National Coalition of Food Importing Associations

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VIA FEDEX AND ELECTRONIC MAIL
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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Comments On Regulatory Procedures Manual; Chapter 9, Imports – Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned [Docket No. 02D-0137]

Dear Sir or Madam:

The National Coalition of Food Importing Associations (the "Coalition" or "NCFIA") is pleased to submit comments to the Food and Drug Administration ("FDA") on the agency's draft Guidance Concerning Recommending Customs' Seizure And Destruction Of Imported Human And Animal Food That Has Not Been Reconditioned. 67 Fed. Reg. 67,410 (Nov. 5, 2002) ("Draft Customs Guidance"). NCFIA has grave doubts concerning the legality of the Draft Customs Guidance. Specifically, it appears that FDA is using the Draft Customs Guidance to circumvent the requirements of § 801(a) and § 304 of the Food, Drug and Cosmetic Act ("FD&C Act"), 21 U.S.C. § 381(a), § 334. NCFIA's objections are detailed below.

BACKGROUND

The FD&C Act sets out two methods by which FDA may proceed when handling the importation of food that may or does violate the FD&C Act. Under § 381(a), the United States Customs Service ("Customs") delivers to FDA samples of foods that are offered for import into the United States.

> If it appears from the examination of such samples or otherwise that such article ... is adulterated, [or] misbranded[,] then such article

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> shall be refused admission.... The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

21 U.S.C. § 381(a) (emphasis supplied). "Section 381 ... is purely an administrative procedure, which allows a quick and efficient means of protecting the American public from unhealthy or mislabeled imported goods." U.S. v. 2,998 Cases, 64 F.3d 984, 989 (5th Cir. 1995).

Courts have regularly held, and FDA has uniformly agreed, that as § 381 plainly states, the owner or consignee of an imported article that appears to violate the FD&C Act may chose to export the product within ninety days. "The parties agree that when the government acts under § 381 and refuses admission, it shall grant the importer 90 days in which to re-export the goods to its foreign supplier and shall destroy the goods unless they are exported." U.S. v. 8 Unlabeled Cases, 909 F. Supp. 129, 131 (E.D.N.Y. 1995) (emphasis in original). An importer's failure to recondition violative product "leaves him only with a choice of voluntary exportation (or destruction ...) or redelivery to Customs." U.S. v. Toshoku America, Inc., 879 F.2d 815, 819 (Fed. Cir. 1989). Accord Carl Borchsenius Co., Inc. v. Gardner, 282 F. Supp. 396, 401 (E.D. La. 1968) ("The defendants [FDA] agree that the owner or consignee could choose to export articles refused admission under the language in subsection (a) [21 U.S.C. § 381(a)]").

A second, judicial, avenue is available to FDA as an alternative to the administrative procedures of § 381. Section 334(a) provides in relevant part, that any article of food that "is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale ... after shipment in interstate commerce" may be ordered condemned by a federal district court. 21 U.S.C. § 334(a)(1) (emphasis supplied). See also 2,998 Cases, 64 F.3d at 988; 8 Unlabeled Cases, 909 F. Supp. at 131. Section 334(d) provides that any food condemned under § 334 shall be destroyed or sold as the court "may" direct and if the article was imported, and the owner or consignee can meet certain conditions, "the court may permit the article to be delivered to the owner for exportation in lieu of destruction." 21 U.S.C. § 334(d)(1). See also 8 Unlabeled Cases, 909 F. Supp. at 131. To initiate an action for seizure and condemnation, and to potentially foreclose the option of re-export, the FDA must prove the goods have been offered for importation (and therefore introduced into interstate commerce) and prove by a preponderance of the evidence that they are adulterated. 21 U.S.C. § 334(a); 2,998 Cases, 64 F.3d at 989.

The procedures and burdens the FD&C Act imposes upon actions under § 381 and § 334 are "quite different." 2,998 Cases, 64 F.3d at 992.

> When the government lacks the ability to prove a violation of the FDCA by a preponderance of the evidence, or when the risks to human health are not major or critical, the government can pursue the

> administrative procedures of § 381 and simply require reexportation of the goods. Consequently, the risk of property loss to the owner is minimized, threats to health and other interests of consumers are avoided, and no significant legal process is required. On the other hand, when the circumstances pose a critical risk to the health of United States citizens, the FDA has the option of initiating a judicial condemnation proceeding under § 334. In this situation, the FDA can destroy the goods without giving the importer the opportunity to re--export, but only after proving by a preponderance of the evidence that the goods are adulterated or misbranded . . . . . At the same time, § 334 allows the government a sure mechanism, i.e., destruction, to prevent the possibility of undetected re-importation of dangerous goods into the United States.

