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July 2, 2003

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

**Re: Docket No. 02N-0277
Establishment, Maintenance, and Availability of
Records 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 25188, May 9, 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 accordance with the requirements set forth in section 306(d) of the Public Health Security and Bioterrorism Preparedness Act (Bioterrorism Act), wherein FDA is called up on to issue proposed and final regulations establishing recordkeeping requirements not later than 18 months after the enactment date of the Act.

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The National Coffee Association shares the FDA's concern with regard to protecting the nation's food supply and therefore submits the comments contained herein for the purpose of facilitating the protection of the U.S. food supply.

As proposed, the above referenced regulations will place significant burden on certain foreign coffee facilities with no corresponding protection of the American public. Further, the proposed regulations, in some cases, will result in unduly disrupting commerce and in inadvertently providing incentive for a new layer of foreign commerce to be created, thereby increasing critical control points where sabotage or adulteration could take place resulting in an increased potential threat to American consumers. Added intermediaries, or layers, in the system of coffee commerce will also result in additional mixing of various types and qualities of coffee prior to determination of the final purchaser, which has the effects of lower overall quality of green coffee available to roasters and to the end consumer, and fewer choices of green coffee types available to roasters and the end consumer.

Establishment of Records

Generally, washed arabica coffee, such as is typically grown in Central America and Mexico, is processed for export under two different scenarios. In scenario one, coffee cherry is first received, commingled and processed at a wet mill, and then transported to a dry mill where it is prepared for export. In scenario two, coffee is received as cherry at a combination wet and dry mill that processes the coffee through to the final stage prior to export. In both scenarios, coffee cherry arrives at the wet mill process in small quantities (the smallest quantity equivalent to approximately 26 pounds of green coffee), often from up to 1000 different immediate prior sources per day.

Scenario one record keeping requirements would begin not at the wet mill, but at the dry mill or at a subsequent location where coffee would be further processed, which is the facility required to register with FDA pursuant to the facilities registration provisions of the Bioterrorism Act. As such, the coffee has been commingled into larger quantities prior to arriving at the facility where recordkeeping begins, thereby significantly reducing the number of and burden to track immediate prior sources.

Scenario two recordkeeping requirements would commence with the mill that receives the coffee cherry due to the fact that in this scenario the mill that

receives the cherry processes it to the point where it is ready for export, thereby requiring this mill to register as a foreign facility in accordance with the Bioterrorism Act and comply with the associated record keeping requirements. It is in this scenario that a tremendous burden is created by the recordkeeping requirements and incentive for a new layer of foreign commerce is created. This is especially so considering the manual, paper-based systems of recording and accounting for payments to those who deliver the cherry at the mill, the fact that cash payments are often provided at an outside weigh station, and the fact that the current paper-based manual systems do not include the full information on every source as would be required by the proposed recordkeeping regulations. All of this is exacerbated by the fact that it is not possible to "mark" individual cherries in a manner that would permit cherries to be tracked and identified as part of larger lots that are transported to the United States as green coffee.

Due to the unrealistic burden created by the proposed regulations, mills in scenario two will be forced to either ignore the provisions of the proposed regulation which require the establishment and maintenance of records, thereby removing the mill's ability to comply with the records inspection provisions of the Bioterrorism Act and subsequent associated proposed regulations, or refuse to accept cherry in small quantities. Should the mill refuse to accept cherries in small quantities a new layer of commerce will be created (scenario three) where cherries are accepted by a third party separate from the mill itself – another corporate entity which functions only as intermediary and collector. This intermediary would commingle cherry into larger lots for the purpose of being transported to the mill where recordkeeping requirements would begin. This third scenario creates an additional critical control point where intentional contamination may occur, thereby increasing the risk to American consumers. Further, scenario three will reduce farmer income, as a part of the price paid for the coffee will go to the newly created level of commerce. Such a reduction in farmer income will further decrease economic and social stability at the farm level, at a time when farmers are in a third consecutive year of financial crisis, thereby inadvertently presenting new security threats to the American public. Finally, the addition of a new layer of commerce will result in an erosion of quality, which will also have a negative economic impact on the farmer and further deteriorate the economic and social stability in coffee growing regions.

The same conclusions are reached when considering the processing of washed coffee outside of Central America, or natural-process coffee (wherein water and depulping is not a part of the milling process) such as is widely exported from

Brazil, Asia, and Africa. The industry infrastructure is somewhat different in each country and case, but the same concerns apply. Central American washed arabica coffee is used as an example to demonstrate the problem.

Providing that the FDA is in agreement that the unintended increased threat to the American public, set forth in scenario three above, is counter productive to the Bio-terrorism Act, the FDA is urged to clarify and confirm that the FDA would not consider information identifying the source of coffee cherry as information that would be considered as being "information reasonably available."

Designating information identifying the source of coffee cherry as not being reasonably available is also consistent with Congress's intent that bio-terrorism regulations not be burdensome nor disrupt the smooth flow of commerce.

Record Availability Requirements

As proposed, section 1.361 requires that "records and other information must be made available within 4 hours of a request if the request is made between 8 a.m. and 6 p.m. Monday through Friday, or within 8 hours of a request if made at any other time..." Such a requirement is not reasonable for many facilities in coffee producing nations that are located in third world countries due to the high level of manual, paper-based systems employed throughout the industry. Creating systems that comply with the proposed timeframes for record retrieval and submission at foreign facilities in coffee producing nations would be extremely costly and highly improbable. Further, even if such systems could be developed they would likely be unreliable. As such, the NCA urges the FDA to amend the proposed regulation, thereby allowing for up to 24 hours to make foreign facility records available from the time a records request is made.

Required Information

Section 1.337 requires foreign facilities to maintain records that indicate "the name of the firm and responsible individual, address, phone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source..." [emphasis supplied] Many individuals that deliver coffee cherry to mills may not have phone numbers, and in fact may live where phone service is not available. As a result of a phone number being required as part of the records, mills would be prohibited from accepting coffee cherry from individuals that did not have phones. Being that the intent of the Bioterrorism Act was not to exclude business people from commerce or to require the installation of phone service, the NCA urges the FDA to require a phone number only if available, as is the case with fax numbers and e-mail addresses.

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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,

A handwritten signature in black ink, appearing to read "Robert F. Nelson". The signature is written in a cursive style with a large initial "R" and "N".

Robert F. Nelson