

EXPERT OPINION STATEMENT  
FOOD ALLERGY RESEARCH & RESOURCE PROGRAM  
UNIVERSITY OF NEBRASKA

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**Allergenicity of Soybean Lecithin**

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Soybeans are well-recognized as allergenic foods. The soybean allergens are found in the protein fraction. The vast majority of this protein is removed in the soy lecithin manufacturing process. Soy lecithin does contain trace levels of soy proteins and these have been found to include soy allergens. However, apparently, soy lecithin does not contain sufficient soy protein residues to provoke allergic reactions in the majority of soy-allergic consumers. Many allergists do not even advise their soybean-allergic patients to avoid soybean lecithin when it is included as an ingredient in food products. From this practical standpoint, we can surmise that most soybean-allergic individuals do not react adversely to the ingestion of soybean lecithin.

Yet, there is, of course, the possibility that some of the more sensitive soybean-allergic consumers might react to ingestion of soybean lecithin, so of course we do advocate the source labeling of lecithin when it is used as a direct food ingredient.

The oily matrix of lecithin and the low protein levels provide a challenge to current analytical methodology. Regarding detection of soy lecithin in food products, the amount of soy lecithin used in most food products would leave residues at levels well below the limit of detection of currently available detection methods.

No conceivable allergenic risks would occur from the use of shared equipment for products that contain soybean lecithin and products that do not. The amount of soybean protein that could conceivably be transferred to the next product manufactured with this shared equipment is extraordinarily low. Therefore, “allergen clean-outs” are not necessary, in our opinion, for shared equipment in situations where the first product

contains soy lecithin as an ingredient and the second does not, if soy lecithin is the only ingredient in the formulation that is derived from a commonly allergenic source.

The Food Allergen Labeling and Consumer Protection Act in the U.S. requires the labeling of soy lecithin when used in any capacity, including use as a processing aid. To date, the Food & Drug Administration has granted only one exemption to soybean lecithin labeling from this law. On February 22, 2013, FDA granted a source labeling exemption for select soy lecithins produced by Solae, LLC when used as a release agent applied directly to food contact surfaces. Soy lecithin products produced by other manufacturers are not currently exempt from source labeling for this purpose. Additionally, on February 25, 2013, the FDA withdrew its May 2, 2006 guidance entitled “Guidance on the Labeling of Certain Uses for Lecithin Derived from Soy Under Section 403 (w) of the Federal Food, Drug, and Cosmetic Act” which originally indicated a willingness by FDA to use “regulatory discretion” in dealing with the labeling of soy lecithin in circumstances where soy lecithin is used as a stick-release or pan-release agent, a common processing aid use in the food industry. The FDA now requires source labeling of soy lecithin when used as a release agent applied directly to the food contact surfaces or as a direct ingredient in the product formulation, with the exception of the specific Solae soy lecithin products directly applied to food contact surfaces outlined in the Exemption Notification.

With respect to the cleaning of shared equipment following the processing of formulations containing soy lecithin, FALCPA does not stipulate the conditions under which extensive allergen clean-up must be conducted. When processing equipment is then used to manufacture other products that do not contain intentionally added soy lecithin, dilution would occur with the other product and would quickly reduce any soy allergen residues by additional orders of magnitude. With this reasoning, no conceivable risk exists from the use of shared equipment in this circumstance and no need exists for extensive allergen cleaning if soy lecithin is the only source of allergen concern. Attempts to assess the adequacy of any preventative controls would be unnecessary because the allergen residue testing methods would be insufficiently sensitive to detect soy protein/ allergen residues on processing equipment surfaces, rinse water or in any subsequent products manufactured on shared equipment. Allergen clean-up after formulations containing soy lecithin as the sole ingredient derived from commonly allergenic sources is not necessary in our opinion as outlined above.