American Association of Exporters and Importers

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December 24, 2003

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

Dockets Nos. 02N-0276 and 02N-0278

Dear Sir/Madam:

For more than 80 years the American Association of Exporters and Importers (AAEI) has been the national voice of American business in support of fair and open trade among nations. AAEI's expertise in international trade and customs matters is widely recognized in Washington and other national capitals. AAEI is the only national association dedicated exclusively to representing the interests of both U.S. exporters and importers before U.S. government agencies, Congress, international organizations, and foreign governments. Accordingly, it is with pleasure that AAEI provides the U.S. Food and Drug Administration (FDA) with its comments to the Interim Final Rules on Food Facility Registration and Prior Notice under the Bioterrorism Preparedness Act of 2002 (the "Act") published on October 10, 2003 [Federal Register: Volume 68, Number 197, Page 58893-59077]

Description of AAEI

AAEI's members include manufacturers, distributors, and retailers of a broad spectrum of products including chemicals, electronics, machinery, footwear, automobiles and automotive parts, food, household consumer goods, toys, specialty items, textiles and apparel, and footwear. AAEI membership also comprises organizations serving the international trade community such as carriers, customs brokers, freight forwarders, banks, attorneys, and insurance firms. AAEI's large and diverse membership base provides it with a high level of credibility among policy makers. As the chief representative of the U.S. international trade community, and of both importers and exporters, AAEI is able with particular effectiveness to make the point that trade restrictions and protectionism ultimately injure the world's largest consumer market and the world's largest exporter: the United States.

AAEI maintains a close and constructive liaison with U.S. Customs and Border Protection ("CBP" or "Customs"), working side-by-side with Customs managers on regulatory and policy initiatives that affect the efficiency and profitability of U.S. companies involved in international trade. AAEI also monitors and works with the Commerce Department, FDA, USDA, USTR, ITC, INS, and DOT, as well as other government agencies that have regulatory authority over trade across U.S. borders.

Because of the breadth of its membership and policy interests, AAEI is often called upon by Congressional committees to offer its technical expertise on policy and regulatory matters involving global commerce. Among the issues on which AAEI has provided testimony are U.S.-China trade, fast track negotiating authority, extension of the Generalized System of Preferences (GSP), and changes to the administration of dumping laws. AAEI also closely monitors export-related issues such as U.S. economic sanctions, export controls, intellectual property rights protection, and elimination of foreign barriers to U.S. exports.

General Comments

AAEI members are pleased by the progress made by the FDA between publication of the proposed rulemaking for Food Facility Registration and Prior Notice in February 2003 and the interim final rulemaking published on October 10, 2003. It is recognized that the FDA reviewed the nearly 500 comments it had received to its original proposal. It was also noticeable that FDA exercised a great deal of care and attention in considering all the comments that were received. AAEI is also appreciative of FDA's efforts at additional outreach for public input into the final regulations and for the continuing efforts by the agency to train, educate and motivate compliance by affected businesses and traders by promising transitional phases of enforcement.

In that regard, AAEI has, itself, solicited comments from its membership on the interim final regulations and, despite the general consensus that these rules are more friendly than those published earlier this year, there is also substantial concern that the interim regulations still do not reflect the unique concerns of specific transactions that take place within the global marketplace. As AAEI is certain that the FDA's intention is not to impede legitimate trade by its promulgation of these regulations or to exceed those authorities intended by Congress under the Act, AAEI respectfully submits the following concerns and suggested remedies to facilitate final rulemaking that clarifies procedures to be undertaken in particular circumstances by specific parties bearing in mind unique business concerns.

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I. Impact of Regulations on Imported Samples

Concern: Samples of articles are often collected or purchased abroad and imported into the United States as commercial samples, for display or distribution at trade shows, for market development, or for scientific research such as compositional analyses, research and development, standard of identity confirmation testing, or quality comparison testing. The sampling and analysis of products in international markets is an integral part of competition in the international trade of articles with food and/or non-food uses. In many instances, the registration number of the manufacturer of these articles may not exist because the manufacturer is not aware that the article is being imported into the U.S. Furthermore, it may be impossible for the sampler or the importer to ever know the manufacturer's registration number because the buyer can only identify the article's seller. Often, sellers will not reveal a product's source to a buyer for fear that the buyer will go directly to the source and cut out the intermediary. These are completely valid reasons to withhold a registration number from a buyer and they represent fully legal transactions. These articles may be imported for lawful purposes and no evidence exists giving rise to the appearance of any FDCA violation associated with the articles. Yet, the registration number may be unknown and from the buyer's, importer's, and sampler's perspectives, the number may be unknowable. The above general description applies to many imported samples.

