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

**Re: Docket No. 02N-0278
Prior Notice of Imported Food Under the Public Health
Security and Bioterrorism Preparedness and
Response Act of 2002**

Dear Sir or Madam:

The National Coffee Association of USA (NCA) appreciates the opportunity to submit comments on the above referenced proposed rule, as published in the Federal Register (68 FR 5428, February 3, 2003).

NCA represents the US coffee industry, which generates \$18 billion annually in sales and conducts \$3 billion in trade with 30 countries from Asia, Africa and Latin America. In addition to the more than one thousand roasters and importers, the industry is comprised of some 10,000 coffee cafés employing persons in every state and region. Through retail, restaurant and coffee café sales the industry serves 177 million consumers annually. NCA membership, consisting, in part, of coffee growers, exporters, importers and roasters, will be impacted by the Bioterrorism Preparedness and Response Act and associated regulations.

The Food and Drug Administration (FDA) is to be commended for its efforts in developing regulations in an expedited time frame in order to comply with the statutory deadline of December 12, 2003, as provided in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The National Coffee Association shares the FDA's concern with

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regard to protecting the nation's food supply and appreciates the tremendous effort put forth by the agency in the development of the above referenced regulation. NCA recognizes the challenge FDA has to comply with the constraints of the Bioterrorism Act, while at the same time developing regulations that don't "...become a barrier to the smooth flow of commerce." (Conference Report at H2858)

The heightened urgency of promulgating the above referenced regulations places extreme importance on developing a final rule that is not overly broad, thereby facilitating compliance and enforcement, and most importantly protecting the U.S. food supply by facilitating FDA's response to a threatened or actual terrorist attack. Although the NCA is supportive of FDA's efforts and generally supportive of the proposed regulation referenced above, the NCA is concerned that some parts of the regulation are more burdensome than necessary to provide for the availability of food import inspection personnel. NCA encourages the FDA to, as instructed by Congress in the Conference Report at H2858, "exercise discretion to ensure that neither the requirements of the notice nor the timing of the prior notice be more burdensome than necessary to provide for the availability of food import inspectional personnel," and reconsider its position on some issues.

Allowance for Low Risk Importers/Coordination with Electronic Information Systems

NCA notes that the proposed regulations do not take into account low risk purchasers and importers. As previously indicated to FDA in comments dated August 30, 2003, NCA urges FDA to adopt a system that provides for articles of food being imported by low risk companies to move through the import process in an expedited manner. NCA encourages FDA to invest the needed resources to develop a system in a timely/priority manner that is coordinated and linked with other existing electronic information collection system(s) such as the Customs Trade Partnership Against Terrorism (C-TPAT) system, Customs' Automated Commercial System (ACS), and FDA's OASIS reporting system, as appropriate. Such a coordinated system could provide efficiencies to both agencies and allow FDA to differentiate low risk importers from others, thereby allowing more resources to be focused on purchasers and importers that are not deemed low risk. Further, a comprehensive coordinated system would significantly reduce duplication of information submission created by the combination of the proposed rule and other requirements for information submission set forth by FDA and Customs, as well as the effect of the Bioterrorism Act on commerce. In fact, Congress has expressly instructed the Secretary to consult with the Department of Treasury to "assure that smooth coordination is achieved between FDA and U.S. Customs" (Conference Report at H2858). This intent is supported statutorily in section 307(b) of the Bioterrorism Act, wherein the Secretary is directed to consult with the Secretary of the Treasury.

Although as proposed FDA is requiring that the purchaser or importer of an article of food submit prior notice, NCA respectfully submits that section 307 of the Bioterrorism Act does not mandate such a requirement be placed on the purchaser or importer. Statute, as set forth in section 801 of the Federal Food, Drug, and Cosmetic act, as amended by the Bioterrorism Act, requires “the submission to the Secretary of a notice...,” however the statute is silent with regard to who submits the notice. As such, NCA argues that FDA can use its discretion in determining from where the FDA receives the information required by the Bioterrorism Act, and therefore has the latitude to obtain the information from other electronic information collection systems, such as those identified immediately above.

