

UPDATE ON THE US FOOD SAFETY MODERNISATION ACT

2012 was to be a busy and significant year for the US Food Safety Modernisation Act (FSMA). Signed in to law in 2011, the last 12 months have seen the majority of its programmes drafted but unfortunately because of government review procedures no major programme has been implemented yet.

Tasked with developing some 90 rules, guidance documents and reports to meet the new FSMA requirements the Food and Drug Administration (FDA) has made some progress. Most notably, back in February the FDA published the Record Access Guidance and Interim Rule and in October the Biennial Facility Registration system was launched.

RECORD ACCESS RIGHTS

Record access guidance allows the FDA access to records including: manufacturing, raw materials (ingredients and packaging) receipts, product distribution, testing, recalls and reportable foods, customer distribution as well as complaints and adverse events in all registered facilities. If requested these records must be provided to the FDA within 24 hours. Failure to do so can result in the suspension of a facility's registration, recalls, injunctions or product seizures.

SHIPPING INTO AND ACROSS THE US

Biennial Registration for all facilities opened on October 22, 2012 and all renewals must be submitted by December 31, 2012. Failure to re-register through this process may result in suspension of registration, as of January 1, 2013. Facilities whose registration is suspended cannot ship products into the USA, nor can they ship goods within the country.

Other FSMA rules, guidance documents and reports achieved by the FDA include:

- Publication of three final rules in the Federal Register.
- Publication of 11 draft and final guidance documents in the Federal Register with a further 2 in clearance.
- Completion and submission of five reports to Congress.
- Publication of notices on state and local food defence capacity and the implementation of FSMA re-inspection fees.
- Anti-smuggling strategy published jointly with the Department of Homeland Security.
- Product tracing pilot studies conducted.
- Memorandum of Understanding signed with the US Department of Agriculture to establish an FSMA implementation grant programme for small-scale produce growers.

In addition, the FDA has made very substantial progress on other major FSMA deliverables, including:

- Four major frameworks for proposed rules and accompanying regulatory impact analyses are now under review at the Office of Management and Budget (OMB), covering: preventive control standards for animal food facilities; foreign supplier verification requirements for importers.
- Proposed rules to establish an accredited third party certification programme and transport safety standards are close to completion within the FDA.
- An advance notice of proposed rulemaking on intentional adulteration drafted and close to completion within the FDA¹.

While the OMB is still reviewing three major rules, a further two are nearing completion and the FDA has delivered:

- Record Access Guidance and Interim Rule – February 2012².
- Report to Congress on US FDA Foreign Offices – February 2012.
- Sprout Safety Alliance Development – February 2012.
- High Risk Facility Definition – March 2012.
- More Data Elements for the Reportable Food Registry – June 2012.
- 2012 Report to US Congress – August 2012.
- Increase Category information for Registration – August 2012.
- Biennial Facility Registration – October 2012³.

On 4 January 2013 the US FDA issued the proposed preventive controls for human food and the produce safety standards. US FDA will receive comments to these proposals until 16 May 2013⁴.

Some 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centres for Disease Control and Prevention. The FSMA will better protect public health by strengthening existing food safety systems and proving oversight of producer and processor compliance.

Find out more information about [SGS Food Safety Solutions](#).

Jim Cook
Consumer Testing Services
Food Safety Technologist
[SGS North America, Inc.](#)
james.cook@sgs.com
t +1 973 461 1493

¹ Progress on FSMA, Changes within the FDA Foods Program, and on Partnerships

² Record Access and Guidance for Industry

³ Registration

⁴ Preventive Control for Human Foods and Produce Standard