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Rapid Risk Assessment:

What is the risk in terms of allergy to UK consumers if sunflower oil is substituted in food with certain fully refined food grade vegetable oils (for example, palm oil, soybean oil or coconut oil) without these oils being labelled on the packaging?

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April 2022

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1. Executive Summary

This rapid risk assessment considers the risk in terms of allergy to UK consumers if sunflower oil is substituted in food with certain fully refined food grade vegetable oils (for example, palm oil, soybean oil or coconut oil) or with unrefined coconut oil without these oils being labelled on the packaging.

According to FEDIOL (the edible oil refiners European trade association), the purpose of refining vegetable oils is to produce a product that meets food safety, customer and quality requirements. Refining has become increasingly critical for the removal of compounds and contaminants, including allergenic proteins. There are two main types of refining, depending on the type of oil, seed, oil bean or nut to refine, and these are physical refining and chemical refining. Both processes involve several steps that are undertaken in line with Hazard Analysis and Critical Control Point (HACCP) principles, so as to achieve at the end a refined vegetable oil meeting legal requirements ([FEDIOL, 2020](#)). Fully refined vegetable oils are described as edible neutralised (alkali refined) bleached and deodorised (N/RBD) oils (Rigby et al., 2011, EFSA Journal, 2014).

Crude vegetable oils (also known as unrefined) are instead obtained by expelling or extraction. These oils contain substances and trace components, which are undesirable for taste, stability, appearance and odour. These trace components include proteins from the seed, bean or nut used to produce the oil, some of which can be allergenic (FEDIOL, 2020).

Fully refined soybean oil

Based on the data available from published clinical studies and the EFSA Scientific Opinion on fully refined soybean oil (EFSA Journal, 2007) we consider:

- the **frequency of allergic reactions to fully refined soybean oil** to be **negligible** (for example, so rare that it does not merit to be considered)
- the **severity of illness in relation to allergic reactions to fully refined soybean oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered)

the **level of uncertainty** to be **low** (for example, there are solid and complete data available).

Fully refined palm oil

Based on the lack of clinically confirmed reports of adverse reactions to palm oil and lack of evidence of severe illness or deaths we consider:

- the **frequency of allergic reactions to fully refined palm oil** to be **very low** (for example, very rare but cannot be excluded).
- the **severity of illness in relation to allergic reactions to fully refined palm oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered).

Based on the data available from the Patterns and Prevalence of Adult Food Allergy (PAFA) and NHS Data project and information gathered from allergy specialists, we consider the **level of uncertainty** to be **medium** (for example, there are some but no complete data available).

Coconut oil

Based on the lack of clinically confirmed adverse reports of reactions to coconut oil in the UK population, and lack of evidence of severe illness or deaths we consider:

- the **frequency of allergic reactions to fully refined coconut oil** to be **very low** (for example, very rare but cannot be excluded).
- the **severity of illness in relation to allergic reactions to fully refined coconut oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered).

Based on the data available from the PAFA and NHS Data project and information gathered from allergy specialists, we consider the **level of uncertainty** to be **medium** (for example, there are some but no complete data available).

The risk associated with **unrefined coconut oil** to sensitive individuals is likely to be higher than for fully refined coconut oil because it will contain more protein. However,

we are not able to estimate the extent to which it will be of greater risk due to limitations in the available data.

This rapid risk assessment may be followed up with further work subject to data availability.

2. Statement of Purpose

This rapid risk assessment focuses on the immediate acute hazard of concern in terms of allergic reactions in UK consumers if sunflower oil is substituted in food with certain fully refined food grade vegetable oils (for example, palm oil, soybean oil or coconut oil). It does not cover intolerance to these oils.

This rapid risk assessment also considers the use of coconut in fully refined and unrefined oils, as both can be used in food production.

For the purposes of this rapid risk assessment palm oil is considered as a fully refined vegetable oil because this oil is present on the market as fully refined only.

