

ROBERT F. NELSON
President & Chief Executive Officer



NATIONAL COFFEE ASSOCIATION OF U.S.A., INC.

15 Maiden Lane, Suite 1405
New York, NY 10038-4003
TEL: (212) 766-4007
FAX: (212) 766-5815
www.ncausa.org

BOARD OF DIRECTORS

Chairman
GREGORY W. WHITE
The Folger Coffee Company

Vice Chairman
JOSEPH APUZZO, JR.
Armenia Coffee Corp.

Secretary/Treasurer
THOMAS D. WESTFELDT
Westfeldt Brothers, Inc.

STEVE BROUGHTON
Wal*Mart Stores, Inc.

SERGIO CANDIDO PEREIRA
Brastrade –
Brazilian Trading Co., Inc.

ROB CASE
Nestlé USA

J. ROY DAVIS, JR.
S & D Coffee Inc.

HENRY C. DUNLOP
Atlantic (USA), Inc.

RICHARD EMANUELE
Coffee America (USA) Corp.

ANDREAS ENDERLIN
Mercon Coffee Corporation

JONATHAN T. FEUER
L.M. Zuckerman & Co., Inc.

JERI FINARD
Kraft Foods North America

PEDRO L. GAVIÑA
F. Gaviña & Sons, Inc.

JAMES KALOYANIDES
New England Coffee Company

KENNETH KIMMEL
Dunkin' Donuts

ALDO UVA
Sara Lee Coffee & Tea
North America

KLAAS A. VAN DER KAAIJ
Rothfos Corporation

TULLIO VIGANO
Fres-co System USA, Inc.

GEORGE J. VUKASIN
Peerless Coffee Company

MARY J. WILLIAMS
Starbucks Coffee Company

July 13, 2004

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

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

Sent via Electronic Mail: fdadockets@oc.fda.gov

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 (69 FR 28060, May 18, 2004).

NCA represents the US coffee industry, which generates \$20 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 17,000 coffee cafés employing persons in every state and region. Through retail, restaurant and coffee café sales the industry serves 167 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 efficient and effective manner, reaching out to impacted industries for input and comment. The National Coffee Association shares the FDA's concern with 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 that 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.

Clerical Error Leading to Refused Admission/Detention

NCA, on behalf of its membership, applauds the outstanding efforts of the FDA in the timely development of the Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes. This development carries forward the FDA's commitment in the preamble of the IFR (68 FR 58995) to coordinate the prior-notice requirements of the CBP with the new Bioterrorism Act prior-notice requirements to ease the administrative burden and facilitate procedural compliance by those engaged in food commerce in the United States.

However, NCA and its membership are concerned that certain procedural issues inherent in the existing CBP prior-notice reporting mechanism may cause an unintended and detrimental impact on the smooth and unimpeded flow of commerce of food products. Such procedural issues, ordinarily imposing at most negligible inconvenience in the ordinary course of business, become worrisome potential trade burdens when they interface with other provisions of the Bioterrorism Act as part of the integration of FDA and CBP rules.

Specifically, the CBP's online prior-notice submission process provides no opportunity for correcting clerical errors. During the submission process, an error requires the user to reenter all data from square one, creating a relatively minor inconvenience and wasted time. However, once the information is submitted, there is insufficient opportunity to change any clerical or other error that was made in the submission process. The result of failure to register properly can result in refused shipment.

In the case of food shipments, as integrated into the CBP process, refused shipment, in turn, may have the further consequence of triggering the application of the Bioterrorism Act's administrative detention regulation, whose final rule was promulgated on May 27, 2004 (68 FR 197). Such impedance, moreover, is particularly perilous to trade because of the frequently perishable nature of the involved products.

The concern of NCA, therefore, is that a shipment refused entry under the CBP system due to a clerical error, not correctable within that system, might result in a lengthy detention process. Such delay would seriously disrupt increasingly exacting supply-chain requirements, such as just-in-time inventory policies, resulting in inventory shortfall and the accompanying high expense of alternate sourcing, delayed finished product manufacture and delivery, and/or potential legal liability under extant contractual obligations. Moreover, commerce would be delayed well beyond the statutory provision and intent, hinging on the principle of "no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days." (Bioterrorism Act, Section 307, amending Federal Food, Drug, and Cosmetic Act Section 801(m)(2)(A)).

Repairing an error with the only available means -- commencing a new, correct filing -- would also, in effect, restart the prior-notice period so as to achieve the legally required prior-notice timeframe from the date and time of the proper submission. Without the opportunity to correct the error post-submission, shippers may well find their shipments frozen in an extended period of delay, frustrating the very purpose of the FDA-CBP Integration Plan aimed at reducing such timeframes, and in an unintended legislative loop between the two regulatory frameworks meant by the Plan to be seamlessly and efficiently integrated.

The National Coffee Association thereby respectfully submits that the FDA create a mechanism or allowance for such clerical errors to be corrected in a manner that does not begin the prior-notice clock from starting over. Furthermore, we would like to convey the importance of a streamlined process, possibly through electronic means, of making clerical corrections or correcting errors of timely filings as a permanent feature of the integrated FDA-CBP process going forward.

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, flowing style with a large initial 'R'.

Robert F. Nelson