

# L.D. Tonsager & Sons, Inc.

Customhouse Broker & Foreign Freight Forwarder

FMC License 1370-R

CHB License: 13335

April 30 2003 '03 APR -4 AM '03

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

Re: Comments on proposed FDA bioterrorism regulations – registration of facilities  
Docket No.: 02N-0276

Dear Sirs:

The following comments are submitted by L. D. Tonsager & Sons, Inc. in response to the Notice of Proposed Rule Making published in the Federal Register of February 3, 2003, relating to proposed amendments to 21 CFR Part 1, implementing certain relevant provisions of P.L. 107-188, the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002."

The purpose of these proposed regulations is to improve the security of the U.S. food supply by enhancing the FDA's ability to oversee and monitor imported food shipments and thereby improve the security of the U.S. food supply. Although we agree with this objective, we believe that:

- The proposed regulations, as written, are seriously flawed.
- If implemented as currently written, they will accomplish little if any real improvement over current regulations and policies.
- These rules are unduly burdensome, and if implemented as currently written, will cause significant economic harm to a large number of both large and small entities, and will cause serious economic damage to the United States.
- These regulations can and should be extensively revised prior to enactment, to increase their effectiveness and to greatly reduce the degree of harm that would otherwise result from adoption in their current form.
- Prior to enactment, a revised version of the proposed regulations, which address the specific concerns listed below, should be published for additional public comment.

## Comments on Specific Provisions of the Proposed Regulations:

1. The "count of facilities" potentially subject to registration per proposed Section 1.225(a), as shown in Tables 1 through 6 of the NPRM discussion, appears to be biased toward counting primarily the types of facilities that are now commonly regarded as being "food storage or handling" locations. The listed counts appear to overlook many types of domestic U.S. transportation company facilities which – under a literal reading of the text – would each have to be separately registered.

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2. These types of facilities include, but are not limited to:
  - (a) Rail yards – where many types of shipments, including containerized (whether or not on rail cars at the time), boxcar (both dry carton and refrigerated/frozen), hopper car (typically grain) and bulk liquid (e.g., milk) may be held for extended periods in the course of their through transit.
  - (b) Container yards – at marine terminals, off-dock holding yards, truck terminals, rail terminals, etc.
  - (c) LTL truck terminals – where cargo, including food shipments, is staged, consolidated, loaded, rehandled, and held for on forwarding, pick-up, or delivery.
  - (d) FTL truck terminals – including relay points and “drop lots” where previously loaded trailers are staged or held for pick-up or for exchange to a new power unit.
  - (e) Customs bonded Container Freight Stations (CFS facilities) where containerized cargo is often held for Customs clearance (and/or other agency release), and/or transloaded from international to domestic transportation equipment.
  - (f) Air cargo-handling agents.
  - (g) Air, ocean, and truck cargo breakbulk terminals.

Because a single domestic U.S. transportation company – even one of small or moderate size – may have literally dozens or hundreds of such locations, the separate registration of each of them as an individual facility (through which imported food products might occasionally pass) will be a huge and unreasonable burden upon many such firms.

3. By the nature of the transportation industry, shipments of food products (both domestic and imported) typically pass through multiple such locations in the course of a single transit. The presence of any particular shipment, at any transportation company individual location which might be subject to registration, is typically quite brief. The presence of any food product shipment at any such individual location will normally be short-term, temporary, fugitive, and/or merely incidental to the transportation of such food products between their actual origin and actual destination. By the time that a recall or hold notice could be distributed to any one of the many possible locations that a food product shipment *might* pass through during the course of its movement, there is a high probability that the shipment – if indeed it ever passed through that particular location – would already have moved on to the next point in its itinerary. Thus, attempts to stop such a shipment at an intermediate point in its transit are likely to be inefficient, ineffective, and a huge waste of time for all parties concerned.

Instead, it is much more efficient to intercept such a food product shipment at the known points (beginning and end) of its scheduled transit, at facilities that are generally or regularly used for the storage or handling of food products.

4. Thus, we recommend that FDA require registration only of facilities which are generally or regularly used for the storage and handling of food products. We accordingly suggest that proposed Sections 1.226 be amended by adding an additional exemption, to read:

“(h) Transportation facilities at which a shipment of food may be temporarily present during the course of its transportation. This would include temporary storage at marine, truck, rail, or air carrier terminals, container yards, container freight stations, and similar types of locations, but does not include a transportation facility that is used for the storage of food, other than in the ordinary course of transportation or pursuant to Section 1.241(e) of this part.”

5. Many of the facilities which will be subject to FDA registration, and which upon registration will be assigned an FDA facility number, are already registered with the FDA and/or other Federal regulatory agencies for various purposes, and have already been assigned facility numbers for such purposes as:
  - (a) U.S. Customs Service bonded facility FIRMS code;
  - (b) FDA establishment number;
  - (c) FDA-assigned Food Canning Establishment (FCE) number;
  - (d) Seafood HACCP importer food number (FDA Affirmation of Compliance code SIF”); and
  - (e) Location number of U.S. domestic party responsible for FDA-regulated goods imported by a foreign Importer of Record (FDA Affirmation of Compliance code “FEI”).