An estimate of the risk associated with unrefined soybean oil has not been included because industry has indicated that they do not intend to substitute sunflower oil with unrefined soybean oil for cooking purposes because the protein burns during food processing and negatively affects product quality.

3. Background

The war in Ukraine has led to industry reporting risks to disruption of the food supply chain relating to sunflower oil. The majority of the UK's sunflower oil supply comes from Ukraine and Russia.

Food businesses are reporting that UK supplies of sunflower oil are likely to be exhausted in a few weeks with some businesses already experiencing severe difficulties. Possible mitigations could include the use of alternative commercially available food grade oils, such as palm oil, soybean oil or coconut oil as a substitute for sunflower oil. It is highly unlikely that industry will be able to re-label products as quickly as oil substitutions may occur, which could lead to the presence of mis-labelled products on the market.

4. Hazard Identification

In the UK there are 14 types of food or food groups that are recognised as allergenic foods of public health importance and therefore regulated. These are celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, nuts, peanuts, sesame seeds, soya and sulphur dioxide. Palm and coconut are not included in the list of 14 declarable allergens. However any foods that contain protein could potentially elicit an allergenic response in a sensitised individual, and these include palm oil and coconut oil.

Allergens in soya

Soybeans and products thereof are recognised as a common cause of food allergies and thus are included on the EU 1169/2011 Annex II list of declarable allergens. However fully refined soybean oil is exempt from the allergen labelling legislation.

Soybean or soya (*Glycine max*) is an edible legume belonging to the *Fabaceae* family. Soybean seed contains approximately 20% oil and 38-40% proteins, among which some proteins that are reactive to IgE antibodies have been identified as allergens. These proteins include Gly m1, 2, 3, 4, 5, 6, 7 and 8 (EFSA Journal, 2014). Other proteins which have been identified as probable allergens include thiol-protease Glym Bd 30k (Helm et al., 2000), and the Kunitz trypsin inhibitor (Gu et al., 2001). There have been studies which suggest IgE binding to Gly m 6 and 5 as a marker for severe allergy to soya (Holzhauser et al., 2009) and Gly m 4 with anaphylaxis (Kosma et al., 2011).

Cross-reactivity between soya and peanut and between soya and cow's milk has been reported by *in vitro* studies (Sicherer et al., 2000). In particular, Gly m4 and 5 have been shown to cross-react with casein in cow's milk (Rozenfeld et al., 2002, Curciarello et al., 2014).

Allergens in coconut

Coconut (*Cocos nucifera*) is a fruit that belongs to the Aracaceae (palms) plant family (Anagnostou, 2017). Coconut has an endosperm which is the edible part of the fruit and this consists of roughly 25% albumins and 75% globulins. The globulins contain the majority of storage proteins implicated in allergic reactions. These proteins include the allergens Coc n2, a 7S globulin, and Coc n4, a 11S globulin (known as cocosin) (Garcia et al., 2005, Hernandez-Santana et al., 2019). Some *in vitro* studies reported cross-reactivity between coconut and peanuts, lentils and other tree nuts (mainly walnuts and hazelnuts) (Teuber and Peterson, 1999, Nguyen et al., 2004, Benito et al., 2007, Gomez et al., 2013).

Reports of allergy to coconut protein in medical and scientific journals are uncommon (Tella et al., 2003). However there are several published accounts in the literature of IgE-mediated reactions from eating coconut products (Couturier et al., 1994, Tella et al., 2003, Benito et al., 2007, Gomez et al., 2015, Anagnostou, 2017, Hernandez-Santana et al., 2019, Kruse et al., 2021), including one case of severe stomach upset in a baby fed infant formula containing coconut.

