

July 21, 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 2002N-0085

REQUEST FOR EXTENSION OF COMMENT PERIOD

Dear Sir or Madame:

Pursuant to 21 CFR §§ 10.35 and 10.40(b)(3) the American Council of Independent Laboratories (ACIL) respectfully requests the U.S. Food and Drug Administration (FDA) extend the comment period for its recently proposed regulation on Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection With Imported Food (the "Private Lab rule"). See 69 FR 23460 (Apr. 29, 2004). Specifically, ACIL requests the FDA to extend the comment period for the Private Lab rule until the later date of:

- 90 days after the date FDA publishes its final rule on Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 1/ (the "Bioterrorism Act"); or
- 90 days after the date FDA fully implements its interim final rules on Prior Notice of Imported Food Under the Bioterrorism Act 2/ and Registration of Food Facilities Under the Bioterrorism Act 3/, which is currently anticipated to occur on or about August 12, 2004; or
- 90 days after the date FDA publishes its Import Strategic Plan.

In accordance with 21 CFR § 10.40(b)(3), ACIL believes that comments cannot feasibly be prepared and submitted in the time allotted by the FDA and that new information will shortly be available that bears upon the impact this proposed

1/ 68 FR 25188 (May 9, 2003).

2/ 68 FR 58974 (Oct. 10, 2003).

3/ 68 FR 58894 (Oct. 10, 2003)

rule will have on affected stakeholders. Moreover, ACIL believes that sound public policy supports the extension of the comment period. With an extension, the agency would be better able to integrate important strategic planning and policy statements with the application of this regulatory authority and thereby better protect the public from safety risks that may be associated with import foods.

Statement of Grounds

1. Comments cannot feasibly be prepared in the allotted time because the data and information upon which FDA relies is inadequate and outdated.

Based upon ACIL's review of the proposed regulation and upon discussions with various FDA officials, the agency has clearly relied largely upon outdated information and an understanding of private laboratory industry practices that were prevalent in the 1990s. These data and information, however, fail to adequately account for 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 10 years, or the substantial progress the public and private science sectors have made together toward developing national and international accreditation standards. These are extremely complex and important issues that require very detailed consideration and deserve more careful and direct negotiations between FDA and its stakeholders to ensure that the agency's regulatory framework actually accomplishes its stated purposes.

A. Inadequacy of FDA's information

ACIL is particularly concerned that the Private Lab rule fails to even mention the tragic terrorist attacks on our nation on September 11, 2001 and the enactment of the Bioterrorism Act. These historical events have 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 the bioterrorism regulations and their impact upon the Private Lab rule are not even referenced in the federal register announcement.

The Private Lab rule 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 23461. To evaluate FDA's interpretation of these discussions ACIL has been identifying industry participants from those meetings to determine, among other things, the extent to which FDA has accurately reflected

the various points of agreement and the positions supported by industry representatives. It has become evident during this process that some of the participants of the 1996 grassroots meetings disagree with the interpretations FDA reports in the Private Lab rule. However, even if FDA's interpretations do accurately reflect those discussions, they represent the thinking, business models, and industry practice of nearly a decade in the past and are no longer current or relevant.

ACIL believes that the failure to include an analysis of the combined impact of FDA's bioterrorism regulations and this proposed Private Lab rule leaves the industry in the untenable position of divining how all of these new regulatory requirements and authorities interact or may be integrated by FDA without adequate agency guidance. Such an analysis is infeasible in the 90 days allotted by the Private Lab rule comment period.

B. FDA's use of outdated data for estimating the rule's impact

FDA clearly admits that it is relying upon five-year old data to develop its estimate of the annual reporting and record keeping burden of this proposed rule. *See* 69 FR 23466. The following are only a few examples of how FDA's use of old data complicates the review of the proposed rule to the extent that the allotted 90 days for preparing comments is woefully inadequate.

First, FDA notes in the proposed rule that in 1999 FDA's data base contained only 1,739 food importers. *See id.* Over the last five years, however, the number of food importers and consignees who would actually be impacted by this regulation has grown by a factor of at least 45. ^{4/} This staggering difference in FDA's own estimates in two very recent publications frustrates any evaluation of FDA's assessment of the impact of the Private Lab rule.

Secondly, it is irrefutable that the number of discrete food importations has exploded over the last five years. For example, FDA stated in its FY 2004 Performance Plan that "FDA-regulated imports have grown at 10 to 12% annual rate for several years." ^{5/} In the Private Lab rule FDA states that in 1999 11,690 food imports were detained for safety reasons and FDA uses that as a baseline

^{4/} *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).

^{5/} *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).

number for estimating shipments that may require the use of sampling services or a private laboratory analysis. *See* 69 FR 23467. 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 59024. Although this estimate does not include the number of food entry lines imported by road or rail, 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. ^{6/} ACIL has yet to locate an FDA estimate of the percentage of the total number of food entry lines that were detained in FY 2002 for safety reasons for comparison with the data presented in the Private Lab rule. Such discrepancies dramatically increase the complexity involved in reviewing, assessing, and preparing comments in response to this rule.

