Inspection

(a) Within 30 flight hours or 5 flight cycles after the effective date of this AD, whichever occurs earlier, perform a one-time detailed inspection of the wing flap actuators for proper bonding of the flap actuator fairings to the lower skin of the wings; in accordance with Part A of the Accomplishment Instructions of Gulfstream Aerospace LP Alert Service Bulletin 200–57A–161, Revision 1, dated November 7, 2002.

Note 1: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Reinforcement of Actuator Fairing Adhesive

(b) If the inspection required by paragraph (a) of this AD reveals either no separation or separation of the flap actuator fairings from the lower skin of the wings that is within the limits specified in Gulfstream Aerospace LP Alert Service Bulletin 200–57A–161, Revision 1, dated November 7, 2002, do paragraphs (b)(1) and (b)(2) of this AD.

(1) Prior to further flight, apply sealant around the edges of the fairings, in accordance with Part A of the Accomplishment Instructions of the service bulletin.

(2) Within 300 flight hours after performing paragraph (b)(1) of this AD, remove and reattach the flap actuator fairings in accordance with Part B of the Accomplishment Instructions of the service bulletin.

Removal and Reattachment of Actuator Fairings

(c) If the inspection required by paragraph (a) of this AD reveals separation of the flap actuator fairings from the lower skin of the wings that is outside the limits specified in Gulfstream Aerospace LP Alert Service Bulletin 200–57A161, Revision 1, dated November 7, 2002: Prior to further flight, remove and reattach the flap actuator fairings in accordance with Part B of the Accomplishment Instructions of the service bulletin.

Actions Accomplished Per Previous Issue of Service Bulletin

(d) Actions accomplished before the effective date of this AD per Gulfstream Aerospace LP Alert Service Bulletin 200–57A–161, dated November 5, 2002, are considered acceptable for compliance with the corresponding actions specified in this AD.

Reporting Requirements

(e) Although the service bulletin referenced in this AD specifies to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(f) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in Israeli airworthiness directive AD 57–02–10–15, dated October 31, 2002.

Issued in Renton, Washington, on April 21, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–9764 Filed 4–28–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 59

[Docket No. 2002N–0085]

RIN 0910–AB96

Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations for persons who use sampling services (services that collect samples for another party) and private laboratories used in connection with imported food. The proposal would require samples to be properly identified, collected, and maintained. Additionally, the proposal would require laboratories to use validated or recognized analytical methods, and to submit analytical results directly to FDA. The proposal is intended to help assure the integrity and scientific validity of data and results submitted to FDA.

DATES: Submit written or electronic comments by July 28, 2004. Submit written or electronic comments on the information collection provisions by June 1, 2004. See section VIII of this document for the proposed effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. 2002N–0085, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2002N–0085 and RIN number 0910–AB96 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Persons who import food products into the United States often use private laboratories to test their food imports and submit the results of such tests to FDA. For example, FDA may refuse admission of an imported food into the United States if the food appears to be adulterated or misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the act). Pending a decision to refuse admission, the owner or consignee of the imported article may wish to present evidence to show that

the product does not violate the act or may wish to apply for authorization to recondition the imported food to bring it into compliance with the act. The owner or consignee may hire a sampling service to collect statistically representative samples for testing and hire a private laboratory to test the food. The private laboratory can then run tests designed to show whether the imported food complies with the act. The private laboratory would report the test results either to the owner or consignee or to FDA directly. FDA, in turn, would evaluate the analytical data to determine whether the imported food complies with the act and can be released into the United States.

Thus, private laboratories can play an important role in demonstrating that imported food products comply with laws and regulations administered by FDA. In doing so, the private laboratories help ensure that imported food products reaching consumers meet FDA requirements and help prevent noncompliant or violative products from entering the market. Additionally, when firms use private laboratories that produce reliable test results, FDA's laboratory resources can be devoted to other regulatory matters.

FDA estimates that importers have used over 100 separate private laboratories to generate analytical data for submission to FDA. These submissions go to FDA offices throughout the United States, and questions have arisen regarding the coordination of FDA and private laboratory services. In 1996, FDA held several ''grassroots'' meetings in Brooklyn, NY, Orlando, FL, Houston, TX, and Oakland, CA, to discuss how FDA might improve its policies and procedures relating to the use of private laboratories and establish a uniform, systematic, and effective approach to assure that private laboratories conducting tests on FDA-regulated products submit scientifically sound data (see Food and Drug Administration, ''Private Laboratory Grassroots Meetings 1996'' (available on the Internet at *http://www.fda.gov*, in the ''ORA'' section, ''Scientific References'' directory)). The grassroots meetings resulted in an action plan which suggested, among other things, that FDA:

1. Establish consistent, and objective national standards for the format and content of analytical data that private laboratories submit to FDA;

2. Require independent sampling so that FDA may be assured that samples collected and tested by private laboratories are truly representative of a lot or shipment and are collected properly to ensure the integrity of any samples that were collected for testing; and

3. Require private laboratories to report analytical results directly to FDA to assure that the results are reported fairly. Even though some participants supported reporting results to FDA directly, other participants stated that sampling results should be sent to the private laboratory's ''client'' first or that direct reporting to FDA would not provide any assurance regarding the private laboratory's competency.

The agency also indicated that it would consider how laboratory accreditation might affect its relationship with private laboratories. Participants at several meetings supported an accreditation concept, but did not agree on the accreditation body. Some participants suggested that FDA or other entities should establish an accreditation process that complies with the International Organization for Standardization (ISO)/International Electrochemical Commissioner (IEC) Guide 58 (''Calibration and Testing Laboratory Accreditation Systems—General Requirements for Operation and Recognition'') procedures. Others suggested laboratories be accredited using ISO/IEC Guide 25 (''General Requirements for the Competence of Calibration and Testing Laboratories''), which has since been replaced by ISO/IEC 17025, ''General Requirements for the Competence of Testing and Calibration Laboratories''. FDA is aware of other ISO/IEC guides, such as ISO/IEC Guide 61 (''General Requirements for the Assessment and Accreditation of Certification/Registration Bodies'') that might be used. Other participants mentioned using the National Environmental Laboratory Accreditation Conference, using validation programs from the Association of Official Analytical Chemists (AOAC), or having FDA set up a separate accrediting system.

Additionally, in 1998, the Senate Governmental Affairs Committee's Permanent Investigations Subcommittee held hearings on the safety of food imports. The committee heard testimony about various methods used to avoid food safety inspections and to introduce adulterated food into the United States. These methods included substituting clean food samples for the adulterated food import and testing multiple food samples until a sample meets FDA's approval (see ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998 (statement of ''Former Customs Broker''); see also ''The Safety of Food Imports; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' May 14, 1998 (statement of Reggie Jang)).

On July 3, 1999, then-President Clinton issued a memorandum on the safety of imported foods. The memorandum identified food safety as a high priority and directed the Secretary of Health and Human Services and the Secretary of the Treasury, among other things, to take all actions available to ''set standards for private laboratories for the collection and analysis of samples of imported food for the purpose of gaining entry into the United States.'' Subsequently, FDA and the U.S. Customs Service (Customs Service) held two public meetings on imported food safety. These meetings, during which interested persons could comment on the issues identified by FDA, including the private laboratories initiative, were held on February 10, 2000, in Los Angeles, CA, and on February 17, 2000, in Washington, DC. FDA addresses comments from those meetings later in this document.

More recently, President Bush strongly supported efforts at FDA and other health agencies to respond to and treat potential bioterrorism attacks. The administration identified improving food safety, particularly in relation to imported food, as a key goal.

In March 2003, the administration launched Operation Liberty Shield, a comprehensive national plan designed to increase protections for American citizens and infrastructure while maintaining the free flow of goods and people across the nation's border with minimal disruption to the economy and American way of life. One component of Operation Liberty Shield involves increased food security, including enhanced inspection of imported food. This proposed rule complements efforts to enhance inspection of imported food by helping assure the integrity and scientific validity of data and results submitted to FDA concerning imported food. Furthermore, Homeland Security Presidential Directive HSPD–9 directs Federal agencies to ''develop nationwide laboratory networks for food, veterinary, plant health, and water quality that integrate existing Federal and State laboratory resources, are interconnected, and utilize standardized diagnostic protocols and procedures.'' In developing the final rule, FDA will coordinate with other Federal agencies to ensure that the protocols and procedures required for private

laboratories fit appropriately within this framework.

