

August 26, 2004

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

RE: Requirements Pertaining to Sampling Services and Private
Laboratories Used in Connection With Imported Food Proposed Rule,
Docket 2004N-0184

Dear Sir or Madame:

The American Council of Independent Laboratories (ACIL) was founded in 1937 as a national trade association representing independent scientific laboratory, testing, consulting, product certifying, and R&D firms; manufacturers' laboratories; and consultants and suppliers to the industry. ACIL defines an independent testing firm as a commercial entity engaged in analysis, testing, inspection, materials engineering, sampling, product certifying, research or development, and related consulting services for the public. An independent laboratory is not affiliated with any institution, company or trade group that might affect its ability to conduct investigations, render reports, or give professional counsel objectively and without bias. ACIL's 300 member companies operate approximately 1,500 facilities across the U.S. and abroad. They range from one-person specialty laboratories to multi-disciplined, international corporations employing thousands of analysts, risk management specialists, consultants, and support staff. ACIL committees carry out programs of broad member interest covering issues such as laboratory accreditation, government relations, and risk management.

One of ACIL's technical sections is the Microbiology and Analytical Chemistry section (MAC). MAC's mission is to promote and protect the interests of firms primarily engaged in microbiology and analytical chemistry services that characterize composition, purity, residue, content, and contamination in the areas of food, pharmaceuticals, cosmetics, and related manufacturing industries. ACIL and the MAC section appreciate the opportunity to comment on the FDA's proposed rule on Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food (the "Private Lab rule"). See 69 FR at 23460 (Apr. 29, 2004).

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I. Introduction

ACIL recognizes the value of this rulemaking effort. We agree that it is important to deter the importation of unsafe food. Further, we agree with the agency that there is a clear need to establish uniformity in private laboratory submissions and to seek improved consistency in the analytical data upon which the agency may rely to make imported food admissibility decisions. We also believe that a critical component to improving this process is to develop standards that will establish uniformity among FDA district offices in receiving and reviewing private laboratory submissions. Ensuring integrity in this process will directly benefit our members, the FDA, and most importantly, the consumers who rely upon our combined efforts.

For the above reasons we commend the agency for taking initiative in this area. ACIL and its members are committed to working with the agency in this process. We believe, however, that this proposed rule does not accomplish the laudable objectives stated in its preamble. Moreover, we have included here a number of serious objections regarding the proposed rule's contents, structure, and regulatory reach. Furthermore, FDA has issued this proposal while relying on outdated data and information and without taking into consideration the dramatic and recent changes in business practices in the food and private laboratory industries. Because of our many concerns ACIL recommends that FDA withdraw this proposal, re-enter discussions with industry stakeholders, and reissue the proposed rule after FDA completes implementation of its new bioterrorism authorities.

Alternatively, and at a minimum, FDA should reengage the industry regarding this exercise of its regulatory authority and issue its final rule in interim form. This would permit the agency's stakeholders to make additional comments regarding any changes from this proposal. Although we recognize the difficulty this may pose this rule has been in development since 1996.

Further, ACIL urges FDA to recognize private laboratory accreditation by granting a presumption that analytical results submitted by accredited laboratories are accurate and competent. Further, FDA should reduce the supporting information that an accredited laboratory must include in its submissions to FDA.

II. General concern and ACIL objections regarding FDA's data, information, and authorities cited in the Introduction

A. Bioterrorism Authorities

ACIL is particularly concerned that the proposed rule does not even mention the enactment of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act"). ^{2/} This historical event has resulted in the most significant changes in food regulation and industry practices since 1906. FDA has promulgated four major regulations based upon its new bioterrorism authorities and those bioterrorism regulations and their impact upon the food importation process are not even referenced in this proposal.

Last year FDA issued two major interim final regulations under the Bioterrorism Act that potentially impact private laboratories and directly impact the administrative process and flow of imported foods. ^{3/} FDA has yet to publicly respond to the many comments submitted to the dockets for those regulations. In fact, FDA has not even completely implemented the bioterrorism regulations. Therefore, their full impact will remain unknown and unknowable until sometime later. ^{4/} The procedural impact these bioterrorism regulations will have on food imports could have a direct effect on the operations of sampling services and private laboratories. This in turn could render obsolete much of the analysis ACIL and FDA is conducting in connection with the Private Lab rule.

FDA has also proposed and taken comments on a regulation requiring food establishments and transporters to establish and maintain a record keeping system under the authority of the Bioterrorism Act. ^{5/} FDA has not issued its record keeping regulation in final form. The Private Lab rule also contains record keeping provisions for all affected parties. ^{6/} Until FDA issues its final regulation under its bioterrorism record keeping authority it is impossible to assess and comment on the combined impact these two regulations will have on ACIL's members or the safety of imported foods.

^{2/} Pub. L. 107-188 (June 12, 2002).

^{3/} See *Prior Notice of Imported Food Under the "Bioterrorism Act"*, 68 FR 58974 (Oct. 10, 2003) (interim final rule); see also *Registration of Food Facilities Under the "Bioterrorism Act"*, 68 FR 58894 (Oct. 10, 2003) (interim final rule).

^{4/} See *FDA Compliance Policy Guide (CPG) Guidance for FDA and CBP Staff*, CPG 110.310, at <http://www.cfsan.fda.gov/~pn/cpgpn.html> (Dec. 2003); see also *Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Act of 2002; Reopening Comment Period*, 69 FR 19763 (Apr. 14, 2004) ("CPG [110.310] states that until August 12, 2004 FDA and CBP intend primarily to emphasize educating the affected firms and individuals"). Very recently FDA issued additional guidance that indicates significant difficulties in implementing the food registration and prior notice interim final rules. See CPG 110.310 (revised) at <http://www.cfsan.fda.gov/~pn/cpgpn3.html> (Aug. 12, 2004).

^{5/} See *Establishment and Maintenance of Records Under the "Bioterrorism Act"*, 68 FR (May 9, 2003) (proposed rule).

^{6/} See e.g., 69 FR at 23472-73 (proposed 21 CFR §§ 59.201(b) and 59.301(c)).

system under the authority of the Bioterrorism Act. ^{5/} FDA has not issued its record keeping regulation in final form. The Private Lab rule also contains record keeping provisions for all affected parties. ^{6/} Until FDA issues its final regulation under its bioterrorism record keeping authority it is impossible to assess and comment on the combined impact these two regulations will have on ACIL's members or the safety of imported foods.

B. Outdated and Inapplicable Data or Information

The data and information upon which FDA relies to justify or assess the impact of the proposed rule are seriously outdated. Therefore, the rule fails to take into consideration the tremendous increase in the volume, variety, and complexity of food imports since 1993, the considerable growth and evolution of the private laboratory industry over the last ten years, or the substantial progress the public and private science sectors have made together toward developing national and international accreditation standards. Additionally, many of the authorities FDA cites promote principals that this proposed rule works directly against or fails to implement.

C. 1996 "Grassroots Meetings"

FDA references "grassroots" meetings held in 1996 during which private laboratory industry representatives and FDA discussed ways FDA might improve its policies and procedures relating to the use of private laboratories. See 69 FR at 23461. The action plan that FDA developed based upon these grassroots meetings, however, was not a consensus document. Moreover, even if FDA and the industry representatives attained consensus regarding the action plan, the underlying facts and discussions that resulted in development of the plan represented the thinking, business models, and industry practice of nearly a decade in the past and are no longer current or relevant.