There are two general scenarios that cause AAEI concern regarding imported samples:

1. Samples for Research or Scientific Analysis or Study Are "Multiple Use" Articles

Many imported samples of food are for research use or scientific analyses or study only and are not for human or animal consumption or general distribution in the U.S. The preamble to FDA's interim final rule on registration states that "if [research and development] facilities and sample facilities manufacture/process, pack, or hold food and this food is not for consumption or actually consumed in the United States, the facilities are not subject to registration." *See* 68 FR at 58921 (2003) (FDA response to comment 67). The prior notice regulation, however, permits omission of the foreign manufacturer's registration number from the prior notice submission only in the event that the article is intended for future export. *See* 68 FR at 58978. There is concern, therefore, that presenting the prior notice without manufacturer or other required registration numbers will result in refusal, even though the registration rule exempts such facilities from registration. AAEI is concerned that this sole exception places a burden of proof on the submitter to overcome what may appear to be an inadequate prior notice submission for failing to include the registration number resulting in refusal of admission under sections 801(1)(l) and (m) of the FDCA. The process to explain the absence of the registration number will take time, during which the importer, owner, or consignee will incur

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unnecessary storage and transportation costs associated with a prior notice entry review, secured storage, and/or refusal of admission.

Suggested Remedy: These samples are not for human or animal consumption but are for the purpose of research or scientific analysis. The samples may be in retail packaging or in collection containers. They may be labeled in compliance with the FDCA or may lack required labeling or English labeling and may, therefore, be misbranded within the meaning of FDCA section 403. The samples may arrive in multiple packaging varieties and sample container sizes, all in the same imported shipment or delivery resulting in dozens of separate prior notice submissions due to the mandatory requirement to provide the estimated quantity, including the packaging description. *See* 68 FR at 58978. *See also* 21 C.F.R. § 1.281(a)(5)(iii). Some analyses require the sample be prepared at the point of collection, and some sample preparation necessary to ensure the analyte can be recovered from the sample renders the article a non-consumable. Although some analyses can be conducted in other countries, many times states that rely on the analytical results require the analyzing laboratory to be certified by the state or a federal agency or department, such as the Environmental Protection Agency, the U.S. Department of Agriculture, or the FDA.

These logistical difficulties in submitting prior notice seem unnecessarily burdensome to both the industry and the FDA. Furthermore, although the articles could ordinarily be directed to a food use, they have scientific or research and development, non-food uses. Consequently, these samples are "multiple-use" articles as described by FDA in the preamble to the prior notice interim final rule. *See* 68 FR at 58986-87.

FDA provided a standard for determining whether prior notice is required for an imported item with multiple uses, saying:

> FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.,* submitter, transmitter, manufacturer, grower, shipper, importer, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.

In the case of all of the samples described herein, none of the persons involved in importing or offering the product for import has any belief or expectation that the imported substance (the sample) will be directed to food use. Furthermore, the prior notice requirements are so burdensome, and the importation of samples so frequent, that there is a likelihood that FDA's prior notice rule will tend to drive analytical laboratory operations, and the jobs and technology associated with those labs, out of the United States.

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Consequently, AAEI urges FDA to state explicitly that all imported samples for any scientific research, for example, compositional analyses, research and development, standard of identity confirmation testing or quality comparison testing are "multiple-use" articles to which the above quoted standard applies for determining whether prior notice is required.

2. Samples for Trade Shows, Market Development, Commercial Demonstration and the Registration Number Requirement in Prior Notice

A second example of import samples for which AAEI members have concern involves articles imported for commercial purposes that may or may not be consumed, excluding samples for scientific or research uses. For instance, two critical aspects of international trade include the ability to directly compete with other international or domestic companies in a particular market and the ability to identify potential new international markets for expansion, sales, and distribution. Often, food samples are imported for the purposes of identifying whether a foreign food product would find a favorable market in the U.S. or to identify whether interest in such products is regional or seasonal.