This proposed rule would codify the requirements for sampling services and private laboratories used in connection with imported food. By doing so, the proposed rule would help deter the importation of unsafe food.

II. Description of the Proposed Rule

The proposal would add in title 21 CFR a new part 59 entitled ''Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food.'' The proposal would create four subparts. Subpart A of proposed part 59 would contain general information, such as scope and definitions. Subpart B of proposed part 59 would describe the obligations of persons who use private laboratories to submit data to FDA. Subpart C of proposed part 59 would establish requirements for sampling services. Subpart D of proposed part 59 would establish requirements for private laboratories.

A. Proposed Subpart A—General Information

1. Who Is Subject to This Part? (Proposed § 59.1)

Proposed subpart A of part 59 would consist of two provisions. Proposed § 59.1 would describe the rule's scope and state that proposed part 59 applies if you:

- Use a sampling service to collect samples of an imported food in connection with an FDA enforcement action; or
- Use a private laboratory to collect, analyze, or test samples of an imported food in connection with an FDA enforcement action.

The proposal would explain that FDA enforcement actions would include, but not be limited to, product seizure, refusal of imports, or the issuance of an injunction.

You would also be subject to part 59 if you are a sampling service or a private laboratory and you have been hired or retained to collect, test, and/or analyze an imported food in connection with an FDA enforcement action. For example, if you are a private laboratory, and an importer wants you to test an imported food and to use your test results to ask FDA to allow the imported food into the United States, you would be subject to part 59. In contrast, if an importer wants you to test an imported food to determine whether a food meets other Federal requirements (i.e., requirements not administered by FDA or standards that are not involved in an FDA enforcement action), part 59 would not apply to you because no FDA enforcement action is involved.

You should also note that, if you are a private laboratory that collects its own samples in connection with an FDA enforcement action, you would be subject to the requirements for sampling services, in addition to the requirements for private laboratory analysis.

2. What Definitions Apply? (Proposed § 59.3)

Proposed § 59.3 would define three terms.

Proposed § 59.3(a) would define FDA as the U.S. Food and Drug Administration.

Proposed § 59.3(b) would define ''private laboratory'' as an independent person who analyzes or tests samples of imported food. Please note that section 201(e) of the act (21 U.S.C. 321), in turn, defines ''person'' as including individuals, partnerships, corporations, and associations.

Proposed § 59.3(c) would define a ''sampling service'' as an independent person who collects samples of an imported food. The definition would explain that sample collection may include collecting samples from lots of imported food in conformance with FDA-recommended sampling procedures and schedules (see, e.g., Food and Drug Administration, *Investigations Operations Manual*, ch. 4—Sampling (January 1999)).

As stated earlier, you should note that a private laboratory may also be a ''sampling service'' if the private laboratory collects its own samples for testing or analysis in connection with an FDA enforcement action. In other words, a private laboratory that acts as a sampling service would be subject to the requirements for sampling services in addition to the requirements for private laboratories.

B. Proposed Subpart B—Requirements for Persons Using Private Laboratories and Sampling Services in Connection With Imported Food

Proposed subpart B of part 59 would describe the requirements for persons who use private laboratories and sampling services in connection with imported food.

1. What Requirements Apply if You Use Sampling Services? (Proposed § 59.101)

Under proposed § 59.101, if you intend to use a sampling service to collect samples of an imported food in connection with an FDA enforcement action, you must:

- Notify the FDA district office that is reviewing the entry of the imported food of your intent to use a sampling service. Your notification must include the name and address for each sampling service you intend to use, each sampling service's qualifications and knowledge of sampling procedures, a primary contact (name and phone number) for each sampling service, the address where the sampling records will be maintained, and the reason(s) why the food is being sampled;
- Give to each sampling service the Customs Service entry number, FDA entry line number (if applicable or available), the location of the lot that will be sampled, sufficient information to identify the lot to be sampled, and the name and address of the private laboratory that will test the sample;
- Not influence or interfere with the manner and process in which samples are collected. For example, you should not prevent the sampling service from collecting the samples itself, dictate how samples are collected, or restrict the sampling service's ability to obtain a representative sample from the imported food; and
- Maintain control of the lot from which the sample was taken until FDA notifies you that you can release the lot or take other action on the lot.

2. What Requirements Apply if You Use Private Laboratories? (Proposed § 59.103)

Under proposed § 59.103, if you use a private laboratory to test or analyze samples of an imported food in connection with an FDA enforcement action, you must:

- Notify the FDA district office that is reviewing the entry of the imported food of your intent to use a private laboratory and to have the private laboratory submit the results and supporting data to FDA. Your notification must include the private laboratory's name and address, its qualifications, a primary contact (name and phone number), the address where the test will be conducted (if different from the private laboratory's address), and the reason(s) why the product is being tested or analyzed;
- If the private laboratory will obtain the sample for testing, give to the private laboratory the Customs Service entry number and FDA entry line number (if applicable or available);
- Not influence or interfere with the manner and process in which samples are tested and/or analyzed. For example, you should not tell the private laboratory how it should test the samples or which piece of equipment to use;
- Maintain control of the lot from which the sample was taken until FDA

notifies you that you can release the lot or take other action on the lot; and

• If more than one private laboratory is or will be conducting tests, notify all private laboratories involved and FDA. The notice must state how many private laboratories are conducting or will conduct tests or analyses and describe those tests or analyses.

Proposed §§ 59.101 and 59.103 are intended to notify FDA about any sampling service or private laboratory that will be used in connection with an imported food and to enable those parties to perform their tasks effectively and independently. They are also intended to deter manipulation, alteration, or substitution of the samples that a private laboratory will test or selective reporting of a private laboratory's results. A 1998 Senate hearing on the safety of food imports noted these types of abuse when a former customs broker testified that some unscrupulous importers attempt to deceive FDA by selecting samples that may not be from the correct shipment or by submitting multiple samples to a private laboratory for testing until they obtain a sample that will comply with the act and reporting only the successful test (see ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998 (statement of ''Former Customs Broker'')).

FDA considered whether to require all importers who analyze their products to use independent sampling services. Such a requirement could help ensure that samples are not manipulated, altered, or substituted during the sampling process, but could be unfair to those importers who sample their own imported food in a legitimate manner. FDA, therefore, invites comment on whether this rule should require the use of independent sampling services.

3. What Requirements Apply if You Collect Your Own Samples? (Proposed § 59.105)

Proposed § 59.105 would apply if you collect samples of your own imported food and intend to have them tested or analyzed in connection with an FDA enforcement action. In brief, the proposal would require you to adhere to the same requirements that a sampling service must observe. The requirements for sampling services, which are described in more detail in the following discussion of proposed § 59.201, are intended to ensure that samples are correctly identified, collected, and maintained. These requirements also should help deter unscrupulous food importers from attempting to manipulate samples or to substitute foods that are known to be in compliance with the act for a possibly adulterated or misbranded imported food.

C. Proposed Subpart C—Requirements for Sampling Services

What Are the Requirements for Collecting, Identifying, and Maintaining Samples? (Proposed § 59.201)

Proposed subpart C of part 59 would describe the requirements for sampling services. In brief, if you are a sampling service who is subject to the rule, proposed § 59.201(a) would require you to perform the following operations independently:

• Verify the location, identity, and size of the lot to be sampled;

• Collect samples following established procedures that ensure the sample's integrity, accuracy, and representational nature;

• Ensure the integrity of the sample after the sample is collected. You can do this by including proper identification to avoid mixups between samples, avoiding contamination of the sample and the lot to be sampled, maintaining sterility or appropriate temperatures, or taking other measures to protect the sample's integrity;

• Identify all containers from which samples are collected. You can do this by placing the FDA entry line number or Customs Service entry number on the sample container that is to be shipped to the private laboratory and also by identifying the container from which the sample was collected;

• Complete a sample collection report for each sample collected. The proposal would require that the sample collection report, at a minimum, document sample collection methods and sample preparation techniques; and

• Prepare and ship the sample, using precautions where necessary to prevent contamination, to maintain the sample's integrity, or to maintain sterility or appropriate temperatures, and ship the original sample collection report directly to the private laboratory.

