

## Notes To The File

**Summary of Outreach Meeting to Canada on the Bioterrorism Act  
Registration of Food Facilities and Prior Notice of Imported Food Shipments  
Proposed Rules  
February 4, 2003  
Ottawa, Canada**

**(These notes are not intended as a verbatim transcript of the meeting,  
but a summary of the key points discussed.)**

### **FDA Participants:**

Leslye Fraser, Associate Director for Regulations, Center for Food Safety and Applied Nutrition (CFSAN)

Bob Lake, Director, Office of Regulations and Policy (CFSAN)

Steve Niedelman, Assistant Commissioner for Regulatory Affairs, Office of Regulatory Affairs

Melinda Plaisier, Assistant Commissioner for International Programs, Office of the Commissioner

### **Session One:**

**Canadian Government Participants:** Representatives from CFIA; Trade Policy Staff; Fisheries; Agriculture; Health Canada; Grains, Oils & Seeds; Processed Fruits and Vegetables

### **Registration**

(CFIA)

- Explain the requirement to have a U.S. Agent, why is it necessary, how can it be done?
  - *The Bioterrorism Act requires foreign facilities to have a U.S. agent. Larger policy rationale is that those who are doing business in the U.S. should have a U.S. point of contact. The proposed requirements are consistent with those we currently require for devices, biologics, and drugs.*
  
- Does the U.S. Agent have to have any direct dealings/relationship with the Canadian company?
  - *Yes. The proposed rule would require the U.S. agent to reside or maintain a place of business in the U.S. The facility can choose who it wants to serve as their U.S. agent once this requirement is met. FDA will treat representations of the U.S. agent as those of the facility and communications to the U.S. agent as communications to the facility. The facility can also choose to designate its U.S. agent as its agent-in-charge for purposes of registration. FDA recommends that the facility and the U.S. agent enter into a contract, but it is not required.*

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- Customs House Brokers: Can they serve as the U.S. Agent if they agree to that arrangement?
  - *Yes, at the facility's designation.*
- Liability: Could the U.S. Agent be held liable for any violations of the Act?
  - *The proposed rule does not address liability.*
- We said we were developing guidelines on food categories. What are they?
  - *The food categories in our regulations contained in 21 CFR 170.3. FDA believes that these are at a level of detail broad enough not to be problematic, while providing useful information about a facility to FDA to enhance communications with facilities that might be affected by an actual or potential bioterrorist attack or other food-related emergency.*
- Once registration is up and running, can firms register in anticipation of exporting to the U.S. – even if the likelihood is in the future?
  - *Yes*
- What is FDA's interest in live hogs? We thought it was an APHIS responsibility?
  - *Yes, the transport of live hogs still remains with APHIS. However, the definition of food under FDA's jurisdiction does include live animals. We do not see this provision impacting the movement of these animals. Because farms are exempt, hog farmers will not need to register. If the hogs are going to slaughter, they fall under USDA's jurisdiction.*

(Agriculture)

- Canadian facts: 130 land border crossings; 7000 trucks per day just on one bridge (between Windsor and Detroit); 1.2 billion per day in food trade
- What if there are multiple agents, selling into a market/auction setting. They likely will not know the purchaser is moving the products into the U.S. Would the seller be responsible for registering?
  - *The purchaser would have to let the manufacturer know they are importing into the U.S., so the manufacturer/facility would have to register. (A lot of discussion about this and how difficult/impractical that would be. We asked for specific comments on this to the record.)*
- What if there is a load of multiple products and one portion of the load is from an unregistered facility. Would the entire load be held up or denied entry?
  - *No, the portion of the load from the unregistered facility would have to be separated out from the entire load.*
- How will this be enforced? Will we audit? Do random checks? How will we actually enforce?

