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Health Canada's Position on Highly Refined Oils Derived from Food Allergen Sources

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Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

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Background

The enhanced food allergen labelling regulations took effect on August 4, 2012. In part, these regulations require that whenever a priority food allergen is used as an ingredient or component of ingredients in the manufacturing of prepackaged foods (with some exceptions), the food allergen source must be declared on the label of the food, either in the list of ingredients or in an optional, separate "contains:" statement. "Food allergen" is defined under Section B.01.010.1 (1) of the Canadian Food and Drug Regulations as "any protein from any of the following foods, or any modified protein, including any protein fraction, that is derived from any of the following foods:

(a) almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;

(b) peanuts;

(c) sesame seeds;

(d) wheat or triticale;

(e) eggs;

(f) milk;

(g) soybeans;

(h) crustaceans;

(i) shellfish;

(j) fish; or

(k) mustard seeds."

Health Canada commonly refers to the allergens on this list as "priority" food allergens.

Since the regulatory definition of a food allergen is specific to protein or protein fractions derived from food allergens, ingredients that are derived from a food allergen but which have been processed in a way that removes the protein are not themselves considered to be food allergens. Therefore, it is Health Canada's opinion that the enhanced labelling regulations would not apply to these processed ingredients.

Highly refined oils may be derived from a priority food allergen source. However, because of the degree to which they have been refined, contain no protein or an amount of protein that is too small to pose a health risk. Health Canada's position is that the enhanced labelling regulations would not apply to highly refined oils. This position was developed in consultation with, and agreement of, the Canadian Food Inspection Agency (CFIA).

It is the responsibility of companies to ensure that their food labels respect all Canadian labelling requirements. If a company determines that an oil product derived from a priority food allergen is not a food allergen source for the purposes of labelling, it must be prepared to provide evidence that the oil is sufficiently refined. For example, documentation confirming the refining steps used to obtain the highly refined oil and information from the manufacturer or supplier confirming the levels of any residual protein content may be required.

Oil production and refining

Refined oils are produced using a number of different steps. The crude oil is generally produced by mechanically pressing the source seed or bean in expellers after a preheating step in indirectly heated conditioners.[1] The crude oil can then be treated using a number of different refining steps. Degumming, neutralizing, bleaching and deodorizing are all steps that are used to treat the crude oil and produce what is then considered to be a highly refined oil.

Certain unrefined oils can contain significant quantities of protein, as high as 300 micrograms per gram[2] (µg/g = parts per million). In contrast, highly refined oils contain very little protein, with published data showing low µg/g values or lower[2, 3]. Each of the steps used in refining the oil will reduce the amount of protein in the final product. When highly refined oils are used as ingredients in other foods, the concentration of any residual protein would be further diluted in the final food.

Edible Oils

Edible oils can be derived from a number of priority food allergens, including soybean, peanuts, tree nuts (hazelnut, almond, Brazil nut, pecan, pistachio, pine nut, cashew, walnut, and macadamia nut), sesame seed and fish. In addition, specific grades of mustard seed are sometimes used to make canola oil.

Soybean Oil

The residual amounts of protein in highly refined soybean oil are very low, such that they are considered to be of no health significance for soy allergic individuals. This has been corroborated by food challenge studies[4]. Therefore, highly refined soybean oils will not be considered food allergen sources and will not have to be labelled according to the enhanced allergen labelling regulations. As noted previously, manufacturers must be prepared to provide evidence that their oil is indeed highly refined and contain very little or no residual protein. In practice, this means that highly refined soybean oil that is not subject to enhanced allergen labelling may be labelled as either soybean oil or as vegetable oil when used as an ingredient in prepackaged foods. In addition, when highly refined soybean oil is the only ingredient derived from soybean in a food that contains other priority allergens, soy will not have to be declared in the "contains:" statement, if the manufacturer chooses to put one on the label.

Soybean oil that is not highly refined will need to be treated as a food allergen unless the producer can provide sufficient evidence that the level of protein in the oil will not pose a risk for soy allergic consumers.

Peanut oil

While studies have found that peanut-allergic individuals react when exposed to peanut oil, it is not always clear in these studies whether the peanut oil was refined or unrefined. In one of the largest studies with refined peanut oil[5], 60 peanut-allergic individuals were challenged with crude and refined peanut oil. None of the participants had adverse reactions to the refined peanut oil while six subjects reacted to the crude oil. This study concluded that refined peanut oil does not present a risk to the vast majority of peanut-allergic individuals. The same conclusion was also reached by a sub-committee on peanut allergy of the UK Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment following a detailed review of the literature[6].

In Canada, sections B.01.009 (4) and B.01.010 of the *Food and Drug Regulations* require that whenever peanut oil is present as an ingredient, or component of an ingredient, in a food, the source of the oil, "peanut", must always be identified. The enhanced allergen labelling regulations do not change this requirement and therefore all peanut oil, whether highly refined or not, will have to identify its source in all cases.

