

**Summary of Outreach Meeting to the European Commission (EC) and
Representatives of the Food Industry in the European Union (EU) on the
Bioterrorism Act Registration of Food Facilities and
Prior Notice of Imported Food Shipments Proposed Rules**

March 5, 2003
Brussels, Belgium

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

FDA Delegation:

Dr. Murray Lumpkin, Principal Associate Commissioner
Melinda Plaisier, Assistant Commissioner for International Programs
Leslye Fraser, Associate Director for Regulations, Center for Food Safety and Applied
Nutrition

Morning Session Participants:

EC Officials: approximately 15-20 representatives from the following Directors General
(DGs): Enterprise, Health, Trade, Agriculture, and Taxation/Customs

Others: representatives from the U.S. Mission to the European Union, Foreign
Agriculture Service

Registration

?? How is this a risk-based approach? And, how does it comply/fulfill traceability?

- *This proposed rule is not an evaluation of the food or facility. It is simply a registration that requires certain information: 1) to ensure that FDA has full knowledge of domestic and foreign facilities manufacturing/processing, packing or holding food under FDA's jurisdiction that is consumed by humans or animals in the U.S.; and 2) to allow FDA to be able to communicate with affected facilities in the event there is an actual or potential terrorist threat that affects the U.S. food supply.*
- *In that vein, this provision serves as a risk communication and risk management tool.*

?? VEA – Sent Comments in last August – VEA listing – did we consider using the VEW listing?

- *Yes, we did consider this, as well as other registration requirements that affected facilities may be subject to (e.g., other U.S., state, or foreign government registration requirements or state permitting requirements). However, at this time, given our statutory deadlines, the statutory mandate that all affected facilities must register with FDA, and the fact that not all*

of these other registration systems require the same information to be submitted, FDA did not adopt this approach in the proposed rule. Moreover, it would be a significant task to ensure the compatibility of the various IT systems that are used by each of these registration/permitting systems, such that FDA could quickly and easily access the information in the event of an actual or potential terrorist threat (e.g., identify all the affected facilities and notify them). FDA also sees using the registration information as part of its prior notice evaluation (see prior notice rule); thus, we need to have the information in one FDA database FDA can easily access. As stated in the proposed rule, FDA is seeking comment on how to minimize the burden if a facility is subject to multiple registrations, while ensuring that FDA has a workable database of facilities.

- ?? US Agent – Is one required? Cost? What are the responsibilities? Legal responsibilities? Liability?
- *Yes, the statute requires that beginning December 12, 2003, any foreign facility that manufactures, processes, packs or holds food for human or animal consumption in the U.S. must have a U.S. Agent as part of its registration. We estimate the cost will be approximately \$1,200 per year. This estimate is based on how much U.S. Agents charge companies to meet the U.S. Agent requirements under our existing drug, biologics, and medical device registration regulations.*
 - *Regarding the responsibilities of the U.S. Agent, the only proposed requirement is that the U.S. Agent reside or maintain a place of business in the U.S., consistent with the requirements we have for U.S. agents in our existing regulations noted above. Our intent was to leave as much flexibility as possible. We would welcome comments.*
 - *There is nothing in the statute or proposed rule about legal responsibilities or liability. We do, however, suggest – as per normal business practice – that there be a contractual agreement between the foreign facility and the U.S. Agent.*
- ?? Fresh Fruits and Vegetables – is every step of the chain expected to register?
- *Not the farm, unless the farm is manufacturing/processing the food (e.g., taking oranges grown in the farm and producing orange juice) and distributing the processed food product into commerce. In addition, foreign facilities that pack or hold the food off the farm would have to register.*
- ?? This appears to be more of an information exercise than a management tool?
- *It is both. For example, with registration, FDA will be able to gather needed information regarding facilities (domestic and foreign) that manufacture/process, pack or hold food that is consumed in the U.S. by humans or animals. With the registration information, in addition to the communication benefits identified earlier, FDA will be better able to better target inspections of facilities, and notify affected facilities of*

regulations and guidance documents that may affect them, further enhancing the safety of the U.S. food supply.

?? Can we answer all of the questions we receive – both by email, telephone calls, and to the Docket? The EC enjoys a special bilateral relationship with the US and they hope we can recognize that relationship throughout this process.