Additionally, FDA notes that the purpose of the grassroots meetings was "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." *Id.* The proposed rule, however, only partially accomplishes these purposes. The rule fails to establish standards or procedural guidelines for how FDA districts are to use scientific data submitted by private laboratories or how long district personnel have to conduct their reviews.

^{5/} See *Establishment and Maintenance of Records Under the "Bioterrorism Act"*, 68 FR (May 9, 2003) (proposed rule).

^{6/} See *e.g.*, 69 FR at 23472-73 (proposed 21 CFR §§ 59.201(b) and 59.301(c)).

Moreover, because FDA does not substantively acknowledge the value of laboratory accreditation, the rule does not adequately address the soundness of analytical data.

FDA cites the three points of an action plan that emerged from discussions with industry representatives at the grassroots meetings. *Id.* (citing Food and Drug Administration, Private Laboratory Grassroots Meetings 1996). Only one of those three objectives, however, is accomplished by this proposed rule. For instance, this proposal does not “establish consistent and objective national standards for the format and content of *analytical* data that private laboratories submit to FDA.” *Id.* The best scientifically valid means to establish such objective national standards is by the FDA standardizing its requirements for all districts. This objective would be furthered substantially by FDA’s acknowledgement and acceptance of laboratory accreditation. This proposed rule accomplishes neither.

Secondly, this proposed rule does not “[r]equire 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.” *Id.* Rather, by this rule FDA will continue to permit importers to collect their own samples. 7/

D. Testimony of Two Federal Felons

For evidence of the need to establish safeguards that reduce the incidences or avenues for fraud in the import process, FDA cites 1998 congressional testimony offered by two federal felons before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations. *See* 69 FR at 23461. One witness, a former customs broker, testifying anonymously as “Mr. Broker,” discussed various schemes he had witnessed “unscrupulous” or “problem” importers use to cause unsafe imported food to be distributed in the United States. 8/ The other witness, a former FDA inspector, Reggie Jang, also offered congressional testimony regarding fraudulent activity perpetrated by problem importers. 9/

7/ We address the significance of this point, as it relates to unscrupulous and problem importers, in discussions that follows *infra*.

8/ *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, (statement of “Former Customs Broker”), at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=105_senate_hearings&docid=f:51562.wais (September 10, 1998) (last viewed July 18, 2004). “Mr. Broker” pleaded guilty to a federal felony related to defrauding FDA and Customs.

9/ *See The Safety of Food Imports*; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, (statement of Reggie Jang), at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=105_senate_hearings&docid=f:49134.wais

The substance of both witnesses' testimony focused entirely upon illegal and fraudulent conduct perpetrated by food *importers*. In their separate testimonies, the witnesses described unscrupulous importers substituting clean food product for sampling *in lieu* of adulterated food actually imported. 10/ They also described how the importers maintained "banks" of clean food in case FDA Inspectors wished to collect food samples or placed food from clean food "banks" adjacent to unsafe imported food and directed sample collectors to the clean product. *Id.* Neither witness made any allegation that private laboratories or independent sampling services participated in or even knew of such fraudulent activities.

FDA cites no evidence or testimony in the proposed rule that supports the proposition that the importation of unsafe foods was the result of the activities of independent third party samplers or private laboratories or that such parties contributed to such illegal food imports. Rather all evidence offered in the rule relates to "unscrupulous" or "problem" importers or FDA inspectors. 11/

As the two witnesses demonstrate, FDA already has adequate authority to criminally prosecute the kind of activity that FDA seeks to prevent with this proposed rule. ACIL agrees that FDA is justified in attempting to thwart such illegal activity. This rule, however, will fail in that attempt because FDA proposes to permit importers to continue to collect their own samples from their own imported food shipments for submission to a private laboratory for analyses. 12/ Instead of focusing its efforts where the evidence demonstrates the problems lie, FDA proposes to impose substantial economic and record keeping burdens upon the private laboratory industry.

E. President Clinton's 1999 Food Safety Initiative

FDA cites former President Clinton's 1999 Food Safety Initiative as support for the proposed rule. *See* 69 FR at 23461. President Clinton's initiative

(May 14, 1998) (last viewed July 18, 2004). Mr. Jang pleaded guilty to a federal felony and was awaiting sentencing for accepting bribes from a company seeking to bypass inspections of imported food products.

10/ See footnotes 8 and 9, *supra*.

11/ See e.g., *Safety of Food Imports: Fraud and Deception*, *supra*. n. 8 (transcribing dialogue between "Mr. Broker" and Senator Durbin: "Senator Durbin: In one of the previous hearings, we talked about the complicity of employees of the Food and Drug Administration and other Federal agencies in these schemes. Based on your 20 years of experience, how prevalent is that? How common is it? . . . Mr. Broker: Very honest. FDA, I think I have seen so many opportunities for them out there that that is where the problem has been."). As described in the text accompanying footnote 9, *supra*, former FDA inspector Reggie Jang pleaded guilty to felony charges for accepting illegal bribes in connection with the importation of unsafe food.

12/ See 69 FR at 23472 (proposed 21 CFR 59.105).

directed the Secretary of Health and Human Services and the Secretary of the Treasury 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.” *See id.* (citing former President Clinton’s July 1999 Memo). Although FDA directly quotes this initiative, the proposed rule fails to take into consideration the significant progress the scientific community has made since 1999 in establishing analytical and sampling standards through laboratory accreditation. Further, this proposed rule does nothing to set standards.

F. Homeland Security Presidential Directive #9

FDA cites President Bush’s Homeland Security Presidential Directive (HSPD) #9, which directed 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.” *See* 69 FR at 23461 (citing HSPD #9). Although ACIL and its members are prepared to participate in networks with federal and state laboratories and to develop such standardized diagnostic protocols and procedures, this rule does neither. In fact, because this regulation does not acknowledge the value of laboratory accreditation, the agency rejects the only scientifically reliable means by which diagnostic protocols and procedures are objectively standardized. This proposed rule, therefore, works against the Presidential Directive in this regard.

III. Requiring laboratory accreditation and an intermediate recommendation

ACIL agrees with comments submitted by the National Cooperation for Laboratory Accreditation (NACLA). ^{13/} ACIL would like to emphasize a number of points regarding accreditation.

Accreditation is an internationally proven method that supports the goal of “one test performed anywhere accepted by all.” Utilizing International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) reference 17025 ^{14/} the FDA, other stakeholders, and U.S. consumers can be assured that laboratories accredited to this standard have a well-defined quality system. FDA and the U.S. Department of Agriculture (USDA) have begun pursuing,

^{13/} *See* NACLA comments (June 1, 2004) (copy attached as Attachment #1).

^{14/} *General Requirements for Competence of Calibration and Testing Laboratories*, (formerly Guide 25 & EN45001).

with varying degrees of success, accreditation of their own labs to ISO 17025. 15/ If FDA were to require accreditation of private laboratories and sampling services before accepting their analytical data, a number of issues raised by this proposal would be resolved. 16/

ACIL fully supports private laboratory accreditation and believes this should be accomplished by independent accrediting organizations to ISO 17025 standards. ACIL also recognizes that for accreditation to add value to FDA's import processes, the agency must be willing to assist and cooperate with independent accrediting organizations so that accreditation to ISO 17025 will meet the agency's expectations regarding accredited laboratories' technical and administrative capabilities.