Although prospective customers in the U.S. may consume imported commercial trade food samples, there are legitimate reasons why the importer may not have access to the foreign manufacturer's registration number. By requiring the manufacturer's registration number in prior notice submissions for imported food that is not in its natural state, FDA essentially assumes that all importers and exporters have the market power to compel a foreign manufacturer to reveal its registration number. That is simply unrealistic and ignores the leverage FDA has created in food manufacturers enabling them to define secondary markets even though such markets are completely legal. The Bioterrorism Act does not require inclusion of a manufacturer's or shipper's registration number in a prior notice. Rather, the statute requires prior notice include the "identity of" these entities. FDA has added the registration requirement for its own convenience. But the result is the elimination of certain otherwise legal markets while no food safety or security benefit is derived. This is truly a technical violation with no public health and safety benefit.

Suggested Remedy: All imported samples of food should be exempted from prior notice submissions, or in the alternative, the prior notices for any sample should be exempted from the requirement to provide the manufacturer's facility registration number. The BTA itself was originally intended to require prior notice only for goods imported or offered for import. FDA clearly has demonstrated its discretion to offer exemptions that will allow expeditious entry of goods that pose no risk to the health or safety of any animal or human within the U.S. marketplace, such as the exemption covering personal use food items. This is a circumstance where such an exemption should be provided, fulfilling the purpose of the statute while avoiding a system that

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subjects researchers to the costs and delays of appealing unnecessary refusals at the border.

Concern: Many multinational companies send executive and holiday–type gift baskets to U.S. subsidiaries or customers. The only exemption in the regulation for providing the manufacturer's registration number on the prior notice in connection with products sent as gifts is in connection with those products sent for non-business purposes from one person to another (Section 1.281(6)). To force manufacturers' registration numbers on prior notices for articles that are sent as business gifts with no commercial value or purpose appears to be unnecessary given the FDA's apparent understanding and appreciation of the impossibility of obtaining registration numbers from totally unrelated manufacturers and/or from manufacturers that may have no knowledge that their products will ever be sent to the United States as holiday gifts. There is no reason why business-related gifts should be treated any differently than personal gifts sent to the United States. If the prior notice submission for personal gifts requires only an indication of the manufacturer's name and address as it appears on the product's label, then the same requirement should be enforced and permitted for gifts arriving in the United States from one individual to another in a business setting. There is no more or less of a safety risk with a gift shipped from one person to another than there would be with a gift shipped from one business address to another.

Suggested Remedy: Prior notices submitted for food articles included within shipments of gifts, of nominal commercial value except to generate goodwill among colleagues, should be permitted to reference the manufacturer's name and address as shown on the label in lieu of the registration number of that manufacturer. This is the remedy already adopted by the FDA to permit gifts of a solely personal nature.

Similarly, many of our members have operations in various parts of the world. When personnel are relocated, the company arranges and pays for their personal effects to be shipped to their next posting. As currently written, the regulations would seem to require registration and prior notice for the liquor and processed/preserved foodstuffs that an employee is shipping to his or her next posting, which just happens to be in the U.S. We contend a similar exemption should apply in these circumstances as the only consumption intended is within the family of the person shipping his or her effects.

II. Refusals

Concern: There is a need to implement regulations that provide carriers with greater flexibility regarding where they may deliver refused goods to which they have no title or ownership interest, because of the great variety of circumstances that could lead to a refusal at the port of arrival and FDA's insistence -- as set forth in its preamble to the BTA Interim Regulations but nowhere else in actual Interim Regulation itself -- that its

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only responsibility is to notify the carrier in the event of a refusal. Carriers should be provided with the ability to unload refused cargo quickly and without imposition of further delay that will necessarily impact upon all other customers dependent upon prompt delivery of the remaining cargo that is a part of the carrier's load and in compliance with the applicable import requirements. To claim that the FDA itself is without the resources to advise parties other than the carrier of refusal at the port of arrival is unrealistic, as refusal can easily be conveyed to the party who transmitted prior notice. Further, it is unrealistic to put the burden on the carrier by requiring notice within 24 hours of where the refused merchandise will be delivered under custodial bond (Section 1.283(2)(ii)), and then to expect delivery to be made "immediately". When taken together, these burdens impose an unreasonable obligation and exposure to the business of carriers. A carrier seldom arrives at a U.S. port loaded with only a single importer's merchandise and a carrier is subject to terms of delivery of multiple U.S. customers. To disrupt this entire chain of product distribution by insisting it is up to the carrier to communicate messages of refusal to the appropriate parties and to then consult and cooperate on delivery and/or segregation of the refused merchandise to the detriment of all other merchandise in its load is unreasonable and unnecessary. If the carrier is to bear this burden, the options available to it for unloading the refused merchandise must be several and flexible. Such flexibility may easily be provided without compromising the intent or integrity of the BTA or the FDA's implementing BTA Regulations.

