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Guidance for Industry

Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act

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I. Introduction

The purpose of this document is to provide guidance on the labeling, under section 403(w) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 343(w), of certain uses in food of lecithin derived from soy.(1) In particular, as discussed in more detail below, FDA intends to consider the exercise of enforcement discretion for a food labeled on or after January 1, 2006, for which lecithin derived from soy is used solely as a component of a release agent(2) and the label for such food does not declare the presence of the lecithin consistent with the requirements of section 403(w). FDA intends to consider exercising such discretion when each of the factors discussed in section IV is present.

FDA guidance documents do not establish legally enforceable responsibilities. Instead, guidance documents describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in agency guidance documents means that something is suggested or recommended, but not required.

II. Background

A. Relevant statutory framework

Section 403(i) of the Act, 21 U.S.C. 343(i), requires that a food label bear the common or usual name of the food and, where fabricated from two or more ingredients, the common or usual name of each ingredient of the food, except that spices, flavorings, and certain colors are not required to be individually declared.

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) imposes new labeling requirements on certain foods. If a food is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains a major food allergen, that food must comply both with section 403(i) and section 403(w) of the Act, 21 U.S.C. 343(i), 343(w). Section 403 (w)(1) requires that a food's label reveal the name of the food source from which the major food allergen is derived in a manner specified by that section. This source declaration requirement is extended by section 403(w)(4) to any incidental additive that is, or that bears or contains, a major food allergen, notwithstanding the regulatory exemption for incidental additives in 21 CFR 101.100(a)(3).(3) The requirements of section 403(w) apply to foods labeled on or after January 1, 2006.

Section 201(qq) of the Act, 21 U.S.C. 321(qq), defines "major food allergen" as any one of eight foods or food groups (milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) or an ingredient that contains protein derived from one of the eight foods or food groups. The definition of "major food allergen" excludes any highly refined oil derived from one of the eight foods or food groups, and any ingredient derived from such an oil, as well as any ingredient exempt under the petition process specified in section 403(w)(6), 21 U.S.C. 343 (w)(6), or the notification process specified in section 403(w)(7), 21 U.S.C. 343(w)(7).(4)

B. Food allergy to soy

FALCPA recognizes soy as one of the eight most common food allergens. Although definitive studies assessing the prevalence of soy allergy are lacking, it is currently estimated that 0.2% of children and adults in the U.S. are allergic to soy.(5) Based on this estimate, soy allergy appears to be less prevalent than allergies to other major food allergens.

As with most common food allergens, allergic reactions to soy may result in life-threatening symptoms, such as anaphylaxis. Furthermore, even low levels of soy protein may cause adverse effects in some sensitive individuals. FDA considers an "adverse effect" to be any objective sign of an allergic reaction.(6) Currently, due to limited data, there is no consensus on the minimal dose of soy protein that will elicit an adverse effect (also referred to as the lowest observed adverse effect level or LOAEL). At least some researchers have suggested, however, that the LOAEL for soy protein appears to be higher than the LOAELs reported for other major allergens, such as milk, egg, and peanuts.

C. Lecithin derived from soy

Lecithin is a food ingredient that is derived from plant sources, including soy. Lecithin is isolated following hydration of solvent-extracted soy, sunflower, or corn oil. Lecithin is affirmed as generally recognized as safe (GRAS) with no limitation other than current good

manufacturing practice. 21 CFR 184.1400.[7] Common food applications of lecithin include use as an emulsifier, a stabilizer, a dispersing aid, and an incidental additive, such as a release agent for baked goods. Regardless of its food application, lecithin is generally used in small amounts, with the result that it is, according to one lecithin manufacturer, present in finished foods at levels rarely exceeding 1% by weight of the final food product.

During manufacture of lecithin derived from soy, most, but not all, of the soy protein is removed. Soy allergens, to the extent they are present in lecithin, would be found in the protein fraction of the ingredient. Accurately measuring lecithin's protein content presents challenges to current analytical methodology due to the ingredient's oily matrix and low levels of protein. The GRAS affirmation regulation specifies that the ingredient meet the specifications of the Food Chemicals Codex (FCC). The FCC monograph stipulates that food grade lecithin contain not more than 0.3% hexane-insoluble matter. Because the protein fraction of lecithin would reside in such insoluble material, this specification would limit the amount of protein in food grade lecithin to 0.3% or 300 mg/ 100 g lecithin. At least one major U.S. producer has stated that its manufacturing standard for lecithin derived from soy is set at 0.05% hexane-insoluble material or 50 mg/100g lecithin.

