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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 Cheese Importers Association of America, Inc. (CIAA or the Association) 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").

The Association is a tax-exempt trade association formed more than 50 years ago. Its members comprise a vast majority of the firms that import, market, sell and distribute this nation's supply of imported cheese, butter and other edible dairy products. CIAA members annually import dairy foods having a Customs value of approximately $1 billion.

The Association would like to inform FDA that it endorses and joins in the comments submitted by the National Food Processors Association (NFPA) regarding the Proposed Rule.

While CIAA 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 for the reasons set forth herein.

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.

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.

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 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

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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.

[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.

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.

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 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.

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

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CIAA thanks FDA for this opportunity to comment on the Proposed Rule. The Association is available to assist FDA in the smooth implementation of this important new requirement.

Very truly yours,,

Richard H. Koby,
General Counsel