These provisions are intended to ensure that you properly collect, identify, and maintain samples from the time you collect the sample until the time you deliver the sample to a private laboratory. Additionally, by using the word ''independently,'' the proposed rule would have you perform these sampling operations without interference from or assistance by the person who retained your services. If you are collecting samples and are employed by the person who owns or imported the food (as allowed by proposed § 59.105), the word ''independently'' indicates that you should perform the sampling operations free from coercion or undue interference from your employer. For example, you should determine how samples are to be collected, the methods to be employed, and the quantity to be collected; your employer should not dictate how you will collect samples or provide the samples to you.

If you are a sampling service who is subject to the rule, proposed § 59.201(b) would require you to retain records documenting your compliance with proposed § 59.201(a). These records would include documents showing how you identified, collected, and maintained the sample. You may choose either to follow an FDA procedure for sampling, for example, those published in FDA's investigations operations manual, or any other applicable procedure that ensures the integrity, accuracy, and representational nature of the sample. If you collect samples under an established, non-FDA procedure, the proposal would require you to retain records concerning that procedure. You could do this either by retaining the procedure itself or records referring to the specific procedure if the procedure is publicly available. If you collect samples under an FDA sampling procedure, you can omit the FDA sampling procedure from your records, but you should keep notes to show which FDA sampling procedure you used. The proposal would require you to retain these records for 3 years after you have sent the sample collection report to the private laboratory and to make the records available to FDA, upon request, for inspection and copying.

D. Proposed Subpart D—Requirements for Private Laboratories

Proposed subpart D of part 59 would pertain to private laboratories and would consist of two provisions.

In drafting this proposed rule, FDA carefully considered whether to require private laboratories subject to proposed part 59 to be accredited. Accreditation would show that the private laboratory is competent to perform specific tasks, but would not, by itself, guarantee that a private laboratory's test or analytical results are correct or that it performed the tests or analyses correctly. Nevertheless, accreditation could increase confidence in the private laboratory's results.

The agency also considered whether the accreditation would have to operate in conformance with ISO/IEC 17025 or

with any other specific standard. Both FDA and the Customs Service heard comments at the public meetings that supported requiring accreditation of private laboratories, but some comments wanted less FDA oversight or fewer FDA inspections in exchange for accreditation. FDA also examined accreditation costs and the time required to go through an accreditation process.

Given these considerations, FDA decided to omit a laboratory accreditation requirement from the proposed rule. While the agency strongly encourages laboratories to become accredited, questions about the accreditation standard to be used, how FDA would ensure that the accrediting body is a recognized or competent accrediting body, and other issues suggest that it would be premature for FDA to propose requiring private laboratories to be accredited. The agency invites comment on this subject.

1. What Requirements Pertain to Analyzing Samples, Preparing Analytical Reports, and Maintaining Records? (Proposed § 59.301)

If you are a private laboratory subject to the rule, proposed § 59.301 would require you to observe certain requirements when handling or testing samples, preparing analytical reports, or maintaining records. In brief, proposed § 59.301(a) would require you to:

- Verify that the sample received corresponds to the sample described on the sample collection report. You can do this by identifying the sample by the Customs Service entry number and FDA entry line number (if applicable or available) or other appropriate identifying information in the sample collection report, and by documenting the conditions under which the sample was received (e.g., measures taken to prevent contamination, to maintain the integrity of the sample, or to maintain sterility or appropriate temperatures);
- Confirm the reasons for analyzing the sample;
- Use appropriately validated or recognized analytical procedures to analyze the sample, including the creation and maintenance of a reserve portion of a composite sample; and
- Prepare an analytical report for submission with the original sample collection report and complete analytical package. The proposal would require the analytical package to: (1) Describe the analytical methods used, (2) include an original compilation of all data and corresponding quality control results supporting the test, (3) include reagent blank and spike recovery data, (4) describe instrumental conditions and parameters, (5) include the analysts' signatures, and (6) include calculations. The proposal would also require the analytical report to contain a certificate of analysis.

Proposed § 59.301(b) would require you to provide, as part of your analytical package, an affidavit stating that:

- The analytical package pertains to the only test(s) done on the lot or product and that you are not aware of any other tests being performed on the lot; or
- If you are aware of other tests being performed by other persons, the name and address of the person conducting the other tests. FDA is not proposing to require you to investigate whether other persons are conducting tests; you would only provide this information if you are aware of other tests being performed by other persons.

Proposed § 59.301(c) would require you to submit the analytical package and the original sample collection report to the FDA district office that is reviewing the entry of the imported food. Additionally, it would require you to maintain records relating to proposed § 59.301 for 3 years after you submitted the analytical package and original sample collection report to FDA, and, upon request, to make records available to FDA for inspection and copying.

These provisions are intended to ensure that, if you submit analytical packages to FDA, you have analyzed the correct sample, used appropriate analytical or testing methods, and acted independently. Furthermore, by requiring you to send the analytical package and sample collection report directly to FDA, the proposal would increase the agency's confidence that the analytical package accurately represents the private laboratory's findings. FDA notes that the proposal would not preclude you from sending a duplicate copy of the analytical package to the person who retained your services. FDA is leaving these arrangements up to you and those who retain your services.

2. What Are the Requirements for Private Laboratories Collecting Samples? (Proposed § 59.303)

FDA recognizes that many private laboratories may prefer to collect samples themselves. Thus, to ensure that these private laboratories observe the same requirements that would be placed on sampling services, proposed § 59.303 would state that, if you are a private laboratory who collects samples of imported food in connection with an FDA enforcement action, you must comply with the sampling service requirements contained in proposed subpart C (''Requirements for Sampling Services'').

III. Public Meeting Comments and Responses

As stated earlier, FDA and the Customs Service held two public meetings on February 10, 2000, in Los Angeles, CA, and on February 17, 2000, in Washington, DC, to discuss issues related to the safety of imported food. Several comments focused on the private laboratories issue. Those comments and FDA's responses are addressed in this section. To make it easier to identify comments and FDA's responses to the comments, the word ''Comment'' will appear before the description of the comment, and the word ''Response'' will appear before FDA's response. FDA also has numbered each comment to make it easier to identify a particular comment. The numerical value assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was submitted.

(Comment 1) Some comments said that FDA should expand the rule to cover all private laboratories dealing with any FDA-regulated product instead of limiting the rule to private laboratories involved with imported food.

(Response) While the concepts and principles expressed in the proposed rule may be relevant to private laboratories dealing with FDA-regulated products other than imported food products, FDA has elected to focus on private laboratories involved with imported food. This focus corresponds to concerns regarding the safety of imported food. Additionally, FDA is not aware of any significant problems associated with private laboratories that test or analyze other FDA-regulated products other than imported food products.

(Comment 2) Several comments stated that, if FDA intends to regulate private laboratories and to require laboratory accreditation, FDA should accept the results from those laboratories and either reduce (if not eliminate) its oversight of private laboratories or let those private laboratories act in FDA's place. Some comments argued that private laboratories are able to conduct tests more quickly than FDA's laboratories and reach results that are as good as, if not superior to, FDA's laboratory results.

(Response) The proposed rule does not require laboratories to be accredited. FDA also declines to draft the rule to allow private laboratories to act in FDA's place. Under section 801 of the

act (21 U.S.C. 381), FDA, rather than the importer or a private laboratory retained by the importer, has the responsibility for deciding whether an imported article complies with the act.