- *Entries will be checked at the border for registration and if they are not registered, they will be denied entry.*
- How do we confirm the source? What will we look at?
  - *It will be tied to prior notice, and line entries.*
- Products that go from the Canadian manufacturer straight into storage in Canada before being exported to the U.S. How would we (FDA) know it went through a storage facility?
  - *We would welcome comments.*

(Health Canada)

- Updates are required within 30 days. Explain how it will work.
  - *It will be a challenge. It is a one-time registration, but the Bioterrorism Act requires facilities to provide timely updates of any changes to the registration information. FDA is proposing that changes be submitted within 30 days to implement the requirement to provide “timely updates”. We welcome comments on this proposed requirement.*

(Fisheries)

- Why do public warehouses need to be registered and how will we enforce?
  - *The Bioterrorism Act requires facilities that hold (store) food to register with FDA.*

Prior Notice

(Agriculture)

- A lot of concerns about this provision – particularly when you consider live commodities – (lobsters, fish, etc.) - problems are enormous.
  - *We asked them to submit comments*
- Why is prior notice required to be submitted by U.S. firm or U.S. Agent rather than the exporting firm? The exporter has the most up to date information. With registration, we allow an agent of the Canadian manufacturer, why not allow the Canadian manufacturer under prior notice?
  - *We asked them to submit comments. We have discretion to modify who has to provide the Prior Notice*
- They are also dealing with the “country-of-origin labeling” required under the Farm Bill. It just compounds everything.
  - *Acknowledged the two provisions, but clarified that they are intended for different purposes. Asked for comments.*
- The time – 36 hours seems to be extreme. Did we consider shorter time periods?
  - *We explained the practical realities of why we picked the time we did. We asked for specific comments about the time period.*

- If prior notice is not received by the time the truck hits the border, but there just happens to be an FDA inspector at the border crossing, does the inspector have the discretion to inspect the shipment then let the truck pass?
  - *No. The inspectors do not have that discretion. If prior notice has not been received, the truck will be detained. The Bioterrorism Act requires the affected articles of food to be held at the port of entry.*
- Do both the trucking companies in the U.S. and Canada have to be registered?
  - *No, neither does. Trucks do not have to register unless the truck is being used as a storage facility rather than for transportation.*
- What happens when there are delays at the border? Trucks often get backed up for as much as 2 hours or more. Does the truck have to have information or equipment on the truck to be able to submit an amendment notification?
  - *If the truck is in the queue to get in and the delay is obvious, and prior notice was properly submitted and received, then no further notification would be needed.*
- What about transshipments through the U.S.? Products from Canada that are destined for Mexico or other countries?
  - *Yes, the shipment would require prior notice, even if only passing through the U.S.*

(CFIA)

- Thinks the analysis overlooks the way transactions unfold at the border. In almost all cases when a Canadian exports, the company is required and responsible for everything. The Canadian company will have all of the information, more accurately, more timely. As written, we are creating a third party system with a middleman being the entity responsible. We need to recognize that the Canadian company is the exporter. Once we do that, it totally changes the analysis and impact. The U.S. importer does not own the product; have the data, or the interest. The Canadian company owns the data and owns the product.
  - *We would appreciate more specific information submitted to the docket.*
- What requirements for prior notice are we putting on our domestic industry?
  - *Of the four provisions requiring regulations, this is the one that only applies to entities importing or offering for import articles of food into the U.S.*
- If this doesn't work well, it will have negative impacts on Canadian business – people will lose jobs. Example: peeling/cleaning/bagging carrots...could be done in Minnesota or Manitoba. If the process is too cumbersome or costly, it will be easier to do it in the U.S. and will result in a loss of Canadian jobs.
  - *We would welcome additional information about this scenario and the potential impacts.*

- Bass versus Pike: Why the level of detail? Why not just require “fish”?
  - *Understand the concern, but need to keep in mind the intent of this bill is to counter terrorism. The level of specificity is needed as intelligence about tampering could be to that level of detail as species of fish, lot number, or a specific product originating from a specific manufacturer. This level of detail will allow FDA to not only target inspections on those articles of food for which it has a concern (e.g., a particular species of fish that may have been intentionally adulterated), but also to know the other shipments that are not affected by a particular import alert, for example, and thus, may not need to be examined as a result of the prior notice.*
- Are we open to considering options we did not already consider?
  - *Yes we are, within those areas that the statute gives us discretion. We would, however, need data to support other options, with as much specificity as possible.*

(Fisheries)

