

Following are questions and answers on the topics covered in Donald Kraemer's interview on FSMA preventive control provisions.

GENERAL

WHAT ARE PREVENTIVE CONTROLS?

Preventive controls are scientifically- and risk based-based practices that facilities use to address hazards that their products might be exposed to. Once preventive controls are in place, facilities should monitor them to make sure they are working as they were designed.

WILL FACILITIES THAT MANUFACTURE, PROCESS, PACK, OR HOLD FOOD BE REQUIRED UNDER FSMA TO WRITE AND IMPLEMENT A PREVENTIVE CONTROLS PLAN?

FDA's intention is that all covered facilities would need to develop a plan; identify the hazards, identify and implement preventive controls; and then monitor to make certain that the controls work. However, not every facility will have the same hazards or preventive controls. Each plan should be tailored to fit the facility and the risks associated with the facility's food.

IS THIS REQUIREMENT IN THE STATUTE FOR CREATING AND IMPLEMENTING THESE PLANS EFFECTIVE NOW AND SHOULD FACILITIES CONTINUE TO FOLLOW THE CURRENT GOOD MANUFACTURING PRACTICES (CGMPs)?

The requirement is not effective now and will not be effective before FDA issues a final rule implementing the requirements. Firms need to continue to comply with CGMPs. Further, FDA does not anticipate that the new preventive control requirements will replace CGMPs. Rather, CGMPs will form the foundation for preventive controls.

WILL ALL OF THE REQUIREMENTS FOR PREVENTIVE CONTROLS APPLY TO ALL FACILITIES?

FSMA provides for exemptions or modified requirements in certain circumstances, such as when a facility is already required to comply and is in compliance with seafood or juice HACCP, or if a facility is very small. FDA will address and explain these aspects of the law as part of the rulemaking process to implement the preventive controls provision. There will be guidance and a proposed and final rule issued with ample opportunity for public comment.

EXEMPTIONS

WILL FOOD IN COMPLIANCE WITH THE MANDATORY JUICE OR SEAFOOD HACCP REQUIREMENTS BE SUBJECT TO THE NEW PREVENTIVE CONTROL REQUIREMENTS FOR FACILITIES?

No. FSMA contains an exemption for a facility with regard to food subject to and in compliance with FDA's juice or seafood HACCP regulations.

WHAT IS THE SCOPE OF THE EXEMPTION FOR FOOD SUBJECT TO THE LOW-ACID CANNED FOODS (LACF) REGULATIONS?

The exemption for LACF is limited to microbiological hazards. The preventive control requirements will apply as to other hazards.

PRODUCE SAFETY

HOW WILL FDA TAKE INTO ACCOUNT THE DIVERSITY IN FARMS, GROWING PRACTICES, COMMODITIES, ETC. IN CONDUCTING THE PRODUCE SAFETY RULEMAKING THAT IS REQUIRED BY THE NEW LAW?

FDA recognizes the tremendous diversity in this industry, in size of operations, growing practices, growing conditions, and more. The regulations must provide for flexibility.

WHAT CAN FARMERS DO RIGHT NOW TO PREPARE FOR UPCOMING PRODUCE SAFETY REGULATION AND HOW WILL FDA HELP FARMERS UNDERSTAND AND COMPLY WITH THE UPCOMING REGULATION?

While it will be some time before a regulation outlining produce safety requirements will be implemented, farmers can begin assessing their operations in terms of food safety right now. Another thing farmers can do is review FDA's ["Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables"](#) (also known as the "Good Agricultural Practices" or "GAPs" guide).

At FDA, we have found that a very important key to compliance in any regulation, and what we think needs to happen first in implementing produce safety standards, is education and outreach. There will be considerable effort to develop standardized training programs to help farmers reach the standards FDA will be looking for in the growing and harvesting of produce.

HOW WILL FARMERS GET THIS INFORMATION?

There will be considerable outreach to help producers implement upcoming produce safety standards. FDA is actively working with USDA's Agricultural Marketing Service and Cornell University in a cooperative effort called the Produce Safety Alliance that you'll be hearing a lot about in the months to come. We will consider collaboration and input from our stakeholders, including academia, industry, and consumers, as an integral part of the success in putting together a meaningful education campaign in this area and ensuring understanding of and compliance with the regulations that will be issued.