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REGULATORY ISSUES: NEW INSPECTION APPROACHES AND TECHNIQUES – IMPLICATIONS FOR FOOD SAFETY REGULATIONS

COUNTRY PAPER PROPOSED BY THE USA

SUMMARY

Americans consume an average of 234 eggs per person per year. Some of these eggs will contain *Salmonella* enteritidis (SE) bacteria, capable of causing illness if the eggs are eaten raw or are used in foods not thoroughly cooked. Because eggs can become contaminated internally from the hen, many common egg-handling practices, including holding eggs and egg-containing foods at room temperature instead of under refrigeration, inadequate cooking, and the pooling of eggs to prepare a large volume of an egg-containing food that is then subject to temperature abuse or inadequately cooked, are now considered to be unsafe.

As a result, in an effort to reduce eggs as a source of SE illnesses in the United States, the Egg Safety Task Force is developing a regulatory plan to eliminate egg-associated SE illnesses. The Task Force is composed of designees of the Federal food safety agencies responsible for egg safety, including the Food Safety and Inspection Service, United States Department of Agriculture, and the Food and Drug Administration, United States Department of Health and Human Services. The plan developed by the Task Force is the basis for the new eggs and egg products inspection approaches and techniques described in this conference room document.

After a large outbreak of *Escherichia coli* O157:H7 linked to fresh apple juice products in the western United States, FDA held a public meeting on juice safety that was attended by the Fresh Produce Subcommittee of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF). Following discussions on how best to ensure the safety of juices, the NACMCF recommended the use of HACCP principles in processing juice.

On April 24, 1998, FDA issued proposed rules to require (1) the use of HACCP for all juice and juice products, and (2) warning label statements on untreated fresh juice. The warning label statement requirement is currently in effect; the HACCP rule was published in final form on January 18, 2001 and will become effective over the next three years, based on the size of the firm.

INTRODUCTION

The mission of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture is to ensure that meat, poultry, and egg products are wholesome, not adulterated, and properly marked, labeled and packaged.

The mission of the Food and Drug Administration (FDA), Department of Health and Human Services is to promote and protect the public health by helping safe products reach the market in a timely way, and monitor products for continued safety after they are in use. FDA is responsible for many consumer health products and for foods, with the exception of meat, poultry and egg products. FDA does regulate whole eggs.

This paper will illustrate two new food safety inspection approaches: one for eggs and egg products, and the other for juices.

EGGS AND EGG PRODUCTS

FDA and FSIS have developed a farm-to-table food safety strategy for eggs and egg products. This farm-to-table strategy is intended to control food safety hazards throughout the continuum of production, processing, distribution, and sale of eggs and egg products, to prevent occurrences of foodborne illness. The egg and egg products farm-to-table food safety strategy is founded on two principles:

1. Food safety hazards that can result in foodborne illnesses occur at each stage in the farm-to-table continuum. Therefore, each stage also provides opportunities for minimizing the effect of those hazards.
2. Persons in control of each stage of the farm-to-table continuum are responsible for identifying and preventing or reducing food safety hazards.

Recognizing these principles, FDA plans to cover points of production (on the farm) and retail sale (grocery stores, restaurants, institutions) by:

1. proposing requirements that egg producers implement a consistent, nationwide *Salmonella* enteritidis (SE) risk reduction program for egg production
2. requiring SE environmental testing to verify the reduction measures' effectiveness.
3. at retail, reducing exposure of consumers, particularly at-risk populations, to SE-contaminated egg-containing foods, including:
   - establishing standards for safe egg handling and preparation practices using "egg-relevant" sections of FDA's 1999 Food Code.[1]
   - proposing that all retail establishments be required to use only raw eggs which are clean and sound, have been transported under refrigeration, and are at least U.S. Consumer Grade B quality or better.
   - all liquid, frozen, and dried egg products used by retail establishments will have to be in pasteurized form.
   - establishments that serve primarily at-risk consumers, such as hospitals, nursing homes, day care centers, will have to substitute pasteurized eggs or egg products for raw eggs in certain menu items, such as those that contain raw egg ingredients and are not subsequently thoroughly cooked.