2,998 Cases, 64 F.3d at 992-93.

There are advantages and disadvantages to each approach. Courts have plainly held that an importer does not have the right in a condemnation proceeding to re-export refused product – a court may permit re-export, but the opportunity exists only at the discretion of the court. 2,998 Cases, 64 F.3d at 988; 8 Unlabeled Cases, 909 F. Supp. at 131. It is equally clear that the importer does have the right to re-export the refused article within ninety days if the FDA has proceeded administratively under § 381. Toshoku America, Inc., 879 F.2d at 819; ; 8 Unlabeled Cases, 909 F. Supp. at 131; Carl Borchsenius Co., 282 F. Supp. at 401.

DISCUSSION

I. Introductory Statement

The NCFIA is a coalition of trade associations that represent different segments of the United States food importing community. The members of the NCFIA are: American Spice Trade Association; Association of Food Industries; Cheese Importers Association of America; The Cocoa Merchants Association of America Inc.; and the National Fisheries Institute. The five organizations collectively represent over 650 importers and distributors of imported food products nationwide. These companies, like the vast majority of food industry firms, and the thousands of individuals throughout the country that they employ, share the common commitment that food products, whether imported or domestically produced, be pure, wholesome and in compliance with all applicable regulatory requirements.

II. The Draft Customs Guidance

In the Draft Customs Guidance, FDA seeks to eliminate by guidance fiat, the carefully delineated, and highly specific statutory regime described above that Congress has refined through

repeated amendments over almost a century. The Draft Customs Guidance, without citation to any of the legal authority discussed above, states:

> When a violative imported food appears to represent a significant risk to public health and is not successfully reconditioned, districts should submit a recommendation for destruction to the appropriate Center (Center for Food Safety and Applied Nutrition (CFSAN) or Center for Veterinary Medicine (CVM)) with a copy to the Division of Import Operations and Policy (DIOP) in ORA Headquarters.
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> ...
>
> DIOP should recommend seizure, forfeiture, and destruction by Customs of violative imported food that poses a significant risk to public health.

Draft Customs Guidance at 2 (emphasis added).

To define food that poses a "significant risk," FDA refers to its recall regulations:

> The product violation should represent a significant risk to health such as those covered by Class I recall. Class I recall is defined in 21 CFR 7.3(m)(1) as "...a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death".

Draft Customs Guidance at 2 (emphasis supplied). If adopted, under the Draft Customs Guidance, CFSAN or CVM and DIOP will review the District Office's destruction recommendation, and assess the significance of the risk posed by the product; then DIOP may recommend Customs seize and destroy the product. The DIOP referral would state that the product is an importation that is inadmissible into the United States. Draft Customs Guidance at 2-3.

III. The Draft Customs Guidance Is Contrary To Statutory Authority

The Draft Customs Guidance makes no reference whatsoever to the aforementioned provisions of the FD&C Act that specifically govern the importation of food that appears to be or is violative. The two-track option which allows the agency to proceed under either § 334 or § 381 has existed since Pure Food And Drugs Act of 1906. Congress modeled § 334 and § 381 of the FD&C Act on sections 10 and 11 of the 1906 Act, and did so "without substantial change." See 2,998 Cases, 64 F.3d at 990-91 (citing to H.R. Rep. No. 2139, 75th Cong., 3d Sess. (1938), reprinted in Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record 818, 827 (Dunn ed. 1987)).

The Draft Customs Guidance proposes a method for FDA to circumvent this governing statutory scheme of obligations and remedies that has existed for almost one hundred years. FDA

would eliminate the rights that inure to an importer under § 381 by taking a back door. The Draft Customs Guidance guts the importer's right to re-export while freeing FDA of the burdens the agency must bear in a § 334 proceeding.

If the agency believes the risk to health is so severe that it must foreclose the possibility of re-importation, the FD&C Act and Congress have required FDA to bear the burden of demonstrating the adulteration, by a preponderance of evidence, before FDA is permitted to destroy the article. The Draft Customs Guidance allows FDA to foreclose the importer's re-export right, and to do so on much weaker evidentiary grounds. Under the provisions of the Draft Customs Guidance, FDA can recommend that Customs seize and destroy product simply on the grounds that the product "may" be adulterated and has a "reasonable probability" of harm. Why would FDA ever again go through the cumbersome litigation burdens of § 334, when it can resort to the Draft Customs Guidance instead? The Draft Customs Guidance effectively writes the requirements of § 334 right out of the FD&C Act.

"Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted into law." FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120,125 (2000) (internal quotations and citations omitted). As with the scheme condemned in Brown & Williamson, the Draft Customs Guidance is "inconsistent with the intent that Congress has expressed in the FDCA's overall regulatory scheme." Id. at 126. The Draft Customs Guidance would allow FDA to circumvent the plain limits Congress has long placed on the agency and is, therefore, unlawful.

IV. FDA May Not Eliminate By Guidance What Congress Has Authorized, And Reauthorized

If Congress wished to limit the flexibility of § 381 and § 334, it has had ample opportunity to amend the statute and eliminate the right to re-export. It has not done so, although Congress has amended § 381 many times over the years. See 21 U.S.C. § 381 Historical and Statutory Notes (West 1999). As recently as in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "2002 Bioterrorism Act"), Pub. Law. No. 107-188, Congress, again, looked at the treatment of hazardous articles refused admission into the United States.

The 2002 Bioterrorism Act is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." Note, Public Law No. 107-188. In this broad legislation, Congress amended § 381, among other things, to increase inspections at ports, improve coordination among agencies, develop rapid testing methodologies, provide prior notice of importations, and require marking of goods that have been refused admission into the United States. See e.g., new 21 U.S.C. § 381(h), (j), (k), (m), (n). Even though Congress was addressing the same concerns that FDA uses to justify the Draft Customs Guidance – the problem of "port shopping" in which an importer attempts to re-import articles already refused entry into the United States – Congress did not alter the right of the owner or

consignee to re-export refused articles within 90 days under § 381. See 2002 Bioterrorism Act, § 308, § 309, Pub. Law No. 107-188. See new 21 U.S.C. § 381(n) and § 342(h).

Under the 2002 Bioterrorism Act, Congress required that food refused admission, which presents a threat of serious adverse health consequences or death, and is not destroyed bear the mark: "UNITED STATES: REFUSED ENTRY". See new 21 U.S.C. § 381(n)(1). The apparently intended routine use of the Draft Customs Guidance would render the new statutory provisions of the 2002 Bioterrorism Act meaningless. There is no point in requiring the marking of articles refused entry into the United States when, under the Draft Customs Guidance, FDA can easily order all such articles destroyed.

The Draft Customs Guidance would also substitute the very specific with the very general. The Draft Customs Guidance offers no statutory justification, save a brief mention of Customs' authority under 19 U.S.C. § 1595a(c) to seize food. Section 1595a(c) provides authority for Customs to seize property. It is most often used to halt smuggling and narcotics trafficking, but provides a very general authority to seize merchandise that is subject to any restriction "imposed by law relating to health, safety, or conservation and the merchandise is not in compliance with the applicable rule, regulation or statute." 19 U.S.C. § 1595a(c)(2)(A). In contrast, the elaborate , long established, and well-litigated scheme of the FD&C Act is intended specifically to regulate the commerce of foods, including those that may be hazardous to health. The Draft Customs Guidance leaps over this intricate network of amended statutes and implementing regulations, and replaces a detailed regimen specifically applicable to foods with one that is both general and hostile to the protections provided in the statutory scheme.

V. The Draft Customs Guidance Violates Customs Law

FDA does not have the statutory authority under the FD&C Act to implement the Draft Customs Guidance. The Draft Customs Guidance does not comport with Customs law either. Section 1595a(c)(2) only permits seizure on health or safety grounds if the article "is not in compliance with the applicable rule, regulation or statute." 19 U.S.C. § 1595a(c)(2) (emphasis supplied). The Draft Customs Guidance does not require that FDA or Customs shoulder such an evidentiary burden. If implemented, the Draft Customs Guidance would permit FDA to recommend seizure and destruction if the product "may" be adulterated and has a "reasonable probability" of harm. There is no requirement that FDA or Customs actually prove the adulteration and the harm the product poses to public health. Thus, the Draft Customs Guidance does not comport with the plain language of § 1595a.