Suggested Remedy: Carriers should be permitted a variety of options when and if they are advised that one or more products within a shipment has been refused due to a problem with prior notice. These options may include, without limitation, permission to hold the load at the border while the proper information is submitted to the FDA and before mandatory notice of intended destination for delivery; returning the load to the exporting facility directly; holding the load at a designated carrier's closest facility; and/or holding the load at a designated FDA holding facility, not necessarily a GO bonded warehouse, near the port of entry.

III. Targeting High-Risk Imports

Concern: While AAEI members understand and appreciate that the FDA has yet to become fully familiar with existing CBP security certifications such as C-TPAT so as to have assurances of product integrity and safety throughout the entire supply chain, companies that have put in place systems to ensure and certify the security mechanisms and procedures of their carriers, brokers, manufacturers, exports and warehouses certainly pose lower risks than companies that have not implemented such certified systems. To overlook this fact in favor of uniform review of all prior notices regardless of the identity of the parties or the characteristics of the shipment, is to unintentionally overburden the FDA itself.

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In the preamble to its BTA Interim Final Rules, the FDA states that "The stated purpose of requiring notice of imported food shipments before arrival in the United States is to enable FDA to conduct inspections of imported food at U.S. ports (*see* section 801(m)(1) of the FD&C Act). Thus, FDA intends to use prior notice information to make decisions about which inspections to conduct at the time of arrival. Currently, we intend to focus on conducting these inspections when our information suggests the potential for a significant risk to public health." Why then would the FDA not wish to consider whether or not a prior notice submitter is C-TPAT certified or a member of a carrier security program as a factor of its determination of which articles warrant inspection? While concededly not identical in terms of objectives and qualification, the Customs security programs, especially C-TPAT, and the BTA have overlapping goals and are very similar in terms of intent and objectives, i.e. to secure products and their distribution throughout the supply chain. C-TPAT certified companies have CBP's acknowledgement that they have implemented security systems sufficient to warrant expedited treatment for purposes of entry of products into the United States. It seems likely that the FDA would want to know whether a company is C-TPAT certified or a carrier has a recognized security program as major elements in its assessment of whether a given shipment poses a more "significant risk to public health" than others.

Suggested Remedy: Provide an option, as a part of the prior notice submission, to identify whether or not the submitter is C-TPAT certified. In this way, both CBP and FDA will be able to isolate higher-risk imports that require more attention from both agencies.

IV. Presentation of PN Confirmation Numbers Upon Arrival

Concern: The FDA has indicated to a number of AAEI members that any trucker that is not PAPS-certified will be required to present the PN Confirmation Number upon arrival at the border, even if the PN was submitted via the ACS system. This is contrary to the interim regulations that indicate that the PN Confirmation Number will only be required to be presented in the event the PN was submitted via the FDA PN interface.

Truck drivers will often be unable to obtain the PN Confirmation number prior to arrival given the short distances between traditional shipping points in Canada or Mexico and the United States and the fact that the PN will oftentimes not be submitted until after the trucker has already departed with his load. Necessarily, the PN will not be submitted by the drivers because submissions through ACS systems will only be possible by brokers and other certified personnel and, although arguably truck drivers may be able to transmit the PN through the FDA interface system themselves, truck drivers are not the supply chain participants which most traders operating at either land border desire to hold

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responsible for this important pre-arrival submission. Accordingly, compliance with the BTA regulations in the most feasible manner for traders utilizing the northern border will result in refusals if truck drivers will only be able to deliver goods for which they have PN confirmation numbers on hand.

