5 Steps Toward Working with FDA on Human and Animal Food Guidance Documents

The FDA's Foods and Veterinary Medicine (FVM) program drafts documents, called guidances, that provide the agency's current thinking on how best to comply with laws and regulations governing food, feed and other FDA-regulated products.

But the FDA is not the only source of guidance documents on best practices for compliance with regulatory requirements. Associations or organizations associated with a specific industry and universities also draft guidance documents to capture the best practices to produce food, feed and other regulated products in a way that helps to ensure their safety in accordance with federal regulations.

For example, industry associations may want to draft food safety guidance documents to help their members comply with new requirements under the **FDA Food Safety Modernization Act (FSMA) (/Food/GuidanceRegulation/FSMA/default.htm)**. These documents may be used as resources for FDA in developing future FDA guidances for the food industry.

With the core FSMA rules now final, industry groups have expressed interest in creating guidance documents on these requirements with two goals: providing a valuable resource for their members, and developing industry standards and best practices that can ultimately become part of an FDA guidance in the future.

Whether a guidance document is related to FSMA or another food safety effort, here are five steps that may increase the likelihood that FDA will be involved in the guidance process by providing technical advice, linking to the final document for informational purposes, and/or incorporating industry guidelines into its own guidance:

1. **Define the scope of the guidance document.** A number of factors go into this decision, and FDA involvement in the guidance effort may be influenced by some of them, including:
   - how broadly applicable the guidance document will be, as opposed to having a narrow focus;
   - the extent of the need by industry for the information, such as filling knowledge gaps or addressing key areas of concern or confusion, including issues that may have been identified in investigation of outbreaks of foodborne illness; and
   - the usefulness to the agency, such as a guidance addressing topics not covered by existing or planned FDA guidances.

   Specific questions to be considered in defining scope: Should the guidance document be specific to a single food or commodity or to a class of foods/commodities? Is there a specific aspect of production that will make this guidance unique, such as produce grown in a greenhouse or cheeses aged for a certain number of days? Should the scope be regional, national or international?

Once the food/commodity is determined, the next decision is how much of the process to cover. Should it be a single process or stage of production, or the entire supply chain? To use produce as an example, should the guidance cover growing, packing, fresh-cut processing, transportation, distribution, or all of these?

2. **Establish a work group** and invite experts from industry, academia and government (both state and federal) to participate. These experts should be knowledgeable about the food or commodity, its production and the manufacturing or processing, as applicable.

   Potential participants could be anyone with a relevant interest and/or expertise, including food producers, food industry representatives, consumer groups, academicians with a research background in food production and/or safety, retailers, and experts in the state and federal government.

   A broad and diverse membership often leads to a better guidance document and greater acceptance of the recommendations.

3. **Invite the FDA to participate.** The agency may be able to join meetings to provide technical assistance and to be on the lookout for any potential conflicts with federal regulations. The FDA may also be able to share experience and insights from inspections and outbreak investigations that could be relevant to the guidance.

   This technical assistance has taken many forms in past collaborations, from reviewing and commenting on a draft guidance document, to participating in webinars, to joining face-to-face work group meetings, or a combination of these during the development process. The form depends on many factors, including the complexity of the issues, the make-up of the work group, and the time and resources available.

   To seek FDA participation, **which is not mandatory**, contact Marion Allen in FDA's Office of Foods and Veterinary Medicine/Center for Food Safety and Applied Nutrition (marion.allen@fda.hhs.gov) and your request will be forwarded to the appropriate program office.

4. **Develop the guidance document.** Once the scope of the guidance document has been defined, its components are worked out in a series of meetings and other kinds of communication, such as e-mails, Web meetings and conference calls. This is a labor-intensive endeavor in which the association or other group collaborates with the work group members in a coordination and consolidation role.

   There is flexibility in the development process, depending on the needs and preferences of the association/group overseeing the guidance development and the work group.

   The recommendations in the guidance document should be as specific as possible and be science and risk- based. Quantitative or qualitative risk assessments can be helpful but are not essential. When research is not available on an aspect of the production process, the subject matter experts will provide suggestions to the group based on their knowledge and experience.

   The draft is sent out to the group for review, changes are made, and the process is repeated as often as is necessary until the parties involved are satisfied that the guidance document is complete.

5. **Finalize the guidance.** Once the draft is complete, the final version can be circulated to select members and subject matter experts, or more broadly, e.g. to the members of all groups involved, with a deadline for comments and a posting date scheduled. The guidance can also be sent to state and federal regulators for review.

   When comments have been evaluated and addressed, the guidance may be posted on the web sites of the parties involved. As stated earlier, the FDA may use such a guidance document as a resource in developing its own guidance and for other purposes, such as identifying research, policy development, education or outreach needs. The agency may also link to the guidance document on **http://www.fda.gov/Food/GuidanceRegulation/default.htm (http://www.fda.gov/Food/GuidanceRegulation/default.htm)** as a resource for stakeholders.

   The process of issuing a guidance document generally takes from six months to a year. However, since these documents need not be static, they can be posted without having complete guidance in all areas. Ultimately, the guidance document can serve to raise awareness about potential hazards and as a basic guideline for assessing and addressing those hazards. They can be updated when necessary to reflect changes in state and federal regulations and evolving science and experience.

For Examples of Industry Guidance in Collaboration with the FDA see:
Produce and Plant Products Guidance Documents and Regulatory Information (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Pro-

ducePlantProducts/default.htm)