FDA has repeatedly made it clear it does not wish to take on the role of accrediting private laboratories. FDA has also made it clear that it recognizes the advantages of accreditation to ISO 17025 standards. 17/ FDA, however, must give practical substance to this recognition by permitting only accredited private laboratories to submit results pertaining to FDA enforcement actions. This would enable the agency to concentrate its own limited laboratory resources on other areas.

ACIL also believes it would be reasonable for FDA to permit accredited laboratories to submit only analytical results, accompanied by a copy of their valid certificates. In this way, the time required to conduct the reviews of analytical reports from accredited laboratories would be significantly reduced, saving FDA time while expediting release of import shipments that comply with the Food Drug and Cosmetic Act (FDCA). 18/ FDA should accept accredited lab reports as presumptively competent and accurate, unless FDA possesses some clear evidence to the contrary related to the laboratory. This recommendation would not result in private laboratories assuming FDA's responsibilities because FDA would retain all regulatory authority on any imported lot from which samples were taken and analyzed by a private lab.

15/ The USDA has completed accreditation of all their laboratories and the FDA is progressing in this process with a stated commitment to complete it.

16/ See discussion related to the 1996 "grassroots meetings and the action plan that emerged from those meetings, at section II.C., *supra*; see also discussions related to former President Clinton's Food Safety Initiative, at section II.E., *supra*, and HSPD #9, at section II.F., *supra*.

17/ See *e.g.*, 69 FR at 23468; ("Requiring lab accreditation would provide assurance that the private laboratories testing imported food have the appropriate equipment, personnel, and procedures to conduct their analyses.")

18/ See *e.g.*, 21 USC § 381(h) (requiring FDA to develop information management systems that, among other things, "facilitate the importation of food that is in compliance with the [FDCA].")

There are already competent and internationally recognized accrediting bodies capable of performing accreditations for the 100-200 private laboratories that analyze imported food. ^{19/} In addition, this recommendation would provide an important business incentive for private laboratories to pursue accreditation, which would enhance the overall quality of laboratory data and achieve the stated purposes of the proposed regulation, former President Clinton's Food Safety Initiative and President Bush's HSPD #9.

IV. Comments regarding the proposed language in the rule

A. Regulatory Trigger in 21 CFR 59.1

ACIL believes the phrase "in connection with an FDA enforcement action" is too vague for the trade, private labs, or the field to know when the rule's requirements apply. 69 FR at 23462 (proposed 21 CFR 59.1).

1. In connection with

FDA states that the requirements of this rule apply to private labs used "in connection with" an FDA enforcement action. *Id.* Although the preamble qualifies this phrase with a purpose clause, stating the rule applies when private labs are used "to submit data to FDA," the proposed regulatory language lacks the qualifying purpose clause. *Id.* Therefore the scope of the regulatory language is broader than the applicability FDA provides in the preamble. ACIL suggests FDA qualify the regulatory language in the same manner as in the preamble to avoid inadvertent overreaching in the future.

To illustrate ACIL's concern in this regard, importers may wish to document the condition of imported food for filing a claim against the foreign manufacturer or shipper or for valuing imported food. The importer may have no intention of submitting the analytical results to FDA. Yet these scenarios could reasonably fall within the purview of private lab analysis "in connection with an FDA enforcement action." ACIL does not believe FDA intended to compel private parties to report private laboratory analyses that are never intended to be submitted to FDA and asks FDA to clarify this in the regulatory language.

^{19/} For instance, many of the laboratories performing services for submission to FDA are already ISO 17025 accredited. Furthermore, organizations such as NACLA, the American Association of Laboratory Accreditation (A2LA), and AOAC International's Laboratory Accreditation Criteria Committee (ALACC) would be capable of bringing those laboratories that are not currently accredited up to internationally recognized quality standards. In the end, those laboratories, their client-stakeholders, the FDA, and U.S. consumers would all benefit from this intermediate recommendation.

2. FDA Enforcement Action

FDA states that the requirements in the proposed rule apply only when imported food is sampled or analyzed in connection with an “FDA enforcement action.” 69 FR at 23462 (proposed 21 CFR 59.1). FDA’s regulatory trigger for application of the rule’s requirements is very confusing.

The proposed rule lists only three examples of FDA enforcement actions: product seizure, refusal of admission, and the issuance of an injunction. However, the overwhelming majority of cases where an importer submits private laboratory analyses to FDA involve FDA’s issuance of an import alert ^{20/} or its detention of an imported shipment without physical examination. ^{21/} In other cases, FDA may permit an importer, owner, or consignee to conduct some reconditioning process and then test the product using a private laboratory to demonstrate the article has been brought into compliance. ^{22/} Even in these latter situations, however, the imported food is not refused admission but merely detained. ^{23/}

^{20/} See *Import Information Directives*, FDA Regulatory Procedures Manual (RPM), Chap. 9: at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9dirs.html (last viewed July 22, 2004).

^{21/} See 21 USC 381(a); see also 21 CFR 1.94(a) (“If it appears that the article may be subject to refusal of admission, the district director shall give written notice to that effect, stating the reasons therefore.”) and *Automatic Detention*, RPM, Chap. 9, at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9auto.html (last viewed July 22, 2004). This existing regulation is administratively processed as a Notice of Detention, or a Notice of FDA Action indicating the FDA has “detained” the imported article. See *Notice of Detention and Hearing*, RPM Chap. 9, at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9det.html (last viewed July 22, 2004) (citing 21 CFR 1.94). FDA’s regulations implementing 21 USC 381(a) and (b) never use the words “detained” and “detention,” or the phrase “detention without physical examination.” This may be one reason FDA excludes their use in this proposed rule. In so doing, however, FDA is simply continuing the lack of correlation between its own import procedures and its regulatory authorities and further confusing the industry as to when this proposed rule applies. Instead, FDA should reconcile its regulations and its procedures with this proposed rule making, enabling it to issue a more coherent rule related to the use of private laboratories and sampling services.

^{22/} See 21 USC 381(b); see also 21 CFR 1.95 and 1.96.

^{23/} Interestingly, FDA got it right in the preamble, but wrong in the proposed regulatory language. See 69 at FR 23460 (“*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.”) (emphasis added). For some unexplained reason, however, FDA includes “refusal of admission” in its list of examples of “enforcement action” instead of “detention,” “detention without physical examination,” or the issuance of an “import alert.” See 69 FR at 23462 (proposed as 21 CFR 59.1(c)). To further confuse the issue, FDA indicates that its list of enforcement actions is not all inclusive, followed immediately by an explanation that “[t]his part does not apply if you collect, analyze, or test imported food samples for purposes *not* related to an FDA enforcement action.” *Id.* (emphasis added). ACIL believes this language that exempts sampling or analysis of imported food samples from this regulation requires substantially more clarification.

Despite the fact that the vast majority of private laboratory packages are submitted to FDA in response to an FDA detention, and very often a detention without physical examination based upon an FDA import alert, these actions are not included in the list of examples of "FDA enforcement actions."