D. Allergic potential of lecithin derived from soy

As noted, lecithin derived from soy contains very small amounts of soy protein and it is generally used in small amounts, whether for a functional or technical effect in the finished food or as an incidental additive. The proteins in soy lecithin have been found, in some cases, to be soy allergens, and there are a few case reports in the medical literature of allergic reactions to lecithin derived from soy. However, allergy to lecithin derived from soy has been neither definitively established nor definitively negated by oral food challenge studies. Despite its widespread use in the food supply, FDA is aware of only a few allergen-related complaints about FDA-regulated products containing lecithin derived from soy.[8] Also, FDA is aware that some clinicians believe that foods containing lecithin derived from soy present little or no allergic risk to soy-sensitive consumers, and these physicians do not advise their soy allergic patients to avoid lecithin derived from soy.

E. Labeling of lecithin derived from soy

Before the enactment of FALCPA, the declaration of lecithin derived from soy as a food ingredient was governed solely by 21 U.S.C. 343(i) and FDA's labeling regulations. Thus, when used as an ingredient that is intended to have a technical or functional effect in the finished food (for example, as an emulsifier), the ingredient was required to be declared only by its common or usual name, "lecithin." As noted, under 21 CFR 101.100(a)(3), an ingredient used in insignificant amounts with no technical or functional effect in the finished food (such as a release agent) is not required to be declared on the label. Thus, food manufacturers using lecithin derived from soy as a release agent may have concluded that they were not required to declare lecithin as an ingredient.

FALCPA has altered the way in which lecithin derived from soy must be declared on the food label. Whether intended to have a technical or functional effect in the finished food or used as an incidental additive (such as a release agent), lecithin derived from soy must be declared as an ingredient, using its common or usual name, and with the food source ("soy," "soya", or

"soybeans") declared as required by section 403(w) of the Act.

III. Discussion

FDA is committed to the full and prompt implementation of FALCPA and enforcement of the new legal authority that it provides. As noted, FALCPA defines as major food allergens eight foods or food groups or ingredients that contain protein derived from one of those eight, and requires that major food allergens be declared as set out in section 403(w) of the Act. Given the number of ingredients that meet the definition of a major food allergen, FALCPA will have an impact on an enormous number of food labels. It is well-recognized that various ingredients that are major food allergens present a range of risks to sensitive consumers. In light of the breadth of FALCPA's impact on food labels, the range of risks to sensitive consumers presented by various major food allergens, and the resources required to implement certain FALCPA provisions (such as the notification and petition processes for labeling exemptions), FDA intends to establish implementation and enforcement priorities. A major consideration in setting those priorities will be the public health impact of a particular implementation or enforcement effort.

FDA acknowledges the widespread use of soy lecithin as a component of release agents prior to FALCPA. Although there are no data that establish the exact exposure to soy protein that would result from this use, based on the information available to FDA at this time, it is apparent that when lecithin derived from soy is used as a component of a release agent, the level of soy protein in the finished food is likely to be low. Also, the exposure to allergenic soy protein from such use would be expected to be considerably lower than exposures from other uses of soy lecithin or from soy-containing ingredients commonly used in food. This is due to the relatively low level of soy protein in lecithin derived from soy and the low level of use of the ingredient (lecithin derived from soy) when used as a component of a release agent. In addition, when a substance is used as an incidental additive, the level of the substance in the food can be expected to be low. (9)

There is currently no consensus on the minimal dose of soy protein that will elicit an adverse effect in sensitive consumers. At least some researchers have suggested, however, that the LOAEL for soy protein appears to be higher than the LOAELs reported for other major allergens, such as milk, egg, and peanuts. Absent a consensus on a LOAEL for soy protein and on levels of exposure to soy protein from the use of lecithin derived from soy as a component of a release agent, it is not possible to state unequivocally the risk, if any, that there may be to soy-allergic persons who consume foods for which lecithin derived from soy has been used as a component of a release agent. However, based on the foregoing, it appears that this risk is low compared to the aggregate risk to soy-sensitive individuals presented by the use of other ingredients containing soy protein, as well as the aggregate risk to allergic persons with non-soy sensitivities presented by ingredients that are, or contain protein derived from, one of the other major food allergens.