Required Information

NCA is concerned about the impact the proposed regulations and subsequent information submission requirements will have on coffee commerce. Specifically, NCA notes that the section 1.288(f) of the proposed regulation requires that the “name, address, phone number, fax number, and e-mail address of the manufacturer” be included on the Prior Notice Submission form. Although FDA indicates in the preamble of the above referenced regulation at 68 FR 5429 that such information is currently supplied, it is NCA’s understanding that such information, the name of the manufacturer, for example, is not necessarily supplied to FDA currently, and therefore; such a requirement becomes a barrier to the smooth flow of commerce with regard to coffee that is currently housed, as well as to coffee that might be housed between now and the effective date of the final regulations, in certified warehouses of the New York Board of Trade (NYBOT) and London International Financial Futures and Options Exchange (LIFFE) that are located outside of the United States. In particular, the 350 million pounds of coffee housed in these warehouses will be removed from the potential stream of U.S. commerce due to the fact that no records are accessible that would indicate the manufacturer, and therefore, in accordance with section 1.278 of the regulation, would be refused admission. NCA urges the FDA to clarify if in fact, in accordance with the regulation as proposed, all coffee described above would be refused entry, and to reconsider its position should this be the case. In NCA’s letter to FDA dated August 30, 2002 NCA suggested that consideration be given to “grand fathering” these products and observes that failure to do so would place an economic burden on the industry. In reconsidering its position the FDA is respectfully urged to be mindful of Congressional instruction that “...prior notice requirements never become a barrier to the smooth flow of commerce.” (Conference Report at H2858)

In more general terms, the scope of the information required to be submitted is overly broad and in certain cases exceeds statutory authority. Section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Bioterrorism Act, states that “the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such

article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that the notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article was shipped; and the anticipated port of entry for an article of food.” Further, section 415(a)(2) of the FFDCA limits the type of information that can be collected pursuant to the facilities registration provision of the FFDCA. When sections 415 and 801 of the FFDCA are taken in concert it appears as though much of the information required in section 1.288 of the above referenced proposed rule exceeds the statutory authority granted by the Bioterrorism Act. In this regard, NCA draws the attention of FDA to the following items, which are of most concern to the coffee industry: fax number, e-mail address and phone number of the manufacturer (§ 1.288(f)), and the fax number, e-mail address and phone number of the grower (§ 1.288(g)). NCA takes issue with the requirement of providing this data because in many cases providing this information will not be possible for foreign manufacturers and growers due to the fact that the information may not exist. As such, NCA strongly urges the FDA to amend sections 1.288(f) and (g) by deleting reference to fax numbers and email address and, should the FDA feel compelled to request a phone number for these entities, to ensure that such requirement is optional.

Without stipulating that FDA has the authority to mandate submission of the Customs’ entry number, NCA points out that requiring this number is problematic based on the fact that such number is often non-existent, especially in cases where product is shipped from countries with close proximity to the United States, when the Prior Notice Submission Form must be submitted. In fact, the Customs’ entry number is at times assigned after the shipment arrives. A review of the process is informative: 1. A Bill of Lading is required to make a customs entry; 2. A Customs’ entry is necessary for the assignment of a Custom’s entry number; 3. The Bill of Lading is not issued until the coffee is on the ship; 4. The Bill of Lading must be transmitted in its original form to the importer/customs broker, generally via an overnight courier, prior to the Customs’ entry being made. In some cases, the original Bill of Lading is provided to the courier service upon the ship arriving at the U.S. port; in such a case, it is obvious that the Custom’s entry number would not be existent at the time the Prior Notice Submission must be filed. However, even in cases where the Bill of Lading was sent via courier from the export port, the Customs’ entry number might not be existent in a timely manner; for example, when the shipment comes from a port within close proximity to the United States. As such, the FDA is urged to delete reference to the Customs’ entry number or to consider making this a voluntary field on the Prior Notice Submission form (68 FR at 5464) and revising section 1.288 of the proposed regulation accordingly.

Further, NCA notes that the Prior Notice Submission form limits the number of growers to three. However, section 1.288(g) of the proposed regulation requires

the “name, address, phone number, fax number, and e-mail of all growers...” [emphasis supplied] Although NCA questions the necessity to collect some of this information (see previous comment), NCA suggests that the Prior Notice Submission form be designed in a manner that does not limit the grower information to three growers. In the case of the coffee industry, a very large portion of the growers are small and produce only 5 to 10 bags of coffee. Being that sea containers ship in multiples of 250 to 300 bags, as written, the proposed regulation could require multiple prior notices for single items simply to accommodate identification of growers.