Furthermore, it is remarkably rare for a private laboratory to submit analytical results to FDA after the agency has already issued a Notice of Refusal of Admission. This is because FDA's Regulatory Procedures Manual (RPM) instructs agency field personnel that "[u]nless a Notice of Refusal of Admission was erroneously issued by FDA, consideration should not normally be given to requests to void the Notice in order to give the requestor an opportunity for a hearing or time to submit an application (Form FD 766) requesting permission to relabel or recondition." 24/

Additionally, since the enactment and regulatory implementation of the Bioterrorism Act, FDA has more authorities available to it that can be brought against imported food. FDA's silence regarding these additional authorities creates substantial uncertainty as to when the rule applies. 25/ The following is a list of existing authorities and new bioterrorism authorities that FDA could construe as "enforcement actions":

- FDA's sample collection activities, which invoke other regulatory authorities that apply to the imported food; 26/
- FDA's issuance of an import bulletin, or any private laboratory analysis to respond to concerns the FDA may have related to an import bulletin; 27/
- collection and analysis of a "referee" sample; 28/
- FDA action when goods are imported by a person debarred, including a person seeking to affirmatively establish the food complies with relevant requirements under the Act; 29/

24/ See *Notice of Refusal of Admission*, RPM Chap. 9, at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9nora.html (last viewed July 22, 2004).

25/ This silence regarding the Bioterrorism Act and FDA's implementation of the new authorities also directly affects the economic impact of the proposed rule.

26/ See 21 CFR 1.90. Importers may collect samples simultaneously or immediately after FDA's sample collection and submit the samples for private lab analysis. At this point, FDA has no evidence of the appearance of a violation, yet the agency may develop such evidence through the sampling process resulting in an import detention. Must the private laboratory report the results of such sampling and analysis to the FDA irrespective of FDA's or the private lab's analytical results?

27/ See *Import Information Directives*, n. 20, *supra*.

28/ See *Private Laboratory Grassroots Meetings 1996, Brooklyn, NY Workshop Minutes*, at http://www.fda.gov/ora/science_ref/priv_lab/grassr96/bro1b.html (last viewed July 23, 2004).

29/ See 21 USC 335a(b) and 381(k).

- FDA action when foods that have been previously refused entry are detained as misbranded, or a person seeks to affirmatively establish that such previously refused food complies with relevant requirements under the Act; 30/
- Private lab analysis to demonstrate that imported food FDA has administratively detained does not present a threat of serious adverse health consequences or death to humans or animals; 31/ and
- Private lab analysis presented as evidence that imported food that is subject to an FDA temporary hold does not present a threat of serious adverse health consequences or death to humans or animals. 32/

ACIL believes that until FDA further clarifies what constitutes an FDA enforcement action, or at least defines the criteria the agency will use to determine whether an FDA action is an enforcement action triggering the rule, the trade, the private laboratories, and FDA district offices will be unable to decide whether the rule's requirements are applicable. ACIL further believes that clarification regarding whether the above FDA actions are enforcement actions will strengthen the regulation and will promote uniformity and standardization in the industry and among FDA districts.

B. Definitions in 21 CFR 59.3:

ACIL is concerned that the proposed regulatory language uses many terms that are undefined. FDA should define the following terms to clarify the scope and applicability of the regulation. This will strengthen the rule and promote the uniformity FDA is seeking.

1. Control

FDA requires that an importer who uses a sampling service or private lab in connection with an FDA enforcement action to maintain "control" of the lot from which the sample was taken. 33/ ACIL believes that in the case of food that is under a seizure order the government would have "control" of the food. Moreover, FDA does not indicate whether the person utilizing the services of a sampler or private laboratory must have title to the lot, possession or constructive possession of it (in the case of a lot being held in a public warehouse), or a combination of these property rights. Furthermore, because more than one person may collect samples of

30/ See 21 USC 342(h) and 381(a).

31/ See 21 USC 334(h).

32/ See 21 USC 381(j).

33/ See proposed 21 CFR §§ 59.101(b)(3) and 59.103(b)(3).

an imported food while it is subject to an FDA enforcement action, which party must maintain this control?

ACIL believes FDA's purpose is to ensure the importer can export the food in the instance the agency refuses admission to it and Customs demands its redelivery under the importer's basic importation bond. ^{34/} Therefore, ACIL recommends the regulation clarify that the importer of record be required to maintain control of the shipment to remain consistent with Customs' authorities.

2. Food

FDA's recent bioterrorism regulations used a limited definition of "food" than courts have permitted when interpreting the FDCA. ^{35/} Therefore, ACIL recommends FDA clarify which definition applies to this regulation.

3. Knowledge

FDA requires submission of a notification to FDA when a person intends to use the sampling services of a third party. 69 FR at 23462 (proposed as 21 CFR 59.101(a)(2)). This notification must include the sampling service's "knowledge of sampling procedures." Without clarification as to what FDA considers "knowledge of sampling procedures," ACIL believes this language will result in confusion in the trade and among FDA districts as to the information that must be contained in the notification. Furthermore, it is unclear how the person submitting the notification is to know what the sampling service's knowledge is. ACIL believes that FDA can remedy this by requiring sampling services to be accredited, obtain a certification regarding sampling practices and methodologies, or possess some minimum level of qualified experience.

4. Lot

FDA uses the term "lot" in several proposed sections but never defines the term. ^{36/} This is relevant to sampling procedures and should be clarified to ensure uniformity in FDA's implementation of the regulation.

5. Qualifications

^{34/} See 19 CFR 113.62.

^{35/} See *Prior Notice*, n. 3, *supra*, at 59071 (to be codified as 21 CFR 1.276(b)(5); see also *Registration*, n. 3, *supra*, at 58961 (to be codified as 21 CFR 1.227(b)(4)).

^{36/} See proposed 21 CFR 59.3(c); 59.101(b)(1) and (3); 59.103(b)(3); 59.201(a)(1) and 59.301(b)(1).

FDA requires the person using sampling services or private laboratories to include in a notification to the FDA the “qualifications” of the sampling service 37/ and of the private laboratory 38/ but never defines that term. In fact, ACIL believes that because FDA does not require accreditation of either sampling services or private laboratories, the trade and FDA districts will be unable to meaningfully implement this provision. For instance, how much information must the person using these services gather for submission to FDA? ACIL believes that adopting third party accreditation would rectify this weakness and strengthen the regulation.

C. Notification to FDA under proposed sections 59.101 and 59.103

1. Prior Notification Requirement: Generally

ACIL believes the prior notification to FDA by the person using private lab or sampling services represents inadvertent overreaching by the agency and is unnecessary.

As to the former concern, the regulatory language requires any person who “*intends*” to use a sampling service or private lab in connection with an FDA enforcement action to first notify FDA. 39/ Using a person’s intent to trigger the notification requirement mires the provision’s applicability, will confuse the trade as to when the notification is required, and is outside the scope of FDA’s authority. ACIL believes FDA can correct this by instead requiring that any person who relies upon any private laboratory analysis to overcome an FDA enforcement action precede the lab’s submission with a notification to the agency that samples were collected and will be analyzed by a particular private laboratory. This change would correctly limit the scope of the regulation, accomplish the agency’s well intended desire to deter importers, owners, or consignees from testing imported food into compliance, and create a bright time line for the industry and district personnel.

ACIL also believes this requirement is unnecessary for a number of reasons. First, and historically, FDA’s New York District Office once required importers to file a notification with that district in order to obtain a “blue form,” which would then act as a single use sample collection report for private laboratory analyses. FDA eventually abandoned this practice because it amounted to the importer filing a form to obtain a form. ACIL believes there is little difference

37/ See proposed 21 CFR 59.101(a)(2).

