Preventive Controls for Animal Food

Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

The Food Safety Modernization Act includes regulations addressing the safety of food for animals to provide greater assurance that animal food is safe and will not cause illness to animals or to humans. These regulations will, for the first time, establish requirements for the Current Good Manufacturing Practice (CGMP) for food for animals. In addition, there are requirements for certain domestic and foreign animal food facilities to establish and implement Hazard Analysis and Risk-Based Preventive Controls for food for animals. Information about the rule and the implementation of the rule can be found here. (Link to: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm366510.htm)

Compliance Dates

Businesses have a staggered number of years after publication of the final rule to comply, based on business size. In addition, there will be staggered compliance between the CGMP requirements and the Preventive Control Requirements:

<table>
<thead>
<tr>
<th>Business Size</th>
<th>CGMP Compliance Date</th>
<th>PC Compliance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business other than small or very small</td>
<td>September 2016</td>
<td>September 2017</td>
</tr>
<tr>
<td>Small business</td>
<td>September 2017</td>
<td>September 2018</td>
</tr>
<tr>
<td>Very small business (records to support status as a very small business were required by January 1, 2017)</td>
<td>September 2018</td>
<td>September 2019</td>
</tr>
</tbody>
</table>

*Small business: employing fewer than 500 full-time equivalent employees
*Very small business: averaging less than $2,500,000, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale)

Compliance dates after publication of the final rule for the requirements of the supply chain program:

- **Receiving facility is a small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility’s supplier is required to comply with the CGMP requirements of this rule.

- **Receiving facility is not a small or very small business and its supplier will be subject to CGMPs but not to preventive controls:** six months after the receiving facility’s supplier is required to comply with the CGMP requirements of this rule.
• **Receiving facility is a small business and its supplier is subject to the preventive controls for animal food final rule:** Three years after the rule’s publication date or six months after the supplier is required to comply with the rule, whichever is later.

• **Receiving facility is not a small or very small business and its supplier will be subject to the preventive controls for animal food final rule:** Two years after the rule’s publication date or six months after the supplier is required to comply with the rule, whichever is later.

**Exemptions**

Generally exemptions in this Rule are for farms and mixed type farms facilities that are small and very small businesses. There is a **qualified exemption** for very small businesses that sell at least 50% of their product directly to qualified end users and the value of all food sold is less than $500,000 adjusted for inflation (in the preceding 3 year period).


**Do you want to read more about this?**

**Fact sheet**

[KEY REQUIREMENTS: Final Rule on Preventive Controls for Animal Food](https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food)

**Other important links**

**Food Safety Preventive Controls Alliance** (link to [https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food](https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-animal-food))

The U.S. Food and Drug Administration is working with the Illinois Institute of Technology’s Institute for Food Safety and Health (IIT IFSH), who will administer the Food Safety Preventive Controls Alliance (FSPCA). The FSPCA is a public/private alliance consisting of representatives from the FDA, state regulatory agencies, the food industry, and academia, whose mission is to support safe food production. A standardized core curriculum, training and outreach programs are tools that the Alliance provides to assist animal food processing businesses that must comply with the Preventive Controls for Animal Foods Rule, especially small and medium sized companies. In addition, the FSPCA Technical Assistance Network (TAN) has been set up to address scientific/technical questions related to FDA’s Preventive Controls animal food regulations.

**FDAs Technical Assistance Network or TAN**

The Technical Assistance Network (TAN) is a central source of information for questions related to the FSMA rules, programs, and implementation strategies. You may contact the TAN with questions you have about the Preventive Controls for Animal Foods Rule regulations.

You may submit questions online here. (link to: [https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm](https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm))
Or, you can mail your question to:
Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740