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May 14, 2001

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

RE: Supplemental Comments to Docket No. 00N-1633, Requirements for and Prohibitions on the Re-importation of Imported Food Products That Have Been Refused Admission into the U.S.

Dear Sir or Madam:

On April 6, 2001, the National Fisheries Institute (NFI) wrote FDA to oppose its proposal to require special marking on containers of food refused for safety reasons. In that correspondence, NFI said it was disappointed that FDA refused a request to extend the deadline for receiving public comment submitted by the National Coalition of Food Importing Associations of which NFI is a member. Our letter also indicated that we were actively collecting information about the potential impacts of the proposed regulation on seafood importers, therefore, planned to submit supplemental comments within 30 days. We respectfully request that FDA include the following supplemental comments in the official docket.

The proposed regulation would require marking food shipments refused for safety reasons to indicate that the product was denied entry into the United States; and prohibit persons from refusing to affix the mark, importing a previously refused food and altering, removing, tampering or concealing a mark. As stated in NFI's April 6th letter, we are opposed to the proposed marking requirement for the following reasons:

- The mandatory marking of refused food is unnecessary and unwarranted because FDA has failed to demonstrate that the occurrence of so-called port shopping is a common importer practice.
- The regulation exceeds the former President's intent of stopping "bad actor" importers.
- The marking of refused goods will harm law-abiding importers by unfairly diminishing the value of viable goods.
- FDA appears to lack statutory authority to require the marking of refused goods.

The following additional conclusions are drawn from NFI's further evaluation:

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- FDA's detention without physical examination is a procedure that can already be used to prevent the re-entry of refused goods that have not been repacked.
- FDA's marking proposal could lead to increased re-introduction of refused food.
- FDA's economic impact analysis is incomplete and significantly underestimates the economic harm to law-abiding food importers.

FDA has not provided evidence that food importers on a systematic re-occurring basis undertake port shopping, with the intent of re-entering previously rejected goods. As discussed in our earlier letter we see little incentive for importers to undertake this practice. Moreover, **FDA already has a procedure in place that provides protection against re-introduction of refused food.** When the entry from an exporting packer is identified as violating FDA safety standards, the packer is placed on detention without physical examination status. This procedure prevents products from that packer from entering the U.S. unless the importer of record can provide laboratory evidence demonstrating that the food safety hazard previously identified is absent from the product. FDA can help minimize the threat of re-entry of products by rapidly processing recommendations from field offices to place packers on DWPE status, thereby alerting all Districts to the potential threat of re-exportation of violative goods.

FDA states in the proposal that there are four ways that the rule would increase the deterrence value of the FDA inspection system: port shopping will be reduced, the value of the re-exported items will decrease, reconditioning will become a more favored alternative, and introduction of unsafe food into the U.S. will decrease (Paragraph 2 of Section VII D). Of the four assumptions made by FDA only one is sure to be correct (i.e. the value of re-exported items will be reduced significantly). For the honest importer the marking of refused food will seriously de-value the product and bring profound economic harm.

Will the proposed rule really reduce port shopping and decrease the introduction of unsafe food into the U.S. as assumed by FDA? There is good reason to believe that it will not and FDA has not apparently considered that the rule might have the unintended effect of increasing the flow of refused food to the U.S.

The proposed rule could increase the flow of violative product. The gross de-valuation of refused food that would be subject to the marking requirement will cause a major economic loss to honest U.S. importers and become an economic gain for overseas buyers. The markings are expected to cause a sizable drop in the available pool of potential buyers for refused goods. A dramatic de-valuation of refused food will occur because the number of potential buyers will drop and those who remain will simply rely on the refusal mark to bargain for a very cheap price for goods even when the goods meet the country's food safety regulations or can be readily reconditioned. The value of refused shipments, which today may bring an importer 60-70 cents on the dollar or more, could drop to pennies on the dollar. Conceivably, an unscrupulous overseas buyer will be able to purchase refused product for pennies on the dollar, repack the product, re-sell them to unwitting U.S. importers and still make a tidy profit. It is uncertain to what

degree this practice might occur but the possibility provides reason to seriously question FDA's assumption that the markings will reduce port shopping and the introduction of unsafe food into the U.S.