There are also some reports of serious allergic reactions (anaphylaxis) to coconut (Rosado et al., 2008) and some of these were attributed to cross-reactivity with tree nut proteins (Teuber and Peterson, 1999, Nguyen et al., 2004, Stutius et al., 2010, Australian society of clinical immunology and allergy, 2019). However, coconut is a member of the palm family and only distantly related to tree nuts, and there is no general recommendation that patients with tree nuts allergy should avoid coconut

Allergens in palm fruit and seed

Palm oil comes from the fruit (mesocarp) of oil palm trees (*Elaeis guineensis* and *Elaeis oleifera*) whilst palm kernel oil is extracted from endosperm or kernel (Soh et al., 2009). Palm olein is instead a liquid fraction obtained during fractionation of palm oil (Panda et al., 2012). The protein 7S globulin has been isolated and identified in palm, which is stored in the seed in the early stage of the plant and then in the fruit as it matures (Benito et al., 2007). It has a similar structure to the 7S globulin identified and characterised in coconut, which has been implicated in allergic

reactions. There could be potential for this allergen to cause allergy, although this has not been investigated yet in palm (Gomez et al., 2015). There is also a limited amount of information in the literature on protein content in the palm fruit and seed.

5. Hazard Characterisation

Uses of vegetable oils

Russia and Ukraine account for 80% of the world's sunflower oil production. The current situation is leading to shortages and finding alternative suppliers of sunflower oil will be challenging. Possible mitigations could include substitution with alternative vegetable oils such as palm oil, soybean oil or coconut oil. Therefore, it is likely that these oils will be more widely used in the food industry as an ingredient and/or for cooking in a large array of processed food products, including crisps, nuts, extruded snacks, popcorn, cereal bars, tacos, battered/breaded frozen and fresh meat/fish/vegetables, frozen chips, certain ice creams, canned fish, jarred vegetables, pre-made sauces (for example, jarred pasta sauces) and vegetable suet.

Prevalence of vegetable oil protein allergy

The worldwide literature on vegetable oil protein allergy is limited and true prevalence is unknown in the UK, although generally it is regarded as very rare clinically.

An ongoing FSA funded research project is investigating the prevalence of food allergy in the UK adult population ([Patterns and Prevalence of Adult Food Allergy-PAFA](#)). The results will be published in December 2022. The initial stage of the project involved a community survey of participants aged 18-70. Interim results indicate that of the 1673 respondents, none reported adverse reactions to palm oil, soybean oil or coconut oil. Approximately 26 people reported (in the free text field provided) problems with "oily foods", "fatty foods", "greasy foods", "sunflower/vegetable oil" and "some oils" (clinical confirmation of these adverse reactions is awaited and currently this is self-reported information only). The population sample was designed based on 2011 Census data together with more recent Mid-year Population Estimates (2016) collected, analysed and disseminated

by the Office for National Statistics. The analysis of this initial stage reported that the sample is well balanced with regards to age and gender and has a good representation from lower and upper deciles of deprivation. It also encompasses ethnic diversity with significant ethnic minorities being represented including those of Asian and Black ethnicities. This suggests that the study is statistically representative of the UK population.

The FSA funded a research project to investigate the [prevalence of food allergy and weaning practices in a birth cohort of UK infants](#) in 2005-2009. However, this focussed on the legislated allergens and fruits and did not investigate the prevalence of allergy to palm oil, soybean oil or coconut oil. Data on the prevalence of vegetable oil protein allergy for children in the UK are therefore not available from this study.

FSA and FSS contacted three leading UK allergy specialists, Professor Graham Roberts (President of the British Society for Allergy & Clinical Immunology – BSACI), Dr Paul Turner (Reader in Paediatric Allergy & Clinical Immunology at Imperial College London) and Dr George Raptis (Consultant in Paediatric Allergy, Glasgow), to seek expert opinion on the prevalence and severity of allergy to the vegetable oils that are the focus of this rapid risk assessment. They reported that they had not seen any clinical evidence of food allergy or even sensitisation to fully refined soybean oil, palm oil or coconut oil in the UK or elsewhere during their careers spanning over 20 years.

