

IFAC statement regarding potential allergen labeling for food culture preparations in the United States

The International Food Additives Council (IFAC) is a global association representing manufacturers and users of food ingredients, including live microbial food ingredients. IFAC strives to promote science-based regulations, standards, and specifications for food ingredients and food additives worldwide. IFAC developed the following statement to provide clarification to manufacturers and users when considering potential United States allergen labeling requirements of food and probiotic cultures preparations used in final food products.

U.S. Food Allergen Labeling Laws and Regulations

The U.S. [Food Allergen Labeling and Consumer Protection Act](#) (FALCPA) of 2004 requires that eight major food allergens be labeled on product packaging. These are defined in section 403(w) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and include: milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

Food Ingredients

Food and food ingredient manufacturers must follow FALCPA requirements if a product contains protein derived from one of the eight major food allergens, with the exception of any highly refined oil derived from one of these allergens or any ingredient derived from such highly refined oil. The food source from which a major food allergen is derived must be labeled.

The U.S. Food and Drug Administration (FDA) provides guidance for industry on [Food Allergen Labeling Exemption Petitions and Notifications](#) and defines ingredients as substances that are “derived (e.g., through chemical, biochemical, mechanical, fermentation or bioengineering processes) from a major food allergen and that contain proteins or peptides.” If an allergen is used when manufacturing a food culture, and if the food culture preparation in its finished state does not contain the allergen, a petition to the FDA for labeling exemption must be filed and accepted as per 21 U.S.C. 343(w)(6) and (7).

Use of Substances Added to Food Cultures Preparations

Food cultures, including probiotics, are used as ingredients in the production of final foods including use in dietary supplements. Food cultures are produced by fermentation. After fermentation, food cultures are processed further. The final food culture preparation that is placed on the market may contain additives or other ingredients. These are added after fermentation and are necessary for survival, storage, and to facilitate the application of the food culture preparation in the food production process.

Equipment

In addition to food and dietary supplement labeling laws, the U.S. has food processing regulations as another measure of safety and prevention of cross-contact with food allergens during production. Pursuant to the U.S. Food Safety Modernization Act (FSMA),¹ manufacturers are required to sanitize equipment and surfaces to prevent food allergen cross-contact (21 CFR 117.35(d)). Additional requirements manufacturers must follow include but are not limited to: document hazards, including allergens (21 CFR 117.130(a)(2)); develop a preventive control plan (21 CFR 117.135(b)), and develop a written recall program (21 CFR 117.139(a)).

¹ The U.S. Food Safety Modernization Act (FSMA), enacted in January 2011, fundamentally shifts the focus of food safety in the United States from responding to food safety incidents after they occur to preventing them from happening. FSMA applies to the safe production of all foods sold in the U.S., including agricultural products, raw materials, processed foods, food additives and Generally Recognized As Safe (GRAS) substances, and includes requirements for appropriate Quality Systems, Preventive Controls and Good Manufacturing Practices (GMPs) during product manufacture, transport and storage. These requirements appear in the U.S. Code of Federal Regulations at Title 21, Section 117 (21 CFR 117).

IFAC Position

If the food culture or probiotic product contains one of the 8 major allergens, then it must be labeled as per FALCPA. This applies to all raw materials introduced during the production that could result in allergenic properties. In order to be exempt from allergen labeling, a notification or petition to the FDA must be filed and accepted as per 21 U.S.C. 343(w)(6) and (7).

It is the responsibility of the manufacturer of the final food to ensure that these products are labeled and in compliance with U.S. food labeling laws and regulations mentioned above. In addition, it is the responsibility of food business operators (food culture or probiotic manufactures) that supply to manufacturers of final foods to ensure that those manufacturers are provided with sufficient information to enable them to meet their food allergen labeling obligations.