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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 417

[Docket No. 05-016N; FDMS Docket No. FSIS-2005-0035]

The Use of Ingredients of Potential Public Health Concern

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Compliance with the HACCP system regulations and request for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is publishing this document to inform establishments that prepare meat and poultry products of the need to ensure that they maintain proper control over the use of ingredients, especially those that present a potential public health concern, and over the ingredient labeling of their products. Establishments should ensure that their systems provide such control as part of their next reassessment of their HACCP systems. FSIS invites comments on the matters presented in this document.

DATES: The Agency must receive comments by July 7, 2006.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by any of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. FSIS prefers to receive comments through the Federal eRulemaking Portal. Go to <http://www.regulations.gov> and, in the ``Search for Open Regulations'' box,

select ``Food Safety and Inspection Service'' from the agency drop-down menu, and then click on ``Submit.'' In the Docket ID column, select the Docket Number, FSIS-2005-0035, to submit or view public comments and to

view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the ``Advanced Search'' function in Regulations.gov.

Mail, including floppy disks or CD-ROM's, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 300 12th Street, SW., Room 102 Cotton Annex, Washington, DC 20250.

Electronic mail: fsis.regulationscomments@fsis.usda.gov. All submissions received must include the Agency name and docket number 05-016N and FDMS Docket Number FSIS-2005-0035.

All comments submitted in response to this document, as well as research and background information used by FSIS in developing this document, will be posted to the regulations.gov Web site and on the Agency's Web site at http://www.fsis.usda.gov/regulations_&_policies/2006_Notices_Index/index.asp.

The background information and comments

also will be available for public inspection in the FSIS Docket Room at the address listed above between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Robert C. Post, Ph.D., Director, Labeling and Consumer Protection Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, 1400 Independence Ave., SW., Room 602 Annex, Washington, DC 20250-3700; (202) 205-0279.

SUPPLEMENTARY INFORMATION:

Background

FSIS administers a regulatory program under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.) to protect the health and welfare of consumers by preventing the processing and distribution of meat and poultry products that are unwholesome, adulterated, or misbranded, or otherwise unfit for human food.

Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), all ingredients used to formulate a meat, poultry, or egg product must be declared in the ingredients statement on product labeling. A product is misbranded under the FMIA, PPIA, or EPIA when it contains ingredients that are permitted but are not declared on product labeling.

In addition to avoiding misbranding, the Pathogen Reduction and Hazard Analysis and Critical Control Point (HACCP) regulations (61 FR 38806, July

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25, 1996) require that federally inspected establishments take preventive and corrective measures at each stage of the food production process where food safety hazards are reasonably likely to occur. The preventative actions may be part of an establishments HACCP plan or a prerequisite plan. A failure to adequately ensure that ingredients that have the potential to cause food to be unsafe for human consumption (including adverse reactions to food ingredients) are properly used in meat and poultry products through one or more of these programs will result in adulterated products. Allergenicity and the Food Allergen and Consumer Protection Act of 2004.

There are many foods and food ingredients to which some individuals may have some degree of intolerance or possible allergic reaction. Thus, a lack of control over the use of these ingredients in the production process or incomplete labeling may result in food that is unsafe for consumption by some individuals. On January 1, 2006, the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, became effective. This act amends the Federal Food, Drug, and Cosmetic Act to require that the label of an FDA regulated food that contains an ingredient that is or contains protein from a ``major food allergen'' declare the presence of the allergen in the manner described by the law. Congress passed this Act to make it easier for food allergic consumers and their caregivers to identify and avoid foods that contain major food allergens.

FALCPA identifies eight foods or food groups as the major food allergens. They are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans), peanuts, wheat, and soybeans. These foods account for roughly 90 percent of all food allergies.

Foods in these main categories affect people in two main ways^{1 2}. Food allergies are immunologically mediated reactions to foods or food constituents. These reactions are caused by proteinaceous foods acting as an antigen to the human immune system. These reactions can be severe.

\1\ Taylor, S.L., 1987. Allergic and sensitivity reactions to food components. In: Hathcock, J.N. (ed.): Nutritional Toxicology, Vol. II. New York: Academic Press, pp. 173-198.