Requiring PAPS authorization as the only means of avoiding these delays is to mandate that all truck companies become C-TPAT certified and otherwise comply with the designation requirements. For a variety of reasons, certain companies are unable to bear the expense of enrolling in the PAPS program. Moreover, the FDA seems to have distanced itself from all Customs-related certification programs apparently seeing them as inadequate to meet FDA security guidelines. Accordingly, it is contrary to both FDA's position and the goals of the BTA to advise truckers that unless they participate in the PAPS system, they are unlikely to be able to unload their cargo. It would make more sense to work with Customs to upgrade existing security programs to incorporate FDA's needs.

This is an even more valid concern given the fact that AAEI members have been further advised that truckers not possessing the PN number upon arrival would have, as their only recourse, immediate exportation of that load via an IE. Again, exporters and importers on both sides of the border are willing and making suitable adjustments in existing business operations to ensure compliance with the BTA regulations. To complicate these goals by insisting that drivers present a PN Confirmation number upon arrival, which is quite simply unavailable to them and which, in fact, will be available to Border Port personnel at the time of crossing does nothing to further the goals of the BTA: it is merely an impediment to expeditious delivery of otherwise safe, secure and compliant product.

Suggested Remedy: The BTA Regulations should be uniformly enforced at all borders and in connection with all carriers so that, as set forth in Section 1.279(g) of the BTA Regulations, the PN Confirmation Number will only be required to be presented when the PN is transmitted through the FDA Prior Notice system.

V. Registration Process

Concern: The liability for not registering a facility required to be registered under the BTA Regulations lies with the owner, operator or agent in charge of that facility. Is this the owner of the building which leases out to perhaps hundreds of different tenants portions of that space, only a small percentage of which are related to food storage? If that owner has no obligation to identify the specific tenants within its building that are in food-related businesses, then registration of that building merely by address will not serve the stated purpose of facility registration: "Registration is one of several tools that will enable FDA to act quickly in responding to a threatened or actual

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terrorist attack on the U.S. food supply by giving FDA information about facilities that manufacture/process, pack, or hold food for consumption in the United States" because the FDA will have no knowledge to identify which of the tenants in that building performs the operations related to food products. Moreover, the "agent in charge" of a facility may not have the necessary authority to register a particular facility as this is an undefined term in the regulations. While certainly the manager of a particular facility may have the knowledge about that facility necessary to adequately complete the registration submission, there may be particular facility owners that may elect not to register certain facilities for a variety of reasons. Finally, while it certainly relieves a burden of a facility to enable authorization of a third party to register that facility, without a uniform method of evidencing such authority there is a probability that multiple parties may believe that such authority to register has been vested to it and accordingly multiple parties may register the identical facility, all of which conceivably may lack proper authority to do so.

Suggested remedy: The BTA regulations should be amended to clarify, as set forth by Congress in Section 415 the Act, that the intended registrant of a facility is the party conducting business within that structure. Under the Act, Congress defined the intended registrant of a facility as the party -- whether the owner, operator or owner in charge thereof -- conducting business within a particular facility who then has a further obligation to advise the FDA of all facilities at which it conducts such business. The FDA, however, has eliminated such a precise definition of a facility registrant and, as a result, for example, the owner of a multi-tenant facility who may, in fact, have no role in food-directed business, may register that structure's address with the FDA solely as a means to avoid prosecution under the Regulations. This is an unfortunate consequence of the BTA Regulations not specifying that the necessary facility registrant is that party with knowledge of the food-directed business conducted within the facility's walls. Accordingly, the FDA should amend the BTA Regulations to ensure that facilities are registered by those parties able to provide information helpful to its stated objective of maintaining an inventory of food-related businesses that manufacture or process or store food for consumption in the U.S.

Concern: The regulations clearly indicate that the FDA intends to validate foreign facility compliance with the registration requirements by cross-linking the information contained in the prior notice with facility registration information. However, in connection with domestic facilities, no such verification procedures appear to be in place. This invites discriminatory treatment between foreign and domestic food facilities.

Suggested remedy: The BTA regulations should be amended to clarify the enforcement mechanisms that will be put in place to ensure domestic facility compliance.

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Concern: While mobile facilities are required to register, by their very definition, these facilities will have no address and may perhaps lack additional information required to be submitted in the present form of registration.

Suggested remedy: The BTA regulations should be amended to clarify the required information for stationary and mobile facilities.