Scope of Prior Notice Provisions/Definitions

Section 1.277(c)(3) of the above referenced proposed regulation defines food in a manner that is arbitrary and capricious when read in concert with section 415(a)(1) of the FFDCFA, as amended by the Bioterrorism Act, which limits the scope of the Bioterrorism Act to “food for consumption.” Section 415(a)(1) of the Bioterrorism Act requires that “...any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary.” [emphasis supplied] NCA believes that Congress intended for this limited definition of food to be consistent for all purposes of the Bioterrorism Act. Based on this premise, the proposed regulation (§ 1.277(c)(3)) incorrectly expands the scope to include indirect food additives and food contact packaging. NCA urges FDA to limit the scope of the regulation in a manner that conforms more closely to the Act, by clarifying the definition of “food” in a manner that only applies to food intended for consumption.

NCA is further concerned that the description of “each article of food,” described as “each article of food produced by each manufacturer” in the preamble at 68 FR 5435, taken in concert with sections 1.278 and 1.288, will inadvertently require multiple Prior Notice Submissions for what would normally be a single FDA entry line. For illustrative purposes, a shipment of five sea containers from one exporter and one originating country may have a different manufacturer for each sea container. Such a fact pattern would, under the proposed rule, result in either the need for multiple Prior Notice Submission forms to be submitted, or the coffee being refused admission (§ 1.278(a)). Admittedly, this conclusion is inferred from the definition of “manufacturing” as set forth in section 1.277(c)(6) of the proposed regulation for Registration of Food Facilities under the Bioterrorism Act (68 FR 5418). NCA is hopeful that this is not FDA’s intent, as such a requirement would be extremely burdensome and not provide a public health benefit. NCA requests clarification of the intent of FDA in this regard.

It is also respectfully suggested that FDA consider providing a definition for the term “manufacturer.” Defining this term will remove ambiguity and diminish the probability of misinterpretation of the regulation.

NCA notes that the definition of “originating country” (§ 1.277(c)(4)) fails to clearly

and adequately express FDA's apparent intent, as described in the preamble at 68 FR 5431, wherein FDA states that "[i]f, on the other hand, the article is a processed food, e.g., canned vegetables, the origination country is likely to be the country in which the vegetables were canned. Specifically, section 1.277(c)(4) defines "originating country" as "...the country in which the article of food is produced," except for in the case of fish, without allowing for the consideration of processed food. Articulation of FDA's intent with regard to processed food through expressed language in the definition would again clarify and diminish the probability for misinterpretation. Further, NCA requests clarification that the processes of decaffeinating and blending coffee be considered processing for the purposes of the Bioterrorism Act, thereby clarifying that decaffeinated and blended coffee fall under the definition of processed food, which is origin conferring in accordance with the preamble (68 FR 5431). Treating decaffeinated or blended coffee otherwise would unnecessarily burden commerce, while considering decaffeinated and blended coffee as processed food would provide for consistent application of statute and regulation, and remove any disparate impact on coffee.

Timing of Prior Notice

Section 801(m)(2)(A) of the FFDCA, as amended by the Bioterrorism Act, requires "...that a notice under such paragraph [801(m)(1) FFDCA] be provided by a specified period of time in advance of the time of the importation of the article of food..." The determination of the time period is left to the discretion of the Secretary, provided that the period for submitting the prior notice is "...no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification..." and no more than "...five days." (Section 801(m)(2)(A) of the FFDCA) Further, in exercising the Secretary's discretion, section 801(m)(2)(A) of the FFDCA suggests that the Secretary consider "...the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States, and any other such consideration." Congress further emphasized the importance of utilizing discretion in the Conference Report at H2858, wherein Congress states its intention "for the Secretary to exercise discretion to ensure that neither the requirements for the notice nor the timing of prior notice be more burdensome than necessary to provide for the availability of food import inspectional personnel." In addition, NCA finds it instructive that in the default clause (§ 307(c)(2)) of the Bioterrorism Act provides that eight hours shall be the minimum amount of time that the notice is required to be made in advance of the time of the importation of the article of food, presumably implying that an eight hour notice was ample time to "...enable the Secretary to provide for inspection of food imports at ports of entry." (Conference Report at H2858)

Notwithstanding the aforementioned latitude provided by Congress, it appears as though FDA attempts to treat all imports equally, without consideration for the

locations of the various ports of entry or the similar consideration of the geographical location of the port from which the article of food was shipped, thereby inadvertently mandating an arbitrary and capricious prior notice time period, from as little as 12 hours to up to 36 hours. NCA is especially concerned about the impact that the static time period of "...no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry," as expressed in section 1.286(a) of the proposed regulations, will have on imports of coffee from ports that are geographically close to the United States. As proposed, the regulation disparately impacts coffee commerce from nations located in proximity to the United States, such as Mexico, Canada and Central America.