Sesame Oil

Sesame oil differs from many other oils since the commonly used version is made from roasted sesame seeds and is used principally for its flavour. It is therefore not refined, or is minimally refined, and therefore would be expected to contain significantly more protein than if it were highly refined[2]. One instance of anaphylaxis related to ingestion of sesame oil has been reported[7]. When the allergen-derived oil has not been highly refined to remove residual protein, the food allergen labelling requirements would apply. The source of the oil must be clearly identified in the ingredient list and the priority allergen would need to appear in any "contains" statement that may also appear on the product label.

Tree Nut Oils

As with sesame oil, tree nut oils may not be highly refined and would therefore be expected to contain levels of proteins that could be of concern for an allergic individual. A 1997 study examined the allergenicity of walnut, almond, hazelnut, pistachio, and macadamia nut oils and concluded that these oils may pose a risk to individuals with tree nut allergies, depending on the method of manufacture and processing[8]. For unrefined or partially refined tree nut oils, the allergen labelling requirements would apply.

Fish Oil

Allergic reactions to fish oil are not documented in the medical literature[9]. In general; oils derived from fish are highly refined and are not considered a source of fish protein. Therefore, where the refining process has removed fish protein from the final oil product, the refined oil is not subject to the enhanced allergen labeling regulations. If, however, a fish oil product was not highly refined, then the enhanced allergen labelling regulations would apply.

Examples of Application of Enhanced Allergen Labelling Regulations

Sesame oil serves as a useful example to demonstrates when the enhanced allergen labelling regulations would apply. Despite federal Food and Drug Regulations provisions for ingredient class names "vegetable oils" or "vegetable fats" for certain vegetable fat or oil ingredients, some provincial regulations require the declaration of vegetable oils by their common names for dairy substitutes such as margarine. For example, prepackaged margarine sold at retail must carry a full ingredient list, which would include sesame oil if it had been added to the margarine. However, under the previous labelling regulations (in force up to August 4, 2012), if margarine was used as an ingredient in another prepackaged food, the components of margarine did not need to appear on that food's label because the components of margarine were exempt from declaration once the margarine was added to another prepackaged food. As such, if sesame oil was a component of the margarine, any protein from the sesame oil would be considered a "hidden allergen" since the sesame oil would not necessarily have been declared on the final food product; only " vegetable oil margarine" would be declared. Under the new enhanced allergen labelling regulations, any priority food allergen or allergen-derived ingredient that contains the allergenic protein must be declared on the food's ingredient label, even if it is a component of added margarine or other ingredients that would otherwise be exempt from component declaration. This means that sesame must now be declared, either in the list of ingredients or in a separate food allergen "contains" statement.

On the other hand, if highly refined soybean oil containing negligible residues of soy protein is used as an ingredient in margarine, and the margarine itself is used as an ingredient in another food product, then soybean will not need to be declared on the final food product that contains margarine as one of its ingredients.

Exemption from component declaration also exists for other ingredients, such as flavours and seasoning blends. Edible oil (for example, sesame oil) could be used as part of a flavouring preparation or as a spice extractive carrier for seasoning blends. However, under the enhanced allergen labelling regulations, any allergen-derived oil that contains the allergen protein and that is a component of a flavour or seasoning blend must be declared on the label of foods containing the flavour or seasoning blend.

Table 1 – Summary: Refined Edible Oils and Their Respective Labelling Requirements

Oil Type	Enhanced Allergen Labelling Required when Unrefined?	Enhanced Allergen Labelling Required When Highly Refined?
Soybean Oil	Subject to enhanced food allergen labelling requirements	No, provided manufacturers are prepared to provide evidence, but declaration as ingredient still required
Peanut Oil	Subject to enhanced food allergen labelling requirements	Subject to enhanced food allergen labelling requirements, but declaration as ingredient still required
Sesame Oil	Subject to enhanced food allergen labelling requirements	No, provided manufacturers are prepared to provide evidence, but declaration as ingredient still required
Tree Nut Oils	Subject to enhanced food allergen labelling requirements	No, provided manufacturers are prepared to provide evidence, but declaration as ingredient still required
Fish Oil	Subject to enhanced food allergen labelling requirements	No, provided manufacturers are prepared to provide evidence, but declaration as ingredient still required

Conclusion

- The presence of priority allergen proteins acts as the trigger for determining when the enhanced allergen labelling requirements apply. Therefore, an ingredient derived from a priority allergen would not be subject to the enhanced allergen labelling requirements if the allergenic protein was not present in the ingredient.

- Highly refined (degummed, neutralized, bleached and deodorized) oils derived from food allergen sources are generally not subject to the enhanced allergen labelling requirements as the refining process has been determined to remove the allergenic protein from the oil.
- The very low levels of protein present within highly refined oil are not considered, based on the available science, to pose a risk to the health of individuals with food allergies.

- Companies must be prepared to provide evidence that allergen-derived ingredients (for example, allergen-derived oils) are highly refined and contain negligible levels of protein if they consider that the ingredient is not subject to the enhanced allergen labelling regulations.

- Highly refined oils would still have to be labelled according to all other existing labelling requirements, such as the requirement to declare the source for peanut oil (whether highly refined or not) and the requirement to declare the refined oil as an ingredient in the ingredient list of a prepackaged food to which it has been added, if applicable.

Additional Information

For more information please contact the Food Directorate's Bureau of Chemical Safety.

References

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