Concern: Because importers have no means to verify registration numbers for foreign suppliers/manufacturers, there is an increased likelihood of multiple registrations for the same facilities and/or unauthorized registrations. The possibility of duplicative, impromptu and perhaps unauthorized registration of foreign facilities as a means to facilitate entry is necessarily increased because of the concern by importers and the absence of a standardized form of authorization in the BTA regulations. While the FDA is prohibited under the BTA from disclosing specific registration information to third parties, it should develop a means whereby it is able to provide an importer with information to confirm or deny the registration of a given foreign supplier in order to know whether or not a product exported or intended for export from that facility may be legally entered into the United States. To deny such a process is to intentionally favor refusal and/or fraudulent registration.

Suggested remedy: Provide a means for verification of facility registration, even if such verification does not disclose any information beyond affirmation or denial. In addition, as already suggested, there must be a standardized, uniform form for authorization to register that is made a part of the BTA Regulation to permit unauthorized registration of foreign (and, in fact, domestic) facilities.

VI. Coordination Among Agencies

Concern: There has been a proliferation of security-related rulemaking since September 11, 2001 and, as a result, a hodgepodge of requirements exists for what needs to be filed when and by whom in connection with imported goods. This will necessarily lead to delays, added costs and unnecessary burdens on importers and exporters alike.

For example, on December 5, 2003, the Department of Homeland Security published its final rules for advanced cargo manifest transmissions (Federal Register, Volume 68, Number 234, Page 68139-68177]. Under these rules, the U.S. Principal Party in Interest or its agent must electronically submit to DHS required cargo information pursuant to the following requirements: for cargo arriving by vessel no later than 24 hours prior to departure from the foreign port; for cargo arriving by air no later than 2 hours prior to the scheduled departure time, or at "wheel's up" (depending upon place of departure); for cargo arriving by truck no later than 1 hour or 30 minutes prior to arrival of that truck at the border (depending upon whether or not enrolled in FAST) and for rail

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no later than 2 hours prior to arrival at the border. These time frames are largely inconsistent with the submission requirements under the BTA, although much of the information required for both types of filing is the same. As a result, for a single shipment of goods, importers will need to set up systems to ensure timely and accurate compliance with the DHS regulations in addition to and separate from those systems necessary to ensure timely and accurate compliance with the BTA regulations. Insofar as both regulations are intended to ensure the safety of products entering the domestic marketplace, this duplicative effort will necessarily result in increased costs, burdens and delays.

Suggested remedy: It is urged that FDA, CBP and DHS continue their work at coordination of time frames and requirements without unnecessarily increasing the burdens upon U.S. importers and exporters in a manner certain to impede free trade and the free flow of products throughout the global marketplace. Lack of existing technology to permit such coordination is an unacceptable reason for expediting implementation of multiple and conflicting rules to the detriment of tax-paying and law-abiding U.S. businesses.

VII. Prior Notice Data Elements

Concern: While the FDA has indicated that a change in anticipated arrival information after submission of a timely filed and otherwise sufficient prior notice will not render that prior notice inadequate, such a cognizance begs the question of why the information is being requested at all. The recent Memorandum of Understanding between CBP and FDA ensures that the agencies will work together to prevent products from entering the United States if either agency is concerned that they pose a threat to the health or safety of any person or animal located within the domestic marketplace. Coupled with the fact that arrival information will often change between submission of the prior notice and actual arrival of a product at a U.S. port and that such a change is no longer fatal to the prior notice submission, there is no benefit gained by requiring arrival information as a part of the initial prior notice submission.

Suggested Remedy: The BTA Regulations should be amended to eliminate the requirement that prior notice submissions must include anticipated arrival information. Concerned that inaccurate arrival information contained within a prior notice may lead to increased inspections or delays upon arrival -- even in light of FDA assurances that such amendment is not in and of itself fatal to the submission -- U.S. importers are uncomfortable with even unintentionally providing inaccurate information in the prior notice. This fear arises because it is difficult to understand why the FDA would ask for anticipated arrival information at the same time the Agency assures transmitters that if that arrival information is incorrect there will be no penalty assessed. If the information is likely to be imprecise, if the FDA recognizes the likelihood of such imprecision, if the

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FDA has made an agreement with CBP to ensure that no matter the port of arrival sufficient personnel exist to ensure examination of merchandise suspected of prior notice infractions, then why would the FDA still insist upon the transmission of such information except as a means to "catch" an otherwise compliant importer? Because there is no longer a legitimate reason to require anticipated arrival on prior notice and because necessarily the majority of such information will be incorrect at the time of transmission, the BTA Regulations should be amended to eliminate the requirement that prior notice require anticipated arrival information.

