

Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Allergen or Other Misbranding of a Meat or Poultry Product

Background

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), under which the Food Safety and Inspection Service (FSIS) operates, require that all ingredients used to formulate meat and poultry products be declared in the ingredients statement on product labeling according to their common or usual names. A product is misbranded under the FMIA or PPIA when it contains ingredients that are permitted but are not declared on product labeling.

The Agency recognizes that there are situations in which a meat or poultry product enters commerce with ingredients that are not declared on its labeling. In some cases, the undeclared ingredient may be an allergen, which would necessitate removal of the product from commerce. FSIS Directive 8080.1, Revision 4, entitled “Recall of Meat and Poultry Products” outlines the Agency’s policies and procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. FSIS Directive 8080.1 provides that each recall be classified into one of three classes (Class I, II, or III)¹ based on the likelihood that illness or other adverse effects will be caused by consumption of the recalled product. This guidance describes the factors that are considered in assigning a recall class in the situation involving an undeclared ingredient of health concern.

This is a particular concern about health situations in which a meat or poultry product is misbranded and contains ingredients that may cause an allergic response. A food allergy is a specific condition in which a person’s immune system reacts to certain foods. Food allergies should be distinguished from food intolerances. Food allergy reactions range from mild to life-threatening and can include gastrointestinal upset, rash, wheezing, and shock. Food allergies are commonly associated with eight categories of foods; cereals containing gluten (i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these); crustacea; eggs and egg products; fish and fish products; peanuts; soybeans; milk and milk products; and tree nuts. In comparison, food intolerances are non-immunologically mediated reactions. They are caused by a reaction to the chemical composition of a food itself, or by an additive, (e.g., preservatives, colors, flavor enhancers). Some common examples of food intolerance are reactions to sulfites, monosodium glutamate (MSG), histamine, or

¹ Class I is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III is a health hazard situation where the use of the product will not cause adverse health consequences.

tartrazine (FD&C Yellow No. 5). Thus, there are few foods or food ingredients to which some element of the population will not have some degree of allergic response or intolerance. For this reason, complete ingredient labeling is critical.

Various factors are considered in assessing the public health significance of a meat or poultry product that is misbranded because of an undeclared ingredient, and thus, the class to which a recall involving the product should be assigned. The following questions convey examples of factors that are considered in determining the public health significance of a misbranding situation.

What Amount or Dose of an Ingredient is Required to Elicit an Adverse Health Effect?

The significance of this factor for recall classifications is that, for some allergens, there exists a “no observed adverse effect level” that can be used in estimating risk. Thus, in these cases, the higher the amount of the ingredient, the more likely it is to elicit an adverse effect, the more reason to classify the recall as one in which there is a significant public health concern, that is, Class I. Conversely, the lower the amount of the ingredient, the more reason there is to classify the recall as Class II. However, for most known allergens, there is no conclusive scientific evidence to establish threshold levels for eliciting an adverse reaction. Consequently, in most cases, the presence of an undeclared substance that is a known allergen, at any level, poses a public health risk and thus should be classified as Class I unless other factors justify a different, lower classification.

What is the Likelihood, Magnitude, and Severity of an Adverse Effect Among Sensitive Consumers from a Food Containing an Undeclared Ingredient?

The probability of adverse effects among sensitive populations plays a large role in determining a recall classification. The likelihood that an adverse effect will occur as a result of human consumption of a misbranded meat or poultry product is based on probability. Specifically, it is the probability that someone in the most sensitive subpopulation may be exposed to an ingredient that is not declared on a product’s labeling. The magnitude and severity of the adverse reaction, should it occur, are also significant. Generally, the greater the likelihood, magnitude, and severity of an adverse effect in a sensitive population, the more reason to classify it as Class I.

Once Ingested, Are There Circumstances That May Lead to the Bioactivation, Bioconcentration, or Detoxification of a Substance?

This factor directly relates to the level of the hazard posed by an undeclared allergen. It should be considered that, in some limited cases, the presence of a potentially allergenic substance in a food may be innocuous until metabolic systems in a person bioactivate or bioconcentrate the substance, or the substance may be detoxified by the body after it is consumed. The smaller the

population capable of deactivating an allergen, the more reason to classify any recall of product that contains the substance as Class I.

What is the Overall Health Risk Associated with the Consumption of the Product by Various Human Populations, Including the Most Sensitive Subpopulation?

The significance of an undeclared ingredient relates to the most sensitive subpopulation that may be affected. In the case where the ingredient is among the “big eight” categories of allergens, the issue of the number of sensitive individuals is irrelevant because, for any sensitive individual, there is no established threshold, and an allergic reaction is potentially catastrophic. However, in the case where nondeclaration involves ingredients that are *not* among the “big eight” allergens or that are not known to cause food intolerances, the most sensitive individuals in the population that have consumed or may consume the product should be determined. The more significant the reaction to consuming the substance, the more reason to classify it as Class I.

Summary and Conclusion -- What is the Public Health Impact?

The factors identified in this document are central in the evaluation of situations in which a meat or poultry product is misbranded and of the significance of this misbranding for the public health. The public health impact is estimated by the probability that vulnerable individuals will experience an adverse health effect as a result of exposure to an undeclared ingredient. This estimate of impact will ultimately be translated into a recall classification by the FSIS Recall Committee. The Recall Committee may request that a Health Hazard Evaluation Board convene to assist in estimating the risk.

For further guidance on factors to consider in evaluating the public health significance of a misbranded meat or poultry product, contact the Risk Assessment Division, Office of Public Health and Science, FSIS.