(Comment 3) One comment urged FDA to accredit private laboratories itself. The comment stated that only FDA has the necessary experience to judge the adequacy of private laboratory facilities and the competency of their analysts. The comment asked FDA to publish accreditation requirements and create an appeals process, but also said that FDA must absorb accreditation costs itself in order to avoid any burden on small businesses. The comment said a ''user fee'' on all FDA-regulated imports could defray FDA's accreditation costs.

(Response) FDA lacks explicit statutory authority to impose ''user fees'' for this purpose and also lacks the resources that would be necessary to implement and operate an accreditation program for private laboratories. Consequently, FDA declines to adopt the comment's suggestions.

(Comment 4) Some comments asked FDA to ''accredit,'' ''approve,'' or license sampling services. The comments explained that private laboratories should not be held accountable for samples collected by other parties and that the reliability of a private laboratory's results depends largely on the sample being tested. A few comments said that FDA should charge sampling services as part of any accreditation, approval, or licensing program. Other comments suggested that some entity (not necessarily FDA) accredit sampling services.

(Response) FDA recognizes the value in ensuring that sampling services are capable of performing their tasks in a competent manner. However, FDA is unaware of any accreditation system for sampling services, and resource limitations prevent FDA from ''approving'' or licensing sampling services itself or establishing an accreditation, approval, or licensing system for private laboratories.

(Comment 5) One comment sought a governmentwide certification process so that laboratory results would be accepted by all Federal Government agencies. The comment noted that other Federal agencies have certification programs and receive fees for such certifications.

(Response) The proposed rule focuses on importers, sampling services, and private laboratories involved with imported food. A broader initiative would require input across a broad range of agencies. A need for the broader initiative has not yet been demonstrated. The issue of a governmentwide certification program is outside the scope of this proposed rule.

(Comment 6) One comment argued that requiring importers to notify FDA if they intend to use a sampling service or a private laboratory has no benefit. Another comment mistakenly construed the notice as requiring FDA approval before a sampling service or private laboratory began work.

(Response) The notices to FDA in proposed §§ 59.101 and 59.103 are supposed to alert FDA that an importer intends to use a sampling service or a private laboratory in connection with an imported food. It would also enable FDA to check whether the sampling services and private laboratories identified in the notices are, in fact, the same sampling services and private laboratories that collect or test the samples. For example, if an importer notifies FDA that it intends to use private laboratories A, B, and C, but private laboratory X submits the analytical package to FDA, FDA may decide to look into the reasons why the importer used a different laboratory.

No prior FDA approval is necessary before the sampling service or private laboratory may begin work. The agency does not have the resources that would be needed for such an approval system and related matters (such as resolving disputes if the agency decided to not approve a particular sampling service or private laboratory).

(Comment 7) Several comments urged FDA to treat perishable goods differently from other food products. The comments said that delays in admitting perishable goods into the United States reduced their value or their potential value if FDA ultimately refuses admission. Another comment added that some goods have seasonal values so that their value rises or falls over time.

(Response) The proposed rule has no direct bearing on how quickly perishable or seasonal goods are sampled or analyzed or how they are admitted or refused admission into the United States. Consequently, the proposal treats all imported foods alike.

IV. Legal Authority

Several provisions of the act provide the legal authority for the proposed rule. In brief, section 402 of the act (21 U.S.C. 342) defines when a food is deemed adulterated, and section 403 of the act (21 U.S.C. 343) defines when a food is deemed misbranded. The act prohibits a number of actions concerning adulterated or misbranded food, including the introduction or delivery for introduction into interstate commerce of any adulterated or misbranded food. (See section 301 of the act (21 U.S.C. 331).) The act does, however, allow owners or consignees of imported products to seek FDA's permission to take actions to bring an otherwise violative imported food into compliance with the act. (See section 801(b) of the act (21 U.S.C. 381(b).)

The act also authorizes FDA to take various enforcement actions such as injunctions (see section 302 of the act (21 U.S.C. 332)), and seizures (see section 304 of the act (21 U.S.C. 334)).

To enforce these and other provisions of the act, the act authorizes FDA to conduct examinations and investigations (see section 702 of the act (21 U.S.C. 372)), to conduct factory inspections (see sections 704 and 706 of the act (21 U.S.C. 374 and 376)), and to examine and, where appropriate, to refuse admission to imported products (see section 801 of the act). The agency may also take samples for analysis, and, in the case of food samples, may impose ''reasonable exceptions'' and ''reasonable terms and conditions'' relating to the sample collection (see sections 702(b) and 801(a) of the act). Section 701(a) of the act further authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the Department of the Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

Additionally, section 361 of the Public Health Service Act (the PHS Act) authorizes the agency to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries (see 42 U.S.C. 264).

The proposed rule would apply where a person uses a sampling service and/or a private laboratory for an imported food when the sample is to be tested or analyzed in connection with an FDA enforcement action. The sampling service or the private laboratory will provide evidence that may help the agency determine whether the imported food is adulterated, misbranded, or otherwise violates the act or the PHS Act and whether FDA should permit the product to enter interstate commerce. Consequently, FDA must have some confidence and assurance that the sampling service and private laboratory are performing their tasks accurately and reliably. The proposed rule would, therefore, establish uniform requirements for sampling services and private laboratories. In doing so, the proposed rule would further promote the efficient enforcement of the act's

adulteration, misbranding, and prohibited acts provisions, as well as the act's provisions on imports, and inspections and examinations. The proposed rule would also be consistent with the PHS Act's provisions regarding protection against the spread of communicable disease because contaminated food products can spread certain communicable diseases.

V. Environmental Impact

FDA has determined under 21 CFR 25.30(a) and (h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Reporting and Recordkeeping Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food

Description: The proposed rule would, in part, require persons who use sampling services and private laboratories in connection with imported food to notify FDA, to prepare sample collection reports, to keep records regarding sample collection, to prepare and submit analytical reports to FDA, and to prepare and sign an affidavit.

Description of Respondents: Businesses and individuals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
59.101	1,739	4.8	8,329	1	8,329
59.103	1,739	5.0	8,767	1	8,767
59.201(a)(4)	200	44	8,767	1	8,767
59.201(a)(5)	200	44	8,767	1	8,767
59.301(a)(4)	200	44	8,767	2	17,534
59.301(b)	200	44	8,767	0.5	4,384
Total					56,548

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
59.201(b)	200	44	8,767	1	8,767
59.301(c)	200	44	8,767	0.5	4,384
Total					13,151

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based its estimates on the number of food importers (as identified in a database) and the numbers of sampling services and private laboratories that currently submit information to the agency regarding imported food. In fiscal year (FY) 1999, there were 1,739 food importers, and approximately 100 private laboratories submitted analytical data concerning imported food products to FDA. The agency is unable to predict whether the proposed rule will lead to any changes in the number of private laboratories submitting data to FDA, but, for purposes of estimating the information collection burden for this proposal, will assume that 200 private laboratories (twice the number of private laboratories currently submitting data on imported food to FDA) will be affected.

As for sampling services, FDA notes that most private laboratories conduct their own sample collection operations and that there are few (perhaps 10) sampling services. However, because the proposed rule would require private laboratories that collect samples to adhere to the same requirements as sampling services, for those provisions involving a collection of information from sampling services, FDA has decided to count 95 percent of the private laboratories (190 private laboratories) as adhering to the sampling service requirements in addition to the 10 known sampling services, thus resulting in 200 sampling services.

To determine the information collection burden for proposed § 59.101, FDA assumed that all 1,739 food importers would be affected. FDA data for FY 1999 indicates that approximately 11,690 food imports were detained for safety reasons. If 75 percent of these shipments are sampled, this would lead to 8,767 samples. However, FDA's experience suggests that sampling rates vary; in some areas, importers do very little sampling themselves and, instead, use sampling services. As described in section VII of this document, and for purposes of this information collection estimate, FDA will assume that importers will perform

only 5 to 20 percent of the sample collection themselves, so that, at most, 8,329 shipments (95 percent of 8,767 shipments) would be sampled by sampling services. This, in turn, would result in a response frequency of approximately 4.8 shipments per importer (8,329 shipments/1,739 food importers = 4.789 shipments/importer, rounded up to 4.8) and 8,329 sampling service notifications to FDA under proposed § 59.101. Given the minimal nature of the information sought, FDA estimates that only 1 hour would be needed to complete each notification.