Section VII Analysis of Impacts contains the agency's evaluation of the economic impacts associated with the proposed regulation. After reviewing this section, NFI concludes that FDA did not adequately measure the economic impact of the proposed regulation on food importers, most of which are law-abiding small businesses, or properly characterize the typical import transaction process.

Currently most seafood importers buy shipments without a guarantee that the exporter will accept the goods back if an FDA inspection shows the appearance of a violation. Therefore, if the shipment is detained the importer may or may not be able to return the goods to the exporter. In many cases, another buyer must be found. U.S. importers usually lose money on violative shipments because new buyers pay less for the goods then the importers paid. The difference in price is even less favorable to importers when cold storage, shipping and interest expenses are added on. With this in mind FDA's belief that importers begin transactions with knowledge that products are violative, as suggested in Section VII, paragraph D 1., is flawed. The chart provided in this section provides a distorted picture of the import decision-making process. **For the reasons stated above, shipments that appear to violate U.S. law, become a financial liability to honest importers not an opportunity to make a profit.**

The economic impacts of the proposed rule can be divided into two basic types those that are a direct expense to the importer and those associated with the devaluation of products due to the marking. NFI's April 6th letter already documented that the direct cost to physically label the master cases would exceed FDA estimated costs by a factor of about twelve. Although this is the only cost to importers that FDA attempted to quantify, it is the least of the costs associated with the proposed rule.

FDA failed to account for the direct cost associated with the inevitable delays in re-exportation of refused shipments that will result from the marking requirement. Delays will occur for at least two reasons, it will take FDA additional time to arrange for the marking operation to be observed by its staff or designated representative. Any time FDA adds a step to the import inspection procedures a delay can be expected. Secondly, importers expect that arranging for re-exportation of refused goods will take considerably longer under the proposed rule, since the marking will greatly hinder the ability to find a buyers for the goods. We expect the combined effect will easily result in delays of 30 days or more.

Delays cost money. A delay of 30 days would increase importer expenses associated with their interest on loans and cold storage fees. The exact cost per 30-day delay would vary by product, size of shipment, interest rate etc. We can estimate what this cost might be by examining a hypothetical entry of shrimp. The added interest cost for a relatively high value entry such as a 40, 000 lb container of shrimp valued at $150,000 would be about $900.00 if financing were extended by 30 days (assuming a 7.5% interest rate

annualized). In addition, the importer could expect additional cold storage costs (at a bonded public storage facility) of $500.00-$800.00. Importer costs for a single refused shipment, therefore, might total about $2,000.00- $2,300.00, including marking costs of about $600.00. This expense while substantially prohibitive and much higher than FDA's estimate does not include the most costly aspect of the rule, namely the devaluation of the goods.

Seafood importers are not protected by exporter guarantees. Exporters for both financial and regulatory reasons will be either unwilling or unable to provide guarantees to accept refused shipments back from U.S. importers.

Incorporating a term into the letter of credit that conditions payment upon the passage of the shipment by FDA is already (i.e. before implementation of a marking rule) extremely difficult and exceedingly costly. Packers normally receive credit from their banks to finance the shipment of goods. Under normal circumstances, the packer's bank knows that the buyer's bank generally has an irrevocable obligation to pay on the letter of credit, hence the packer's bank will receive payment in short order after the goods are placed on the transporting vessel.

If the letter of credit is conditioned on FDA passage then the packer's bank will now have to finance the entire shipment for the time in which it takes the FDA to approve the goods. This takes much more time, so the packer incurs additional interest, which in turn means that the packer will pass that cost on to the importer.

