



**NATIONAL
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April 4, 2003

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

Re: FDA Docket No. 02N-0278, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002

Dear Sir of Madam:

The National Fisheries Institute (NFI) appreciates the opportunity to offer written comments on the Food and Drug Administration's (FDA) notice of proposed rulemaking, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Federal Register 5428.

The NFI is the nation's leading trade association for the diverse fish and seafood industry of the United States. The NFI represents fishing vessel owners, processors, importers, exporters, distributors, aquaculturalists, seafood retailers and restaurants. NFI is committed to assisting our member companies in providing consumers with safe, wholesome, diverse and sustainable seafood choices.

The NFI commends the agency for proposing expeditiously the implementing regulation for this section of Bioterrorism Act in the interest of providing adequate time to comment prior to reaching a final rule. NFI supports the underlying goals of the Bioterrorism Act and FDA's efforts to carry them out. FDA is also to be commended for providing opportunity last summer to offer pre-proposal comments on implementing the provisions of the law. Nevertheless, it appears that FDA has not provided adequate trade input into the development of this rule and appears not to have heeded much of the advice it received in August 2002.

NFI has substantial concerns that the stand alone prior notice system proposed by FDA is far too complex and lacks the level of flexibility to be workable. NFI fears that the prior notice requirements as proposed will create a large backlog of detained goods at port of entry that will overwhelm FDA inspection capabilities and cause profound financial impacts to the industry resulting in increased food costs to consumers. We urge FDA to provide additional opportunity for dialogue concerning prior notice to attain a better understanding of the limitations facing the industry and the potential impacts associated with the proposal.

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FDA has vastly underestimated the monetary and human resources that would be required by the agency and the industry to implement the expansive information system proposed. NFI previously submitted comments to Office of Management and Budget concerning the industry's cost to comply with this burdensome data collection and transmittal system in the context of the Paperwork Reduction Act. NFI wishes to incorporate those comments herein by reference.

NFI is a member of the National Coalition of Food Importing Associations (NCFIA). The organization is also submitting comments on behalf of its member associations. NFI supports the NCFIA comments and wishes to incorporate them into our letter by reference.

The following conclusions and recommendations are made regarding the proposed rule, these points are elaborated on later in our letter:

Observations

- FDA has made little effort to customize the prior notice rule to allow for differences in the nature of imported food or the manner of transportation.
- FDA has substantially increased the amount of information necessary for prior notice submission beyond the seven basic elements named in the Bioterrorism Act without adequately explaining the rationale for this enormous expansion and full consideration of the importer's ability to obtain this information in the specified time frame.
- After electing to vastly expand the amount of information necessary for prior notice, FDA concludes that it must develop a stand alone system separate from the Customs Automated Commercial System (ACS). However, it does not acknowledge that the incompatibility is largely due to its own expansion of the data elements required for prior notice.
- FDA indicates in its analysis that all or most of the information that it proposes to include in the prior notice system is available at the time of ordering the product. Very often, particularly in the fresh fish business, this is simply not true. Many contracts with shippers call for a variety of species to be delivered depending on availability of the harvest. Species and amount of fish in an entry and much of the arrival information are not known by noon the day before arrival.
- FDA established a minimum time frame for prior notice submission (i.e. noon the day before the shipment arrives) that in many cases cannot be met by significant segments of the food industry, including fresh fish and shellfish.

- FDA’s effort to provide a small amount of flexibility, through amendments and updates is far too limited to substantially reduce the likelihood of unacceptable prior notice submissions due to changing or unavailable information.
- FDA has grossly underestimated the training costs and other implementation costs for the proposed rule.

