



*National Cooperation for Laboratory Accreditation*

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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%."

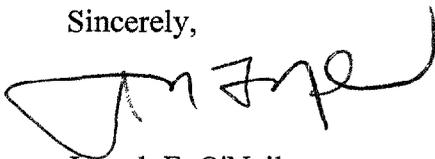
- "Those costs may be particularly prohibitive for very small labs."

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