\2\ Lemke, P.J., and Taylor, S.L., 1994. Allergic reactions and food intolerances. In: Kotsonis, F.N., Mackey, M., and Hjelle, J. (eds.): Nutritional Toxicology. New York: Raven Press, pp. 117-137.

Food intolerances are non-immunologically mediated reactions. They are caused by a reaction to the chemical composition of a food itself or to an additive, such as a preservative (e.g., sulfites) or a flavoring (e.g., lactose).

There are many foods or food ingredients to which some individuals may have some degree of intolerance or possible allergenic response.\3\ The manner that a person reacts to an allergen is highly individualistic, varying in degree, onset time, location of reaction, and the amount of the food needed to trigger the response. Because of this concern and with the advent of FALCPA, it is the view of FSIS that it is important for processors to review their processes to ensure that those processes provide the basis for confidence that the intended ingredients will be used, that the proper package will be used, and that all ingredients will be correctly labeled on products, especially those ingredients that contain protein such as those identified by FALCPA.

\3\ National Institutes of Allergy and Infectious Diseases, NIH, USHHS, 1999. Health Matters Fact Sheet: Food Allergy and Intolerances, January.

Evaluation of Controls for Allergens Under HACCP Reassessment

Section 417.4(a)(3) states that every establishment shall reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. The Agency has determined that failure of establishments to control the use and declaration of the ingredients identified by FALCPA represents information that could alter the hazard analysis and, ultimately, the HACCP plans of any establishment that prepares meat and poultry food products with ingredients that are potential sources of food sensitivities and thus of public health concern.

Therefore, establishments that produce multi-ingredient products should consider, as part of their next annual HACCP reassessment, their control of ingredient use, particularly the use of those identified by FALCPA, and what further actions should be taken to maintain proper control through the production process. Establishments that prepare meat and poultry products that have already taken into account in their HACCP plans the need to control the use of ingredients need not give special consideration to such ingredients in their next annual reassessment. Establishments in both groups, however, may wish to use this opportunity to review their processes to ensure that they include mechanisms to control the use of all ingredients.

If the reassessment results in a determination by the establishment that it needs to take additional steps to ensure proper ingredient use, particularly the use of those identified in FALCPA, it must be addressed through HACCP or a prerequisite program. For example, a reassessment may reveal that the establishment uses ingredients identified by FALCPA. As part of the reassessment, the establishment may choose to verify that it has controls in place to ensure, or that

it has other means (through the use of a prerequisite program) of ensuring, that the ingredients to be used in the product to be produced, and only those ingredients, are available at the time of production; that the list of these ingredients matches the ingredient list on the label that is to be applied to the product; and that records are produced and maintained to verify that the proper ingredients are used.

FSIS Actions To Enforce and Facilitate Compliance With the Reassessment and Labeling Requirements

The Agency will instruct inspection program personnel to verify, as part of their review of the establishment's next annual hazard analysis reassessment, that meat and poultry establishments have considered in the reassessment the use of ingredients, particularly those identified by FALCPA. Before performing that verification, inspection program personnel will ensure that all establishments are aware that the Agency has issued this document.

On an ongoing basis, FSIS inspection personnel will verify that establishments' food safety systems are designed to ensure that product that bears the mark of inspection is in the proper package and bears the proper label, particularly when the product includes ingredients that are capable of causing adverse reactions in sensitive individuals.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this document in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements for the regulations that require meat and poultry establishments to reassess their HACCP Plans have already been accounted for in the Pathogen Reduction/HACCP Systems information collection approved by the Office of Management Budget (OMB). The OMB approval number for the Pathogen Reduction/HACCP Systems information collection is 0583-0103.

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and, in particular, minorities, women, and persons with disabilities are aware of this notice, FSIS will announce it online through the FSIS Web page located at

http://www.fsis.usda.gov/regulations/2006_Notices_Index/

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available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free electronic mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update is available on the FSIS Web page located at <http://www.fsis.usda.gov>. Through the Listserv and its Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an electronic mail subscription service which provides an automatic and customized notification when popular pages are updated, including Federal Register publications and related documents. This service is available at

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Done at Washington, DC on May 1, 2006.

Barbara J. Masters,
Administrator.

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