[1] The Food Code is FDA's guidance for use and adoption by the States and other governing bodies and includes best practices for the retail sector for handling and preparing potentially hazardous foods, including shell eggs.

- retail establishments that serve the general public will be given options for serving ready-to-eat foods prepared with raw or undercooked eggs and will be required to adhere to times and temperatures for cooling and holding foods containing raw or undercooked eggs that are not thoroughly cooked.

For FSIS's part, that agency plans to address hazards arising within egg packing facilities and egg products plants:

1. In the near future, FSIS will propose implementing a complete shell egg packing facility inspection program to ensure that shell eggs are not adulterated, and are properly marked and packaged, as well as properly refrigerated and labeled. The foundation for this program would be FSIS's current science-based food safety strategy, which was implemented in meat and poultry products establishments beginning in the mid-1990s.
2. FSIS also intends to propose to apply this strategy in plants processing egg products.

As a central theme of its food safety strategy, FSIS stresses the responsibility of establishments to maintain effective sanitation, develop and implement a system of preventive controls, and achieve a reduction of microbial pathogens. The specific goal of FSIS's egg safety strategy is to reduce the risk of foodborne illnesses associated with the consumption of shell eggs and egg products, primarily *Salmonella* Enteritidis (SE), to the maximum extent possible.

FSIS's egg safety strategy includes:

1. provisions for systemic prevention of biological, chemical, and physical hazards through the adoption of Hazard Analysis and Critical Control Point (HACCP) Systems by egg packing facilities and egg products plants;
2. efforts to strengthen the responsibilities of egg packing facilities and egg products plants for maintaining effective sanitation;
3. food safety performance standards that provide market incentives to egg packing facilities and egg products plants to improve safety; and
4. efforts to address hazards that arise throughout the food safety continuum from farm to table.

Under the new science-based system, the egg industry would assume full responsibility for production decisions and execution. FSIS would verify compliance with the food safety standards and related requirements that it set, and under HACCP, verify process control and pathogen reduction and control. Inspection program personnel would be able to focus more attention on those areas of greatest risk in the egg or egg products production system.

With the shift to HACCP and greater reliance on performance standards, producers will be given greater autonomy to make decisions affecting their own operations. In return, producers will be expected to take responsibility for setting up process control measures that are specific for their site and operations, to achieve the performance standards established by FSIS. As noted earlier, this approach has been successfully implemented in all federally inspected meat and poultry products establishments.

FSIS has chosen HACCP as the organizing structure for its egg and egg products food safety program because HACCP has been proven to be the optimal framework for building science-based process control into food production systems to prevent food safety hazards. HACCP also focuses FSIS inspection on the most significant hazards and controls.

In addition to requiring the development and implementation of HACCP systems in egg packing facilities and egg products plants, FSIS is also proposing to require the development, maintenance, and adherence to written sanitation standard operating procedures (Sanitation

SOPs) by these entities. FSIS believes that effective facility sanitation is essential for food safety and the successful implementation of HACCP. Insanitary facilities or equipment, improper product handling practices, poor personal hygiene, and similar insanitary practices create an environment conducive to contamination of products. There are direct and substantial links between inadequate sanitation and the contamination of eggs and egg products by pathogenic bacteria. Sanitation SOPs are necessary because they would clearly define each facility's responsibility to consistently follow effective sanitation procedures and would substantially minimize the risk of direct product contamination and adulteration.

FSIS's current egg products regulations mandate step-by-step processing measures. FSIS is proposing to replace these regulations with new performance standards that would spell out the objective level of food safety performance that each plant must meet. Performance standards set forth levels of pathogen reduction and limits on pathogen growth that food manufacturers must achieve in order to produce unadulterated products, but allow the use of customized, plant-specific processing procedures. This will allow plants to develop and implement processing procedures adapted to the nature and volume of their production.

