National Coalition of Food Importing Associations

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

Re: Docket No. 02N-0277; Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The National Coalition of Food Importing Associations (NCFIA or the Coalition) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule implementing § 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) on maintenance and inspection of records for foods. 68 Fed. Reg. 25188 (May 9, 2003) (hereinafter the "Proposed Rule").

NCFIA is a coalition of trade associations that represent different segments of the food importing community. Members of NCFIA include the following trade associations: American Spice Trade Association, Cheese Importers Association of America, Association of Food Industries, The Cocoa Merchants' Association of America, and the National Fisheries Institute. Companies belonging to NCFIA member associations annually import over $13.5 billion in food products.

NCFIA joins in the comments of the National Food Processors Association (NFPA) regarding the Proposed Rule. The Coalition specifically joins in the comments of NFPA that state that FDA should, among other things:

- Provide safeguards to ensure that the Bioterrorism Act is implemented in accordance with all applicable constitutional limits on FDA's authority;
- Eliminate the lot tracking proposal which would impose an enormous burden on industry;
- Change the records access time requirement from 4 hours to within a time frame not to exceed 24 hours;

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- Exclude food packaging materials beyond immediate food-contact packaging from the scope of the record keeping regulation; and

- Lengthen the various implementation times following publication of the final rule.

While NCFIA strongly endorses the purposes of the Bioterrorism Act and the Proposed Rule, we believe that FDA lacks the statutory authority to apply the Bioterrorism Act's recordkeeping and records inspection provisions to foreign facilities and that the records access provisions of the Proposed Rule fail to expressly incorporate the statutory limitation on such authority.

I. FOREIGN FACILITIES

1. Section 306 of the Bioterrorism Act does not apply to foreign facilities.

Section 306 of the Bioterrorism Act adds a new § 414 of the Federal Food, Drug, and Cosmetic Act (FDC Act) (21 U.S.C. § 350c) providing recordkeeping and records inspection requirements applicable to "each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports" food. Nowhere in § 306 did Congress indicate that it intended to cover overseas persons or facilities. Nor is there anything in the legislative history of the Bioterrorism Act indicating that Congress intended that § 306 apply to foreign facilities.

2. There is a longstanding presumption in the law that legislation does not apply outside the borders of the United States unless Congress clearly expresses such an intent.

Congressional legislation is presumed not to apply extraterritorially, unless a contrary intent is clearly expressed by the Congress. As the U.S. Supreme Court has held, "[i]t is a longstanding principle of American law 'that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States.'" *E.E.O.C. v. Arabian American Oil Co.*, 499 U.S. 244, 248 (1991) (quoting *Foley Bros. v. Filardo*, 336 U.S. 281, 285 (1949). "Acts of Congress normally do not have extraterritorial application unless such an intent is clearly manifested." *Sale v. Haitian Centers Council, Inc.*, 509 U.S. 155, 188 (1993). "[T]he presumption against extraterritorial application of United States statutes requires that any lingering doubt" be resolved against a statute's extraterritorial reach. *Smith v. U.S.*, 507 U.S. 197, 203 (1993). *See also* American Jurisprudence 2d, Statutes § 359.

According to the Supreme Court, statutes with broad jurisdictional language regarding "interstate commerce" or "foreign commerce" do not apply overseas absent specific language indicating Congressional intent to reach beyond U.S. borders. *E.E.O.C.*, 499 U.S. at 250-51. (listing the Federal Food, Drug, and Cosmetic Act as one of several statutes "none of which have ever been

held to apply overseas"). Therefore, unless Congress clearly expressed its intent in the Bioterrorism Act that Section 306 should apply overseas, FDA may not infer extraterritorial operation based on the agency's belief that this would make implementation more efficient.

3. Under governing case law, FDA may not infer legislative intent to give a statute extraterritorial reach.

In determining whether to give a statute extraterritorial reach, the Supreme Court generally has looked to several factors including the language and structure of the statute, its purpose, and its legislative history. All of these considerations lead to the conclusion that Congress did not intend that § 306 of the Bioterrorism Act should apply overseas. To the contrary, they indicate that Congress did not intend the recordkeeping and records inspection provisions of § 306 to apply overseas.

First, nowhere in the language of the Bioterrorism Act is there any indication that Congress intended § 306 to apply overseas. Where the Bioterrorism Act did intend to reach foreign facilities, it said so explicitly. For example, § 305 of the Bioterrorism Act requires registration of certain "foreign facilities" defined as "a facility that manufactures, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States." Section 306, on the other hand, contains no reference to "foreign" anything. As the Supreme Court has held, "[w]hen it desires to do so, Congress knows how to place the high seas within the jurisdictional reach of a statute." *E.E.O.C.*, 499 U.S. at 258 (quoting *Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 440 (1989).[1]

Not only does § 306 not use the word "foreign," it does not use the word "facility" either. Section 306 applies to *persons*, not *facilities*. Yet, in the Proposed Rule, a statutory provision that applies to *persons* who manufacture, process, pack, distribute, receive, hold, or import food is inexplicably applied also to foreign *facilities* that manufacture/process, pack, or hold food for human or animal consumption in the United States.