Recommendations

1. FDA should reduce the amount of information that must be included in the prior notice so as to be consistent with the Bioterrorism Act or, at minimum, adopt a prior notice requirement that does not mandate (except for grower identification, if known) more information than the U.S. Customs Service (Customs) requires;
2. Consistent with the recommendation above, adjust the information required in the prior notice then re-consider coordinating with Customs to use the ACS to avoid duplication of effort;
3. Adopt a four hour prior notice requirement with ability to amend up to the time of entry and, where necessary, such as with air and truck shipments of perishables, up to three hours after arrival at the port of entry;
4. Allow amendments to correct inadvertent filing errors;
5. Do not invalidate prior notice submissions that are flagged for an amendment and subsequently go without amendment;
6. Tailor prior notice requirements to accommodate different modes of transportation (rail, vessel, air, truck) and different food products (perishable, non-perishable, short and limited shelf life, temperature sensitive, etc.). Allow air and truck shipments more than one amendment up to three hours after arrival;
7. Follow, obtain from, and coordinate with Customs on day, time, and port of entry information;
8. Limit grower identity information to known growers of raw agricultural products;
9. Clarify and limit “article of food” definition;
10. Provide for verification or validation of prior notice entries; and
11. Allow for back-up system practice.

General Comments

If finalized without revision, the proposed prior notice requirements will dramatically increase the costs associated with import entries due to a number of factors including: the training of filers, importers, carriers, shippers, etc., who must work together to understand and conform to the requirements; additional time and, labor to input and submit the requested information; possible software upgrades; and the likely devaluation or loss of seafood shipments when entries are held as a result of apparent filing inadequacies and errors associated with prior notice requirements.

The information that FDA plans to require in a prior notice submission far exceeds the information specified in the Bioterrorism Act. The proliferation of data required (the submission form could be up to five pages of information per line entry) will take much longer and require considerably more resources than currently necessary to make entry with U.S. Customs.

Requiring separate prior notice for each of the following data elements: brand, species, package size and type and, possibly product size of the fish or shellfish will result in multiple prior notice submissions for shipments previously entered with U.S. Customs as a single entry. This will increase both complexity of and labor costs associated with making entry as well as substantially raise the likelihood of errors.

Other requirements such as time of arrival in port will require greater coverage by filers perhaps approaching twenty-four hours, seven days a week. This will necessitate overtime or additional staffing by brokers and, perhaps importers. These are costs that FDA makes no attempt to calculate. Our analysis further suggests it may be problematic to even obtain precise arrival time information in the time constraints proposed. Arrival times are dictated primarily by the carriers: cargo ship line, airlines or truck transportation companies. Importers have little ability to obtain exact arrival times from these sources in a way that is reliable and timely enough for FDA demands.

The aforementioned problem can occur with all three major modes of transportation but might be most acute with airlines. Airlines do not have to notify importers or shippers of changes such as flight delays, cancellations and/or cargo being bumped from flights. In today's environment of shrinking airline flights, food cargo on more flights than ever are subject to these changes. When an airline bumps part of a shipment, under the best of circumstances, a shipper might be notified that some number boxes in the shipment made the flight and some number did not. This information is not available generally until after the flight leaves and the airlines will not tell the importer which part of the shipment was sent (e.g. whether the boxes of cod got bumped or whether it was the haddock). These circumstances dictate that a more flexible prior notice system be implemented.

The complexity of and the current time lines proposed for the prior notice system could result in devaluation or loss of seafood products. NFI is particularly concerned with perishable fresh seafood imports. The FDA stipulated minimum submission time is

noon the day before the shipment arrives. In the fresh fish business the harvest of fish may be occurring the day before the shipment arrives, which will make accurate prior entry notification, in many cases, impossible under the proposed system, particularly given the amount and type of information FDA plans to require.

FDA's Economic Analysis Of the Prior Notice Proposed Rule

FDA has emphasized the Prior Notice Proposed Rule will represent a new way of doing business. FDA fails, however, to include many aspects of the costs to achieve this new business reality. For instance, reams of information that have never been collected before will now have to be supplied. Importers, brokers, suppliers, manufacturers, shippers, warehouses, truckers, airlines, ocean carriers, freight forwarders, consolidators, non-vessel operative common carriers, and others will all have different pieces of information that will have to be communicated for the first time, or will have to be communicated in a different way, or at a different time. FDA makes no estimate at all of these costs.