- *We very much appreciate and support our good bilateral relationship with the EU. However, it is important that we treat all of our trading partners equally, and that we proceed to develop, finalize and implement regulations consistent with the Administrative Procedure Act. Typically, FDA's response to questions and comments we receive is provided in the preamble to the final rule.*
- *FDA is conducting significant outreach to affected parties through these types of meetings, satellite downlink meetings, and posting summaries of the meetings and videotapes in our Dockets so others may access the information.*
- *We affirmed that the session we were having was actually the fourth face-to-face meeting to discuss the food provisions in the Bioterrorism Act and/or the proposed regulations, and that due to the tight statutory timeframes we were under to develop the final rules for these two provisions as well as the other two rules we are developing to implement the Bioterrorism Act (records and detention), and the fact that the public comment period closes April 4, it was highly unlikely we would be able to grant another "dialogue" before the comment period closed.*
- *We confirmed that we would submit a general summary of the day's discussion to the Docket, but that it should not be in lieu of formal comments from the Commission. We stressed the need for them to submit their comments to the Docket by the close of the public comment period, April 4. Further, we explained that it was logistically impossible for us to maintain a continued dialogue (i.e., provide them with answers to questions submitted via e-mail or react to comments submitted to the Docket) before the rules are made final given resource and time constraints.*

?? Paper Registration – what happens if someone registers by October 12, but they have not received their confirmation by December 12, and their products are held up. Isn't that grossly unfair?

- *We confirmed that paper registration will simply take longer, due to having to be mailed and manually entered by FDA into our database once a completed and legible form is received. In the event the registration is received and not all data fields are completed, or we have questions, it would have to be mailed back. We strongly recommend electronic registration because the facility will receive an "instantaneous receipt of registration and its registration number electronically, but FDA will certainly be looking at how we can manage paper registrations in the most efficient way so that we do not have the situation identified above. In part*

it will depend on how many paper forms FDA receives. FDA intends to publish the final rule by October 12th to give facilities two months to register before the statutory deadline of Dec. 12th.

- ?? At the end of the 1980's, the EU passed legislation – “Batch Identification”. If we haven't already looked at that, would we look at that to see if that legislation adequately addresses these rules.
- *We will take a look at that legislation, but we need them to submit specific comments to the Docket on how they think that legislation fulfills the registration requirements in the Bioterrorism Act.*

Prior Notice

- ?? How much of the information we are requiring is different from what Customs requires? And, couldn't that information just be added to the existing Customs form?
- *There is some new information, such as the location of where an article is being held if the food is offered for import without adequate prior notice; the grower (if known); amendments; updates; and the submission type.*
 - *As mentioned in the overview, at this point in time, we are unable to have the Customs information serve also as the FDA prior notice, as Customs has informed us that it cannot modify its existing system by the December 12th deadline, and its new system, ACE, is not expected to be operational until 2005 (estimated). It is certainly our goal to reduce duplication of efforts and hope by 2005 to have a link to ACE, so one submission will serve both federal requirements. We will continue to discuss this issue with Customs as we develop the final rule.*
- ?? Have we worked with Customs on these rules? Are we aware of Customs latest efforts – 24 hour manifest rule? Will they now have different timelines to comply with? Did we consider modes of transportation? We need to look at definitions.
- *Yes, not only have we worked closely with Customs on these rules, but both registration and prior notice were jointly issued by FDA and the Department of Treasury (Customs was part of Treasury at the time the rules were signed). Again, we are working with our sister agencies to reduce duplication and create efficiencies where we can across federal requirements, while meeting our statutory objectives.*
- ?? Inadequate notice – how would a shipper know if changes occurred in timing of delivery? And, particularly for perishable products?

Amendments – could be very problematic when shipments essentially get out of the control of the facility/shipper – unforeseen circumstances.

- *We would welcome comments. We recognize that the facility or shipper may not have control over delays once the shipment is being transported. The proposed update provision was intended, in part, to address changes that occurred after the prior notice is submitted (e.g., an exporter intends to ship a particular manufactured food item on Wednesday, submits the prior notice on the preceding Saturday, but the production line breaks down on Tuesday, causing a delay in shipment). We will look at what changes may be needed to this provision to ensure it is able to accomplish the stated objective.*

?? Registration number - why is it not required for all entities in prior notice?

- *Registration is for certain affected facilities – not all; prior notice is for all articles of food imported or offered for import into the U.S. The two proposed rules do not cover the same “universe.” For example, farms do not have to register; however, food from a foreign farm requires prior notice. Also, registration is only required for certain foreign facilities manufacturing/processing, packing or holding food intended for consumption in the U.S. Prior notice is required for any food that is imported or offered for import into the U.S., even if the food will be consumed elsewhere (e.g., food imported for export requires prior notice). So there will be food subject to prior notice even if a facility associated with that food is not required to register.*

?? If a product is held up at the port-of-entry, is there any provision for appeal?