For proposed § 59.103, FDA notes that not all food samples lead to laboratory analyses. In fiscal year 1999, FDA received 8,767 laboratory tests or analyses on imported food. Thus, for proposed § 59.103, the agency assumes that all 1,739 food importers may be affected and that 8,767 private laboratory notifications may result. The frequency of responses per importer, therefore, would be approximately 4.6 (8,767 notifications/1,739 importers = 5.04 notifications per importer). Again, given the minimal nature of the information sought, FDA estimates that only 1 hour would be needed to complete the notification.

For proposed § 59.201(a)(4), (a)(5), and (b), the agency, as explained earlier, estimates that 200 sampling services would be affected. Although sampling services have submitted reports to FDA as part of an analytical package for a submission from a private laboratory previous to this proposed rule, these submissions are not considered a ''usual and customary business practice.'' Usual and customary business practices are not included in the burden calculated in the Paperwork Reduction Act Analysis. However, because the sampling reports are in response to government requirements, they are not considered usual and customary. Because proposed § 59.201 would, in essence, pertain to sample collection reports that are sent forward to private laboratories (as opposed to reports of all samples) and because FDA receives approximately 8,767 laboratory tests or analyses on imported food annually, the agency estimates that the proposal would result in 8,767 sample collection reports and records each year, at a frequency of 44 sample collection reports per sampling service (8,767 tests/200 sampling services = 43.8 tests per sampling service, and each test should result in a sample collection report). While sample collection reports would be prepared and records would be kept regardless of the regulation (because the sampling service would document its procedures for the importer's or private laboratory's use), FDA cannot determine whether the proposal would require sampling services to devote additional time to such reports and records. Consequently, FDA has assigned 1 burden hour per identification of the containers from which samples are collected, 1 burden hour per sample collection report for reporting purposes, and 1 burden hour per sample collection report for recordkeeping purposes.

FDA estimates that 200 private laboratories would be subject to the information collection requirements in proposed § 59.301(a)(4), (b), and (c). Because FDA currently receives approximately 8,767 laboratory reports annually, the agency estimates that the proposal would result in preparation, submission, and recordkeeping of 8,767 analytical packages and affidavits each year, at a frequency of approximately 44 packages and affidavits per private laboratory (8,767 laboratory reports/200 private laboratories = 43.8 laboratory reports per private laboratory, with each report resulting in an analytical package and affidavit). The analytical packages submitted by private laboratories are also not considered usual and customary business practices, because they are in response to government requirements. They are also included in the estimate of paperwork burden. The analytical packages described in the proposed rule are similar to analytical packages currently submitted to FDA, so the agency has assigned only 1 burden hour for the preparation of each analytical package (proposed § 59.301(a)(4)) and another burden hour for recordkeeping purposes (proposed § 59.301(c)). As for the affidavit described in proposed § 59.301(b), the information sought in the affidavit does not require a person to conduct any investigations, research, or examinations in order to complete the affidavit, so FDA has assigned 30 minutes for each affidavit.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit comments regarding information collection to OMB (see **ADDRESSES** and **DATES**).

VII. Analysis of Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is a significant regulatory action as defined by the Executive order and so is subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because most food importers are small businesses, the proposal could have a significant economic impact on a substantial number of small entities. The agency's Regulatory Flexibility Act analysis appears later in section VII.F of this document.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). As discussed later in section VII.G of this document, FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

B. Need for the Regulation

Current policies for sampling services and private laboratories do not create sufficient safeguards to prevent importers testing into compliance, which is testing multiple samples from a shipment and submitting only those results that will allow the shipment to enter the United States, or banking samples, which is retaining samples from a previous, acceptable shipment and submitting these samples instead of samples from the shipment that should be tested. Both of these activities permit importers to market adulterated or misbranded foods in the United States, representing a health hazard for American consumers.

Also, there is a lack of consistency in standards for sampling services and private laboratories across districts. Currently, ch. 21 entitled ''Guidance on the Review of Analytical Data,'' *FDA Laboratory Procedures Manual* lays out guidance for importers and their agents.

Although this guidance provides important information for importers, it is not sufficiently specific and may have contributed to a lack of consistency between districts. This lack of consistency creates barriers to entry for new private laboratories, inhibiting the competitiveness of the industry.

C. Regulatory Options

1. No New Regulatory Action

FDA can take no new regulatory action and rely on current guidance with enhanced enforcement to improve the quality of test submissions for food imports on detention without physical exam (DWPE). However, the current standards for sample collection do not provide safeguards against fraudulent sample collection. The lack of these safeguards makes ensuring appropriate sample collections difficult. Additionally, this will not correct the lack of consistency between districts in laboratory submission requirements.

2. Require the Use of Independent Sampling Services

One goal of the proposed rule is to aid in ensuring that representative samples from questionable shipments are tested correctly. Sampling by the importer creates the possibility that importers will control the composition of samples from their shipments. Requiring the use of an independent sampling service, which may be a third party or the private laboratory doing the testing, would decrease the opportunity for importers to cheat. Because FDA does not know how many importers deliberately take nonrepresentative samples, it is difficult to quantify the benefits, but the rule, if finalized, should reduce the number of violative shipments that enter the United States.

Requiring the use of an independent sampling service would only be costly for those importers who have not previously used independent sampling services. Therefore, the cost of this alternative depends on the number of importers not using independent sampling services. Currently, the number of importers that use independent sampling services varies between districts. Many districts, including Baltimore, Los Angeles, San Francisco, and Dallas, strongly encourage the use of an independent sampling service. In these districts, less than 1 percent of shipments are sampled by the importer. In other ports, such as New York, as much as 27 percent of shipments are sampled by the importer. The percentage of importers using a sampling service is clearly more than 1 percent, but probably less than 27 percent. A reasonable estimate of the percentage of all shipments that are sampled by the importer is between 5 percent and 20 percent.

In FY 1999, approximately 11,690 food shipments were detained without physical exam for reasons that may have led to a laboratory analysis. If 75 percent of the shipments were sampled, 8,767 shipments would have required the taking of a sample by the importer or an independent sampling service. The additional number of shipments that would be independently sampled would be between 438 (5 percent sampled by the importer) and 1,753 (20 percent sampled by the importer) in FY 1999.

The time required to sample a shipment depends on the reason for detention. Using the Office of Regulatory Affairs' workplan and the expertise of former field personnel, FDA estimated the time to sample shipments for different violations. Estimates of sampling time ranged from 3 hours to sample seafood for decomposition to 30 minutes to sample for filth. The weighted average of the sampling times for all shipments that were detained without physical examination was 1.25 hours in FY 1999. A typical laboratory charges $65 an hour for sampling. However, an importer sampling his or her own goods would still have to pay a worker. The Bureau of Labor Statistics reports the average cost to the employer to hire a blue-collar worker in transportation and material moving is $17 an hour. The difference between $65 and $17 an hour would be the incremental hourly cost to the importer for independent sampling. At an average sampling time of 1.25 hours, the average shipment would cost $60 (1.25 x $48) more to be sampled by an independent sampling service. This additional cost would be borne by 438 to 1,753 shipments, giving a total annual cost between $26,280 (438 x $60) and $105,180 (1,753 x $60).

3. Require Lab Accreditation

Requiring lab accreditation would provide assurance that the private laboratories testing imported food have the appropriate equipment, personnel, and procedures to conduct their analyses. Improved performance by private laboratories should reduce the number of test results that falsely approve violative shipments. However, this benefit is mitigated by FDA's careful review of results submitted by private laboratories. During this review, FDA analysts are able to identify most incorrectly done analyses.