The [Anaphylaxis Campaign](#) is the only UK wide charity operating solely for people at risk from severe allergic reactions and anaphylaxis. They have a database of people who have contacted them for advice which includes information on the foods they are allergic to. The database does not include categories for allergy to vegetable oils specifically, although it does include foods from which soybean, coconut and palm oils are derived. The number of people for which allergy to these foods has been recorded in the database is provided in **Table 1**.

Table 1: Number of people for which information on allergy to certain foods has been captured on the Anaphylaxis Campaign database (Anaphylaxis Campaign, personal communication)

Type of food allergy	No. people in Anaphylaxis Campaign database
Soya allergy	9031
Coconut allergy	181
Palm allergy	3

The database does not capture information on whether these peoples' allergies have been clinically confirmed or are self-reported. It is not possible to tell whether they have experienced severe allergic reactions to these foods such as anaphylaxis. It is also unclear whether these people reacted to oils derived from soya, coconut or palm as listed in **Table 1**. The risk of experiencing an allergic reaction to oils derived from the foods listed in **Table 1** will be lower than the risk of experiencing an allergic reaction to the foods themselves, as described in the exposure assessment section. Despite the limitations of this information, it provides useful context as it indicates to the FSA and FSS that there are unlikely to be significant numbers of UK consumers who may experience severe allergic reactions to oils derived from the foods listed in **Table 1**.

Whilst it is acknowledged that anecdotal accounts of allergic responses have been reported, the evidence that is currently available suggests that allergy to these vegetable oils is very rare in the UK in both adults and children.

Severity of allergic reactions to palm, soybean and coconut oil

The main difference between food allergy and food intolerance is that with food allergy the immune system responds to a particular food and leads to an allergic reaction. Food intolerance does not involve the immune system.

The data in the literature on symptoms caused by vegetable oil protein allergy is very limited. We have not found any information in the literature regarding hospitalisations or deaths linked to the consumption of fully refined soybean oil, palm oil or coconut oil either in or outside the UK.

The FSA-funded NHS data project examined data relating to hospital admissions for anaphylaxis and deaths in the UK during a 20 year period from 1998-2018. In total, 152 deaths were identified where the fatal event was probably caused by food induced anaphylaxis; it is unlikely that any of these deaths were associated with the vegetable oils that are the subject of this rapid risk assessment. There were no reports of hospital admissions or anaphylaxis due to vegetable oil consumption although we cannot account for the 'other' or 'unknown' food category (Baseggio Conrado et al., 2020).

Fully refined soybean oil

There is some evidence in the literature that fully refined soybean oil does not cause reactions in soya allergic individuals. Some studies have demonstrated that subjects, with substantial histories of adverse reactions following ingestion of soya, did not have any reactions after exposure to fully refined soybean oil (Bush et al., 1985, Crevel et al., 2000, Taylor et al., 2004, Rigby et al., 2011, Patel and Bahna, 2016).

In particular, EFSA published a scientific opinion on fully refined edible neutralised (alkali refined) bleached and deodorised (N/RBD) soybean oil in 2007 related to a notification from FEDIOL and IMACE. The opinion describes a clinical study undertaken in order to obtain information on the potential allergenicity associated with soybean oil. Twenty nine patients (8 infants/young children, 14 children and 7 adults) with a history of soya allergy were selected and none showed reactions to oral challenge with soybean oil up to a 16ml cumulative dose. Two further clinical studies were performed to address any potential concerns linked to cross-allergenicity in susceptible individuals. The Scientific Panel on Dietetic Products, Nutrition and Allergies concluded that they do not consider the reported symptoms such as gastro-intestinal symptoms and mild nausea to indicate severe allergic reactions after exposure to soybean oil challenge doses (for example, 12, 24 and 48ml). Taking into account all the information available, the Panel considered that it is **not very likely** that fully refined soybean oils will trigger a severe allergic reaction in susceptible individuals under the conditions of production and use described by the applicant (EFSA Journal, 2007).