38/ See proposed 21 CFR 59.103(a)(2).

39/ See proposed 21 CFR 59.101(a) and 59.103(a). This is partly due to the agency’s failure to carry the purpose clause from the preamble discussion related to 21 CFR 59.1 into the actual regulatory language. See discussion in section IV.A.1., *supra*.

between this abandoned practice and requiring the importer to tell the FDA of its intent to use the services of a third-party sampler or private laboratory.

Second, because the importer may never inform the private laboratory that particular samples are connected with an FDA enforcement action, FDA will never know that the importer is not testing the imported food into compliance. Moreover, after making the notification, collecting the samples, and submitting them, the importer may have a change in the intent to submit the results and desire to simply export the shipment. Neither this proposed rule nor any other regulation prevents the importer from changing courses of action in mid-stream.

Third, under current local procedures the Southwest Import District (SWID) requires the sampler to make an appointment with the district before sampling the goods. ^{40/} Therefore, in at least one FDA district, the procedure proposed by this provision is already in operation. Yet ACIL believes the analyses conducted on samples collected in SWID are no more accurate or reliable than private lab analyses conducted for foods imported through ports other than those within SWID's jurisdiction.

As justification for requiring this prior notification, FDA states in a response to an earlier comment that the notification will enable the agency to ensure that the sampler and private lab employed by the importer were the same sampler and private lab the importer indicated he or she would use. ^{41/} Essentially, FDA is assuming the existence of the notice in order to find it necessary that the notice be accurate. Then, to ensure that the notification is accurate, the notice is deemed necessary. ^{42/} This is a fully circular argument.

2. Substance of the Notification

ACIL is concerned that FDA's required notification regarding the intent to use the services of a sampler or private laboratory must contain information that the importer, owner, or consignee of the food is unlikely to have. For instance, the proposed rule requires the notification contain the sampler's "qualifications and knowledge of sampling procedures" and the "qualifications" of

^{40/} ACIL has been unable to find any statement of regulatory authority that grants to SWID or any other district the power to create mandatory local procedures such as this one. Further, to the best of ACIL's knowledge, SWID has never provided a written procedure that private labs or third party samplers may cite in their own procedures to establish internal controls to insure compliance with this local rule.

^{41/} See 69 FR at 23465 (FDA response to comment 6).

^{42/} Another way to say this is that FDA is asserting that the notice is necessary to ensure the notice is accurate. But if the notice is unnecessary then its accuracy is irrelevant.

the private laboratory. ^{43/} The rule is unclear as to how FDA expects the importer, owner, or consignee to be able to represent the scientific qualifications or knowledge of another private party. ^{44/} Without accreditation, what should the person submit?

Furthermore, FDA requires the notification to include the place where the sampler maintains records relating to the sampling and where the private lab will actually perform the analysis. ^{45/} ACIL believes the former requirement is tantamount to requiring the importer, owner, or consignee to enforce the regulation for FDA by ensuring the compliance the third party sampler. The latter requirement assumes the importer, owner, or consignee should understand how the private laboratory is organizationally structured.

D. Requiring Original Collection Reports and Data Collection

The proposed rule requires that the private laboratory submit to the FDA the “original” compilation of all data and the “original” collection report. ^{46/} ACIL believes this is unnecessary and unwise.

First, after years of involvement in this business, many of our members have experienced situations, some with alarming frequency, where FDA district personnel have lost documents. If FDA requires original documentation in order find a submission acceptable, then the loss of original documents could require samples be recollected and reanalyzed. This adds layers of potential costs that are wholly unnecessary and will result in disputes among the parties, including the FDA, as to who should bear the added costs. Copies should be sufficient, particularly given the rule’s record retention requirement. ^{47/} In any event, the potential of losing original documents and subsequent costs of reanalyzing the samples should be considered in the agency’s review of the proposed rule’s impact. Moreover, ACIL notes that duplicate documents are adequate for federal courts and believes they should be adequate for FDA. ^{48/}

^{43/} See proposed 21 CFR 59.101(a)(2) and 59.103(a)(2).

^{44/} This is another example of how this regulation could be strengthened significantly if FDA required third party samplers and private laboratories used in connection with FDA enforcement actions be accredited. Recognizing accreditation would permit the importer, owner, or consignee to cite to the other party’s certification, further standardizing the process.

^{45/} See proposed 21 CFR 59.101(a)(4) and 59.103(a)(4).

^{46/} See proposed 21 CFR 59.103(a)(4)(ii) and (c).

^{47/} See proposed 21 CFR 59.103(c).

^{48/} See *Fed Rules of Evidence*, Rule 1003, Admissibility of Duplicates. (“A duplicate is admissible to the same extent as an original unless (1) a genuine question is raised as to the authenticity of the original or (2) in the circumstances it would be unfair to admit the duplicate in lieu of the original.”) (emphasis added).

ACIL believes FDA should also accept electronically scanned copies of the original documents in lieu of paper, which would further reduce the costs of complying with the regulation.

E. Permitting Importers to collect samples under proposed 21 CFR 59.105

ACIL is very troubled by FDA's persistence in permitting importers to collect their own samples.

FDA states numerous times and in a variety of ways that one of the agency's purposes is to prevent unscrupulous and problem importers from collecting samples from substitute shipments, collecting from certain higher quality portions of a shipment, banking higher quality food for sampling purposes, or testing imported product into compliance. Permitting importers to continue to collect samples for submission to private labs, however, completely undermines these purposes. ^{49/} It is surprising this escapes the agency even when the two points are presented in succession. ^{50/} For instance, FDA notes that the proposed rule's requirements for third party samplers ^{51/} apply to importers who collect their own samples. Then FDA immediately follows with the assertion that these requirements should help deter unscrupulous 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. This seems counterintuitive at best. While recognizing that the vast majority of food importers possess the character, integrity, and knowledge to follow the sampling procedures, unscrupulous importers would be in the best position to engage in fraudulent conduct if they collect their own samples with no supervision.

ACIL believes this provision represents a serious flaw in the proposed regulation and should be corrected. An intermediate solution would be to define the phrase "problem importers", ^{52/} and establish a list of such persons whose private laboratory results must be the product of analysis of samples collected by a qualified, disinterested third party. This would balance the financial interests of those who attempt to comply with the regulations with the agency's interest in deterring

^{49/} FDA notes that the costs associated with requiring importers to hire a third party may be too burdensome for small importers. That explanation, however, misses the point entirely. In this instance, the burden would be properly placed upon the importer – who has the obligation to ensure that imported food complies with the Act. Furthermore, the importer possesses the ability to shift the additional costs against the food manufacturer or shipper, who share the responsibility for processing and shipping safe food to the U.S.

^{50/} See e.g., 69 FR at 23463.

^{51/} Proposed as 21 CFR 59.201.

^{52/} See e.g., *Priority Enforcement Strategy for Problem Importers*, RPM Chap. 9, at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9strat.html (last viewed July 23, 2004).

unscrupulous and problem importers. In any event, ACIL believes that granting wholesale permission to all importers to collect their own samples in connection with an enforcement action completely undermines the agency's purposes and is unwise for food safety and security reasons.