Requiring accreditation is currently subject to a number of difficulties. First, there are very few accrediting bodies qualified to accredit laboratories. Since a small percentage of private laboratories that submit results to FDA are currently accredited (10 to 15 percent of more than 100 private laboratories), the infrastructure to accredit unaccredited private laboratories does not currently exist. Second, the preferred accreditation standard is being changed from ISO/IEC Guide 25 to ISO/IEC Standard 17025. Laboratories and accreditors are in the process of adopting the new requirements, creating additional strain on the accreditation process. Third, accreditation is costly. The fees to an accrediting body would be at least $6,900 for the first year per private laboratory. This fee does not include the costs to the laboratory of actions needed to meet accreditation standards: Hiring additional personnel, training, proficiency testing, and quality assurance procedures. The additional costs would typically be much larger than the accreditation fees. These costs may be particularly prohibitive for very small labs (33 percent of private labs have fewer than five employees).

4. The Proposed Rule

The proposed rule would require food importers to prenotify FDA of their use of a sampling service or a private laboratory. It would also create requirements for sampling services collecting imported food samples and create requirements for private laboratories testing imported food samples and submitting laboratory reports to FDA.

D. Benefits of the Proposed Rule

1. Shortened Review Time

Review of a typical private laboratory test package requires, at most, 3 days by FDA (although most reviews occur within 1 to 2 days). If the package is found to be unacceptable, FDA contacts the laboratory or importer and attempts to reach a consensus about the test results, whether the problem is inappropriate or inaccurate analytical reports or dubious test results. This dialogue with the lab and importer can greatly increase the amount of time the imported food is held at the port. Creating more consistent requirements for laboratories will reduce the number and length of delays in reviewing analytical packages. Since shipments lose value while the analytical package is being reviewed, a benefit of this rule would be the gain in value of shipments due to the shortened review time. This benefit is difficult to quantify in dollar terms, due to variation in shipment value, perishability, and review times.

For some shipments, such as fresh produce, there is a considerable deterioration of shipment value associated with delay, so the benefits of shortened review will be considerable.

2. Reduced Potential Fraud by Importers

Fraudulent activities by food importers have been alleged in the General Accounting Office (GAO) Report ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable'' (GAO/RCED–98–103) and ''The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998 (statement of ''Former Customs Broker''). These fraudulent activities include banking samples and testing into compliance. Both of these inappropriate activities would be more difficult for importers with required prenotification of private laboratory use and direct reporting of results to FDA.

Requiring importers to notify FDA of the private laboratory being used for testing before submission of the analytical package will discourage importers from using multiple laboratories to test samples and choosing the results most beneficial to their businesses. If the importer is required to notify FDA of the laboratory used before submitting samples to the laboratory, the importer is committed to using results from that laboratory. A secondary benefit of prenotification is improved communication between the private laboratory, the importer, and FDA, which may reduce review times.

Requiring the direct reporting of results from the lab to FDA would prevent importers from submitting multiple samples to a lab then choosing among the results for submission to FDA. It would also prevent importers from choosing not to submit results from violative shipments, ensuring that violative shipments will not be tested into compliance and admitted into the United States.

A secondary benefit to direct reporting would be improved enforcement of disposal of hazardous shipments and better tracking of shipments for removal from DWPE. Because FDA may recommend destruction of a shipment that poses a health hazard, the importer may not choose to report results showing that the shipment is a health hazard and instead take the shipment to another port. Also, the decision to remove an importer from DWPE is often affected by several (five or more) consecutive nonviolative shipments. If direct reporting is not required, the importer can choose not to submit results from any shipments that would disrupt the count of consecutive nonviolative shipments.

3. Health Benefits Resulting From a Reduction in Violative Food Entering the United States

It is difficult to determine how many violative shipments are admitted to the United States. Without knowing how many of these shipments are illegally admitted into the United States by importers banking samples or testing into compliance, FDA cannot quantify how much the proposed rule would reduce shipments of violative food admitted into the United States. However, the agency can quantify the costs of some of the illnesses that typically arise from consumption of violative imported foods.

Filth was the most common reason for detention in FY 1999. While filth itself may not pose a danger, it indicates that the food has been held in unsanitary conditions and so is at a higher risk for microbial contamination. Microbial contaminants such as *Salmonella* spp. and *Escherichia coli* O157:H7 can cause acute gastrointestinal illnesses, as well as chronic sequelae. Other risks associated with filth include dental injury, and aflatoxicosis (Ref. 11). Contamination with *Salmonella* and *Listeria* were also common reasons for detention (2,322 and 809 shipments, respectively). *Listeria monocytogenes* infection in a pregnant woman may result in spontaneous abortions or encephalitis in the newborn. For immuno-compromised persons, exposure to *Listeria* can result in septicemia or meningitis.

Illegal food additives (741 shipments) have been linked to gastroenteritis and disruptions of the nervous system (Ref. 11). Color additives (1,008 shipments), yellow no. 5 (46 shipments), and excess sulfites (47 shipments) were also common reasons for detention. These additives can cause allergic reactions with some sensitive individuals, ranging from mild contact dermatitis to a severe allergy attack (Ref. 11). Pesticide contamination (1,529 shipments) may also pose long-term risks of cancer, as well as kidney, liver, or central nervous system changes (Ref. 11). Foreign objects in food (381 shipments) may pose a hazard ranging from simple dental injury to esophageal perforation (Ref. 11).

Table 3 of this document shows some of the possible illnesses and injuries that can result from violative foods and includes their symptoms and an average cost per case. The quality-adjusted life days (QALD) (Ref. 10) column represents the lost utility per day to a consumer from an illness. It is essentially the loss to the consumer due to symptoms and problems associated with the illness. The QALDs are valued in dollars by multiplying the number of lost days by the value of a statistical day, $630 (64 FR 36516 at 36523, July 6, 1999). This value of a statistical life day is drawn from the economic literature (Ref. 12). The medical cost column is the direct, medical cost of illness, which includes hospitalization and doctor visits. Most illnesses arising from *E. coli* O157:H7 or *Salmonella* are self-limiting and short in duration. However, both *Salmonella* and *E. coli* O157:H7 can be serious. *E. coli* in some cases can result in kidney damage or death. *Salmonella* can sometimes trigger chronic arthritis and, in a small percentage of cases, can result in death.

TABLE 3.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE RULE

	Potential Harm	Symptoms	QALD Loss	Dollar Value of Lost QALDs	Medical Costs	Total Cost
Allergens[1]	Contact dermatitis	Reddening, swelling, itching of skin	2.10	$1,325	$125	$1,450
	Allergic reaction	Difficulty breathing, asthma, rash, possible shock	1.03	$646	$550	$1,196
Listeria contamination[2]	Moderate and severe listeriosis	Fever, nausea, diarrhea, may result in stillbirths, coma, death	1,754	$1,104,979	$9,548	$1,114,527

TABLE 3.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE RULE—Continued

	Potential Harm	Symptoms	QALD Loss	Dollar Value of Lost QALDs	Medical Costs	Total Cost
Objects in food[3]	Simple dental injury	Toothache, headache	0.23	$145	$0	$145
	Complex dental injury	Simple, plus infection	3.47	$2,187	$3,540	$5,727
	Oral emergency	Sharp pain in mouth, face, neck, bleeding, plus possible metastatic or local infection	4.27	$2,687	$3,540	$6,227
	Tracheo-esophageal obstruction	Choking, difficulty breathing, cyanosis, hypertension	0.48	$304	$0	$304
	Esophageal perforation	Pain in chest, bleeding aspiration pneumonia, requires surgery	13.93	$8,776	$14,160	$22,936
Salmonella contamination[4]	Salmonellosis	Vomiting, nausea, possible arthritis, low probability of death	24.37	$15,357	$2,289	$17,646
E. coli contamination[5]	*Gastroenteritis Hemolytic Uremic Syndrome*	Vomiting, nausea, bloody stools, possible kidney damage, low probability of death	10.79	$6,797	$4,829	$11,626

[1, 2, 3] Mauskopf et al., 1988.
[4, 5] 63 FR 24254.

