

## US FDA ACCREDITATION OF THIRD-PARTY AUDITOR / CERTIFICATION BODIES PROPOSAL

On 29 July 2013 the United States Food and Drug Administration (US FDA) published the proposed rule for the Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and Issue Certifications<sup>1</sup>. This proposed rule is part of the Food Safety Modernization Act (FSMA). Comment period for this proposed rule ends 26 November 2013.

### ACCREDITATION OF THIRD-PARTIES TO CONDUCT FOOD SAFETY AUDITS AND FOR OTHER RELATED PURPOSES

The proposed regulation, as required by FSMA, will establish a system for accreditation of third-party auditors/certification bodies to conduct food safety audits of facilities outside of the United States and territories and to issue food and facility certifications. In this proposed regulation the US FDA has established the procedure to recognize accreditation bodies, the requirements and the recognition of those accreditation bodies. This regulation sets up the procedure and requirements for accreditation of third-party auditors/certification bodies. Additionally the recognition of accreditation of third-party auditors/certification bodies is established. The proposal includes requirements of the third party auditor/certification body to notify the US FDA of conditions in an audited facility that could cause or contribute to a serious public health risk. It also allows accredited third-party auditors/certification bodies to provide certificates of product and facility compliance to the Voluntary Qualified Importer Program (VQIP) or the Foreign Supplier Verification Program (FSVP) (see [SafeGuards 141/13](#)).

The proposed rule sets eligibility requirements for recognition as an accreditation body and third-party auditor. An accreditation body can be a foreign government agency or a private third-party. A third-party auditor can be a foreign government, foreign co-operative or other third-party. Both the accreditation body and the third-party auditors must meet standards for legal authority, competency and capacity, impartiality, quality assurance, and records procedures.

In the future the US FDA will issue qualification standards for auditors and certification bodies and issue the Model Accreditation Standards.



<sup>1</sup> [Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications](#)

For more information on FSMA and how to comment on the proposed regulations is available at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm>

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