F. Regarding Procedures that Sampling Services and Private Laboratories Must Follow under Proposed 21 CFR 59.201 and 59.301

1. General concerns regarding FDA's exercise of jurisdiction

ACIL believes that FDA has designed the proposed rule in a manner that results in the agency exercising regulatory authority over private laboratories and third party samplers in addition to its stated intent of standardizing submissions to the agency. This is most prevalent in the proposed sections that dictate how third party samplers and private labs must perform their services and conduct their businesses. ^{53/}

ACIL believes that FDA's jurisdiction in regulating in this area extends no further than dictating acceptable practices in gathering and reporting formats of data that private laboratories or other third parties might submit to FDA in relation to imported foods or an FDA enforcement action. The distinction is significant. On the one hand, the proposed rule mandates that laboratories or samplers take certain steps and conduct themselves in certain ways. On the other hand, ACIL believes FDA intended to establish various practices and standards that labs and samplers must be able to demonstrate were followed if they wish FDA to consider their submissions acceptable for the purpose of overcoming an enforcement action. Rather than establishing standards, this proposed rule compels conduct of private labs and third party samplers.

FDA has many times admitted that it lacks the authority to regulate private laboratories and ACIL is aware of no additional grant of authority that changes these prior admissions. ^{54/} Therefore, ACIL objects to this exercise of

^{53/} See proposed 21 CFR 59.201 and 59.301, respectively.

^{54/} See e.g., *Guidance on the Review of Analytical Data Generated by Private Laboratories*, FDA Laboratory Procedures Manual, Chap. 21, at http://www.fda.gov/ora/science_ref/lpm/lpmtc_dec02.html (last viewed July 23, 2004) ("Although FDA has no legislative authority to directly regulate these private laboratories, this guidance is provided to ensure the scientific credibility of data submitted to the Agency.") See also *Private Laboratory Grassroots Meetings 1996: A Final Report and Action Plan*, at http://www.fda.gov/ora/science_ref/priv_lab/grassr96/grassr.html (Mar. 25, 1997) (defining "private laboratory" as including only those laboratories which not [sic] regulated by Good Laboratory Practices and/or Good Manufacturing Practices.") The FDA's Final Report and Action Plan stated, "the private lab communities are defined as those which are not regulated by FDA. These

authority. ACIL believes this difficulty can be resolved by proposing an administrative rule that does not purport to regulate the laboratories but instead identifies the practices that FDA expects private laboratories to follow before FDA will accept laboratory packages for review as evidence to overcome an enforcement action. FDA's recognition of laboratory accreditation would further assist in resolving this difficulty because the FDA could simply require labs be certified to the stated standard before the agency would accept packages from them.

While ACIL supports establishing standards for increasing control of private sampling and uniformity in private laboratory submissions under FDA's DWPE program, it also believes the agency must provide the laboratory industry with procedural safeguards that ensure districts do not misuse their authority. To this end, FDA should establish a formal notice and review process that clearly identifies an avenue for appeal should the agency consider disqualifying a laboratory from the program. In addition, FDA should develop policies and procedures that ensure districts discuss purported analytical deficiencies with private laboratories before advising the laboratories' clients of the agency's findings. The existing system, in practice, has resulted in disputes among laboratories and their clients, which has result in an unnecessary increase in professional liability risks for legitimate laboratories. ACIL also believes laboratory accreditation would play a critical role in establishing protections and due process for the participating laboratories.

2. Reserve Portions of Composite Samples

The proposed rule requires private laboratories "to create and maintain reserve portions of a composite sample" if the analysis involves sample compositing. ^{55/} ACIL observes that this practice is not customary in the private laboratory industry. FDA does not indicate the purposes for maintaining composite reserves. ACIL presumes it is for conducting an audit of the sample or the shipment from which the samples were taken. However, the proposed rule never mentions anything regarding an auditing process and never claims the authority to conduct lab audits. Moreover, the rule fails to identify procedures districts must follow to conduct audits, how the reserve portions will be utilized, how much of the composite should be maintained in the reserve, or how long they must be retained.

laboratories are not required, by law, to assure they are in compliance with Good Laboratory Practices and Good Manufacturing Practices." It is precisely these private laboratories FDA now asserts it has the authority to regulate while identifying no new or additional congressional mandate or authority. ACIL objects.

^{55/} See 69 FR at 23472 (proposed as 21 CFR 59.301(a)(3)).

ACIL believes this new requirement will be very costly to its members and should be removed. Furthermore, ACIL notes that the cost attributed to this requirement is not included in FDA's cost analysis for the proposed rule.

3. Affidavit

The proposed rule requires private laboratories to submit an affidavit to FDA that states:

(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. 56/

ACIL objects to this requirement on a number of grounds.

First, the proposed rule fails to identify any consequences for failing to comply with its requirements. ACIL believes the implications of affirmatively requiring a statement in an affidavit directly threatens private laboratories with criminal prosecution under Title 18 U.S.C. section 1001. ACIL fails to see how exposing private laboratories to potential criminal liability will meet the agency's stated objectives of ensuring that unscrupulous and problem *importers* do not import unsafe food or establishing uniform standards with regard to private lab submissions. Moreover, this provision amounts to the FDA requiring private labs to police the importers. While this regulation exposes private laboratories to criminal prosecution, it permits unscrupulous and problem importers to collect their own samples. 57/ This is a counterproductive result.

Although FDA states in the preamble that the affidavit requirement will not "require a person to conduct any investigations, research, or examinations in order to complete" 58/ this is a gross oversimplification. This requirement will require private laboratories to create internal information systems that track samples by key data points to ensure that various laboratory divisions of the same company are not conducting analyses simultaneously on the same shipments. Private laboratories do not track their samples by entry number so many of our members would have to revise their existing information management systems to ensure compliance. ACIL assumes FDA would attribute all information within the

56/ See 69 FR at 23473 (proposed as 21 CFR 59.301(b)).

57/ See discussion at section II.D., *supra*.

58/ 69 FR at 23467.

possession of a company to be known by that company. Therefore, any person signing the affidavit could have that knowledge imputed to him or her in a later enforcement action against the affiant.

Furthermore, because different food lots in the same entry may be sampled and analyzed by different laboratories, or different divisions within the same laboratories, the affidavit requirement is too imprecise. For instance, the affidavit requirement fails to identify who must sign the affidavit, increasing the likelihood that different districts will establish different procedures and thereby compound the existing problems of non-uniformity.

G. Comments regarding FDA's analysis under the Paperwork Reduction Act of 1995

ACIL is particularly concerned about FDA's estimated impact analysis regarding the burdens compliance with this rule will place on industry. *See* 69 FR at 23466-7. FDA clearly admits that it is relying upon five-year old import data to develop its estimate of the annual reporting and record keeping burden of this proposed rule. *See* 69 FR at 23466. The following are only a few examples of how FDA's use of old data complicates the review of the proposed rule.

- 1,739 food importers in FDA's data base in Fiscal Year (FY) 1999. *See id.*
 - Over the last five years the number of food importers and consignees who would actually be impacted by this regulation has grown by a factor of at least 45. 59/
- 11,690 food imports were detained for safety reasons in FY 1999. *See* 69 FR at 23467. FDA uses that as a baseline number for estimating shipments that may require the use of sampling services or a private laboratory analysis. 60/ It is irrefutable, however that the number of discrete food importations has exploded over the last five years. For example:

59/ *See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, 68 FR 59024 (reporting FY 2002 statistics that there are approximately 77,427 importers and consignees who received imported food shipments).