An adverse reaction to soybean oil in an infant has been reported (Hidalgo and Zamora, 2006). However, there is no information on the severity of the infant's illness and whether the consumed soybean oil was fully refined or not.

Palm oil

Allergy to palm oil has not been described in the clinical literature. No instances of allergic reactions to palm oil have been reported (Crevel et al., 2000).

However, there are some reports in the grey literature on the internet ([Palm Oil Allergy – INSTAH](#)) of consumers indicating they have experienced allergic reactions to palm oil, although it is unclear whether these illnesses have been clinically confirmed.

Coconut oil

Coconut oil used in food production could be either cold-pressed (unrefined) or fully refined (Liu et al., 2019). Unrefined coconut oil is considered more likely to present an allergy risk for people allergic to coconut. The data in the literature on symptoms caused by allergy to fully refined coconut oil is very limited with one study reporting adverse reactions to coconut oil in an infant (Couturier *et al.*, 1994), but it was not specified if this was fully refined or unrefined.

However some blogs on the internet (e.g. [The Side Effects of Coconut Oils - CoconutOils](#)) reported adverse reactions to coconut oil. It is unclear if these reactions have been clinically confirmed and if the consumed oil was fully refined or unrefined.

6. Exposure Assessment

Effects of processing on refined vegetable oils

The production of fully refined vegetable oils involves several steps. According to [FEDIOL](#), there are two main refining processes used to refine crude oils, involving using a chemical/alkali substance to refine or physically refining, both differ in the way free fatty acids are removed. This degree of processing affects the levels of

protein found in the oil. Refined oils have a lower level of protein than unrefined ('cold-pressed' or 'virgin') oils, which have a higher level of protein and hence carry a greater risk. However, the final level of protein in refined oil depends on the quality and efficiency of the refining steps (Verhoeckx et al., 2015).

Rigby et al. (2011) demonstrated that the refining process substantially reduces the protein content of the oils. The results of this study showed that the protein content of fully refined soybean oil was significantly lower (242-262 ng/g oil) than that of crude oil (86,000-87,900 ng/g oil).

Effects of processing on cold-pressed (unrefined) vegetable oils (e.g. coconut oil)

Seeds with a high oil content are usually mechanically pressed and further treated in the extractor. The pressure exerted in this process squeezes out the oil. Some raw materials are pressed without heating, such oils are known as cold-pressed oils. However, the cold pressing process does not extract all the oil and therefore it is used in the production of only a few edible oils. In addition, crude oils might contain substances and trace components, which are undesirable for taste, stability, appearance and odour. These trace components include proteins, some of which can be allergenic (Martin-Hernandez et al., 2008, FEDIOL, 2022).

Exposure assessment limitations

Exposure assessment for allergens in ingredients usually involves taking into account:

- 1) the concentration of allergenic protein that may be present in the ingredient,
- 2) what proportion of the final product will comprise the ingredient, and
- 3) the reference amount (for example, the amount of the food eaten on a typical eating occasion)

Calculations are then performed using this information to determine the total dose that may be consumed on a single eating occasion and then compare it with an eliciting dose to determine whether defined proportions of the allergic population may react.

We currently do not have specific data from industry or the literature on the amount of protein that may be present in certain vegetable oils that are the subject of this rapid risk assessment. However, some data are available in the literature for coconut oil (Hernandez et al., 2008). In addition, we do not have any data on the level of allergenic proteins from these oils in finished products that would be consumed in portions of food on a single eating occasion when substituted for sunflower oil. The ability to carry out exposure assessment is further limited by the lack of eliciting doses for palm or coconut to compare with likely exposure doses in order to determine whether susceptible individuals may react at any given dose.

The lack of clinically verified reports of allergic reactions to these vegetable oils by UK consumers suggests that the level of protein in fully refined vegetable oils may be too low to elicit a reaction, although it is not possible for us to carry out an exposure assessment to confirm this.

