should not be limited to particular food products.**

The proposed rule appears to allow amendments to further specify product identity only in the case of “fresh produce” and “fresh, wild-caught fish.” 68 Fed. Reg. at 5462. Further specification of product identity should be permitted for other products as well.

- **FDA needs to provide clearer guidance regarding what it means when it says that an amendment may not change the “general identity” of the article of food.**
- **Notifying FDA of an intention to amend should not be a precondition for amendment.**

A submitter may believe it has complete information at the time it submits the prior notice, but that information may subsequently change for reasons beyond the submitter’s control. FDA should accept amendments even if the submitter did not indicate an intention to amend in the original prior notice.

- **More than one amendment should be allowed.**

The proposal to allow only one amendment is unnecessarily restrictive. We believe allowing more than one amendment will save both FDA and industry time.

**4. The final rule should provide for a rolling minimum notice period.**

The proposed rule would require that prior notice be submitted to FDA no later than noon of the calendar day before the article of food is to arrive at the border crossing in the port of entry. FDA states that the submitter will know all of the information required in the prior notice by that time.

AFIA questions whether all of the information required in the prior notice will be “sufficiently fixed” by noon of the calendar day before arrival. Particularly in the case of overland shipments from Canada and Mexico and air shipments, it is unrealistic to assume that all of the required information will be fully known by that deadline. For example, if a facility is located across the border in Canada or Mexico and exports its daily production to the United States, it is unlikely to know the lot numbers of product a day in advance.

AFIA proposes that FDA use a rolling minimum notice period of 8 hours prior to arrival at the port of entry. In addition, FDA should consider establishing a program allowing a shorter notice period for importers or products coming from Canada and Mexico that are identified as low-risk.

**5. If an article of food is refused admission and held at the port of entry for failure to submit a prior notice, that determination should be reviewable.**

Under the proposed rule, an article of food is to be refused admission if it is offered for import with no prior notice or an inadequate prior notice. According to FDA, “Congress did not provide for any kind of application, petition, or appeal of FDA’s determination that an article shall be refused admission for failing to comply with prior notice requirements.” 68 Fed. Reg. at 5432. While not entirely clear, it appears to be FDA’s position that, because Congress did not explicitly provide a right to appeal a refusal of admission under the prior notice provision of the Bioterrorism Act, no such right exists. If this is FDA’s contention, we believe the agency is in error.

The Administrative Procedure Act states that judicial review shall apply to agency action “except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law.” 5 U.S.C. § 701(a). The courts have held that “there is virtually a presumption in favor of judicial review unless a contrary purpose is fairly discernable in the statutory scheme.” *Hayes Intern. Corp. v. McLucas*, 509 F.2d. 247 (5<sup>th</sup> Cir. 1975) (citing *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967)). The absence of express statutory language authorizing judicial review is not enough to overcome this presumption of reviewability. Agency action typically is found to be non-reviewable only if there is a showing of “clear and convincing evidence” of a legislative intent not to allow review. *Abbott Laboratories*, 387 U.S. at 140 (citing H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946) (“To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.”)).

While the Bioterrorism Act does not expressly provide for review of agency decisions, there is no evidence in the statute or its legislative history to overcome the presumption in favor of review. Accordingly, the final rule should provide a mechanism for review, both administrative review within FDA and judicial review, if an article of food is refused admission for failure to submit a prior notice. FDA further has not provided for any procedures to be followed when an article of food is refused due to lack of, or inadequate, prior notice. Procedures for the handling, disposition and storage of food, and notification to responsible parties should be set out in the final rule.

**6. The prior notice data system should rely in part upon other database information.**

Some of the difficulty that arises with the proposed rule is that it requires the filer to enter information FDA already possesses. For instance, if the filer provides the manufacturing firm’s FDA registration number, the filer should not also need to manually enter contact information, address, phone and fax numbers, and email address. This information is already within FDA’s

control and is likely to be at least as accurate as the information in the possession of the filer. Yet, as contemplated in the proposed rule, the filer will have no way to validate or verify data elements such as another party's FDA registration number and accompanying information. If this information is incorrect, the prior notice is also incorrect, and FDA may refuse to admit the article of food into the United States.

The final rule should not require the filer to provide information FDA already has in its possession. Alternatively, the filing system could be designed so that the registration and prior systems are linked. Upon the entry of a valid FDA registration number, the system automatically fills in the other relevant fields on the prior notice form.

**7. The exporter should be permitted to file a prior notice.**

FDA proposes that only a purchaser or importer who resides or maintains a place of business in the United States, or their U.S. agent would be authorized to file a prior notice. Proposed 21 C.F.R. § 1.285. In AFIA members' experience, in many instances, a foreign seller acts as its own importer. This is true, for instance, with intra-company shipments. Additionally, the shipping company has a longstanding supply agreement with the customer to ship animal feed or feed ingredients as they are manufactured. Last, Canadian-based feed companies may have customers across the United States border and these farmers, ranchers, dairies, and feed mill operations would not wish to undertake the regulatory burden of filing of a prior notice.

In these instances, the foreign company would want to be able to file the notice. AFIA suggests that the final rule allow for entities other than importers, purchasers, and their agents, to file a prior notice.

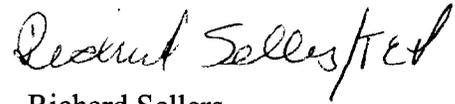
**8. FDA should exclude from the prior notice requirement foods not intended to be consumed in the United States.**

FDA has determined that all food "offered for import" that is brought across the United States, must be subject to a prior notice, including that intended for foreign trade zones, immediate re-export, in-bond transport, and even if not intended for use or consumption within the United States. 68 Fed. Reg. at 5430. AFIA disagrees with this expansive inclusion and urges that FDA focus upon that food which, as the Bioterrorism Act intended, presents a "threat of serious adverse health consequences or death" to the citizens of the United States. There are ample controls, laws, and regulations governing food brought into the United States that is not to be consumed in the United States. These controls protect the United States from the use of such foods as a vehicle for bioterrorism. A further layer of regulatory oversight is not necessary. It is appropriate to exclude from the prior notice requirement food products intended for immediate export and food products traveling under bond and others not for retail consumption.

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We appreciate this opportunity to comment.

Respectfully submitted,

A handwritten signature in black ink that reads "Richard Sellers". The signature is written in a cursive style with a large, sweeping initial "R".

Richard Sellers  
Vice President, Feed Control and Nutrition