



March 6, 2003

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Mr. Robert Lake
Director, Office of Regulations and Policy
Center for Food Safety and Applied Nutrition
Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD, USA 20852

Dear Mr Lake:

DOCKET NUMBER: 02N-0276
TITLE: Section 305, Bioterrorism Preparedness;
Registration of Food Facilities

The Fisheries Council of Canada (FCC) is the seafood processor industry trade council in Canada. As such, the member firms we represent produce the majority of Canadian seafood processed and marketed to the USA. We are concerned about the impacts of the draft regulations put forward in the Federal Register on February 3, 2003 to implement the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*. We would ask you to take the following into consideration in making amendments to the regulations prior to their finalization.

Facility: In section S1.227(c)(2) a facility is defined as "any establishment, structure, or structures, under one management at one general physical location".

FCC would ask you to remove the "one physical location" part of the definition and allow multi-plant operators to register as one firm, with one number, and state for your records the number and location of the facilities they operate.

The reason for this request is for cost control purposes. In seafood, multi-plant operators often pack a similar product at several physical locations. The product is coded for safety purposes, etc., but often is then co-mingled in the warehouse for storage prior to export. The draft regulation on "prior notice" requires that information on the shipment contain the plant registration number for the product in the shipment in addition to name brand, pack size, etc.

Having multiple plant registration numbers on the production of a similar product will now require the separation and control in the warehouse of all products by plant registration number and the loading of carriers will have to contain this new number on both cartons and shipping documents. This will have implications as to the cost of inventory systems, warehousing costs,

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and add to the complexity of accurately loading container carriers and matching the documentation when, in fact, the product will be identical in form, packaging, etc.

If the intent of the system is to identify responsibility, ownership, and a point of contact, it seems the firm with ownership control over several production points can provide this level of assurance while having one registration number with FDA for the firm.

<p style="text-align: center;">DOCKET NUMBER: 02N-0278 TITLE: Section 307, Bioterrorism Preparedness; Prior Notice of Imported Food Shipment</p>

When must notice be submitted: In section S1.286, prior notice must be submitted no later than noon of the calendar day before the day the article of food arrives at the border crossing.

Fisheries Council of Canada (FCC) would ask you to consider two categories of products for prior notice. Shipments of live or fresh perishable seafood products to the USA border would have to be preceded by a prior notice to FDA of no less than **four** hours before the shipment arrives at the border point. Fresh perishable or live seafood shipments would **not be** allowed an amendment to the initial pre-notification information. All other shipments of seafood would be subject to the proposed rule of pre-notification by FDA, before noon of the day preceding arrival at the point of entry. These shipments would be allowed a one-time amendment on volumes up to two hours before arrival at the border under the conditions stated in the proposed regulations.

FCC would like to see this amendment due to the number of plants and shippers who are currently close to the border and who ship a fresh product (lobster, fillets, crab, etc.) with a very restricted shelf life in the trade. These products could lose up to a day between loading the carrier and notifying FDA and entry to the USA. Four hours notice could still allow for inspection action at the border on these fresh and live products without losses in economic value of the product and risks of spoilage and yields.

The proposed rule for originating country is trade restrictive In the section S 1.277 of definitions, it defines the originating country for purposes of notification in the case of wild caught fish that is harvested from the waters of the United States or by a United States flagged vessel or processed on a United States flagged vessel to be from the USA. *“Otherwise the originating country is the country under which the harvesting vessel is flagged.”*

FCC would propose that the standard rules of origin used by USA Customs and under the World Trade Organization (WTO) trade rules be used to convey country of origin on the product being imported to the USA.

Fish is a globally traded and sourced raw material product and seafood processors often source such raw material from several countries to make a like product for export. A five pound cello-wrapped cod fillet could have been made in a Canadian plant from Alaskan, Icelandic, or

Norwegian harvested raw material. Keeping two sets of records for both Customs and for FDA prior notice would again place an undue cost hardship on firms. It would not be consistent with the trade rules used world wide to convey country of origin labelling requirements and it would cause greater likely hood of control errors in warehousing and loading carriers with like products from mixed raw material sources. It is also unclear how this provides any greater security of the food beyond knowing the details of the responsible firm exporting to the USA market.

Customs-Trade Partnership Against Terrorism (C-TPAT): The USA Customs Service has a voluntary program in place called Customs-Trade Partnership Against Terrorism. Many Canadian processor firms and carriers are filing their security programs with Customs under this program to provide ease of access at the border. This assumes that Customs will have some increased level of confidence in the security of food from these firms. FDA, in their program, is giving no credit to firms who are cooperating with Customs on this initiative.

Fisheries Council would propose that FDA create a field in their electronic prior notice form in which the firm could fill in if they have been approved as a C-TPAT shipper. This would be one more item for the FDA to build into their system which will identify the shipments to target for inspection by Food Security Officers at the point of entry to the USA.

Conclusion

There are a number of additional issues in the draft regulations which will cause Canadian seafood exporters to have extra costs and extra complications in servicing USA seafood customers. Some of these are the need for USA agents for registration purposes. Firms will have to use USA "importers or customers or their agents" in order to give prior notice by noon the day before entry. The expected time of arrival at the border notice and the amending process will require new systems between carriers, truck drivers, and the firm in Canada who utilizes their services and the USA agent for notification purposes.

However, the Canadian industry understands that the American people want to increase their confidence in the safety of their food supply and that the FDA is trying to institute the changes to achieve this goal. Canadian seafood processors are prepared to work with the FDA through the regulatory process to achieve that increased degree of food security. We request that the proposed changes outlined above are accommodated in the final regulations.

Sincerely



Ronald W. Bulmer
President

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