



NATIONAL
FOOD
PROCESSORS
ASSOCIATION

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July 28, 2004

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. 2004N-0184; Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food; 69 Federal Register 23460; April 29, 2004.

Dear Sir or Madam:

The National Food Processors Association submits the following comments on the above referenced proposal.

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers and international office (Bangkok, Thailand), its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical assistance, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

First, NFPA fully supports the general premise that samples taken in response to a regulatory action should be from the lot or lots in question, should be representative of the lot, and should be tested using appropriate analytical procedures utilizing good laboratory practices.

NFPA agrees that the scope of the regulation should be limited to sampling of imported food in connection with an FDA enforcement action as described in the proposed 21 CFR § 59.1. "Enforcement actions include, but are not limited to, product seizure, refusal of imports, or the issuance of an injunction. This part does not apply if the firm collects, analyzes, or tests imported food samples for purposes not related to an FDA enforcement action."

Use of Sampling Services

NFPA supports the proposed 21 CFR § 59.101 but requests that FDA clarify the intent of the proposed § 59.101(b)(2) which states that the importer

“(2) Not influence or interfere with the manner and process in which samples are collected;”

FDA should confirm that this does not mean the firm cannot specify the minimum requirements, including the specific sampling procedure and other procedures necessary to ensure the integrity of both the sample and the product remaining in the container after sampling, that the sampling firm must meet to ensure compliance with § 59.201 “What are the requirements for collecting, identifying, and maintaining samples?”

NFPA notes that, in addition to ensuring that the integrity of the sample is maintained during and after sampling as required by the regulation, additional sampling procedures may need to be specified in order to avoid contamination and/or to maintain the security of the remaining product during and after the sampling procedure. In cases where the product has a security or tamper evident seal on each container, the importer may require that the sampling firm verify the security seal is intact prior to sampling, note the seal number if one is used, and then require that the sampling firm affix a new seal as supplied by the importer or other designated entity on the container after sampling and duly record such action. Indeed, FDA itself has a provision for such action in its Investigation Operations Manual (IOM) section 424 In Transit Lots, which states in part:

“Resealing Conveyances - If it is necessary to break the commercial seal to enter a railcar or other conveyance, reseal the door with a numbered self-locking ‘U.S. Food & Drug’ metal seal. Record in your regulatory notes (and on C/R if sample taken) the number of the car or conveyance, the identifying number on any car seals removed, and the number of the FDA metal seals applied.”

Because the record of the sampling collection procedures must be maintained in compliance the § 59.201 and be made available to FDA on request, all additional procedures would be available for the agency to review and ensure that the requirements have not compromised the sampling procedure.

Use of Private Laboratories

NFPA requests that FDA clarify the intent of the proposed § 59.103(b)(2) as it applies to private laboratories which states that the importer

“(2) Not influence or interfere with the manner and process in which samples are tested and/or analyzed;”

FDA should confirm that specifying the specific tests or methods of analysis to be used does not constitute interfering with the test procedure. This information will be provided to FDA with the results of the test so the agency will be able to review and ensure that the requirements have not compromised the analytical results.

Sampling and/or Testing Your Own Samples

The proposed § 59.105 provides that individuals or firms may conduct their own sample collection in connection with an FDA enforcement action provided they comply with the requirements for sampling services as proposed in § 59.201. NFPA supports this provision.

NFPA requests that FDA further recognize that firms may also conduct their own testing in response to an FDA enforcement action provided they comply with the requirements for private laboratories as proposed in § 59.301.

Accordingly, NFPA requests that the proposed § 59.105 be amended by adding a paragraph at the end of that section to require that firms testing their own product comply with the requirements for private laboratories and amend that section to read as follows:

“§ 50.105 What requirements apply if you collect and/or analyze your own samples?

‘If you collect your own imported food samples and intend to have the samples tested or analyzed and used in connection with an FDA enforcement action, you must comply with subpart C of this part.

‘If you test your own imported food samples and intend to have the test results used in connection with an FDA enforcement action, you must comply with subpart D of this part.’”

Requirements for Private Laboratories

The proposed § 59.103(b)(4) provides that if you use or are using more than one laboratory to conduct tests, you notify all private laboratories involved and the FDA. The notice must state how many private laboratories are conducting or will conduct tests or analyses and describe those tests or analyses. NFPA supports this requirement.

The proposed § 59.301 (b) provides that the private laboratory submit an affidavit stating that the private laboratory is either not aware of any other tests being performed or is aware of other tests that are being or have been performed by other persons, and the name and address of the person who is conducting or who has conducted the other tests. NFPA supports this requirement with the recognition that this information relate only to sampling conducted in response to an FDA enforcement action and not to other sampling and testing that the company may have contracted to be conducted on the product in question or on other products not involved in the FDA enforcement action.

While NFPA has no objection to the person or laboratory submitting information that they are aware of other laboratories or persons testing the product with respect to the FDA enforcement action, FDA should be aware that the firm contracting with the private laboratory may contract for other sampling and testing of the product involved in the enforcement action for items unrelated to the enforcement action as well as sampling and testing of other products not involved in the enforcement action. The regulation should state clearly that the only information to be submitted to FDA is that information directly related to the enforcement action. Accordingly, NFPA requests that § 59.301(b) section (1) and (2) be amended as follows:

“(b) You must provide, as part of your analytical package, an affidavit stating that:

- (1) The analytical package pertains to the only test(s) done on the lot or product in response to the FDA enforcement action and that you are not aware of any other tests being performed in response to the FDA enforcement action; or
- (2) If you are aware of other tests that are being or have been performed by other persons in response to the FDA enforcement action, the name and address of the person who is conducting or who has conducted the other tests in response to the FDA enforcement action.”

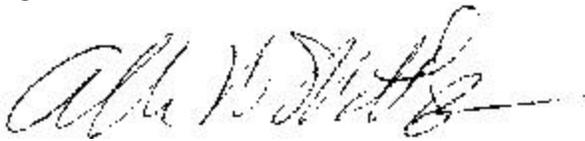
NFPA supports this requirement provided that FDA recognize that the contracting firm is required only to inform FDA of all private laboratories which will be conducting work related to the FDA enforcement action and not of any other work unrelated to such action.

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FDA should expect to receive the results of any and all testing conducted in response to the FDA enforcement action but not testing conducted to determine that the product otherwise met company or other non-enforcement action related specifications unrelated to the FDA enforcement action.

Thank you for providing this opportunity to comment on the proposal.

Regards,

A handwritten signature in black ink, appearing to read "Allen W. Matthys", with a horizontal line extending to the right from the end of the signature.

Allen W. Matthys, Ph.D.
Vice President
Federal and State Regulations