



FSMA Supplemental Regulations - FSMA Gamechangers for Dairy Plants - November 2014

Since July of 2011, when the first requirements of FDA’s Food Safety Modernization Act became enforceable, the US dairy industry has been waiting for the next shoe to drop. On September 29, 2014, FDA published significant changes (“Supplementals”) to 4 of the 7 main proposed FSMA regulations. These changes will have a direct impact on how dairy plants manage their food safety programs and adds three additional FSMA requirements (supplier management, environmental testing, and product testing) that were not addressed in the original proposed regulations on Preventive Controls for Human Food and Animal Feed. Most dairy plants will also have to comply with the GMPs for animal feed if they discard or sell any dairy products or byproduct for use as animal feed.

Below is a table containing the changes proposed in the Supplementals which added more FSMA-mandated requirements for dairy processing plants. The comment period for these amendments closes on December 15, 2014.

<p>Preventive Controls for Human Food: Supplemental Changes</p>	<p>Revised definitions for “farms,” to include the packing or holding of a raw agricultural commodity (RAC) (milk) from other farms, but if the farm “processes” the RAC, then it will have to register and comply with this regulation. Farms are generally exempt from FSMA & its regulations.</p> <ol style="list-style-type: none"> 1. Change criteria for a hazard analysis (HA) & Preventive Controls (PC) from “reasonably likely to occur” to “significant hazard” based on severity & probability. 2. Requires plant written procedure for <ol style="list-style-type: none"> a. Product testing (could be for incoming ingredients or packaging, in-process product or finished product). For ready-to-eat foods, this will require finished product testing b. Environmental monitoring (note this does not require Zone 1 swabbing and testing) c. Supplier control program if the supplier is being relied upon to control hazards in the supplied material. Facilities would not be required to establish a supplier program for food they only pack or distribute (not a “receiving facility”). d. Addressing economic hazards in the HA intentionally introduced for purposes of economic gain and that could cause illness or injury in the absence of their control. 3. Any “human food” diverted to “animal feed” would require that plant to demonstrate compliance with the FSMA Animal Feed GMPs from the point of diversion from the human food processing stream to the point where the diverted product left the plant as animal feed.
<p>Comment Period Closure 12/15/14 Final Publication By 8/30/15</p>	

<p>Preventive Controls for Animal Feed: Supplemental Changes</p> <p>Comment Period Closure 12/15/14</p> <p>Final Publication By 8/30/15</p>	<p>1. Human food processors already complying with human food requirements & cGMPs that divert some finished product as waste into the animal feed market will be required to demonstrate compliance with the preventive controls GMPs for animal feed from the point where the product was diverted from the human food to the animal feed chain. (part 507 including HA & PC not required).</p> <p>2. Requires plant written procedure for</p> <ul style="list-style-type: none"> a. Product testing (could be for incoming ingredients or packaging, in-process product or finished product). For ready-to-eat foods, this will require finished product testing b. Environmental monitoring (note this does not require Zone 1 swabbing and testing) c. Supplier control program if the supplier is being relied upon to control hazards in the supplied material. Facilities would not be required to establish a supplier program for food they only pack or distribute (not a “receiving facility”). d. Addressing economic hazards in the HA intentionally introduced for purposes of economic gain and that could cause illness or injury in the absence of their control.
<p>Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals: Supplemental Changes</p> <p>Comment Period Closure 12/15/14</p> <p>Final Publication By 10/31/15</p>	<ul style="list-style-type: none"> 1. Hazard analysis: <ul style="list-style-type: none"> a. The FDA is proposing a more comprehensive evaluation of food and supplier risks by combining the proposed requirement that an importer: b. Conduct a compliance status review of each food to be imported <ul style="list-style-type: none"> Analyze the hazards in each food. 2. The FDA is also expanding the risk factors that must be considered. This broader evaluation of risks would require importers to consider such factors as: <ul style="list-style-type: none"> a. The nature of hazards in food b. The entity that will be applying hazard c. Controls, such as the foreign supplier or the foreign supplier’s ingredient supplier d. The foreign supplier’s procedures, processes, and practices related to food safety e. Applicable U.S. food safety regulations and information regarding the foreign supplier’s compliance with those regulations, and f. The foreign supplier’s food safety performance history 3. FDA is asking for input on whether importers should be required to consider hazards that may be intentionally introduced for purposes of economic gain as part of its hazard analysis. 4. Supplier verification - The FDA is proposing a provision for required supplier verification activities that is a hybrid of the two options presented in the originally proposed rule.

