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ACIL Microbiology and Analytical Chemistry Section Files Comments on FDA Proposed Rule

WASHINGTON, DC, August 30 – The Microbiology and Analytical Chemistry (MAC) Section of the American Council of Independent Laboratories (ACIL) submitted extensive comments in response to FDA's proposed rule governing Requirements Pertaining to Sampling Services and Private Laboratories Used in Connection with Imported Food Proposed Rule (Docket 2004N-0184.)

The Section's Executive Committee believes this to be one of the most important proposed regulations it has addressed in many years. Its impact on the independent food testing industry would be substantial.

ACIL recognizes the value of this rulemaking effort. It is important to deter the importation of unsafe food. Further, ACIL agrees 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. 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 ACIL members, the FDA, and most importantly, the consumers who rely upon their combined efforts.

ACIL and its members are committed to working with the agency in this process. However, ACIL believes that this proposed rule does not accomplish the its stated objectives. ACIL included in its comments a number of serious objections regarding the proposed rule's contents, structure, and regulatory reach. For example, FDA has issued this proposal while relying on outdated data and information and without taking into consideration the dramatic and recent changes in business practices in the food and private laboratory industries. (This rule has been in development since 1996.) Because of our many concerns, ACIL recommended 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, ACIL recommended that 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.

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

More than a dozen food related associations and individuals submitted comments in addition to ACIL. The MAC Executive Committee will continue to monitor this activity and gladly offers to work with the FDA to design a rule that will enhance enforcement activities and food safety without undue negative impact on the food and testing industries.

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 the 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.

The comments are available for viewing on the ACIL Web site (www.acil.org) under News and Press.

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