Moreover, an additional element of risk is added to the transaction (i.e. refusal of the goods). In such a case, the packer must therefore recall the goods. The costs associated therewith are, in the long run, passed on to the importer. The risk will increase under the marking rules because the shipments will be further stigmatized and the reaction of government officials and potential buyers will be unknown. Most packers will refuse to incorporate this element into the letter of credit and simply sell their goods to another country that does not have such an unduly restrictive barrier to entry.

Re-exportation to the source country will become more difficult. The refusal marking will undoubtedly lead to numerous inquires concerning the product. The country of origin may question whether the product was adulterated while in the US and might believe it is being used as a dumping ground for product refused entry into US commerce even though the product may not violate any of its specific standards or regulations. All of the speculative concerns will make the once easy job of re-exportation much more difficult.

The proposed rule will unreasonably devalue refused shipments even when the goods do not violate specific standards in other countries. As NFI's April 6th letter indicates, U.S. food safety standards are, in many cases, more restrictive than those of other countries. Today, importers normally find buyers in countries that either have different food standards or can readily recondition the product. If refused entry markings are mandated, importers expect that the refused shipments will be nearly or completely un-saleable. Estimates of the percentage of shipments that would have to be either

reconditioned in the U.S. (if even possible) or destroyed range up to 80-90 percent. As stated previously, the dynamic for arranging the disposition of refused entries is expected to result in a gross devaluation of the product to potentially pennies on the dollar. Under such conditions honest importers would take a catastrophic loss and opportunities would arise overseas to repack, sell and re-ship this product to the U.S. for a sizable profit.

Reconditioning would not necessarily become a more favored alternative as assumed by FDA. Reconditioning options in the U.S. are limited and expensive. For microbiological contaminants the only viable option is to cook the product adequately to assure thermal destruction of the organism. Cooking is a viable option for only a limited number of species and product types (i.e. there is little or no market for certain pre-cooked species).

Shrimp is one of the few species where cooking is technically a viable option, however, the economics are unfavorable, in part, because the cooking process reduces the weight of the lot (i.e. converting raw shrimp to cooked shrimp results in product shrink). The degree of shrink varies with the size and species of shrimp but can be upwards of 45%. The approximate cost to cook shrimp (i.e. handling, cooking and repacking/re-labeling) is about $0.55/lb. Therefore, the processing cost (not including the shrink) for a full container load of shrimp is about $22,000. If the shrimp needs to be peeled before cooking the cost could double. The loss in product weight and added expense associated with cooking and repacking/re-labeling in combination make this reconditioning option economically difficult.

The U.S. zero tolerance standard for *Listeria monocytogenes* in cooked and ready to eat food differs from many other countries around the world. If a cooked seafood is found to contain this organism, there is no reconditioning option in the U.S. at this time because irradiation is not approved and re-cooking will, in most cases, yield an unmarketable product.

FDA has alternatives to this proposed rule. Detention without physical examination is in place now and provides an effective deterrent to prevent product re-introduction. FDA must assure that this mechanism is implemented efficiently to rapidly alert Districts regarding the detention of goods from affected shippers. FDA should continue and accelerate efforts to work in cooperation with U.S. Customs Service to enforce effective measures targeted at so-called "problem" food importers who undermine import inspection procedures to knowingly and willingly reintroduce refused foods.

In conclusion, NFI opposes the proposed regulation because it is unwarranted and unfairly harms law-abiding importers. Moreover, the marking requirement will likely fail to reduce the reintroduction of previously refused food and could actually facilitate this practice. Markings will have an enormous direct and indirect economic impact on all importers. If the FDA can demonstrate with credible evidence that there are a small number of bad actors that routinely engage in port shopping, then an alternative control measure should be considered that targets these egregious violators.

Thank you for your attention to our comments. As previously stated, NFI requests that you accept these additional comments into the official docket.

Sincerely,

Robert L Collette

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