FDA assumes only 77,427 filers will need to be educated about the Prior Notice Proposed Rule but the number is actually much greater. Customs brokers and importers tell NFI that two would be the minimum number of individuals they expect will need training. In many cases, the number could be a half dozen or more. Therefore, FDA's dollar value cost estimate for training could easily be multiplied by a factor of 2-3X. Moreover, firms will need to educate their suppliers, manufacturers, customers, drivers, suppliers, warehouses, growers, carriers, shippers, and other entities involved the importation of food. As these entities control much of the information the Prior Notice Proposed Rule requires be disclosed, they will need to learn the rule's requirements, even if they have no direct filing responsibilities. No cost estimates are made for these training needs.

We understand that in some instances U.S. buyers want no involvement in the process of importing products. In these situations a foreign seller acts as the importer and will import goods into the United States through a customs broker. The final rule will need to allow the foreign seller or the broker to make the prior notice filing with FDA.

FDA also assumes that there are 4.7 million line entries per year and that each line will require a separate notice. FDA analysis suggests that the average entry will have 2.6 lines. It appears that FDA has grossly underestimated the proliferation of lines and notices its proposal will create. For example, NFI foresees as many as dozens of prior notices for a single container of frozen shrimp as follows:

1. more than one notice depending on whether shrimp is cooked or raw;
2. within cooked or raw, different product forms (e.g. peeled and deveined, peeled undeveined, etc.) if they have a different FDA product code;
3. for raw shell-on shrimp, as many as 10 different sizes;

4. within each size, different product forms if they are packed differently, which is often the case, such as IQF (e.g. bags of different sizes) Vs block frozen (cartons); and
5. within each category above, as many as 4 brands.

This combination of shrimp products which is often contained in a single shipment could easily require several dozen prior notices. This would be dramatically more than FDA predicts as an average.

FDA further assumes one hour to learn the rule if the responsible party has Internet access. 68 Fed. Reg. at 5441, col. 3 and Table 1. Brokers and importers tell NFI that they will need one day seminars for their staff to attain adequate training. They cite, as an example, electronic filer training seminars on the FDA OASIS system held several years ago. They further note that re-training was necessary, in some cases, because of the error rate. The complexity of the proposed prior notice system is far greater than OASIS, thus the training effort will likely need to exceed that expended on OASIS. FDA training costs might underestimate the actual cost by a factor of six to eight.

Moreover, FDA assumes only 45 minutes of time for a filer to complete the prior notice screens of information. 68 Fed. Reg. at 5442, col. 3 and Table 3. However, this estimate is based on the questionable assumption that an entry will consist on average of only 2.6 lines. As previously, stated NFI believes this will be a gross underestimate for many seafood entries. In addition, the information required in the Prior Notice Proposed Rule does not reside in a single place at this time, thus we believe that the actual filing time, including information gathering, will be much longer.

The Prior Notice Proposed Rule requires that filers include the estimated day and time of arrival. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives 3 hours later or 1 hour earlier than reported in the notice, the Prior Notice Proposed Rule requires that the filer correct the arrival information. If a shipment arrives outside this 4-hour arrival window, the prior notice is inadequate, the product will be refused, and a new prior notice must be made. Thus, brokers and importers will need to establish operations that operate around-the-clock, 24 hours a day, seven days a week, to assure that if estimated times of arrival suddenly change, the prior notice can be amended. FDA does not estimate the costs for an importer, currently operating with normal business hours, to establish a 24/7 filing operation.

NFI understands from filers that they believe it will be necessary to hire additional staff to provide the additional services associated with compliance with the Prior Notice Proposed Rule. NFI understands that brokers and other filers are estimating that the cost of each import entry will increase by as much as 70% if the Prior Notice Rule is implemented as proposed. As the average cost of an entry is approximately \$110 currently, this means the additional cost per entry will be \$77 for a total cost per entry of \$187.