- *If a product is held at the port-of-entry for inadequate prior notice or lack of registration, the “violation” will be self-evident. Both registration and prior notice will provide for an automatic response. Long before the product reaches the port-of-entry, the facility will have received its registration number and the importer or broker will have received confirmation of prior notice if both are adequately completed. The notifications will be date and time stamped.*
- *There is no provision in this proposed rule or the statute for an appeal; the Agency’s routine appeal process may apply, but we would need to confirm this.*

?? Must look at registration and prior notice together – what’s the real benefit? Much of the information will be useless – many may register that never end up exporting to the U.S. This appears to be more of an information exercise than a management tool?

- *We see these two provisions together as pieces of a safety net. Together, they will provide a system of checks and balances, and certainly will be used as a management tool. It is information gathering, but it will provide us with information that can be used to both protect American consumers (e.g., prior notice allows FDA to know what food is being imported into the U.S. before its arrival, which allows FDA to determine whether we need to have inspectors available when the food arrives). Both also would allow us to contact you, in the event of a threat.*

?? How will we verify the information?

- *As mentioned above, together, over time, these provisions – in addition to other measures – will provide somewhat of a self-check, as we will have knowledge of which facilities and entities are providing food to American consumers. We also anticipate conducting random audits, and when data do not make sense, we will certainly follow-up (e.g., during the registration or prior notice filing process, or inspections at the border).*

?? We view these provisions as trade restrictive.

- *We take our obligations under WTO very seriously. We filed our notices under WTO on February 6, and we are conducting the risk assessment required under the SPS Agreement. It is certainly our goal to ensure that these regulations are as least restrictive to trade as possible while meeting our statutory objectives, and we believe they will not be an impediment to trade. We would welcome any specific comments you might have about exactly how these provisions will restrict trade and what, in your view, would minimize that impact while meeting the statutory objectives.*

?? There is no “intermediary” for registration. Did we consider having an “intermediary” such as a foreign government verify the registrations and/or submit them to FDA?

- *As we read it, the Bioterrorism Act requires each affected facility to register directly with FDA, not through an intermediary. We do not see authority to require that. We also would have concern about imposing that duty on all foreign governments without their consent due to resource implications.*

?? Summary Comment from the EC: They are looking for a system that is not disruptive to trade and is workable; they want to have an open dialogue with FDA throughout; and they need to complete their own review and submit formal comments to the Docket.

Afternoon Session Participants:

Industry: Approximately 25-30 representatives from food trade associations and agriculture cooperatives.

Others: Representatives from the U.S. Mission to the EU, Foreign Agriculture Service

Registration

- ?? What about food ingredient makers who only export ingredients to their subsidiaries in the U.S. Do they have to register?
 - *Yes, facilities that are exporting food ingredients directly to the U.S. are required to register. The definition of food includes both finished food products and food ingredients.*

- ?? The new law says “may” have a U.S. Agent, why are we requiring it? It appears a way for us to restrict trade and create more U.S. jobs.
 - *Actually, the statute says that each affected foreign facility “shall” have a U.S. agent, so it is a mandatory requirement in the statute.*

- ?? Spirits industry is concerned about the overlap with other registration or permitting requirements and duplication of information and efforts. Can’t we use the registration from the Bureau of Alcohol, Tobacco and Firearms (BATF)?
 - *We understand your concern about overlapping or multiple requirements. However, the statute requires affected facilities to register with FDA, and at this point we cannot accept registration to other federal agencies as registration to FDA. We also have a concern about inconsistent information from using various registration systems that facilities may be submitting to meet different requirements. We would welcome comments on how to minimize duplication and reduce burden while meeting the objectives of the statute.*

- ?? What about spirits – we export in bulk, and we also export blends and bottled products. Who has to register? (It’s a multi-step process – distill – blend – store/age – bottle.)
 - *It depends on at what stage in the process the spirits are being exported to the U.S. If bulk spirits are being exported directly to the U.S. for further processing, then the bulk manufacturer/processor must register. If the bulk spirits are further manufactured/processed outside the U.S., then the last manufacturer/processor, must register, but the upstream manufacturers/processors located outside the U.S. would not have to register.*

- ?? How will we assess the information we receive?
 - *As we mentioned previously, we will do random audits, we expect a system of checks and balances to develop over time, and we certainly will be checking information as the registration and prior notice is being filed.*

Registration, however, is not an evaluation. We are not assessing either the facility or its food. By issuing a registration number, FDA only is verifying that the facility has registered with FDA.