Second, § 306 of the Bioterrorism Act does not provide any mechanisms for overseas enforcement of its recordkeeping and records access requirements. Such failure to provide mechanisms for overseas enforcement is compelling evidence that Congress did not intend § 306 to apply overseas. *See E.E.O.C.*, 499 U.S. at 256. Section 306 of the Bioterrorism Act provides that failure to maintain the required records is a prohibited act under § 301 of the FDC Act, subject to

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[1] "Congress' awareness of the need to make a clear statement that a statute applies overseas is amply demonstrated by the numerous occasions on which it has expressly legislated the extraterritorial application of a statute." *E.E.O.C.*, 499 U.S. at 258.

injunction under § 302 and criminal prosecution under § 303. Neither of the enforcement actions for a prohibited act, injunction or prosecution, can be taken overseas. If Congress had intended that § 306 should apply overseas, it would have provided a meaningful enforcement mechanism. For example, Congress could have provided that food products from foreign facilities that fail to comply with § 306 are adulterated and may not be imported into the United States. The fact that the Bioterrorism Act did not provide meaningful penalties for foreign facilities that fail to maintain the required records is further evidence that Congress did not intend to reach foreign facilities.[2]

Third, giving § 306 extraterritorial application would produce anomalous results. Section 306 requires maintenance of records "needed by the Secretary *for inspection* to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food...." (emphasis added). Yet, FDA lacks the authority to inspect foreign facilities. FDA acknowledges its lack of authority to inspect overseas facilities when, in the preamble to the Proposed Rule, the agency states that it "plans to take the appropriate steps and work closely with foreign governments to obtain access to the needed records if a threat of serious adverse health consequences or death to humans or animals from adulterated food necessitates inspection of records in foreign countries." 68 Fed. Reg. at 25191. If records are required to be retained *for inspection*, and FDA does not have the authority to inspect foreign facilities, this is further evidence that Congress did not intend the recordkeeping requirements of § 306 to apply to foreign facilities.

Finally, as discussed above, the legislative history of the Bioterrorism Act offers no indications, clear or otherwise, that Congress intended § 306 to have extraterritorial application.

4. FDA has offered no explanation of its statutory authority for applying the proposed rule to foreign facilities.

In the Proposed Rule, FDA extends the § 306 recordkeeping and records inspection requirements to all foreign facilities that are required to register with FDA under § 305 of the Bioterrorism Act. However, FDA does not, and cannot, cite any authority in the Bioterrorism Act for this interpretation.

FDA's only explanation is that the agency "believes if these foreign firms were not required to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food, trace back of food products from outside the United States would be

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[2] In stark contrast, in Section 305 of the Bioterrorism Act, Congress amended § 801 of the FDC Act in order to add a new enforcement mechanism for foreign facilities which fail to register. Under new § 801(l)(1), articles of food exported by an unregistered foreign facility are to be held at the port of entry and may not be delivered to the importer, owner or consignee until a proper registration is submitted.

severely compromised." 68 Fed. Reg. at 25191. FDA further states that "this approach provides the most efficient and effective strategy for obtaining needed information on food from foreign countries." *Id.* However, the agency's desire for efficiency cannot overcome the clear indications that Congress did not intend § 306 to apply overseas.

5. Extraterritorial application of Section 306 would potentially open all U.S. food exporters to similar requirements promulgated by our trading partners.

For policy reasons, applying Section 306 of the Bioterrorism Act to foreign facilities has the potential to create major new problems for U.S. food exporters. For reasons of reciprocity and maintenance of favorable trade relations, the United States would be hard pressed to object if our trading partners were to impose similar recordkeeping and records access requirements upon U.S. companies exporting food to their markets. Thus, extraterritorial application of the proposed rule could open U.S. exporters to the recordkeeping demands of the more than 150 foreign nations to which U.S. companies export food.[3] This would be a recordkeeping nightmare.

In conclusion, FDA does not have the authority to apply the recordkeeping and records inspection requirements in § 306 of the Bioterrorism Act to foreign facilities. Therefore, the final rule should apply to domestic persons only.

II. RECORDS ACCESS AUTHORITY

New § 414(a) of the FDC Act, added by § 306 of the Bioterrorism Act, provides that if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, then, if certain precedent conditions are complied with, FDA has the right to inspect and copy "all records relating to such article that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals."[4]

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[3] NCFIA believes this is further evidence that Congress did not intend for Section 306 to have extraterritorial application.

[4] While § 306 of the Bioterrorism Act contains a second records inspection authority (*i.e.*, § 306(b) which amends § 704(a) of the FDC Act), the legislative history makes clear that FDC Act § 704(a) "would provide the Secretary no greater access (either in circumstances during which records access is permitted, the types of records that may be accessed, or protections afforded records that are obtained)" than FDC Act § 414. *Congressional Record* H2858 (May 22, 2002) (managers' report).

This means that FDA may have access to these records for only two purposes: (1) for the purpose of determining whether an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, and (2) for the purpose of conducting a tracing investigation with respect to such an article of food. The statute identifies these, and only these, purposes. Moreover, the legislative history makes clear that FDA's authority to inspect and copy records is limited to these purposes.[5] Congressional intent to limit the circumstances in which FDA may have access to these records is also evidenced by the statutory requirement that FDA must provide a company with written notice before obtaining access to the records.

In the proposed rule, however, FDA appears to take the position that the agency may inspect and copy such records whenever it has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It is clear that Congress did not intend to give FDA such open-ended access to these records. Both the plain language of the Bioterrorism Act and its legislative history indicate that Congress intended to impose limitations on the circumstances in which FDA may have access to the required records. Those limitations are that an FDA official must present appropriate credentials and a written notice, and the purpose of the records inspection must be either to determine whether the food is adulterated and poses a threat or to conduct a tracing investigation.

Unless these limitations on records access authority are clearly and conspicuously set forth in the regulations, then the risk that FDA might exceed its statutory authority will be needlessly increased. The final rule, therefore, should include language which corrects this oversight.

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[5] "[T]he Secretary would have authority to gain access to and copy only those records needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences.... The managers envision procedures whereby no agency personnel will have access to records without a specific need for such access...." *Id.*

NCFIA thanks FDA for this opportunity to comment. The Coalition and its member trade associations are available to assist FDA in the smooth implementation of this important new requirement.

Very truly yours,,

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