4. Other Consumer Benefits

Although problems such as insects or filth in food may not necessarily represent a direct health threat, they show that the food was not held in sanitary conditions. Moreover, consumers who purchase food expect it to be clean and sanitary. The Food Marketing Institute found 89 percent of consumers surveyed ranked a clean, neat store as a very important factor in selecting their primary supermarket. If consumers pay a premium, believing their food is sanitary and the food is not, this payment represents a social loss. However, FDA cannot quantify the economic benefit from avoiding this social loss because the agency does not know what percentage of the price of food is a ''cleanliness premium.''

E. Costs of the Proposed Rule

The costs of this proposed rule arise from the new activities required over and above those already in existence. ''The Laboratory Procedures Manual,'' chapter 21 entitled ''Guidance on the Review of Analytical Data Generated by Private Laboratories'' lists the information that should be included in analytical packages for sample collections and analyses conducted by private laboratories that conduct analyses on FDA-regulated commodities imported into the United States submitted to FDA (Ref. 13). This is guidance for FDA field personnel who receive analytical packages from private laboratories on how to review these packages. This guideline replaces and is very similar to that in the ''Regulatory Procedures Manual,'' part 9, chapter 52 entitled ''Private Laboratories,'' revised January 1988 (Ref. 14). It specifies that submissions should include information on how the sample was collected, including identification of the sample, what sample collection procedures were used, and how the samples were prepared. For the analyses, the submissions should contain a description of the analytical methods used, raw data and results, instrumental conditions and parameters, analysts' signatures, and statements from the laboratory director and the importer that the report contains all analyses related to the sample.

To verify that the national guidance is followed, we communicated with field personnel in four districts: Los Angeles, San Francisco, Baltimore, and Southwest. Field personnel in all districts confirmed that they follow the national guidance or district guidance that has the same elements as the national guidance (Refs. 15 and 16). Since importers were not previously required to prenotify FDA of their intention to use a private laboratory, this requirement is a cost of the rule. Notification would likely require 30 to 60 minutes of a secretary's time at a cost of $17 per hour (Bureau of Labor Statistics). For 8,767 shipments each year, this cost would range from $74,519 to $149,039. Importers are also required to prenotify FDA of their intention to use a sampling service. Eighty to 95 percent of importers use sampling services, so this will require between 7,014 and 8,329 additional notifications. This additional cost will range between $59,619 and $141,593; this gives a total cost of $134,138 to $290,626 per year.

F. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. The primary impact of this rule will be on food importers. The small business definition for food importers is 100 employees or fewer; this definition applies to more than 95 percent of food importers. A search of companies in the Duns Market Identifiers database found 1,739 food importers that would potentially be affected by this rule. Of the 1,739 potentially affected food importers, 1,700 had fewer than 100 employees (Ref. 4). FDA finds that this proposed rule may have a significant economic impact on a substantial number of small entities, particularly if the notifications required by the rule are distributed unequally across firms.

FDA considered additional flexibility for small businesses by waiving the notification requirements. However,

since the vast majority of importers are small, this would reduce the benefits of the rule significantly. Also, the overall effect of the rule will be beneficial to small business, due to the clearer guidelines for gathering and handling samples and submission of analytical packages.

G. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). FDA has determined that this rule is not a significant action as defined in the Unfunded Mandates Reform Act and will not have an effect on the economy that exceeds $100 million adjusted for inflation in any one year. The current inflation-adjusted statutory threshold is $110 million.

VIII. Submission of Comments and Proposed Effective Date

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments regarding this proposal. Sumit written comments regarding information collection to OMB (see **ADDRESSES**). Two paper copies of any comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Aureli, P. et al, ''An Outbreak of Febrile Gastroenteritis Associated With Corn Contamination by *Listeria Monocytogenes*,'' *New England Journal of Medicine*, pp. 1236–1241, April 27, 2000.

2. Bureau of Labor Statistics, Employer Costs for Employee Compensation Summary, *http://stats.bls.gov/news.release/ecec.nws.htm*, 1999.

3. Congressional Hearing, ''The Safety of Food Imports: Fraud and Deception in the Food Import Process; Hearing Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations,'' September 10, 1998.

4. Dialog Classic, Search of Wholesalers Who Import With SIC Codes Between 5141 to 5149 That Are Importers, February 29, 2000.

5. Dalton, C. B. et al, ''An Outbreak of Gastroenteritis and Fever Due to *Listeria Monocytogenes* in Milk,'' *New England Journal of Medicine*, pp. 100–105, January 9, 1997.

6. Food and Drug Administration, ''Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Final Rule,'' (63 FR 37029 at 37037, July 8, 1998).

7. Food and Drug Administration, ''Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis of the Proposed Rule to Require Refrigeration of Shell Eggs at Retail and Safe Handling Labels,'' (64 FR 36516, July 6, 1999).

8. Food Marketing Institute, Consumer Attitudes and the Supermarket, Research International USA, 1999.

9. GAO Report, ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable'' (GAO/RCED–98–103).

10. Kaplan, R. M., J. P. Anderson, and T. G. Ganiats, ''The Quality of Well-Being Scale: Rationale for a Single Quality of Life Index,'' edited by Walker, S. R. and Rosser, R. M., *Quality of Life Assessment: Key Issues in the 1990s*, The Netherlands: Kluwer Academic Publishers, 1993.

11. Mauskopf, J. A., M. T. French, A. S. Ross, et al., ''Estimating the Value of Consumers' Loss From Foods Violating the Federal Food, Drug, and Cosmetic Act,'' Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.

12. Viscusi, W. K., ''The Value of Risks to Life and Health,'' *Journal of Economic Literature*, vol. 31, pp. 1912–1946, December 1993.

13. U.S. Food and Drug Administration, ''Laboratory Procedures Manual,'' chapter 21, available at *http://www.fda.gov/ora/science_ref/lpm/lpchtr21.html*, accessed on 3/17/2003.

14. U.S. Food and Drug Administration, ''Regulatory Procedures Manual,'' chapter 9-52, ''Import Procedures, Private Laboratories,'' revised 1988.

15. U.S. Food and Drug Administration, Baltimore District SOP Manual, S.O.P. # 609 Private Laboratories.

16. U.S. Food and Drug Administration, Pacific Region Private Laboratory Guidelines, Private Laboratory Analytical Collection Report, revised April 1995.

List of Subjects in 21 CFR Part 59

Foods, Imports, Laboratories, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR chapter I be amended as follows:

1. Part 59 is added to read as follows:

PART 59—REQUIREMENTS PERTAINING TO SAMPLING SERVICES AND PRIVATE LABORATORIES USED IN CONNECTION WITH IMPORTED FOOD

Subpart A—General Information

Subpart B—Requirements for Persons Using Private Laboratories and Sampling Services in Connection With Imported Food

Subpart C—Requirements for Sampling Services

Subpart D—Requirements for Private Laboratories

Authority: 21 U.S.C. 331, 332, 333, 334, 341, 342, 343, 344, 348, 371, 372, 374, 376, 381, 393; 42 U.S.C., 264.

Subpart A—General Information

§ 59.1 Who is subject to this part?

(a) The requirements in this part apply to you if you:

(1) Use a sampling service to collect samples of an imported food in connection with an FDA enforcement action; or

(2) Use a private laboratory to collect, analyze, or test samples of an imported food in connection with an FDA enforcement action.

(b) This part also applies to you if you are a sampling service or a private laboratory and you have been hired or retained to collect, analyze, or test an imported food in connection with an FDA enforcement action.

(c) 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 you collect, analyze, or test imported food samples for purposes not related to an FDA enforcement action.

§ 59.3 What definitions apply?

(a) *FDA* means the U.S. Food and Drug Administration.

(b) *Private laboratory* means an independent person who analyzes or tests samples of imported food.

(c) *Sampling service* means an independent person who collects samples of an imported food. Sample collection may include collecting samples from lots of FDA-regulated products in conformance with FDA-recommended sampling procedures and schedules.

Subpart B—Requirements for Persons Using Private Laboratories and Sampling Services in Connection With Imported Food

§ 59.101 What requirements apply if you use sampling services?