- ?? Not clear who this requirement applies to. Thought growers did not have to register.
- *Growers generally do not have to register; they are exempt as farms. Food from a farm, however, is subject to the prior notice requirement.*
- ?? Economic Impact Study – it acknowledges that the U.S. Agent will cost more for foreign exporters. Isn't this discriminatory?
- *We welcome any comments you might have on the economic impact analysis, but we based the estimate on the costs U.S. Agents charge drug, biologics, and medical device companies. We do not view this as discriminatory, but we welcome further comment.*
- ?? Confidentiality – how will we protect the information we receive?
- *As a regulatory agency, FDA has a long history of receiving, managing, and protecting confidential commercial, trade secret, personal privacy, and other protected information. The statute precludes FDA from disclosing the registration number or registration information under the Freedom of Information Act (Act gives access to government information to the public under certain circumstances). We are also looking at password protections and other Information Technology tools we can use so that exporters can assess their registration, but keep it protected from access from others. Further, just as we will protect this information, we strongly recommend that you also protect your registration number, for the following reasons: 1) To prevent someone from using your registration information to attempt to export illegal, gray-market, or intentionally adulterated food into the U.S.; and 2) The registration is not an FDA endorsement of the safety, quality, wholesomeness of the commodity – thus the registration should not be used publicly as such.*
- ?? Concerned about the requirement to give a home phone. That's a violation of personal privacy.
- *We too, share a commitment to protecting personal privacy information. We will look at this for the final rule. What FDA needs is a means to reach you in the event of an emergency after-hours.*
- ?? When is a registration considered acceptable? What happens when data entry mistakes are made, such as an incorrect telephone number?
- *Some data entry mistakes will be easy to catch, such as an address that doesn't actually exist, an incorrect city, etc. However, something like an incorrect telephone number, will be difficult to catch, unless we later attempt to reach someone at a number provided.*

Prior Notice

- ?? What about a company that sells and ships to Mexico. Do they have to give prior notice?
- *Yes, if the food commodity is being shipped to Mexico via the U.S. FDA must receive prior notice for any article of food imported or offered for import into the U.S. for any reason.*
- ?? Growers – how do we define? Just the name?
- *Yes, just the name if known. The proposed rule specifies what information would be required for grower.*
- ?? Fully endorse Canada and Mexico’s comments to broaden the definition of who should be authorized to provide prior notice.
- *We would welcome any comments.*
- ?? Processing of all notifications – any guarantees the system will function efficiently?
- *Our IT experts assure us that the system will be up and running and functioning. We are developing a new system with a full understanding of the expected usage, including peak usage times. It is our expectation that the system will work as planned.*
- ?? Concerned about how long it will take if inadequate registration or notification – and the notice is “rejected” for lack of data and has to be resubmitted?
- *The filing process – if electronic – is automatic. Thus, if your registration notice has all mandatory fields filled out, you will immediately receive a confirmation and registration number. If they are not filled out, the system will not allow you to submit your registration until you have completed all mandatory fields. Once a completed form is submitted electronically, the facility will receive an instantaneous confirmation and registration number. Paper registrations will take much longer, as FDA will have to manually assess whether the form is legible and complete before registering the facility. If it is not, the form will be returned to the sender to complete.*
 - *With prior notice, adequacy will be assessed once the food arrives. The system will tell you that you submitted a notice with the date and time of receipt; FDA cannot tell whether the notice is complete or adequate until it is compared with what food actually is imported or offered for import and when that food arrives. If the food arrives the same day the notice was submitted, notice is inadequate (must be submitted by noon of the calendar day before arrival under the proposed rule). If a shipment contains 5 different articles of food, but only 4 had timely and accurate prior notices, then only the article of food for which there was no prior notice will be deemed as having inadequate prior notice and must be held*

at the port of entry.

- ?? Delays – boats are delayed all the time – can the importer be held accountable when delays occur that are out of their control?
- *We recognize there may be unforeseen delays in transportation, and welcome any comments you might have.*
- ?? What about bulk products with dual use? (Starch Industry) – both a food and a drug excipient. When it is sent in as only an excipient, any chance it will be held as a food and delayed?
- *In some instances, FDA may be able to tell whether an item is a food ingredient or a drug ingredient (e.g., starch in the above example is being shipped to a food company). We need to consider this question more and welcome comments on this.*
- ?? Spirits industry – we already have to give prior notice to other federal agencies. Is this in addition?
- *Yes, at this time. You must fulfill the requirements to FDA once final, as well as any other requirements you may be subject to.*
- ?? CTPAT and CSI (24 hour rule) – any effort to link to these? If a company is a CTPAT partner, can they be exempted?
- *The Bioterrorism Act only exempts food subject to USDA's exclusive jurisdiction; food jointly regulated by FDA and any other federal agency is subject to the prior notice requirements, unless it is food being imported in a traveler's personal baggage (proposed requirement). We are working closely with Customs and anticipate having our systems linked by 2005 to minimize duplicative notices, but at this time, Customs has informed us that they cannot modify their system to accept prior notices by our statutory deadline of Dec. 12th.*

Submitted by: Melinda Plaisier March 14, 2003