VI. The Draft Customs Guidance Violates the Administrative Procedure Act

Agency actions are unlawful and will be set aside if, pursuant to the Administrative Procedure Act ("APA"), they are "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). As discussed above, FDA would exceed its statutory authority if it were to finalize and enforce the Draft Customs Guidance. The Draft Customs

Guidance circumvents the plain language and intent of the FD&C Act. It eliminates by guidance rights of importers that Congress and Courts have repeatedly affirmed. Adoption of the Draft Customs Guidance would not withstand a legal challenge under the APA.

VII. The Food Safety Rationale For the Draft Customs Guidance Is Unfounded

FDA justifies the Draft Customs Guidance on food safety grounds. However, the Draft Customs Guidance attempts to plug a perceived hole in the food safety net that does not need filling. FDA already has ample authority, and has had the authority since 1906, to eliminate the threat of re-importation of hazardous articles. Congress and the Courts have tested and approved these methods. This is not an instance where an agency must refer a matter to another agency because it lacks the statutory authority to pursue a potential wrongdoer. FDA already has the authority under § 334 to eliminate the risk of re-importation by referring the matter to the Department of Justice to initiate a seizure and condemnation action.

VIII. The Draft Customs Guidance Will Not Improve Public Health And Safety

According to the Draft Customs Guidance its purpose is "to ensure that imported food that poses a significant risk to public health is not distributed or exported or subsequently re-imported into the U.S.". The members of the NCFIA are at a loss to understand FDA's concern with this alleged illegal conduct, as we categorically maintain that the perceived practice, commonly referred to as "port shopping," is so rare that many knowledgeable food importers insist they do not know of even a single instance of port shopping.

As proof of the presumably widespread existence of port shopping the FDA has historically offered either no or insufficient evidence. Specifically, the agency relies on the conclusory statement of the General Accounting Office ("GAO"), which is not supported by any facts, concerning the existence of the conduct. Rather, the GAO relies on the anecdotal testimony before the Permanent Subcommittee on Investigations, Senate Committee on Government Affairs of an anonymous, previously debarred, customs broker. This unconvincing substitute for real fact finding and reliable investigation is completely unacceptable in the NCFIA's view.

FDA's assertion that port shopping goes on to any significant degree is implausible for the simple reason that importers have no economic incentive to engage in the practice, a fact which the GAO and FDA have apparently failed to even consider. To appreciate this lack of economic incentive, it must be remembered that there is little or no cost to the importer in the event merchandise is refused admission and must be re-exported. This is due to the fact that sale contracts almost universally provide that the goods must meet U.S. Government standards and in the event the merchandise is refused entry by the U.S. government the seller agrees: (a) to either take back the rejected goods or permit the buyer to sell them to another overseas market; and (b) to reimburse the buyer for any payment made against such goods, plus freight, insurance, labor, cartage, storage, interest and other expenses incurred by the buyer in re-exporting the goods. If the GAO and FDA

had conducted a proper investigation they would have discovered that this is standard business practice throughout the food industry.

There is, moreover, no commercial incentive for an importer to sell refused merchandise to its customers. Like other members of the food industry, importers strive to sell their products to repeat customers with whom they have established long term relationships. A supermarket chain or a food processor customer would be deeply disturbed if it discovered that one of its importer suppliers sold it goods which were refused admission for safety reasons. That would not only be the last time the importer got an order from that customer, but it is likely that news of the offensive conduct would spread throughout the trade, thereby threatening the importer's very survival as a viable business.

Not only has FDA failed to present any convincing proof that importers are, as it charges, bringing unsafe food back into the United States through port shopping, it has also failed to present any epidemiological evidence showing that public health has been jeopardized by the introduction of these re-imported foods. FDA and other Federal agencies (e.g., The Centers for Disease Control and Prevention) keep and release detailed information regarding outbreaks of food borne illness caused by imported foods and domestically produced foods alike. The failure of FDA to cite from this extensive collection of pertinent data to even a single instance of a food borne outbreak caused by a refused food that was subsequently re-imported attests to the fact that the Draft Customs Guidance will do little or nothing to improve public health and safety.

CONCLUSION

For the reasons stated above, the Coalition is opposed to the Draft Customs Guidance. The two-track statutory scheme of § 334 and § 381 not only grants FDA enforcement powers, it also places limits on the agency's authority. Litigation has repeatedly upheld these limits and Congress has repeatedly reaffirmed them. NCFIA urges FDA to reconsider and then withdraw the Draft Customs Guidance. This Guidance, if implemented, will not survive the court challenge that will most assuredly follow.

Respectfully submitted,
National Coalition of Food Importing Associations

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