

Allergens- Voluntary Labeling Statements

This guidance document assists firms formulate voluntary labeling statements regarding the possible presence of allergens in products. Label review for meat, poultry, and egg products is required by statute at 21 USC 607(d), 456(c), and 1036(b), respectively.

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), under which the Food Safety and Inspection Service (FSIS) operates, 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.

FSIS recognizes that there are many foods and food ingredients to which some individuals may have some degree of intolerance or possible allergic reaction. That is why complete labeling is so critically important. FSIS supports practices that promote accurate informative product labeling including voluntary statements on labels that alert people who have sensitivities or intolerances to the presence of specific ingredients. For example, a phrase such as "Contains: milk, wheat gluten, soy" has been accepted by the Agency on labeling immediately following the ingredients statement. Additionally, further clarification of the source of a specific ingredient in a parenthetical statement in the ingredients statement on labeling, e.g., "whey (from milk)," is encouraged as a means of informing consumers who may be alerted to a more recognizable term.

In limited situations, the use of factual labeling statements about a product's manufacturing environment, e.g., "Produced in a plant that uses peanuts," may be used where good manufacturing practices, and effective sanitation standard operating procedures (SSOPs), cannot reasonably eliminate the unintended presence of certain ingredients. For example, where chopped peanuts are used in making a dry Thai-style meat sauce mix, the necessity exists for a dry processing environment and, thus, the production equipment cannot be washed with water or other fluids. In this instance, peanut dust may become airborne and unavoidably contaminate other meat or poultry products manufactured in the same production area. In this situation, a statement about the manufacturing environment, as described above, or the use of a "may contain (name of allergenic ingredient)" statement may be used on meat and poultry product labeling. However, this type of statement is not acceptable where it is used as a replacement for poor SSOPs, i.e., cross-contact because of an establishment's failure to adequately wash equipment between the manufacture of different lines of products. The Agency believes the indiscriminate use of such elective statements does not promote good manufacturing practices under a HACCP system and is not helpful for consumers. Consequently, the use of factual statements about a product's manufacturing environment, e.g., "Produced in a plant that uses peanuts," and the use of may contain statements, e.g., "may contain peanuts" may only be used in cases where establishments show that adequate SSOPS cannot effectively eliminate the cross contact issue.

Guidance documents lack the force and effect of law, unless expressly authorized by statute or incorporated into a contract. USDA may not cite, use, or rely on any guidance that is not available through their guidance portal, except to establish historical facts.

The Agency will consider any non-misleading symbols, statements, or logos that industry may want to include on labeling to inform consumers of the presence of potential food allergens in meat, poultry, or egg products. Requests to consider such features need to be submitted to the Agency as a policy inquiry, and not as label approval submissions.

Guidance documents lack the force and effect of law, unless expressly authorized by statute or incorporated into a contract. USDA may not cite, use, or rely on any guidance that is not available through their guidance portal, except to establish historical facts.