To meet the proposed performance standards, egg products plants would need to demonstrate that their processing of egg products:

1. would achieve, or exceed, specific amounts of relative reduction of *Salmonella*, and
2. would limit the amount of relative growth of *Salmonella* after thermal treatment not to exceed amounts specified in the regulations.

Both egg packing facilities and egg products plants would also be required to ensure that actual or theoretical relative pathogen growth in their eggs or egg products would not exceed the performance standard, under normal handling conditions, from the time the eggs enter the facility or plant until the products reach the consumer.

JUICE PRODUCTS

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The HACCP regulation requires all processors to use HACCP procedures in the processing of juice and juice products. This will ensure the safe and sanitary processing of these foods. HACCP requires the implementation of the following seven principles:

- Conduct a hazard analysis
- Determine the critical control points
- Establish critical limits
- Establish monitoring procedures
- Establish corrective actions
- Establish verification procedures
- Establish recordkeeping documentation procedures

5-log pathogen reduction: The regulation also requires use of a 5-log pathogen reduction process, which is a 100,000-fold reduction in the numbers of the pathogen that is most likely to pose a problem in the juice. The reduction must occur under good manufacturing practices in one facility just prior to or after packaging, start with fruits and vegetables that are cleaned and culled of damaged fruits and vegetables, and be applied directly to the juice, except that citrus processors may opt to use surface treatments. Citrus processors using surface treatments must test product for generic *E. coli* to verify that the surface-treatment process is functioning properly.

Exemptions: Processors making shelf-stable juices or concentrates that use a single thermal processing step from consideration of microbial hazards are exempt from the regulation. The thermal treatment used in these processes results in a pathogen reduction that is thousands of times higher than 5-log. A copy of the thermal process used to achieve shelf-stability or concentration must be included in the written hazard analysis, and the process must be analyzed for the potential occurrence of chemical and physical hazards.

Retail establishments are also exempt from the regulation. A retail establishment is an operation that provides juice directly to consumers and does not sell or distribute juice to other business entities. "Provides" includes storing, preparing, packaging, serving, and vending. (Examples include juice bars that sell juice made on the premises directly to consumers, juice made and sold in grocery stores). States and the Food Code cover these types of firms. The total amount of juice processed by all retailers probably totals less than half of 1%.

Public health benefit: the expected public health benefit of this rule is the prevention of 6,000 illnesses per year, including 2 deaths. The value of illness prevented is estimated to be $150 million per year. The costs to industry are estimated at $50 million the first year and $23 million annually thereafter.

Implementation plan: FDA has developed an implementation plan for the regulation as it takes effect. A Hazard Guide for juice processors is being drafted. Training will be provided for FDA and state inspectors and for industry (particularly smaller processors). FDA has met with the Juice Alliance and states to begin developing training modules. FDA is working with the State of California to produce a juice processing video for use by processors.

FDA will enforce the regulations through inspection of all high-risk firms annually, even before the effective date of the final rule. It collects and analyzes samples for pathogens and other contaminants. Processors of untreated juices, including firms producing citrus juices using surface treatments, fall into the category of high-risk firms.

Education: The agencies emphasize education for all participants in the farm-to-table continuum. Current efforts include outreach through the FightBac campaign and an education campaign targeted for immunocompromised individuals, seniors, health professionals, health educators, public affairs specialists, parents and childcare providers.

Summary : Juice Products

- Use of HACCP techniques can be required as a way to ensure the safety of a class of products, in this case fresh juice and juice products, following identification of a public health problem
- FDA developed a specific standard, a 5-log pathogen reduction, as a benchmark for safe juice processing
- Exemptions were provided for certain shelf-stable juices or concentrates and for retail establishments
- An implementation plan involving training for state and local government officials and the industry is key to the success of this approach
- Juice safety is one of the topics we are addressing through our food safety education efforts.