60/ ACIL would also like to know how FDA defines "safety" in the context of this rulemaking. Which OASIS charges does FDA include in the "safety" category? Which analytes are included? Upon what scientific risk assessment does FDA base the assertion that these 11,690 detentions were for "safety reasons?" Where is this scientific risk assessment published? Which detentions did FDA *not* include in the "safety" category? More importantly, why would FDA detain a shipment that is not for "safety reasons?"

- FDA stated in its FY 2004 Performance Plan that “FDA-regulated imports have grown at 10 to 12% annual rate for several years.” 61/
 - As recently as October 10, 2003, however, FDA estimated that in Fiscal Year (FY) 2002 approximately 2.9 million food entry lines were imported into the U.S. by sea and air alone. *See* 68 FR at 59024.
 - FDA claimed in August 2003 that of the 7.8 million FDA-regulated line entries that entered the U.S. in FY 2002, roughly two-thirds, or 5.2 million, were foods. 62/
- 18,000 FDA refusals in 2001. *See* 69 FR at 23467.
 - FDA clearly must have detained more than 18,000 products in FY 2001 in order to refuse admission to that many. 63/

We also note that FDA possesses all of the relevant and most current data in its own databases including the new food establishment registration system, the new prior notice system, the Operational and Administrative System for Import Support (OASIS), and the Field Accomplishment and Compliance Tracking System (FACTS). ACIL also believes FDA can more accurately state the number of detentions without physical examination and refusals the agency issued in the last fiscal year so as to project a more reasonable cost analysis.

H. Comments regarding FDA’s Analysis of Impacts

In FDA’s analysis of the proposed rule’s impacts, the agency states:

Current policies for sampling service and private laboratories do not create sufficient safe guards 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. 69 FR at 23467.

61/ *See Department of Health and Human Services U.S Food and Drug Administration Congressional Justification FY 2004 Annual Performance Plan,* <http://www.fda.gov/ope/fy04plan/2004pp-agency.html> (Jan. 2003).

62/ *See The Food and Drug Administration’s Strategic Action Plan Protecting and Advancing America’s Health: Responding to new challenges and opportunities,* <http://www.fda.gov/oc/mcclellan/strategic.html> (Aug. 2003).

63/ In the last several years FDA ceased publishing on the Internet its import detentions and instead only publishes its import refusals of admission under 21 U.S.C. § 381(a). ACIL is unable to compare current detention numbers with FDA’s reported FY 1999 detention data.

FDA presents no evidence to support this statement other than outcomes from discussions with industry that occurred nearly a decade ago. ^{64/} Furthermore, this statement ignores the significant progress industry has made toward private laboratory accreditation and the development of national and objective accrediting standards and procedures over the last several years. FDA adduces no evidence that any laboratory or sampling service has ever knowingly participated in any scheme to defraud the FDA's importation process.

FDA also discusses a lack of "consistency in standards for sampling services and private laboratories across districts." *Id.* Although FDA's assessment may be correct, the inconsistency often rests in the FDA's own internal procedures and not among accredited laboratories or sampling services. ACIL believes that FDA's inconsistency in its own implementation of agency guidance has "create[d] barriers to entry for new private laboratories, inhibiting the competitiveness of the industry". *Id.* The rule, as proposed, however, fails to address the internal FDA inconsistencies among the various districts and regions.

For instance, FDA has published a number of guidance documents directed at agency personnel for reviewing private laboratory package submissions. ^{65/} Despite FDA's attempts to establish internal uniformity, there remains "no single set of procedure" prescribed for FDA districts. *Id.* Therefore, FDA's own guidance documents admit adaptation by individual districts to suit their particular needs. The result, however, is that the private laboratory industry must constantly update its understanding of the various procedures district by district. This inconsistency in receiving and reviewing private laboratory analytical packages should be expected given FDA's handling of the process over the years. But this regulation does not address the problem of inconsistency across FDA districts.

One of the most disappointing aspects of this proposed rule is that it fails to impose upon FDA personnel any standards or guidelines upon which industry could rely to unify the agency's processes or to establish timeframes within which the districts must review the packages and render an import admissibility decision. Instead, the rule merely cites varying editions of FDA laboratory procedures manuals and regulatory procedures manuals; a Baltimore District SOP

^{64/} See section II.C., *supra*.

^{65/} See e.g., *Guidance on the Review of Analytical Data Generated by Private Laboratories*, FDA Laboratory Procedures Manual, Chap. 21, at http://www.fda.gov/ora/science_ref/lpm/lpmtc_dec02.html (last viewed July 18, 2004) ("Although FDA has no legislative authority to directly regulate these laboratories this guidance is provided to insure the scientific credibility of data submitted to the agency.")

for managing private laboratories and; separate Pacific Region guidelines for private laboratories. *See e.g.*, 69 FR at 23471. In addition to these varying agency guidelines, the Southwest Import District (SWID) has their own documents pertaining to sampling and private laboratory analyses. But the rule fails to reconcile agency practice across districts and therefore fails to establish uniform procedures.

FDA's discussion of the proposed benefits of the rule includes the issue of timeliness of FDA's review of private laboratory packages. *See* 69 FR at 23468-9. ACIL disagrees with FDA's estimated review time for private lab packages. In fact, since December 12, 2003, when FDA implemented its prior notice for imported food requirements and reinstated Operational Liberty Shield imported food security screening criteria, virtually every FDA import process has slowed substantially. Review of private laboratory packages is no different. In many instances, different districts require certain personnel to review all lab packages. At times this creates a substantial backlog and FDA's lab package review process can extend for weeks before rendering an admissibility decision.

V. Conclusion

We reiterate our appreciation of the value of this rulemaking effort. Further, we agree with the importance of deterring the importation of unsafe food, with the clear need to establish uniformity in private laboratory submissions and with the goals of improving consistency in the analytical data upon which the agency may rely to make imported food admissibility decisions. We also believe that a critical component to improving this process is to develop standards that will establish uniformity among FDA district offices in receiving and reviewing private laboratory submissions. Ensuring integrity in this process will directly benefit our members, the FDA, and most importantly, the consumers who rely upon our combined efforts.

We believe, however, that this proposed rule does not accomplish the agency's own stated objectives. For the reasons stated in these comments, ACIL recommends FDA withdraw this proposal, re-enter discussions with industry stakeholders, and only re-propose the rule after FDA completes implementation of new bioterrorism related authorities.

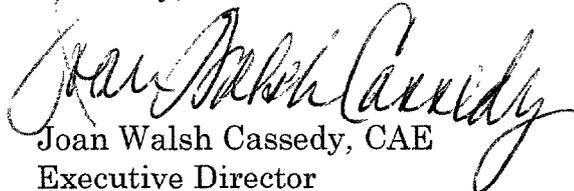
Alternatively, and at a minimum FDA should reengage the private laboratory industry regarding this exercise of its regulatory authority and issue its final rule in interim form. This would permit an opportunity to submit additional comments regarding any changes from the proposal.

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A final point bears repeating. ACIL believes that FDA should recognize private laboratory accreditation by granting a presumption that analytical results submitted by accredited laboratories are accurate and competent. Further, FDA should reduce the supporting information that an accredited laboratory must include in its submissions to FDA. This would permit FDA to ensure the safety of imported food on a risk basis while maintaining its concentration on laboratories that are unable or unwilling to seek accreditation. This would tie reduction in agency review time to scientifically valid risk-based criteria while enabling the agency to establish a bright line procedure for its own staff to follow, thereby further reducing inconsistencies across FDA districts.