(a) If you intend to use a sampling service to collect samples of an imported food in connection with an FDA enforcement action, you must notify the FDA district office that is reviewing the entry of the imported food. Your notification must inform the FDA district office that you intend to use such services and include:

(1) The name and address for each sampling service you intend to use,

(2) Each sampling service's qualifications and knowledge of sampling procedures,

(3) A primary contact (name and phone number) for each sampling service,

(4) The address or addresses where the sampling records will be maintained, and

(5) The reason(s) why the product is being sampled.

(b) You must also:

(1) Give to each sampling service the U.S. Customs Service entry number, FDA entry line number (if applicable or available), the location of the lot that will be sampled, sufficient information to identify the lot to be sampled, and the name and address of the private laboratory that will test the sample;

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

(3) Maintain control of the lot from which the sample was taken until FDA notifies you that you can release the lot or take other action on the lot.

§ 59.103 What requirements apply if you use private laboratories?

(a) If you use a private laboratory to test or analyze samples of an imported food in connection with an FDA enforcement action, you must notify the FDA district office that is reviewing the entry of the imported food. Your notification must state that you intend to use a private laboratory and to have the private laboratory submit the results and supporting data to FDA. Your notification must also include:

(1) The private laboratory's name and address,

(2) The private laboratory's qualifications,

(3) A primary contact (name and phone number) for the private laboratory,

(4) The address where the test will be conducted (if different from the private laboratory's address), and

(5) The reason(s) why the product is being tested or analyzed.

(b) You must also:

(1) Give to the private laboratory the U.S. Customs Service entry number (if the product is imported or offered for import into the United States), and FDA entry line number (if applicable or available);

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

(3) Maintain control of the lot from which the sample was taken until FDA notifies you that you can release the lot or take other action on the lot; and

(4) If you will use or are using more than one private laboratory to conduct tests, notify all private laboratories involved and FDA. Your notice must state how many private laboratories are conducting or will conduct tests or analyses and describe those tests or analyses.

§ 59.105 What requirements apply if you collect 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.

Subpart C—Requirements for Sampling Services

§ 59.201 What are the requirements for collecting, identifying, and maintaining samples?

(a) If you collect samples of an imported food in connection with an FDA enforcement action, you must perform the following operations independently:

(1) Verify the location, identity, and size of the lot to be sampled;

(2) Collect samples following established procedures that ensure the sample's integrity, accuracy, and representational nature;

(3) Ensure the integrity of the sample after collection by including proper identification to avoid mixups between samples, avoiding contamination, maintaining sterility or appropriate temperatures, or taking other measures to protect the sample's integrity;

(4) Identify all containers from which samples are collected;

(5) Complete a sample collection report for each sample collected. The sample collection report must, at a minimum, document sample collection procedures and sample preparation techniques; and

(6) Prepare and ship the sample, using precautions where necessary to prevent contamination, to maintain the integrity of the sample, or to maintain sterility or temperatures, and ship the original sample collection report directly to the private laboratory.

(b) You must maintain records demonstrating your compliance with paragraph (a) of this section for 3 years after you have sent the sample collection report to the private laboratory. These records should include documents showing how you identified, collected, and maintained the sample. You must also make these records available to FDA upon request for inspection and copying. If you collect samples under an established, non-FDA procedure, you must retain records concerning that procedure. However, if you collect samples under an FDA sampling procedure, you can omit the FDA sampling procedure from your records, but you should keep notes to show which FDA sampling procedure you used.

Subpart D—Requirements for Private Laboratories

§ 59.301 What requirements pertain to analyzing samples, preparing analytical reports, and maintaining records?

(a) If you are a private laboratory conducting tests or analyses on an imported food, and the results and supporting data of those tests or analyses will be used in connection with an FDA enforcement action or submitted directly to FDA, you must:

(1) Verify that the sample received corresponds to the sample described on the sample collection report;

(2) Confirm the reasons for analyzing the sample;

(3) Use appropriately validated or recognized analytical procedures to analyze the sample, including the creation and maintenance of a reserve portion of a composite sample; and

(4) Prepare an analytical report for submission with the original sample collection report and complete analytical package. The analytical package must:

(i) Describe the analytical methods used;

(ii) Include an original compilation of all data and corresponding quality control results and supporting data supporting the test;

(iii) Include reagent blank and spike recovery data;

(iv) Describe instrumental conditions and parameters;

(v) Include the analysts' signatures;

(vi) Include the analysts' calculations; and

(vii) Contain a certificate of analysis.

(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 and that you are not aware of any other tests being performed; or

(2) If you are aware of other tests that are being or have been performed by other persons, the name and address of the person who is conducting or who has conducted the other tests.

(c) You must submit the analytical package and the original sample collection report to the FDA district office that processed the entry of the imported food. Additionally, you must:

(1) Maintain records relating to the requirements under paragraphs (a) and (b) of this section for 3 years after you submitted the analytical package and original sample collection report to FDA, and

(2) Upon request, make records available to FDA for inspection and copying.

§ 59.303 What are the requirements for private laboratories collecting samples?

If you are a private laboratory and collect samples of an imported food in connection with an FDA enforcement action, you must comply with subpart C of this part.

Dated: April 22, 2004.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

[FR Doc. 04–9699 Filed 4–26–04; 11:58 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[WV–089–FOR]

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; withdrawal.

SUMMARY: We are withdrawing a proposed rulemaking for an amendment to the West Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The proposed rulemaking pertained to the State's response to several letters that we had sent it, which identified changes to SMCRA and the Federal regulations and that may require amendments be made to the State coal regulatory program. We are withdrawing the proposed rulemaking, because, for the 12 items published as a proposed amendment, the State actually provided rationale for not making some changes, rather than proposing changes, and for various other reasons.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office, 1027 Virginia Street East, Charleston, West Virginia 25301. Telephone: (304) 347–7158; Internet address: *chfo@osmre.gov*.

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253 (a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the West Virginia program on January 21, 1981. You can find background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning West Virginia's program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Submission of the Amendment

By letter dated August 15, 2000, we requested that the West Virginia Department of Environmental Protection (WVDEP) provide us a response to six 30 CFR part 732 notifications that we had previously sent the State (Administrative Record Number WV–1178). The Federal regulations at 30 CFR 732.17(d) provide that OSM must notify the State of all changes in SMCRA and the Federal regulations that will require an amendment to the State program. Such letters sent by us are often referred to as ''732 letters or notifications.'' On December 20, 2000 (Administrative Record Number WV–1191), the WVDEP responded to our August 15, 2000, letter. We note that in its December 20, 2000, letter, the State incorrectly cited a March 6, 2000, letter from OSM rather than our August 15, 2000, letter.

The Federal regulations at 30 CFR 732.17(b) provide that the State regulatory authority shall notify OSM, as a possible program amendment, of any significant events or proposed changes which affect the implementation, administration or enforcement of the approved State program. In a January 12, 2001, **Federal Register** notice (66 FR 2866), we announced receipt of the State's December 20, 2000, letter and published it as a proposed rulemaking. In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on whether the proposed amendment satisfies applicable program approval criteria.

The State's December 20, 2000, letter addressed 22 part 732 items. For six of the items (identified in our **Federal Register** notice as 2, 3, 6.F, 6.G, 6.H, and 6.I), the State indicated that it would be submitting proposed changes in the future. These items relate to coal extraction incidental to the extraction of other minerals, special reclamation fund, prime farmland, qualified SOAP (Small Operator Assistance Program) laboratory, qualifications for SOAP assistance, and filing for SOAP assistance, respectively. We stated that, for those items, we would announce the proposed changes in a future proposed rule upon their submission. For four items (identified as 4, 5, 6.J, and 7 regarding subsidence and water replacement, ownership and control, bond release, and staffing, respectively), we stated that (for various reasons described in the notice) the State had not submitted program changes. Therefore, we did not make these 10 items part of the proposed rule.

For the remaining 12 items addressed in the State's December 20, 2000, letter, we did characterize the State's responses as a program amendment and invited comments on the proposal. However, for each of these 12 items, the WVDEP actually asserted that no additional changes to the West Virginia program were necessary for the reasons explained in its letter. The State responses for which we requested