

Food Safety Modernization Act

Still time for public comment, but be prepared to comply with new rules.

On Jan. 16, 2013, the proposed rule outlining the requirements of the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) was published for public comment. So,

the milling industry needs to take note, because the countdown has begun, and the period for public comment will end on May 16, 2013.

The proposed FSMA rule focuses on preventive controls for human food that can cause foodborne illnesses. The rule applies to domestic and foreign companies that manufacture, process, pack, or hold food.

Under the proposed rule, firms would be required to implement written plans that identify hazards, specify steps to prevent those hazards, identify and record monitoring results, and specify

actions taken to correct problems.

The FDA will continue to inspect facilities to confirm the plans are implemented and evaluated properly.

Under the proposed rule, the first compliance date would be one year after the final rule is published in the *Federal Register* for most companies.

The FDA is proposing to allow two years for small businesses (e.g., fewer than 500 employees) and

three years for very small businesses to comply. The definition of a very small business would be comprised of the following three different levels based on total annual sales and adjusted for inflation: less than \$250,000, less than \$500,000, and less than \$1 million.

The FDA also will hold public meetings to explain the proposal and provide additional opportunity for input.

Background on FSMA

The FSMA was signed into law in January 2011, "to better protect public health by helping to ensure the safety and security of the food supply."

FSMA is significant to the grain ►

Management



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milling industry, because it mandates facilities to implement a HACCP program or similar plan to:

- Evaluate hazards.
- Identify preventive controls.
- Implement actions to minimize or prevent these hazards.
- Verify that preventive controls are adequate.
- Take corrective action when needed.
- Maintain a written plan and documentation.

HACCP plans or similar programs no longer will be voluntary to provide a safe, reliable ingredient to customers but required by law and enforced by the FDA.

The proposed rule will apply to all facilities that are required to register under FDA's current food facility registration regulations.

FSMA has two main parts:

1. It includes provisions requiring hazard analysis and risk-based preventive controls.

2. It revises the Current Good Manufacturing Practice (CGMP) requirements found in 21 Code of Federal Regulations (CFR) part 110. The modi-

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- Mark Fowler, associate director, IGP, KSU

fied CGMPs will be a new 21 CFR part 117 titled "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."

Hazard Analysis, Risk-Based Controls

FSMA hazard analysis and risk-based preventive control requirements are similar to HACCP systems but with some subtle differences.

Although both FSMA and HACCP preventive controls are science-based, HACCP has developed standards that are defined and widely accepted across the food industry.

Based on FSMA changes, preventive controls may be required at points other than at critical control points, and critical limits would not be required for all preventive controls. This is an important difference, because FSMA allows some subjectivity into the system by allowing companies to develop controls that fit their products and operations.

At a minimum, facilities will be required to write and implement a food safety plan to include the following:

- Hazard analysis that identifies and evaluates known or reasonably foreseeable hazards.
- Preventive controls implemented to minimize or prevent identified hazards significantly including:
 - Processing risks.
 - Food allergens.
 - Sanitation.
 - Recall plan.
- Monitoring procedures to ensure preventive controls are performed and documented.
- Corrective actions for when preventive controls are not implemented properly.
- Verification activities to ensure ►

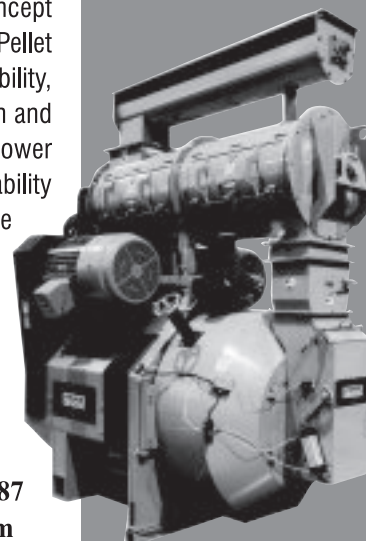
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preventive controls are consistently implemented and effective.

- Recordkeeping where facilities are required to keep a written food safety plan and records of preventive controls, monitoring, corrective actions, and verification.

A qualified individual would be required to prepare the food safety plan, develop the hazard analysis, validate the preventive controls, review records, and conduct a reanalysis of the food safety plan or oversee these activities.

To be qualified, an individual would

be required to complete training successfully, in accordance with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system.

The CGMP regulation would be revised and changed to offer more details about meeting existing requirements for protecting against food contamination, as well as cross-contamination of food allergens.

The FDA also is requesting comments on mandating training for employees and supervisors, including a requirement for records that document that training.

Comment Procedures

The process for comment of this proposed rule is set by the Administrative Procedure Act. Final rules issued by FDA under this process have the force of law.

There are three steps in the comment process.

Step 1: FDA proposes a rule and requests comments.

Step 2: FDA considers your comments and issues a final rule.

Step 3: Companies comply with the rule based on the "effective date."

FDA is proposing the effective date of this law to be 60 days after the final rule is published, which could be July or August 2013, with compliance dates depending on size of the company.

Again, small businesses would have two years to comply, and very small businesses would have three years, while all other businesses would have to comply within one year after publication of the

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final rule.

The full text of proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food," is in the *Federal Register* for public review and comments.

The proposed and final rules, with supporting documents, can be found on the FDA's official website www.regulations.gov, as well as on the FSMA website: www.fda.gov/Food/FoodSafety/FSMA/default.htm.

FSMA is the most extensive change of FDA's food safety regulations in more than 70 years. Change is inevitable and expected, but forced change is often uncomfortable and difficult to accept.

I encourage everyone to read the full text of the FSMA rule and make your support and concerns known, as our industry enters into the next era of FDA regulation.

Mark Fowler is associate director of the International Grains Program (IGP), Department of Grain Science and Industry, Kansas State University, Manhattan.

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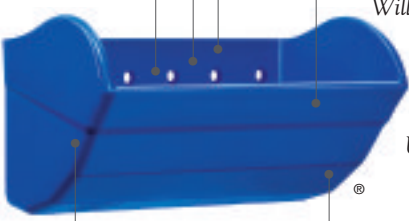
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