VIII. Dual Use Products

Concern: As described above in connection with the comments about imported samples, the preamble to the BTA Regulations indicates that the FDA will determine whether or not a substance is a food or non-food, if it could reasonably be considered either, "if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use." However, for purposes of both CBP guidance and anticipated FDA enforcement guidance documents, there does not yet appear to be any uniform procedure for proving or disproving that a particular item is not, by anyone in the supply chain, intended for direct food use. This is especially true since the sole determination of whether or not a prior notice will be required is the combination of HTS codes with FDA product codes and these have already been categorized so that the systems are "triggered" to require (or not require) the prior notice filing by a designation of either FD3 or FD4. Accordingly, an importer will bear the burden of proof to show that there is no intention by any party involved in the importation that the substance will be directed to a food use, after the article has been refused and while the importer is paying storage and transportation costs associated with such a refusal.

Suggested Remedy: Amend the data elements in the prior notice submission to permit an affirmation that a substance is not directed for a food use in order to avoid the requisite refusal for an article otherwise categorized as requiring such a submission. Submitters of the prior notice at the time of submission already know whether or not anyone within the supply chain reasonably knows whether the article will or will not be reasonably directed to a food use. Accordingly, there must be a method provided allowing the submitter, or the transmitter, to disclaim the need for prior notice at the time of prior notice transmission.

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IX. Exemption of Certain Foreign Trade Zone Imports from Prior Notice Requirement

Concern: AAEI believes that articles of food imported and admitted into an FTZ in or adjacent to the port of arrival as "zone restricted status" merchandise, and then exported from the port of arrival under an IE entry, is sufficiently similar to the IE entry process that it "in essence" subjects the food to the same restrictions as would be imposed if the food were refused admission under section 801(m) of the Act. Therefore, we believe FDA should exempt such imports from the prior notice requirements.

Suggested Remedy: In the case of imported food that is admitted into an FTZ in or adjacent to the port of arrival under a Customs and Border Patrol (CBP) Form (CF) 214 and removed for export from the port of arrival on an out-bound conveyance, we believe that the cargo is sufficiently controlled by CBP regulations and the bond conditions governing the FTZ and its owners and operators that prior notice should not be required. We recognize that FDA has already considered whether food admitted into an FTZ is "imported" into the U.S. (68 FR at 58991), however, FDA did not discuss the significant control CBP has over merchandise with a "zone restricted status" in an FTZ. Furthermore, we understand that FDA's decision to exempt food imported under an "IE entry" from the requirements of the prior notice rule is based upon the distinction that they are "subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export." *Id.* We believe, however, that the "IE bond" contains precisely the same conditions as those in a basic importation bond, and that this is a distinction without a difference. *See* 19. C.F.R. §§ 113.62 and 146.67(b). Rather, the issue is whether the articles "in essence" remain in the port of arrival until they are exported. We respectfully submit that CBP's recently published procedures for handling food that is refused under section 801(m) of the Act could be adapted to permit the admission of food under "zone restricted status" into an FTZ prior to export from the port of arrival even without requiring prior notice of the initial importation while maintaining the essence of FDA's concern.

Food that is imported for export from the port of arrival could be entered into an FTZ under a "zone restricted status", which permits admission into a zone solely for exportation, destruction, or storage. *See* 19 C.F.R. § 146.44(a). Once merchandise is so designated, the restriction cannot be abandoned and cannot be removed to the Customs territory for domestic consumption unless the FTZ Board determines it to be in the public interest to do so. *Id. See also* 19 U.S.C. § 8a(b) (defining "Board" as "the Board established to carry out the provisions of" the FTZ Act). Although the preamble to the interim final rule states that articles admitted into an FTZ may be entered for consumption (68 FR 58991), such entry on goods that are in a "zone restricted status" may only occur if the FTZ "Board has ruled that [the] merchandise can be entered for

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consumption." *See* 19 C.F.R. §§ 146.63(b) and 146.70(a). In fact, before "zone restricted status" merchandise may be removed from a zone and entered for consumption, the CBP District Director must endorse the ruling made by the Board that the removal is in the public interest. *See id.* at § 146.70(b). Additional restrictions also apply to "zone restricted merchandise." *Id.* at §§ 146.64(b); 146.70(a); *see id.* at § 146.2. Furthermore, direct and immediate export of articles admitted in a zone occurs under "an entry for Immediate Export" on a CF 7512. *Id.* at 146.67(a) and (b).