To minimize confusion, especially about which of one facility’s multiple registration numbers apply to which types of activities, we strongly recommend that:

- (a) FDA include, on its food facility registration for 3537 or electronic equivalent, optional fields for:
  - (1) type of other facility registration number, with checkable options including the above types of registration codes, as well as an option for an “other” type of code, and
  - (2) the appropriate registration number for each option that is checked.
- (b) The FDA food facility registration number should be cross-linked in the appropriate FDA database(s) with each other type of facility registration number (if any) that also applies to the facility.

(c) To facilitate efficiency and minimize duplicate reporting of information, FDA should whenever possible use the Customs Service FIRMS code, as reported on Customs documents and in Customs entry data transmissions, as a primary location identifier for imported food items being held in a “secure facility” in accordance with proposed Section 1.241(e).

6. Because the information about facilities which have registered under these provisions will not be subject to public disclosure, there is no mechanism for an importer or other interested party to verify whether a particular facility has registered with FDA for this purpose, or whether the facility’s registration data is still current. (The operator of such a facility might, either innocently or otherwise, erroneously represent the facility as being registered under proposed Section 1.230 through 1.234.) Thus, even importers and submitters who desire to be fully compliant with FDA requirements will be deprived of any means of determining whether a prospective shipment (through a particular packer, shipper, warehouse, etc.) would be in compliance with the law. This creates a “Catch-22” situation, in which the only way the importer can find out for sure whether a facility is *really* registered with FDA is to send a food shipment through that facility, and risk an inadvertent and unknowing violation of law, despite the importer’s best good-faith efforts to comply.

Importers and other interested parties (such as carriers or forwarders who may need to subcontract the storage of food shipments to a third-party warehouse) should be able to verify, with the FDA, whether a particular facility is in fact registered with the FDA under this provision. These interested parties should be able to query the validity of a specific registration number, and verify with FDA that the location and other essential aspects of the registration on file match the information provided by the facility operator. This will permit importers and other parties similarly situated to exercise due diligence and reasonable care, and will greatly facilitate their informed compliance with the law.

7. Many foreign facilities do not already have U.S. domestic agents or representatives as defined in proposed Section 1.227(c)(12) and apparently required by Section 1.232(f). Their current role in the supply chain simply does not require them to have direct contact with any U.S. entity. For example, a foreign warehouse that merely holds packaged food products on behalf of a foreign freight forwarder would be hired as a service provider by that foreign forwarder, nor by the U.S. importer or any other party with a U.S. presence.

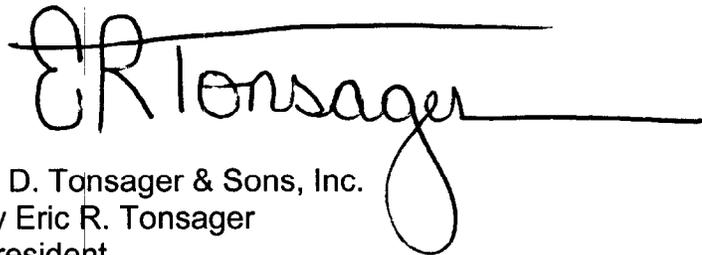
The importer may not know, and may not have any practicable means of learning, whether such a foreign entity is actually registered with FDA. Even if the foreign entity does submit registration information, either directly to FDA or through a U.S. agent, neither the importer nor FDA will have a practical means of verifying the accuracy of that information, within a reasonable time. This will be likely to delay FDA release of many imported food shipments, and cause importers to incur substantial storage costs for those shipments while they are being held in secure storage as provided by proposed Section 1.241(d) through (g).

Conversely, some foreign facilities may desire to directly control their own communications with the FDA, rather than filtering those communications through a U.S. agent. If FDA contact with the foreign facility must be through the facility's U.S. agent, both the foreign facility and FDA may be placed at substantial risk if the designated agent fails to fulfill its obligations to either or both. Thus, foreign facilities desiring to control and conduct their communications directly with FDA should have the option to do so, without a resident U.S. intermediary being required.

8. The costs of complying with the proposed registration requirements in their current form will be enormous, due largely to the extremely large number of affected locations, even for many very small businesses. Even if the time and administrative cost of a single initial registration is modest, the large number of locations – even for many small firms – and the burden of keeping details for each location current will be a cumulatively great administrative and financial burden on a large number of both small and large businesses.

Thank you for your consideration of the above comments.

Respectfully submitted,

A handwritten signature in black ink that reads "ER Tonsager". The signature is written in a cursive style with a long horizontal line extending to the right. The letters "ER" are large and stylized, followed by "Tonsager" in a more standard cursive script.

L. D. Tonsager & Sons, Inc.  
by Eric R. Tonsager  
President