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ANALYTICAL CHEMISTRY
FOOD MICROBIOLOGY
ENTOMOLOGY

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Ref: Food and Drug Administration, HHS
21 CFR Part 59

Docket No. 2002N-0085
RIN 0910-AB96

**Comments on the Proposed Rule: Requirements Pertaining to Sampling Services and
Private Laboratories Used in Connection With Imported Food**

With respect to the Proposed Rule, we have serious concerns with Proposed §59.105, a provision that would allow importers or persons with a vested interest in an imported food to collect their own enforcement samples from detained products. Further, Proposed §59.3 (c) needs to define those companies or persons who have a vested interest in the product and are therefore not an independent sampling service.

Allowing importers, companies or persons with a vested interest to collect their own samples in connection with an FDA enforcement action is analogous to permitting airline passengers to screen their own luggage or themselves before boarding aircraft. This is a matter of food safety and security. Independent sampling by trained professionals is in the best interest of public safety and effective enforcement action.

Importers and warehouse companies have a vested interest in the product. For an importer, the financial risk of an FDA detention and refusal is great. Though most importers are persons of high integrity, it is naïve to assume that an importer or a party that has a vested interest in the product can always be trusted to take unbiased representative samples. It is also naïve to expect that employees of an unscrupulous importer will never be coerced, or that a public warehouse will always report insanitary conditions in their facility. It is unlikely that a less reputable importer will always alert FDA if some of the detained product has already been distributed or if it is mislabeled, misbranded, or missing an allergen warning. If importers and parties with a vested interest could always be trusted to comply with 21 CFR, you would not need FDA

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intervention at all. Enforcement samples and the subsequent analytical data are forensic evidence used by FDA to enforce federal law. An independent sampler acts on behalf of FDA and is trained in proper sample identification and collection technique.

Importers and warehouse companies do not meet the criteria of an independent sampling service and this should be specified in the definition contained in Proposed §59.3 (c). Goods stored in a public warehouse serve as collateral and can be held against payment of storage and handling fees. Refused or detained products are a liability and could be abandoned to the warehouse or trucking company by a defaulting importer. As such, warehouses and even transportation companies have a vested interest in the product. Consider Sections 402(a)(3) and 402(a)(4) of the Food Drug and Cosmetic Act that address filth in foods and foods held under insanitary conditions. You cannot expect the importer, warehouse or trucker to report that they have held the product under insanitary conditions. Even the Coffee, Sugar & Cocoa Exchange mandates that licensed independent samplers, not the truckers or warehouses, collect Exchange samples and report storage conditions. Food products loaded in trucks are inaccessible for random sampling. However, some importers will ask truckers or warehousemen to collect FDA enforcement samples when products are detained. Tailgate samples taken from a truck or ocean container are restricted, not random, and often an insufficient number of packages are accessible to ensure a statistically valid sample. The unbiased independent sampler is trained to take random samples from multiple sites in accessible lots, to check for shortages, and to inspect the product for rodent, bird, insect filth, and other insanitary storage conditions. Further, once a product is removed to a warehouse from a pier, airport, or border crossing, it could be repacked, remarked, or otherwise manipulated for any number of reasons. Independent samplers are trained to use bills of lading, commercial invoices, warehouse receipts, and their experience with these products to check package integrity, markings, and to properly identify lots.

Professional independent sampling services and private laboratories have personnel that are trained in lot identification, labeling laws, product coding, aseptic sampling technique, random sampling, and how to avoiding cross-contamination of samples. These samplers are trained to maintain sample integrity, use the correct types of sample containers and employ temperature control measures for refrigerated samples. Independent samplers are skilled in checking quantities, sample identification, preparation of sample collection reports, and digital photo documentation. Training includes the use of references such as the FDA Investigations Operations Manual (IOM). A valid sample is described in Chapter 4 of the IOM as,

“A valid sample is the starting point and keystone for most administrative and legal actions. As evidence, the sample must support the government’s charge there is a violation of the law. Also, it must conform to the rules on admissibility of evidence.”

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There is a well documented legal chain of custody when samples are collected by skilled independent samplers. Most importantly, the analysis of the sample is meaningless if the sample is biased, fraudulent, collected or handled improperly, or not traceable to the lot under detention. The IOM also advises that, "Proper sample collection is the keystone of effective enforcement action."

There are more than enough independent samplers to collect FDA enforcement samples. There are many more independent sampling services than the 10 estimated by FDA and they are located at numerous ports and boarder crossings. In addition, many private laboratories conduct independent sampling. Should the need develop for more samplers in more locations these companies will expand their services. It was therefore alarming to read in part VII C.2 of the Proposed Rule that in the port of New York, where there are more independent samplers than in any other region, "as much as 27 percent of shipments are sampled by the importer." This is not because there aren't independent samplers available or that the cost of independent sampling is high. On the contrary, independent sampling is relatively quite inexpensive and there are more than enough skilled independent samplers to handle the work.

Unskilled warehouse laborers, truck drivers, and general office workers are not likely to have been trained in aseptic sampling, and other sample collection requirements contained in Chapter 4, IOM. FDA sets standards of education and training for their own inspectors who perform sample collections. In 1994, FDA New York District Office (FDA-NYDO) gave an Imported Food Sampling Workshop in New York that our staff as well as many other independent samplers attended. In addition, we retain the services of a former FDA inspector to train new personnel in sample collection technique. Other in-house training is provided by a staff food scientist and entomologist. Similar in-house training is conducted by other independent samplers and private laboratories. An independent sampler is a trained skilled professional that has no vested interest in whether the product is released or refused entry.

FDA has chosen not to include a requirement for accreditation of independent samplers or private laboratories. However, competence can be demonstrated by education, training, performance, and by peer review. Sampling workshops, such as that provided by FDA-NYDO in 1994, could be organized by professional associations in cooperation with FDA. Organizations such as the Association of Official Analytical Chemists (AOAC) or the American Council of Independent Laboratories (ACIL) could play a key role in providing such training. Workshops and short courses could be developed with FDA and given in each FDA District. Just as an Analyst Resume must accompany independent laboratory reports when submitted to FDA, it should also be required that a Sampler Resume accompany the Sample Collection Report.

We support the required use of independent sampling services as an integral part of the goal to ensure food safety and security. However, if importers are permitted to collect their own enforcement samples, there is nothing in the Proposed Rule that will effectively deter an

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unscrupulous importer from substituting foods or manipulating samples. If proper sample collection is truly the keystone of effective enforcement action, than the following changes should be made to 21 CFR Part 59. The Proposed §59.105 should be removed or changed to prohibit sampling by an importer; a company or person that has a vested interest in the product; or a person that is related to or directly associated with the importer. In defining an independent sampling service, the Proposed §59.3 (c), should exclude importers, warehouses and trucking companies or any other persons with a vested interest in the food.

Sincerely,



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Please read the comments on the Proposed Rule, 21 CFR Part 59.

Sincerely,

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