

in the news

Food and Agriculture



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A Preview of Expected 2014 FDA and Legislative Actions Relating to the Food Industry

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2013 was a pressure packed year for the Food & Drug Administration (“FDA”) and legislation in the food area and 2014 promises to continue at the same pace. The FDA is under looming Court imposed deadlines for the completion of regulations implementing the Food Safety Modernization Act. Additionally, the FDA as well as legislative action is attempting to tackle difficult issues such as Trans-Fats, GMOs, food safety, and other general labeling requirements. Below are some of the things you can expect to see in food regulations this year:

I. Food Safety Modernization Act*

A. Produce Safety

Pending Proposed Regulation: *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*, Docket Number: FDA-2011-N-0921, was issued on 1/4/2013.

- Although the public comment period closed on 11/22/2013, both stakeholders and politicians have been asking for a reissuance of portions of the proposed rule, seeking additional time to comment on the new revisions.

* Per court order, the FDA must issue all final rules under the FSMA by 6/30/2015.



B. Human Food Risk Analysis

Pending Proposed Regulation: Current Good

Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, Docket Number: FDA-2011-N-0920, was issued on 1/16/2013.

- 11/22/2013 – The public comment period closed on the outstanding proposed rule.
- Per the **Focused Mitigation Strategies to Protect Food Against Intentional Adulteration** issued on 12/24/2013, amendments will be issued to the language of this proposed rule to require that risk-based analysis consider certain types of intentional adulteration. Additional public comment will be allowed for these amendments.

C. Foreign Supplier Verification

Pending Proposed Regulation: Foreign Supplier

Verification Programs (FSVP) for Importers of Food for Humans and Animals, Docket Number: FDA-2011-N-0143, was issued on 7/26/2013.

- 1/27/2014 – The public comment period is scheduled to close on the outstanding proposed rule.

D. Accreditation of Food Safety Auditors

Pending Proposed Regulation: Accreditation of Third-

Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, Docket Number: FDA-2011-N-0146, was issued on 7/26/2013.

- 1/27/2014 – The public comment period is scheduled to close on the outstanding proposed rule.

E. Animal Food Risk Analysis

Pending Proposed Regulation: Current Good

Manufacturing Practice and Hazard Analysis and Risk-Based

Preventive Controls for Food for Animals

Docket Number: FDA-2011-N-0922, was issued on 10/29/2013.

- 2/26/2014 – The public comment period is scheduled to close on the outstanding proposed rule.
- Per the **Focused Mitigation Strategies to Protect Food Against Intentional Adulteration** issued on 12/24/2013, amendments will be issued to the language of this proposed rule to require that risk-based analysis consider certain types of intentional adulteration. Additional public comment will be allowed for these amendments.

F. Mitigation Against Intentional Adulteration

Pending Proposed Regulation: Focused Mitigation

Strategies to Protect Food Against Intentional Adulteration, Docket Number: FDA-2013-N-1425, was issued on 12/24/2013.

- 2/20/2014 – Public meeting to discuss the proposed rule.
- 2/27/2014—Public meeting to discuss the proposed rule in Chicago.





- 3/13/2014—Public meeting to discuss the proposed rule in Anaheim.
- 3/31/2014 – The public comment period is scheduled to close on the outstanding proposed rule.

G. Sanitary Transportation of Food

Pending Proposed Regulation: On 1/31/2014 the FDA released its draft of its final proposed regulation relating to the sanitary transportation of food, published 2/5/2014.

- 2/27/2014—Public meeting to discuss the proposed rule in Chicago.
- 3/13/2014—Public meeting to discuss the proposed rule in Anaheim.
- 3/20/2014—Public meeting to discuss the proposed rule in Maryland.
- 5/31/2014—The public comment period is scheduled to close on the outstanding proposed rule.

H. Anticipated Amendments to Regulations

- Per the [Focused Mitigation Strategies to Protect Food Against Intentional Adulteration](#) issued on 12/24/2013, amendments will be issued to the language of pending proposed regulations relating to Human Food Risk-Analysis and Animal Food Risk-Analysis to require consideration of economically motivated adulteration that could result in serious adverse health consequences or death. The FDA is also proposing to amend the current seafood and juice HACCP regulations and the dietary supplement current good manufacturing practice (CGMP) rule to require consideration of this type of intentional adulteration. Public comment will be allowed for these amendments.

I. Pending Proposed Guidance Documents

- Comments may be submitted anytime - [What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide, Guidance for Industry, Docket Number: FDA-2011-D-0643](#)
- Comments may be submitted anytime - [What You Need To Know About Registration of Food Facilities; Small Entity Compliance Guide, Guidance for Industry, Docket Number: FDA-2012-D-1003](#)
- Comments may be submitted anytime - [Questions and Answers Regarding Food Facility Registration \(Fifth Edition\) Guidance for Industry, Docket Number: FDA-2012-D-1002.](#)
- Comments may be submitted anytime - [Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories, Guidance for Industry, Docket Number: FDA-2012-D-0585](#)
- Comments may be submitted anytime - [Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food \(Edition 5\), Guidance for Industry, Docket Number: FDA-2011-D-0598](#)





- Comments may be submitted anytime - **What You Need to Know About Administrative Detention of Foods**, Guidance for Industry, Docket Number: **FDA-2011-D-0643**.
- Comments may be submitted anytime - **Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act**, Guidance for Industry, Docket Number: **FDA-2011-D-0721**.
- Comments may be submitted anytime - **Fish and Fishery Products Hazards and Controls Guidance**, Guidance for Industry, Docket Number: **FDA-2011-D-0287**.

II. Trans-Fats

Pending Proposed Regulation: **Tentative Determination Regarding Partially Hydrogenated Oils; Request for Comments and for Scientific Data and Information**, Docket Number: **FDA-2013-N-1317**, was issued on 11/8/2013.

- 3/8/2014 – The public comment period is scheduled to close on the outstanding proposed rule.

III. GMOs

No Pending Proposed FDA Regulation: The FDA has continued to provide no additional oversight or requirements

for any food products that contain GMO ingredients, but there are a number of proposals to the FDA, federal and state legislation, and ballot initiatives for GMO labeling requirements. Future actions to monitor include:

- Continued requests made of FDA to provide a clear -definition of “natural” that would include genetically modified foods. (the FDA has continued to “respectfully decline” to formally define the term “natural” as recent as January 6, 2014 in letter requests from three federal judges, we will continue to monitor and provide updates)
- Federal legislation that calls for the FDA to develop a “voluntary” federal labeling standard for genetically modified food (this proposed action would supersede any state labeling requirements).
- Additional ballot initiatives on the horizon. Last year saw the passage of GMO labeling requirements in Connecticut and Maine (these bills further require additional States to pass GMO labeling requirements before each go into effect). California and Washington both saw defeat of ballot initiatives for the requirement of GMO labeling in 2013. In 2014, it is estimated that between 20-30 states will continue to move forward legislation and/or initiatives on GMO labeling requirements.





For More Information



The Food & Agriculture Group at Polsinelli will continue to keep you updated on all updates and changes in the law.

The Food & Agriculture Group at Polsinelli is a cross-disciplinary group comprised of attorneys who practice law in every practice area. We can assist you with your business at every step of the food chain from R&D through transportation and delivery of the end product. For questions regarding any aspect of your own business, please contact any of the professionals in the Food & Agriculture Group.

For questions about this proposed rule, how it fits within the overall framework of the FSMA and, more importantly, how it affects your business, please contact the authors of this alert:

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