Furthermore, FDA calculated only the costs of delayed shipments of highly perishable foods -- Canadian and Mexican fresh produce and fish/seafood. FDA ignored the costs of lost value from fresh products arriving by air from all of Latin America and Europe. In addition, the cost of delayed entry is very significant for both perishable and non-perishable foods. There will be storage costs and additional transportation costs for articles of food refused entry due to inadequate notice. FDA did not consider these costs.

In sum, FDA's cost calculations for compliance with the Prior Notice Rule, as proposed, are incomplete and vastly understated.

FDA's Estimates Of Costs For 4 and 8 Hour Notice Are Flawed

FDA's calculations of the costs to the fresh fish and seafood industry from shipments refused entry due to inadequate prior notice are understated and flawed. FDA concludes that its proposed prior notice timeframe of noon of the day prior to arrival at port of entry, with one opportunity to amend, is the least costly to industry (Table 17, 68 Fed. Reg. at 5435). Yet, for that option to be the least costly, FDA assumes, without explanation, that under the other options (4 hour prior notice or 8 hour prior notice), filers will only be able to amend a filed notice entered by noon of the previous day, and may not amend if the notice is filed 4 or 8 hours prior to arrival. By eliminating the opportunity to amend a prior notice filed 4 or 8 hours prior to arrival at port, FDA significantly inflates the costs of those proposals and does not offer a true comparison of the costs of each option.

INFORMATION COLLECTION ISSUES

FDA is seeking far more information than the seven simple data elements set forth in Section 307 of the Bioterrorism Act, 21 U.S.C. § 381(m)(1). Yet, the agency does not explain how demanding so many details will effectuate the purpose of the Bioterrorism Act. The statute does not require the collection of this information; it is FDA, not affected industry, who should be required to put forth an explanation for needing so much information. The NCFIA comment letter says that, before it may so exceed the Bioterrorism Act's requirements, FDA should put forth how all this information, most of it highly redundant of existing government reporting requirements, will allow FDA to better perform its mandate of identifying which imports to inspect. NFI refers FDA to the NCFIA letter for further elaboration on this comment.

The Prior Notice Proposed Rule Duplicates Existing Reporting Requirements Without Attempting To Coordinate With Existing Reporting Requirements

After electing to vastly expand the amount of information necessary for prior notice, FDA concludes that it must develop a stand alone system separate from the Customs Automated Commercial System (ACS). However, it does not acknowledge that the incompatibility is largely due to its own expansion of the data elements required for prior notice.

All of the information 21 U.S.C. § 381(m)(1) mandates is captured by the OASIS/ACS system and interface. FDA should look again at the existing data capture achieved in the OASIS/ACS submission. Ideally, FDA and Customs could agree to push back by a period of hours the time at which brokers currently make the OASIS/ACS entry. In the absence of better coordination with Customs, the Prior Notice Proposed Rule imposes not only duplicative burdens upon industry, but duplicative burdens upon FDA as well, for FDA will have to review information on the same shipment of goods twice, once to determine whether to inspect the goods, and then to determine whether or not the goods should be entered into United States commerce.

In the alternative, FDA should look to the information capture under way with Customs. Currently shippers must notify Customs of a vessel's manifest, 24 hours prior to loading. Customs is wrestling with promulgating another notification regimen for air and land shipments as well. The vessel rule has had enormous repercussions to trade and Customs had not yet begun to fully unravel and address the problems of diminished supply. FDA is urged to heed the mandate of the Bioterrorism Act and coordinate the prior notice final rule with Customs.

FDA Is Mistaken In Its Assumption That Most Information Is Fixed Or Known At Time Of Purchase Order

FDA justifies its lengthy prior notice requirement and limited amendment options as justified because in most circumstances, the information required in the prior notice is generated and known at the time the article is ordered or purchased. This is frequently not the case. Sometimes, the information can change; in other instances, the information sought for the prior notice is not known and/or does not exist. FDA should clarify that a prior notice will not be rejected for failure to include certain information where that information does not exist

NFI shares the following common example of a fresh fish importation from Central and South America. Typically, an importer or other purchaser will place an order for a variety of fish with the foreign supplier. The supplier will commit to a certain amount and species.