Thirdly, the agency states in the Private Lab rule that “[i]n FY 2001 FDA refused about 18,000 products offered for import entry into the U.S.” *Id.* Although FDA has not broken this number down in terms of product categories, the agency clearly must have detained more than 18,000 products in order to refuse admission to that many. Assessing the true impact of this rule, therefore, requires researching similar FDA refusal data for FYs 2002, 2003, or 2004 to compare with the 11,690 food detentions in FY 1999. ^{7/}

Fourthly, FDA states in this proposed rule that the agency received approximately 8,767 private laboratory tests in 1999. *See* 69 FR 23467. Because the majority of private laboratory analyses on imported food are conducted in accordance with an FDA Import Alert or as a result of a detention without physical examination, the impact of this rule reaches far beyond domestic importers, consignees, private laboratories, and sampling services. FDA’s Import Alert system is primarily targeted at products from foreign manufacturers, shippers, and at times whole geographic regions or countries. ACIL believes the 90 days allotted for submitting comments is insufficient to estimate the impact this rule will have on foreign food manufacturers, foreign food exporters, importers, sampling services, and private laboratories. Our review is further complicated by FDA’s failure to include the impact on foreign companies in its own estimates.

^{6/} *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/mccllellan/strategic.html> (Aug. 2003).

^{7/} 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). Therefore, ACIL is concerned that it will be impossible to make a comparison with FDA’s FY 1999 detention data to assess the true impact of this rule.

Based upon the above observations ACIL believes it is impossible to obtain and evaluate the relevant and current data to adequately prepare comments to the Private Lab rule in the 90 days allotted by FDA. This data is critical, however, to assessing the impact this proposed rule will have on affected businesses and individuals. 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.

2. Anticipated future information that bears on this process

This 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. ^{8/} FDA has yet to publicly respond to 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 after at least August 12, 2004. ^{9/} 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 much of the analysis ACIL and FDA is conducting in connection with the Private Lab rule obsolete.

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. ^{10/} FDA has not issued its record keeping regulation in final form. The Private Lab rule also contains record keeping provisions for all affected parties. ^{11/} Until FDA issues its final regulation on the bioterrorism record keeping regulation it is impossible to assess and comment on the combined impact these two regulations will have on ACIL's members.

^{8/} See nn. 2 and 3 *supra*, and accompanying text.

^{9/} 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”).

^{10/} See n. 1 *supra*, and accompanying text

^{11/} See *e.g.*, proposed 21 CFR §§ 59.201(b) and 59.301(c).

3. Integration of this rule with agency strategic planning and risk-based principles would serve to better protect the public

Finally, FDA has reported numerous times that it is developing an Import Strategic Plan (ISP) that FDA has yet to publish. ^{12/} ACIL believes the ISP will contain principles that impact various existing and potential uses of private laboratories' services in connection with a more risk-based approach to evaluating the safety and security of imported foods. ACIL is very concerned that ISP principles may not be reflected in this proposed regulation. Without access to FDA's ISP ACIL cannot assess whether the Private Lab rule is consistent with the risk-based approaches and strategies the agency reports it is pursuing in managing imported food safety and security. Integrating the role of private laboratories into a risk-based import program would better protect U.S. consumers from food safety and security risks.

Action Requested

Based upon the stated grounds ACIL respectfully requests that FDA extend the comment period for the Private Lab rule until the later date of:

- 90 days after the date FDA publishes its final rule on Establishment and Maintenance of Records Under the Bioterrorism Act; or
- 90 days after the date FDA fully implements its interim final rules on Prior Notice of Imported Food Under the Bioterrorism Act and Registration of Food Facilities Under the Bioterrorism Act, which is currently anticipated to occur on or about August 12, 2004; or
- 90 days after the date FDA publishes its Import Strategic Plan.

Conclusion

ACIL remains committed to working with FDA to develop "uniform, systematic, and effective approaches to assuring that private laboratories conducting tests on FDA-regulated products submit scientifically sound data" to the agency in connection with imported food. 69 FR 23461. Therefore, ACIL invites FDA to enter a proactive dialogue similar to the grassroots meetings conducted in

^{12/} See *FDA Commissioner's Progress Report to Secretary Tommy G. Thompson: Ensuring the Safety and Security of the Nation's Food Supply*, at <http://www.cfsan.fda.gov/~dms/fssrep.html> (July 23, 2003). See also *FDA FY 2005 Budget in Brief, Promoting and Protecting Public Health*, at <http://www.fda.gov/oc/oms/ofm/budget/2005/BIB/BIB2005.htm> (last viewed July 17, 2004).

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1996 to ensure that the most recent and credible information, data, and evidence are considered in developing the Private Lab rule.

Should you have questions regarding this request please do not hesitate to contact me.

Sincerely,



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