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- a. Option 1 of the original proposal, annual on-site auditing of foreign suppliers would have been required when the foreign supplier controls the hazard in a food and the hazard is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals (SAHCODHA hazard). In other circumstances, the importer could determine an appropriate verification activity from among several specified methods, (site auditing, sampling and testing, review of supplier food safety records, and any other method deemed appropriate by FDA).
- b. Option 2, on-site auditing would not have been mandatory under any circumstances. Instead, the importer would determine the appropriate verification activity, based on:
 - Risk presented by the hazard
 - Probability that exposure will result in serious harm or death
 - Food & supplier's compliance status

The approach that the FDA is proposing would provide importers the flexibility to determine appropriate verification measures based on food and supplier risks, while acknowledging the greater risk to public health posed by the most serious hazards in foods. When there is reason to believe that a hazard will cause serious injuries or deaths, a clear, rigorous verification standard is required in the form of annual on-site auditing of the supplier. Importers would be allowed to use a different approach (possibly including less frequent auditing) only if they can establish that it will provide adequate assurance that the hazard is controlled.

5. Consistency with other proposed FSMA rules - To make the proposed FSVP rule consistent with the revisions to the proposed rules on preventive controls for human food and preventive controls for animal Food, FDA revisions include:
 - a. Changing the definitions of "very small importer" and "very small foreign supplier" to having no more than \$1 million in annual food sales rather than the previously proposed limit of \$500,000 in annual food sales
 - b. Deeming that importers that operate food facilities in compliance with any potential supplier verification provisions that may be included in the FSMA Preventive Controls regulation are in compliance with any parallel FSVP requirements to avoid duplicative regulations.
6. Compliance Dates - In general, the compliance date would be 18 months after publication of the final FSVP regulations. There would be some exceptions. For the importation of food that is also subject to the Preventive Controls & Produce Safety Rules, the importer would be required to comply with FSVP regulations 6 months after the foreign supplier is required to comply with Preventive Controls or produce Safety regulations. The compliance dates for those regulations vary, depending on the rule and size of the operation.
7. See the Preventive Controls for Human Foods above for additional details on the changes proposed in the Supplementals that would be referenced for Foreign Suppliers and the requirements to be met by importers and brokers bringing food or food ingredients into the US marketplace.

Mike Taylor, the senior official at FDA with primary responsibility for getting FSMA and all of its parts up and running, stated that these newly published Supplementals will not affect the overall deadlines for publication and enforcement of the FSMA regulations identified in the table below.

FSMA Regulation	Final Rule Publication	Effective Date	Industry Compliance Date(s)
Preventive Controls for <u>Human Food</u> - Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food	No later than August 30, 2015*	60 days after publication of final rule	<u>Very Small Businesses</u> - Defined as less than \$1,000,000 in plant annual sales of human food. - 3 years after publication of final regulation. <u>Small Businesses</u> (fewer than 500 persons & does not qualify for exemption) - 2 years after publication <u>All Other Businesses</u> - 1 year after publication.
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for <u>Food for Animals</u>	No later than August 30, 2015*	60 days after publication of final rule	<u>Very Small Businesses</u> - Defined as less than \$2.5 million in plant annual sales of animal food. 3 years after publication of final regulation. <u>Small Businesses</u> - fewer than 500 persons - 2 years after publication. <u>All Other Businesses</u> - 1 year after the publication.
Food Defense/Intentional Adulteration	No later than May 31, 2016*	60 days after publication of final rule	<u>Very Small Businesses</u> - less than \$10,000,000 in total annual sales of food - 3 years after the publication. Written program not required. <u>Small Businesses</u> - fewer than 500 persons - 2 years after the publication. <u>All Other Businesses</u> - 1 year after the publication.
Sanitary Transportation of Human & Animal Food	No later than March 31, 2016*	60 days after publication of final rule	<u>Small Businesses</u> - employs fewer than 500 persons and motor carriers having less than \$25.5 million in annual receipts - 2 years after the publication. <u>All Other Business</u> - 1 year after the publication. Note dairy plants have a responsibility to ensure their contract transport companies are compliant with this FSMA regulations
Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals	No later than October 31, 2015*	60 days after publication of final rule	The importer would have to comply 6 months after the domestic compliance date for the Preventive Controls Regulations
Accreditation of Third-Party Auditors	No later than October 31, 2015*		The FDA intends to implement the program at the earliest date possible after publication of the final rule and the final Model Accreditation Standards.

*Note that the “Final Rule Publication” date in the table above is based on US FDA agreeing to meet the court-ordered deadline.

It is important that all dairy plants re-register with FDA and update their information by December 31, 2014, even if nothing has changed since first registering two (2) years ago. See the FDA registration website at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm314178.htm> for more information. Failure to register by December 31st could result in FDA taking action against all finished product and closing the plant.

To conclude, some dairy plants have already started the journey toward full FSMA compliance, improving their operational programs and budgeting for capital expenditures. Other plants are taking a “wait and see” approach. It is likely that in late 2016 or 2017, FDA will identify dairy plants not complying with the FSMA regulations and take strong action against these plants to send a signal to the rest of the dairy industry that FDA is serious about enforcement of these new requirements. As a result, taking a “wait and see” approach may put your plant in jeopardy and not allow enough time for your plant production and quality assurance staff to ensure the plant food safety program is compliant with FSMA. A positive step is for company and plant managers responsible for budgets to build increases into the capital, operational and training budgets for 2015 and 2016 in order to ensure that their plant(s) achieves FSMA compliance and avoids FDA enforce-

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