As the fish is caught, the supplier then takes the fish to the airport for shipment to the United States. Frequently, the airplane cannot accommodate all of the shipment. Some of it may be sent on one flight; the remainder on another flight, maybe that day, and maybe another. Even then, the flight information may be wrong, the shipment may have been split among different flights, including on different airlines than anticipated and certainly, the arrival and quantity information provided in the prior notice will be incorrect. In reality, communications technology from Central and South America is antiquated and availability of reliable communications networks can be sporadic. Even with better technology, South and Central American and European fresh fish shippers may not have the capability to communicate updated and detailed quantity, species, and arrival information to the importer within the prior notice deadline and the importer will not know now exactly what is in the shipment until he goes to the airport to pick it up.

This is, in part, because neither the shipper nor the importer can force the airline to submit more detailed information pre-flight.

NFI is puzzled by FDA's plan to invalidate prior notices when an amendment is requested and is subsequently not needed. The fact that the shipment does not need an amendment cannot be known with certainty by noon the day before arrival, so fresh fish importers will, in many cases, have to assume an amendment might be needed. The request for an amendment and subsequent cancellation of that request in no significant way hinders FDA's ability to review the information provided because in these circumstances all of the necessary information has been previously filed. Imposition of this policy would seriously hamper fresh fish imports. This segment needs expanded amendment capability not unjustified restraints.

The entry type and Customs ACS entry number or other Customs identification number associated with the import

The NFI supports the comments submitted by the NCFIA on this aspect of the FDA proposal.

The complete FDA product code

As alluded to earlier, there are numerous instances in the trade where the purchaser places a general order in a "pipeline" – for an amount of some class of product to be delivered over a period of time. Under these circumstances, the importer does not know the exact product he is getting, or the amounts, until the products are shipped. The importer will not know the species, variety, or amounts of product until it is shipped.

Such changes and uncertainty mean that the precise product identity, including its complete FDA product code, is not known at the time the importer places the order. FDA should allow for liberal amendments to accommodate this type of business uncertainty and for changes to and clarification of an article's identity. NFI suggests that amendments be allowed generally up to the time of arrival. For air shipments, an additional amendment should be allowed up to three hours after flight arrival. This will provide additional time for importers or consignees to examine the shipment and provide updated information on quantity and identity.

The trade or brand name

As demonstrated in the shrimp example found in our comments above concerning FDA's economic analysis, it is not uncommon for a single product, which would be subject to a single OASIS line entry and prior notice, to contain multiple brand names. The statute does not require brand identity and, arguably the more useful information is the manufacturers name. FDA should reconsider requiring brand name At the very least,

the final rule should clarify that FDA will not reject an article for failure to include trade or brand information where such information does not exist.

The quantity described from smallest package size to largest container

As discussed above, frequently, a purchase order is for delivery of product over a period of time. An importer does not know the amount of product to be shipped on any given day. This flexibility allows for short term commercial uncertainties such as fluctuations in supply, weather, manufacturing problems, personnel changes or illness, transportation problems, inadequate cargo space, and the many other factors that can affect what a foreign supplier is able to ship on a given day.

Frequently, the importer does not even have the detailed package size information the Prior Notice Proposed Rule would require. Currently, with many types of products, multiple package sizes are lumped together in a single ACS line entry on the OASIS form. This problem is substantial for fresh seafood because the fish may not even have been entirely unloaded by the proposed deadline. Therefore, the processor will not know the size of the fish to be cut and/or packed for export. The size of the fish will dictate the size and configuration of the package. FDA should clarify how departing from the current practice is necessary to further its inspection identification mandate.