All merchandise in FTZs is strictly controlled and supervised by the zone operator and under the control of CBP. *See id.* at §§ 146.3; 146.23; 146.51; 146.12 and 146.32(b)(4). Violations of CBP requirements regarding the management of an FTZ in any particular, including adequate supervision and control over goods under "zone restricted status" are subject to civil penalties and liquidated damages. *See id.* at § 146.81, citing 19 U.S.C. § 81s. In more egregious cases, the CBP Port Director may suspend the activated status of a zone for 90 days (19 C.F.R. § 146.82) or recommend to the Board that the privilege of operating a zone or subzone be "revoked for willful or repeated violations of the [FTZ] Act." *See id.* at § 146.83, citing 19 U.S.C. § 81r. Furthermore, and consistent with FDA's recent Compliance Policy Guide regarding FDA's and CBP's joint enforcement policy, an unauthorized withdrawal into domestic commerce of "zone restricted status" foods, for which no prior notice has been received by FDA, would constitute an "importation contrary to law" within the meaning of 19 U.S.C. § 1595a(b). *See CPG 110.310, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,* http://www.cfsan.fda.gov/~pn/cpgpn.html (last viewed Dec. 19, 2003). Such activity would subject any person who "directs, assists financially or otherwise, or is any way connected in any unlawful activity mentioned in [section 1595a(a)] . . . to a penalty in the amount equal to the value of the article . . . ." *See* 19 U.S.C. § 1595a(b).

Finally, we believe that CBP's procedures for handling food entries that are subject to prior notice but for which no such notice has been received or the notice is inadequate, requiring the food to be "held" in the port of entry, permit a similar process as recommended herein with regard to FTZ "zone restricted status" entries. CBP states that for food that is subject to a "BTA hold", the shipment is to be retained in the port of arrival. *See Interim Bioterrorism Act (BTA) Procedures for Trade Partners* 25, http://www.cbp.gov/ImageCache/cgov/content/import/commericial_5fenforcement/bioterrorism/bta_5fprocedures_2edoc/v2/bta_5fprocedures.doc (last viewed Dec. 19, 2003). But CBP allows for the movement of a shipment that is refused under 801(m) "if [the] shipment cannot be held within the port limits." *See id.* at 26. In such cases, CBP permits the refused food to be "sent to the nearest suitable facility outside the port" under a CF 7512. *Id.* CBP requires certain cautionary language to be added to the CF 7512 indicating the food is not "currently" admissible and allows 48 hours to deliver the food to a designated facility. *Id.* These procedures permit, therefore, in-bond movement of

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foods that are refused under section 801(m) of the Act and storage outside the port of arrival. To accomplish this, CBP established strict supervision and monitoring requirements and tracks the food from the port of arrival to the suitable storage location outside the port of arrival limits. The CF 7512 used for the in-bond movement must be clearly marked that the food is not "currently" admissible to ensure adequate notice to CBP officials of the status of the goods. Remarkably, the carrier delivering the refused food in-bond to the storage facility outside the port of arrival limits has 48 hours to complete the delivery.

Based on the foregoing considerations, AAEI believes the FDA should exempt zone restricted status imports from the prior notice requirements.

CONCLUSION

AAEI appreciates the opportunity given to its members, and others in the industry, to provide further comments to the FDA on its BTA regulations. It is sincerely hoped that the concerns noted in this correspondence, together with the suggested remedies, are helpful to the FDA and will be carefully considered as they are of great import to the importing community.

Should there be any further questions or concerns regarding the foregoing comments or any other issue impacting upon AAEI's members, it is respectfully requested that the undersigned be contacted directly.

Respectfully submitted,
American Association of Exporters and Importers

By:

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