

National Coalition of Food Importing Associations

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By Federal Express and Electronic Mail

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

Re: Docket No. 2004N-0184; Requirements Pertaining to Sampling Services
and Private Laboratories Used in Connection With Imported Food

The National Coalition of Food Importing Associations (NCFIA or the Coalition) appreciates this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food. 69 Fed. Reg. 23460 (April 29, 2004) (hereinafter the "Proposed Rule").

NCFIA is a coalition of trade associations that represent different segments of the food importing community. Members of NCFIA include the following trade associations: American Spice Trade Association, Cheese Importers Association of America, Association of Food Industries, The Cocoa Merchants' Association of America, and the National Fisheries Institute. Companies belonging to NCFIA member associations annually import over \$13.5 billion in food products.

Except for some minor divergence of opinion which we describe below, NCFIA joins in, and does hereby endorse, the comments of the American Council of Independent Laboratories (ACIL) regarding the Proposed Rule. The Coalition specifically joins in the comments of ACIL stating, among other things, that:

- The Proposed Rule does not accomplish the important objective of establishing consistent and objective national standards for the format and content of analytical data that private laboratories submit to FDA in order for the agency to make decisions regarding the admissibility of imported foods.
- The best and only scientifically valid means of establishing such objective national standards is through FDA's acknowledgment and acceptance of accreditation of private

laboratories, instead of focusing on the addition of burdensome, unnecessary and counterproductive notification and record keeping requirements.

- Once FDA accepts that important benefits will be realized for all concerned by the use of private laboratory accreditation, FDA should adopt a policy which treats analytical results submitted by accredited laboratories as presumptively accurate without the need for time consuming agency review.
- FDA should withdraw the Proposed Rule, then initiate new discussions with industry stakeholders and only repropose the rule after FDA completes rulemaking with respect to implementation of its new authority under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

As previously mentioned, with respect to two of ACIL's comments NCFIA would like to point out that a slight divergence of opinion exists. Although our differences are relatively minor, NCFIA believes that, since these comments are for the public record, it is important to describe them herein.

1. Prior Notification Requirement.

ACIL states in section IV.C.1. of its comments that in lieu of the notification requirements of proposed 21 CFR 59.101(a) and 59.103(a) FDA should instead require "any person who relies upon any private laboratory analysis to overcome an FDA enforcement action precede the lab's submission with a notification to the agency that samples were collected by a particular private laboratory." NCFIA would like to recommend a slightly different approach which not only addresses FDA's concern that the analytical tests are not being performed by more than one private laboratory, but also does away with the need to require private laboratories to submit an affidavit to FDA pursuant to proposed 21 CFR 59.301(b), which ACIL quite correctly strongly objects to (see, ACIL comments section IV.F.3.).

Subject to the need for in depth discussions between FDA and industry stakeholders pertaining to this complex issue, NCFIA recommends that the importer or other person relying on private laboratory analytical results with respect to the admissibility of an imported article certify in writing to FDA that the certificate of analysis and analytical work sheets submitted by the private laboratory are the only test(s) performed domestically on the lot or food product. This self-certification would, subject again to further dialogue with industry stakeholders, need to be submitted to FDA in some sort of simultaneous manner with the private laboratory's analytical package.

2. Collection of Samples.

NCFIA supports the general concept that someone other than the importer should collect samples. This is not a simple issue, however, and much more information, thought and analysis is

needed before FDA and industry stakeholders are capable of formulating rules and procedures which take into account the variety of real world circumstances and exigencies that exist. We are in fundamental agreement that the integrity of the sample is paramount, but a one size fits all approach to sample collection is clearly not warranted if we agree that it is good policy to avoid unnecessary logistical and economic problems. For example, there are numerous routine instances where it would be appropriate for the operator of the public warehouse where the goods are stored to collect the sample. These instances arise whenever sophisticated sampling service knowledge or expertise is simply not required and the instructions of the private laboratory to the warehouse operator should suffice (e.g., to collect a canned tuna sample the standard is two whole cans each from twenty-four cases).

Finally, without further information collection and analysis followed by discussion in an open public forum, we cannot support at the present time ACIL's "intermediate solution" of establishing a list of "problem importers" who would be prohibited from collecting their own samples.

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NCFIA thanks FDA for this opportunity to comment. If you have any questions regarding these comments, please do not hesitate to contact us.

Very truly yours,

Richard H. Koby,
Coalition Coordinator