The lot or code numbers or other identifier of the food if applicable

Importers do not typically know the lot numbers of the imported product. This is not information that is provided to them by shippers or suppliers. Moreover, many products do not have lot numbers at all. FDA should at a minimum clarify what is intended by the terms “lot, code, or other identifying number.” The requirement is very vague and it is not clear what FDA hopes to gain from such information, particularly where the statute does not require it. Again, FDA should also make clear that the agency will not refuse entry to products for inadequate notice where there is no lot, code or other information to provide. Even if known, some entries will have far more than the four identifiers provided.

The anticipated arrival information

As discussed above, the Prior Notice Proposed Rule requires that filers include the port of entry and estimated day and time of arrival. Proposed 21 C.F.R. § 1.288(k)(1), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives 3 hours later or 1 hour earlier than reported in the notice, the Prior Notice Proposed Rule requires that the filer correct the arrival information. Proposed 21 C.F.R. § 1.288(k)(2), 68 Fed. Reg. at 5462, col. 1. If a shipment arrives outside this 4-hour arrival window, the prior notice is inadequate, the product will be refused, and a new prior notice must be made. As NCFIA notes in its comment letter, requiring updates to filed notices when, as is very common, arrival information changes, will necessitate importers providing 24 hour a day, 7 days a week operations.

FDA should reconsider the arrival requirements and make them more flexible, as envisioned and mandated in the Bioterrorism Act. Where an article's entry arrival information (port, date, time of day) changes due to routine shipping delays, weather, and other similar circumstances beyond the control of the importer, FDA should not penalize the importer by refusing to admit product. If FDA persists in demanding arrival information that frequently changes and is not known, then the term "arrival" must be defined to clarify when the article is deemed to have arrived at the port – e.g., when a truck arrives at a border crossing, when a vessel crosses into a United States port, if it is a containerized shipment, the time the container is unloaded, the time the container is scheduled to be picked up, etc.

The NCFIA letter states that, "if detailed arrival information is vital to FDA's identification-for-inspection functions, than... Customs is the much more reliable source for this information. Customs has direct communications with vessels, port authorities, truckers, border crossings, airports and airlines. Customs captures reliable arrival information through these existing communication networks that importers do not have. These communications provide Customs with arrival information calculated within minutes. Whatever information FDA receives from importers regarding arrivals, that information is likely to be far less accurate and reliable than what could be obtained through Customs." NFI urges FDA to look to Customs for the accurate arrival information the agency believes it needs.

The Final Rule Must Clarify Provisions Regarding Identification Of Known Growers

FDA requests comments on whether it should require grower information for botanicals, unspecified fish and seafood, and processed foods. There is no evidence whatsoever that Congress intended to reach beyond this definition of "grower" of plants or crops to require identification of those who catch, harvest, or even cultivate fish, shrimp, and other aquatic products. Aquaculture and commercial fishing are very distinct activities that share little with the traditional practices of growing, farming, and harvesting. If Congress had intended to cover these types of entities and practices within the grower identification provision of Section 307, 21 U.S.C. § 381(m)(1), it would have done so explicitly.

The NCFIA letter notes that, "This provision for grower identification is inadequate for many types of imported agricultural products", and goes on to explain why. It would also be inadequate for fish and shellfish, particularly shrimp, for similar reasons. In addition, the three spaces for grower information on the proposed form would be entirely too few to accommodate the many aquaculturists raising fish.

TIMING ISSUES

NFI agrees with the NCFIA's suggestion that FDA abandon the fixed calendar day standard of noon of the day prior to port arrival. Such a standard severely penalizes the filer with delays of up to 36 hours if the prior notice is submitted one minute beyond

noon. To avoid this penalty, it is likely that filers will jam the FDA notification system to avoid the noon cut off and penalty, resulting in delays and system overload. In the alternative, a rolling notification of four hours prior to estimated arrival at the port of entry, which is closer to current practice and, NFI believes, likely to be far less disruptive to trade, should be adopted

FDA's Extremely Limited Amendment Options Would Be Very Burdensome And Costly

The FDA should allow amendments up to time of arrival, especially for perishable shipments arriving by air and truck. More than one amendment may be needed for certain kinds of shipments, including air shipments coming from Latin America and Europe. As previously stated, importers and their agents will not be able to finalize the prior notice information related to quantity and identity until the airlines make their shipments available, typically a few hours after flight arrival.