If you have any questions regarding these comments, please do not hesitate to contact me.

Sincerely,



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Executive Director
American Council of Independent Laboratories
1629 K Street, NW Suite 400
Washington, DC 20006

Cc: John Szpylka, Chair, Microbiology and Chemistry Section, ACIL
Martin Mitchell, Past Chair, Microbiology and Chemistry Section, ACIL
Thomas Zierenberg, Vice Chair, Microbiology and Chemistry Section, ACIL
Benjamin L. England, Esq., Hogan & Hartson LLP



National Cooperation for Laboratory Accreditation

2004 04 JUL -6 09:31
June 1, 2004

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 2002N 0085
RIN Number 0910- AB96

Dear Sir or Madam:

We are submitting comments from the National Cooperation for Laboratory Accreditation (NACLA) on the FDA proposed rule regarding "Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection with Imported Food."

NACLA is a not-for-profit organization that is a partnership of private- and public-sector organizations. It is addressing a critical need in the U.S. conformity assessment system: a coordinated approach to the accreditation of testing and calibration laboratories.

The objective of the rulemaking is unassailable, of course. In the modern world, with its global economy and international free trade, the volume of imported food will continue to increase, making initiatives to ensure the safety of these imports ever more important.

Further, NACLA applauds FDA for its reliance on private, third-party laboratories to provide the test data on imported food, which is the critical component in ensuring food safety.

Because of the vital role of these laboratories in the "safety chain," NACLA strongly encourages FDA to reconsider that part of the proposed rule that deals with "Requirements for Private Laboratories": Subpart D, Part 50.301. We suggest that a clause be added to that Part, stating that "you (the private laboratory) must be accredited by a qualified accreditation body."

We realize that FDA gave serious thought to requiring that the private laboratories on whose test data it will rely be accredited, but, in the end, "decided to omit a laboratory accreditation requirement from the proposed rule." NACLA questions that decision and believes that including an accreditation requirement will strengthen the final rule and enhance its objective: safe imported food for the U.S. consumer.

In our opinion, FDA's own words justify inclusion of an accreditation requirement: II D. (pg. 23463): "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

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the tests or analyses correctly. Nevertheless, accreditation *could* increase confidence in the private laboratory's results." (Cf., Section II D - pg. 23463)

We've put "could" in italics, because we think it is self-evident that a process that "shows that the private laboratory is competent" will increase confidence. And isn't confidence in a laboratory's data such a vital element in the "food safety chain" that any reasonable means that enhances it ought to become a requirement.

In its proposal, FDA gives several reasons for deciding to omit an accreditation requirement (cf., Section VII C 3 - Pg. 23468.) In the following paragraphs, permit us to cite these reasons and give our perspective on them.

- FDA asserts that the acknowledged accreditation benefits of providing "assurance that the private laboratories testing imported food have the appropriate equipment, personnel and procedures to conduct these analyses" and of promoting "improved performance" by these laboratories that "should reduce the number of test results that falsely approve violative shipments" are "*mitigated*" (our italics) "by FDA's careful review of results submitted by private laboratories."

We believe the more correct way to put this is: The benefits of accreditation will "enhance" FDA's review process - and the combination of both processes will increase confidence in the accuracy of the data.

- "There are very few accrediting bodies qualified to accredit laboratories," and "the infrastructure to accredit unaccredited private laboratories does not currently exist."

There are several points to be made here. First, accreditation is a market driven service. Because so few food-testing laboratories have sought to be accredited, few accrediting bodies offer the service. We know of two qualified organizations that offer the service now; and, if FDA were to require accreditation, more accreditation bodies would enter the market. Second, the number of 200 private laboratories cited by FDA (Section VI, pg. 23467) is not large; three or four accreditation bodies could easily accommodate this demand.

Third, to address a related concern raised earlier in the proposed rule (Section II D, pg. 23464) - "how FDA would ensure that the accrediting body is a recognized or competent accrediting body" - the NACLA program operates precisely to meet this need. NACLA rigorously evaluates accreditation bodies and grants recognition only to those found to be competent. If it were to rely on NACLA-recognized accreditation bodies, FDA would be joining NIST and a department of DOE, both of which are relying on data from laboratories accredited by a NACLA-recognized body.

- "The preferred accreditation standard is being changed from ISO/IEC Guide 25 to ISO/IEC Standard 17025," and this is "creating additional strain on the accreditation process."

First, the transition from Guide 25 to Standard 17025 was completed a couple of years ago and the "additional strain" is a thing of the past. Second, there is an excellent standard specifically for food-testing laboratories that fully incorporates the Standard 17025 requirements and adds specific criteria that a food-testing laboratory must meet. The specific criteria were developed by a broad group of experts in the food-testing field, representing FDA, CFSAN, FSIS, laboratories, food-processing firms and related associations. The current sponsor of the document is AOAC International. It is entitled: "Accreditation Criteria for Laboratories Performing Microbiological and Chemical Analyses in Foods, Feeds and Pharmaceutical Testing."

- "Accreditation is costly," in accreditation fees and in "costs to the laboratory of actions needed to meet accreditation standards"

First, logic would lead one to conclude that if a laboratory is already a competent organization that operates in accordance with commonly accepted principles of best testing-business practice, it will not need to expend huge effort to comply with the accreditation standard. And, if it isn't this kind of laboratory, then it badly needs to make the improvements that accreditation dictates, no matter what the cost. If it fails to do this, FDA should not accept its data.

Second, the benefits of accreditation outweigh the expense of the fees and ancillary costs. This is regularly attested to by laboratory officials. It was graphically illustrated by one of the speakers at NACLA's annual Laboratory Accreditation Forum in April of this year. The speaker, David Evanson, is Vice President of Operations and Analytical Services at Silliker, Inc., a major laboratory network in the food testing field. In his talk on "The Values of Laboratory Accreditation," Mr. Evanson cited specific, measurable improvements in a number of areas of the Silliker operation directly attributable to accreditation: Reduced errors; Improved client satisfaction; Improved training; Improved purchasing procedures; Minimized legal expense exposure; and Client retention. In the area most relevant to the FDA rulemaking, reduced errors, he presented these metrics: "microbiology proficiency program error reduced 70% network wide;" "proximate test standard deviation reduced 50% network wide;" "microbiology retests reduced 65%."

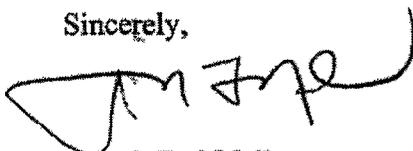
- "Those costs may be particularly prohibitive for very small labs."

First, a number of small laboratories in other fields of testing are accredited and have experienced benefits comparable to those cited by Silliker. Second, if a small laboratory finds it extremely burdensome to meet the standard for competent laboratory performance, doesn't that bring into question the wisdom of FDA accepting test data from that laboratory, especially when public health is at stake.

For the many reasons cited above, NACLA urges FDA to reconsider its position and to include an accreditation requirement in its final rule. Because so many food-testing laboratories are not presently accredited, we recommend that the accreditation requirement take effect two years after the final rule takes effect. This will allow interested laboratories sufficient time to comply with the requirement.

We appreciate having this opportunity to comment and would welcome an opportunity to discuss this matter with FDA officials.

Sincerely,



Joseph F. O'Neil
Executive Administrator