7. Risk Characterisation

In this rapid risk assessment, we used the qualitative scales for the frequency of occurrence and severity of foodborne risks and level of associated uncertainty that is described in the multidimensional risk assessment framework outlined by the Advisory Committee on the Microbiological Safety of Food (ACMSF, 2020), as described in Annex I. The key sources of uncertainty are listed in the next section.

As described above, palm oil and soybean oil are considered only as fully refined vegetable oils for the purposes of this rapid risk assessment. Fully refined vegetable oils are described as edible neutralised (alkali refined) bleached and deodorised (N/RBD) oils (Rigby et al., 2011, EFSA Journal, 2014). Allergen risks associated with fully refined and unrefined coconut oils are considered as both forms can be used in food production.

Fully refined soybean oil

Based on the data available from published clinical studies and the EFSA Scientific Opinion on fully refined soybean oil (EFSA Journal, 2007) we consider:

- the **frequency of allergic reactions to fully refined soybean oil** to be **negligible** (for example, so rare that it does not merit to be considered)
- the **severity of illness in relation to allergic reactions to fully refined soybean oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered)
- the **level of uncertainty** to be **low** (for example, there are solid and complete data available).

Fully refined palm oil

Based on the lack of clinically confirmed reports of adverse reactions to palm oil in the UK population, and lack of evidence of severe illness or deaths we consider:

- the **frequency of allergic reactions to fully refined palm oil** to be **very low** (for example, very rare but cannot be excluded).
- the **severity of illness in relation to allergic reactions to fully refined palm oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered).

Based on the data available from the PAFA and NHS Data project and information gathered from allergy specialists described above, we consider the **level of uncertainty** to be **medium** (for example, there are some but no complete data available).

Coconut oil

Based on the lack of clinically confirmed adverse reports of reactions to coconut oil in the UK population, and lack of evidence of severe illness or deaths we consider:

- the **frequency of allergic reactions to fully refined coconut oil** to be **very low** (for example, very rare but cannot be excluded).

- the **severity of illness in relation to allergic reactions to fully refined coconut oil** to be **negligible** (for example, no effects or so mild they do not merit to be considered).

Based on the data available from the PAFA and NHS Data project and information gathered from allergy specialists described above, we consider the **level of uncertainty** to be **medium** (for example, there are some but no complete data available).

The risk associated with **unrefined coconut oil** to sensitive individuals is likely to be higher than for fully refined coconut oil because it will contain more protein. However, we are not able to estimate the extent to which it will be of greater risk due to limitations in the available data.

8. Key sources of uncertainty

The key sources of uncertainty for fully refined palm oil and refined or unrefined coconut oil are:

- The degree to which the refining process removes proteins from fully refined palm oil and fully refined coconut oil and the amount of protein that may remain in these oils.
- The extent to which industry intends to use these oils in food and the amounts involved.
- The amount of protein that would be included in servings of final food products that would be eaten on a single eating occasion if these oils are substituted for sunflower oil
- The amount of allergenic protein that needs to be consumed in order to elicit an allergic reaction
- Whether the lack of confirmed clinical data on allergic reactions to these oils could be due to under-reporting.

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Annex I - Interpretation of probability categories used in this risk assessment

(Tables from ACMSF ([ACM/1065](#)) adapted from [EFSA 2016](#) modified from [OIE 2004](#)).

Frequency category	Interpretation
Negligible	So rare that it does not merit to be considered
Very Low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very High	Events occur almost certainly

Severity category	Interpretation
Negligible	No effects, or so mild they do not merit to be considered
Low	Mild illness: not usually life-threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (for example, transient diarrhoea)
Medium	Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (for example, diarrhoea requiring hospitalisation)
High	Severe illness: causing life-threatening or substantial sequelae or illness of long duration (for example, chronic hepatitis)

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is

Uncertainty category	Interpretation
	provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them