IV. Guidance

Consistent with the need to establish its enforcement priorities, FDA intends to consider the exercise of enforcement discretion for a food labeled on or after January 1, 2006, in which

lecithin derived from soy is used as a component of a release agent and the label for such food does not declare the presence of lecithin consistent with the requirements of section 403(w) of the Act. The agency's intent to exercise its enforcement discretion for a limited period for the foregoing use of lecithin will help FDA to apply its increasingly limited resources to efforts associated with implementation and enforcement of FALCPA that are expected to have a more acute public health impact.

The agency intends to reconsider its enforcement priorities with regard to the labeling of lecithin derived from soy used as a component of a release agent approximately 18 months after the issuance of this guidance. The agency expects that, during the period in which FDA intends to consider the exercise of its enforcement discretion as described above, manufacturers of foods that use lecithin derived from soy as a component of a release agent will revise as necessary the labels of their relevant food products to comply with FALCPA and begin to label their products using the FALCPA-compliant labels by the end of the enforcement discretion period.

FDA intends to consider exercising such discretion when all of the following factors are present:

1. The food was labeled on or after January 1, 2006.(10)
2. The lecithin derived from soy used as a component of a release agent satisfies each of the specifications for lecithin in the Food Chemicals Codex, 5th Edition.(11)
3. The lecithin derived from soy is used solely as a component of a release agent as described in this guidance.
4. The release agent in which lecithin derived from soy is a component is used at the lowest level possible consistent with current good manufacturing practice.

The agency emphasizes that this guidance does not apply if the lecithin derived from soy used as a component of a release agent does not comply with the Food Chemicals Codex specifications or if the lecithin derived from soy is used other than as a component of a release agent as described in this guidance.

Notes:

(1) FDA has previously advised food manufacturers that the names "soy," "soya," and "soybeans" are all acceptable names for this legume. http://www.cfsan.fda.gov/~dms/alrguid.html. In this guidance document, FDA uses the term "soy."

(2) In this document, the term "release agent" refers to an agent used to facilitate the release of foods (such as baked goods) from food contact surfaces, such as conveyor belts, molds, extrusion equipment, and baking pans, where the agent has been applied directly to the food contact surface, rather than incorporated into the food for such purpose.

(3) 21 CFR 101.100(a)(3) exempts from the ingredient declaration requirement any incidental additive that is present in a food at insignificant levels and has no functional or technical effect in the food.

(4) Under the petition process, an ingredient may be exempt if the petitioner demonstrates that the ingredient does

not cause an allergic response that poses a risk to human health. Under the notification process, an ingredient may be exempt if the notification contains scientific evidence that demonstrates that the ingredient does not contain allergenic protein, or if FDA previously has determined, under section 409 of the Act, that the food ingredient does not cause an allergic response that poses a risk to human health.

(5) [Draft] Report of the Threshold Working Group, Center for Food Safety and Applied Nutrition: Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food ([Draft] Threshold Report) at p. 11-12. See 70 Fed. Reg. 35258 (June 17, 2005), and http://www.cfsan.fda.gov/~dms/alrgn.html.

(6) Draft Threshold Report at p. 51.

(7) The lecithin affirmed as GRAS may be bleached with hydrogen peroxide or benzoyl peroxide. Also, enzyme-modified lecithin is affirmed as generally recognized as safe for use as an emulsifier, 21 CFR 184.1063), and hydroxylated lecithin is an approved food additive for use as an emulsifier, 21 CFR 172.814.

(8) This information on the relatively low number of consumer complaints must, of course, be considered in the current regulatory context in which processing aid uses of lecithin derived from soy are not uniformly declared on food labels. In the absence of such declaration, a food allergic consumer who experiences an adverse reaction to a food product may not associate that reaction with soy because the label does not declare its presence in the food.

(9) FDA believes that at least some food manufacturers, relying on 21 CFR 101.100(a)(3) prior to FALCPA's enactment, did not consistently identify lecithin derived from soy in a food's ingredient statement when the substance was used as a component of a release agent. Thus, consumers, including soy-allergic consumers, were likely consuming these small amounts of lecithin derived from soy (with its low level of soy protein) when they consumed these foods.

(10) Foods labeled prior to January 1, 2006, are not required to comply with FALCPA's labeling requirements so FDA need not consider the exercise of such discretion with respect to foods labeled before January 1, 2006.

(11) FDA encourages lecithin producers to reduce, to the extent possible, the level of protein in their soy lecithin products and also encourages food manufacturers using lecithin derived from soy as a component of a release agent to reduce, to the extent possible, the level of soy lecithin in finished foods.