As such, NCA respectfully requests that FDA reconsider the period of time in advance of the time of the importation of an article of food that prior notice must be submitted. In doing so, NCA urges the FDA to give particular weight to the location of ports and the effect on commerce of such period.

Updating Arrival Information

In accordance with Section 1.294 and the definition of "you," as provided in section 1.277(c)(6), when an arrival update is required, such update must be submitted by the purchaser or importer of the article of food. NCA recommends that the regulation be revised, thereby authorizing the carrier to submit arrival updates. Such authorization would greatly reduce the number of arrival updates and the burden on commerce, while continuing to provide the same level of protection to the public. It is suggested that FDA consider linking the prior notice information with the manifest as a vehicle for accommodating this efficiency.

Exemption for Samples

Consistent with Congressional instruction, as expressed in the Conference Report at H2858, "that the Secretary should exercise discretion in promulgating and implementing these rules to assure that prior notice requirements never become a barrier to the smooth flow of commerce," and in accordance with section 415(a)(1) of the Bioterrorism Act, which limits the scope of the Bioterrorism Act to the regulation of "food for consumption," NCA respectfully requests that FDA consider exempting shipments of coffee samples for purposes of prior notice. [emphasis supplied] Coffee samples, which are generally shipped via couriers such as DHL and Federal Express, are not "for consumption," but instead used for analysis, and therefore should correctly be exempt. NCA observes that there is FDA precedent for treating samples used for laboratory analysis differently for inspection purposes such as expressed in federal poultry inspection regulations (9 CFR 381.207) and for those used for personal use as expressed in federal meat inspection regulations (9 CFR 327.16).

Held Product Procedures

Section 1.278(e)(1) of the proposed regulations states that in cases where no prior notice or an inadequate prior notice is provided “the article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal for admission under section 801(m)(1) of the Act.” However, the regulations are silent with regard to a time limit for this process. NCA strongly urges FDA to provide language limiting the time allowed for such process; the inclusion of such language would be consistent with Congressional instruction which states “if an article of food were offered for import without providing the required prior notice, the article of food would be held at the port of entry until the Secretary has determined that notice is complete, but it would not be held longer than the unelapsed period of prior notice unless there is other basis for doing so.” (Conference Report at H2858) [emphasis supplied] In doing so, NCA respectfully urges FDA to adopt language that closely tracks the narrow time frame provided for in the Conference Report at H2858. Consideration of this issue is especially important because as the proposed regulation is currently drafted some shipments, especially those from ports in close proximity to the United States, will be in violation by default (for example see previous comments regarding Customs’ entry number in Required Information section). As such, an efficient and time-limited process is necessary to ensure that the burden on commerce is minimized.

NCA notes that the preamble (68 FR 5432) states that it is the position of FDA “that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances.” FDA is respectfully urged to provide confirmation of this stipulation in the final rule.

Security of Data

The NCA is extremely concerned about the security of data submitted to FDA in accordance with the above referenced regulation, especially considering the fact that the data may be accessible through the Internet. The FDA is strongly urged to employ measures that ensure the data is protected. Congressional intent is clear that the information collected pursuant to the Act shall not be subject to disclosure under 5 U.S.C. 552. In fact, the Bioterrorism Act expressly exempts from disclosure “...any registration documents submitted pursuant to ...[the Bioterrorism Act]” and “[i]nformation derived from such list or registration documents...” (§415(a)(4) FFDC) As such, the industry has an expectation that any and all information will be treated as privileged and confidential. Concern arises from the appearance that a registration number alone may provide access to a record. Access to a record with a registration number alone is troublesome,

based in part, on the high probability that registration numbers, which are required on the "Prior Notice Submission" as published in 68 FR at 5464, may become part of the commercial documentation between parties buying and selling coffee. Therefore, the FDA is urged to take any and all necessary actions/precautions to ensure the confidentiality of information submitted pursuant to the Bioterrorism Act.

Again, the National Coffee Association appreciates the opportunity to submit comments on the above referenced proposed regulation and looks forward to future opportunities to work with the Food and Drug Administration in the promulgation of regulations that protect the nation's food supply from terrorist attack.

Sincerely,



Robert F. Nelson