

Patricia D. Royal
80 Main Street
Plympton, MA 02367
Tel: 781-585-9370
FAX: 781-585-6370

Quality Systems Consulting, Inc.

To: U.S. FDA Office of Policy and Planning

Fax: 301-827-6870

From: Patricia D. Royal

Date: May 21, 2004

Re: Docket No: 2004-0184: Public Health Security and Bioterrorism; Food Importation; Sampling services and private laboratory Requirements. **Pages:** 4

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Attached are comments to the proposed rule as described above.

Please feel free to contact me if I have sent this message to the wrong place or if there is any confusion over the docket number (which as I understand has changed).

Sincerely,

Patricia D. Royal

2004N-0184

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Subject: [Docket No: 2004N-0184; RIN No: 0910-AB96][FR Doc:04-09699];[Page 23460-23473]; Public Health Security and Bioterrorism; Food importation; sampling services and private laboratories requirements.

Quality Systems Consultants, Inc. (QSC) offers the following comments on the subject of the proposed rule. Founded in 1997, Quality Systems Consultants, Inc. is a small consulting company specializing providing technical evaluations and quality assurance services to laboratories and industries regulated under U.S.FDA in addition to non-regulated biology and chemistry laboratories that operate under the ISO 17025. The scope is broad and includes laboratories that analyze food products, veterinary products, medical devices, toxicology and residue chemistry.

Quality Systems Consultants, Inc. supports the Food and Drug Administration efforts in its attempt to establish a uniform approach to monitoring imported food products, and to ensure the validity and integrity of scientific data generated from sampling and analyzing food products imported into this country.

The goals of the proposed rule are noble. The proposal as stated, would establish guidelines for laboratories testing food products to use "validated or recognized analytical methods... and is intended to help assure the integrity and scientific validity of data and results submitted to FDA". However with this said there appears to be several shortcomings with the proposed rule that QSC wishes to comment on. Most comments pertain to Subpart D- Requirements for Private Laboratories.

1) The proposed rule does not but should specify a quality standard under which laboratories shall operate.

Quality systems standards have been in existence since the early 1970s and have been shown to increase the quality, integrity, and reliability of data generated by testing laboratories. They emerged from cases of negligence and fraud in the pharmaceutical industry. With the implementation of GLP and GMP programs under the U.S. FDA, U.S EPA, and OECD programs these serious problems of data integrity and reliability have been greatly improved. While no program can as stated in the proposal "guarantee" reliable data, only through continual oversight can infractions be contained.

There are many testing programs in the U.S. and internationally that are not regulated, but do rely on external and internal monitoring programs that promote data integrity and consistency. Many of these programs operate under ISO standards, most notably ISO 17025. The international acceptance of this standard and its MOU provide consistent oversight and implementation across international borders. This is an important consideration when attempting to establish a program to monitor food imports.

Long standing experience has shown that the success of regulated and non-regulated testing, has been greatly enhanced when laboratories operate under a

specific standard that describe the requirements for facility operations and structure, equipment maintenance and calibration, quality control of analytical measurements, along with demonstrated competency of the technical and quality assurance staff; the implementation is monitored by an independent quality assurance professional either internal to the laboratory or as a third party.

2) The current proposed rule does not specify quality assurance oversight.

The proposed program includes routine food testing along with potential bioterror testing. The goals of this proposed standard as stated are two fold: first to ensure the reliability of data submitted to FDA, and second to assign "FDA oversight to other regulatory matters". Without recognized third party oversight using trained quality assurance personnel this program will fall short of its intended goals, and will lead to inconsistent implementation of testing programs and inconsistent data quality and integrity submitted to the U.S.FDA.

3) The proposed rule does not require laboratory Accreditation or any other standard requirements.

Standards exist to address the needs of food testing laboratories, and have been successfully in operation for several years. The ISO 17025 Standard coupled with the AOAC Accreditation Criteria for Laboratories Performing Food Microbiology and Chemical analyses in Foods, Feeds, and Pharmaceutical Testing Standard can provide an internationally recognized program that will produce standardized quality and data integrity, and external and internal monitoring of laboratory program implementation.

Together, these programs provide the food testing industry with specific guidelines to operate their facility, ensure adequate instrument operation by technically qualified staff, along with the maintenance and calibration of equipment, and computer validation. They also provide competent quality assurance professionals to monitor these laboratories to ensure conformance with recognized international standards of food testing laboratories.

Most commonly found food contamination are listed in the proposed rule under Table 3. These types of analyses are routinely conducted at food testing laboratories under standardized methods, including those of U.S. FDA. Before accreditation, a laboratory must demonstrate competency either through successful participation in external proficiency testing program or by equivalent internal programs. More unique testing programs require method validation before being included in any accreditation program. Proficiency testing programs have shown to improve technical execution of analyses, standardize quality standards, and enhance the evaluation of technical competency.

- 4) The current proposal states that the "laboratory would report the test results either to the owner or consignee or to FDA".**

Many laboratories use electronic data submission to sponsors and to U.S. FDA. This necessitates a laboratory to be in compliance with 21CFR Part 11. This rule is in flux and has been problematic with many laboratories. Until these requirements and the issues surrounding these requirements are resolved clearer guidance should be given to food testing laboratories.

- 5) While the proposal addresses sampling, it does not address subsampling conducted in the laboratory.**

Often large samples are received at a laboratory. These samples must then be subsamples according to standard operating procedures to ensure either technical or statistically representative samples are analyzed. Requirements for subsampling are given in the AOAC food program and should be incorporated in any laboratory requirement.

The importance of this proposed rule cannot be underestimated. The responsibilities of the testing laboratories and those of the U.S. FDA must ensure and require that laboratories operate on a level of integrity and excellence that can only be acquired by implementing a program that requires a recognized standard that includes external monitoring of activities and data.

For these reasons, QSC suggests that the U.S. FDA reconsider its conclusion, and suggests that Accreditation to ISO 17025 and the AOAC food program be specified as the quality and technical standards of this rule. As owner and active member of the quality assurance profession I welcome any comments or questions to this response.

Sincerely,



Patricia D. Royal, M.S. RQAP
President
Quality Systems Consultants, Inc.