As stated previously, FDA should not invalidate a prior notice solely on the basis that an intended amendment was not subsequently needed. Invalidation on this basis will threaten widespread and costly detention of perishable fish shipments and overwhelm FDA inspection personnel without benefit to food security.

NFI also agrees with the NCFIA's comment that FDA must clarify the provisions regarding updates of known information that was incorrectly transmitted and liberalize the amendments to allow for other changes to a previously filed notice. Without a more realistic approach, FDA's requirements will increase filing burdens and harm the accuracy and utility of the information to be collected. FDA decisions to refuse product, particularly for minor omissions and inaccuracies to information the Bioterrorism Act does not even require, will jam the flow of trade. FDA should keep in perspective its experience with electronic filing for OASIS where error rate was high.

The Prior Notice Proposed Rule Does Not Allow For Different Modes Of Transportation And Types of Food

21 U.S.C. § 381(m)(2) describes the regulations FDA must promulgate to effect the identification-for-inspection goals of the Bioterrorism Act:

Regulations ... shall require that a notice ... be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import... In determining the specified period of time required ... [FDA] may consider, but is not limited to consideration of, the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration

21 U.S.C. § 381(m)(2).

FDA has not, however, customized the Prior Notice Proposed Rule in any way to allow for the many different foods that enter the United States and their manner of arrival. A single set of requirements applies to every shipment, regardless of whether it is an ocean vessel from New Zealand, a small air container of high-end cheeses and truffles, arriving by air freight from Europe, or a truck's daily crossing into the United States from a Canadian plant an hour from the border crossing. FDA makes no allowance for the differences and challenges that arise depending upon the product being imported and the mode of transportation. A noon of day prior to arrival notice requirement might be reasonable, if adequate allowance is made for amendments, for a trans-Pacific, ocean going vessel that is at sea for more than a week. Noon of the previous day, however, is likely to be unworkable for companies shipping fresh, frozen, and highly perishable goods from locations within 60 miles of United States land borders or within hours via air.

Not all types of imports pose the same contamination and bioterrorism threats. FDA's Hazard Analysis And Critical Control Points (HAACP) for fish and seafood, for example, is intended to provide documentation of the safety procedures followed to prevent, among other things, product contamination. Customs is also developing the Customs-Trade Partnership Against Terrorism, or C-TPAT, program with importers in order to identify low risk imports and to streamline the importation of such products. FDA, however, makes no such allowances with the Prior Notice Proposed Rule. Every product, it seems, poses the same potential risk to health.

FDA would do well to look at the problems Customs is experiencing with its initiative to require notification of manifests 24 hours prior to loading. The current rule applies only to vessels and has led to severe interruption in imports by vessel. Customs is wrestling with the implementation of the vessel rule. Significantly, Customs is proposing separate rules to deal with shipments by air and by land. Customs is not attempting, as FDA is, to have one rule fit all the modalities and circumstances of import. Products, mode of transport, the relative risks different products present are all too varied, and the vagaries of importation too unpredictable for a single rule to address all these issues without also grinding importation to a halt.

Other issues

NFI wishes to incorporate by reference, the NCFIA's comments on;

1. Clarifying an "article of food";
2. FDA Procedures In the Event Product Is Refused Entry
3. Practice Back Up Systems
4. Establishment of Verification Or Validation Systems

NFI thanks FDA for this opportunity to comment. NFI and its members are available to assist FDA in assuring the smoothest implementation of the prior notice.

Sincerely,

A handwritten signature in black ink that reads "Robert Collette". The signature is written in a cursive style with a large initial "R" and "C".

Robert L. Collette
V.P. of Science and Technology