

FDA's Animal Feed Safety System (AFSS) Project Plans Update #6

AFSS Framework Document Being Updated

The AFSS Team is revising its Framework Document to make sure the role of research is recognized and to clarify certain definitions, particularly the definition of hazard.

The next version will be #4. It will be posted on CVM's Web site when it is released.

Process control standards regulation anticipated in 2010

The AFSS Team is drafting a process control standards regulation and expects to unveil the proposed rule in calendar year 2010. CVM will publish it in the *Federal Register* for comment.

Process controls are discussed in the Framework Document's Component C, "Process Control for the Production of Feed Ingredients and Mixed Feed." The Framework Document says that process controls are "a systematic approach designed to ensure feed safety through the identification and use of appropriate controls" when feed is being manufactured. The process control standards regulation envisioned by the AFSS Team will include concepts of Hazard Analysis and Critical Control Points and current Good Manufacturing Practices programs, in that the regulation will require feed establishments to determine where and when hazards can be introduced into feed and then establish and implement practices to prevent unacceptable feed risks.

Current regulations covering feed manufacturing address potential problems from feed additive medications, BSE, and biological contamination of canned pet food, for example. On the other hand, no manufacturing regulations exist that would cover most feed ingredients and non-medicated feeds.

The process control standards regulation the AFSS Team is planning to propose will apply during procurement, manufacturing, packaging, storing, and distributing of feed ingredients and mixed feeds. The goal of the process controls will be to prevent or reduce to an acceptable level the risks to animals and humans from hazards in feed. The Framework Document provides an example: The process control standards regulation can require feed manufacturers to have written procedures for testing incoming mycotoxin-susceptible ingredients as a way of addressing the hazard so that it does not become an unacceptable feed risk.

The AFSS Team expects that the process control standards regulation will cover all feed mixing sectors, including ingredient suppliers, mixed feed manufacturers, and on-farm feed processors.

The Team has completed the codified portion of the proposed rule, and the rule's preamble is nearly done. However, the analysis of the economic impact will take additional time.

Safe Feed Guidance

The AFSS Team will release as a planned "deliverable" a "Safe Animal Feeding" guidance document that will help animal producers develop and implement on-farm practices to ensure the safety of animal feed kept on the farm and fed to the farm's animals. The guidance outlines basic measures that may be taken to maintain the safety of all types of feed held on the farm for animal production.

The draft guidance is in clearance. We are not sure when it will be released. But it will be listed on CVM's Web site as soon as it is made public.

AFSS Brochure

The AFSS Team has developed a brochure that presents an overview of the AFSS initiative. It is titled, "Keeping America's Animals Safe and Healthy."

It describes how the AFSS Team is developing a comprehensive system that has a broad focus and does not simply target specific areas of concern, such as BSE or medicated feed. It explains that the AFSS initiative applies to all parts of the animal feed system and that it will be risk-based to make sure significant risks are appropriately addressed. It also has a section titled, "What AFSS will mean to you."

Copies of the full-color, tri-fold brochure are available by contacting CVM via the "Contact CVM" navigational button on the Center's Web site. Also, the brochure is available electronically via the Association of American Feed Control Officials Web site at www.aafco.org/.

Generally Recognized as Safe Status

CVM plans to start a pilot program this summer that will permit a sponsor to inform FDA of the sponsor's determination that the use of a substance in feed, which includes pet food, is "Generally Recognized as Safe," or GRAS.

Earlier this year, the Center's Division of Animal Feeds formed an "Ingredient Safety Team" to handle GRAS notification submissions. When the pilot program begins, the Ingredient Safety Team will include five members. The Team will work with other components of CVM to review the notices.

Under the GRAS notification program, a notifier submits a summary of publicly available information in support of its claim that a substance (as described in the notification) should be considered GRAS under specific conditions of its intended use and not be considered a food additive, which requires pre-market approval by FDA. The

information supplied by the notifier would address both the safety and utility of the substance. CVM will evaluate the submitted notification to determine whether it provides a sufficient basis for a GRAS determination or whether information in the notification or otherwise available to FDA raises issues that cause the Agency to question whether use of substance in feed, which includes pet food, is GRAS.