- So much is “just in time” with live lobsters or freshly caught fish. And, for practical reasons, the shipments often hit the borders at night. Will our agents be working at the borders 24/7?
  - *Changing the way we do business is something we are certainly considering at this point. We have not yet made any decisions, but are considering options that include staffing and business hours changes.*

(Health Canada)

- Concerned if products can’t get into the U.S. they will be diverted for distribution to Canada and Mexico. What kind of notice will we give Canada and Mexico about shipments we don’t let in?
  - *We’d welcome any comments on this point.*

(Vancouver)

- What will actually happen at the border?
  - *Described the process – check to confirm prior notice, and admissibility.*

**Session Two:**

**Canadian Industry Representatives:** Pork Council; Cattleman’s Association; Spirits Canada; Food and Consumers; Animal Nutrition; Agri-Food Trade; Vintners; Fisheries; Aquaculture; Fish Packers; Poultry and Eggs; Egg Marketing; Food Processors; Pulse Canada; Poultry Processors; Trucking Alliance; and Dairy Farmers

**Registration**

- It seems meat, poultry and egg products are exempt?
  - *Yes, they are exempt because they are within the exclusive jurisdiction of USDA.*

- What is the definition of a facility? Would that include “less than a truckload” – warehouse facilities that are used to fill orders? And, what about multiple shipments that are “stored” until consolidated into a full shipment.
  - *If the truck is being parked specifically just to store, it would be considered a storage facility and thus, subject to registration. If the trucks were being “held” to enable consolidation into a full shipment, they would not be subject to registration.*
- U.S. Agent – unclear who and how.
  - *We explained the rationale (as above in the first session), but are open to comments, and encourage them. Many Canadian firms have offices in the U.S. that may serve as their U.S. agent.*
- Does the definition of food include “less than 2% meat”?
  - *Think that is a USDA definition and not sure about the 2%.*
- Physical location. A multioperational firm really complicates life if the requirement is to register every facility versus the firm. Why is that?
  - *It is in the statute. We understand the issue they are raising, but do not think there is statutory flexibility to allow firms to register, instead of facilities. The statute says “each facility” must register with FDA. We welcome comments.*
- Need to clarify thinking about live lobsters. Lots of concerns with prior notice, but also about registration – what about holding facilities?
  - *We understand the logistical issues, and welcome their comments.*
- Spirits industry – would bulk spirits that are sent to the U.S for either bottling or blending be exempt, since the bulk is not going directly into commerce?
  - *No, they would have to register, as the definition of food includes food ingredients.*
- Vessels: salmon trollers gut, clean, package and send the fish directly to the U.S. Are they really processors? Could they be exempt?
  - *It sounds like a processor that would be required to register, We’ll need their comments and data supporting why they should be exempt, and/or why they should not be considered a processor.*
- Rendered products: fats, oils, meat and bone meal – would they have to register?
  - *Yes.*
- Volume: with some 400,000 facilities, how will we realistically manage the volume of information? How will we verify?
  - *Over time, there will be a system of checks and balances to enable us to verify. We’ll have information through the prior notice system,*

*information from registrations, inspections, etc. A system of information will develop to enable validation.*

- Multiple registrations: Canadian manufacturers have to register in Canada, so they have a Canadian registration number, they have to register soon in China, and will have a number there, they get a number from Customs, there are multiple registration numbers. Why can't we use the Canadian registration number? It should be significant or mean something to FDA that the firm has registered in Canada. One industry rep said he would encourage his members to provide the Canadian registration number, whether we ask for it or not. He thinks it is important for us to know the business is registered in Canada. The Spirits industry also raised this issue and said they have a very strong relationship with the U.S. thinks these preexisting relationship could/should be useful.
  - *We appreciate this fact, but need to remind folks why this bill was put in place, and that the registration is an FDA registration. We will create and manage the system. We have to have an FDA number. FDA is seeking comment on ways to minimize duplicative registrations while complying with the statute.*
- If we have problems with the registration, whom will we communicate back to? CFIA?
  - *We will communicate directly with the registrant.*

#### Prior Notice

- Thinks this provision is deviating from the normal rules of trade on country of origin. Example: Cod from Russia, processed in Canada. Under our rules, it would have to be labeled from Russia, not Canada. WTO – requires labeled from Canada. It's going to be a real nightmare for large operations who get fish (or other products) from all over the world that they then commingle as they process. It will be impossible.
  - *We'll look at this. Need to submit comments and specific information.*
- Timing on the proposed rule is horrible for the live lobster industry. Example: in dealing with a restaurant or fish broker in the U.S., within a 24 hour period the order can change as much as 4 or more times – not necessarily the quantity, but the species of fish. The nature of the business is very fluid.
  - *Need to look at this – need specific comments; however, under the proposal, the final quantity would not have to be given until 2 hours before the lobsters arrive at the port of entry..*
- Is there any standard reference to what a “fish” is? (Versus shellfish, molluscan shellfish, etc.)
  - *Reference is the FDA Product Code, which is available on FDA's website.*

- Is the FDA product code different from definitions under harmonized tariff?
  - *That is correct, our code is not the same as the harmonized tariff definitions.*
- Truckers are very autonomous. They may break down on the road, pull off for a few hours, decide to cross a different bridge (port of entry) based on weather, timing, etc. How does this information get passed back?
  - *The industry will need to work this out with their shippers. The system will now be based on prior notice.*
- How will the truckers know the prior notice has been received?
  - *That is an area for comments. The industry also may want to develop communication strategies (e.g., giving the trucker a copy of the prior notice receipt.)*
- Fresh seafood: can see that the amending process where the action will be 2 hours, is just too tight. Is there room to move on the 24 hours?
  - *Yes, there is room to change this for the final rule. Need comments and specific information.*
- A lot of discussion from the trucking industry about the Trade Act and regulations U.S. Customs Service will be writing to implement provisions of that Act.
  - *We acknowledged there well might be multiple new statutory requirements across the government that may seem interrelated, but each has a different purpose. Confirmed we are working with Customs to try to coordinate on the prior notice, and ultimately, our systems will be linked (2005 projected).*
- Are small entities exempted? Any consideration to do so?
  - *No exemptions, but do consider in the economic analysis. Statute does not differentiate or authorize a specific exemption for small entities.*
- Cattlemen: Country-of-Origin in the Farm Bill – concerned this provision is creating a non-tariff barrier to trade, and will U.S. officials be able to use this politically to block entry to the U.S.?
  - *No, we do not anticipate this provision being used for political purposes. Reminded attendees the purpose of the bill and, why it was enacted.*
- Industry in Nova Scotia is spending considerable money to build an IT system with Customs so they can be “fast laned” at the border. Now they are worried these new FDA requirements will stop them. What are we doing to work with Customs on harmonizing these efforts? And, will we really have FDA folks at the border 24/7?
  - *We are aware of CTPAT with Customs and are working with them on database issues. Customs cannot modify their existing computer systems in time to meet the statutory deadline of December 12, 2003. We can't do it at phase 1, but we are sensitive to these issues. Regarding 24/7, prior*

*notice will enable us to get FDA inspectors at the border to inspect particular articles of food when needed, but may not be able to staff 24/7 at the border or need to.*

- Transshipments by Train – what happens when you ship by train? You can't stop the entire train.
  - *We need to look at this, and we welcome comments on how to segregate these shipments.*
  
- Internet is being used to market food between U.S. and Canada and it moves by postal or courier. How will this be managed?
  - *This is a good area for comments. The proposed rule does not specifically address imports via the Internet. We need to look at this issue.*
  
- Who “pulls the trigger” in terms of determining when a product or shipment presents a real terrorism threat?
  - *Really a network of law enforcement agencies that will work together on managing information that indicates a real terrorist threat. Also, technically, in the statute, the authority to make the initial determination rests with the Secretary of Health and Human Services.*
  
- Some firms could be using a different person for every load. It's going to be a real problem. They are already losing insurers, who will only insure to the Canadian border. Now need to find insurers in the U.S. Very serious business implications.
  - *Send in comments.*

*Submitted by: Melinda Plaisier, Feb. 27, 2003*