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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 refined rapeseed oil without rapeseed being labelled on the packaging?

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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 refined rapeseed oil without rapeseed being labelled on the packaging.

Based on the lack of reports of adverse reactions to refined rapeseed oil in the UK population, and lack of evidence of severe illness or deaths we estimate:

- the **frequency of allergic reactions to refined rapeseed oil** to be **very low** (i.e. very rare but cannot be excluded).
- the **severity of illness in relation to allergic reactions to refined rapeseed oil** to be **negligible** (i.e. 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) project and the NHS Data project and information gathered from allergy specialists, we consider the **level of uncertainty** to be **medium** (i.e. there are some but no complete data available).

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 in food is substituted with refined rapeseed oil.

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

Separate work is being commissioned to assess any longer term risks that may occur at a national level from the substitution of sunflower oil with refined rapeseed oil or other oils (e.g. in relation to the toxicological risks from compounds such as erucic acid).

3. Background

Rapeseed (*Brassica napus*) is an important oilseed crop in many countries and is considered to be the second most abundant source of edible oil in the world.

The war in Ukraine has led to industry reporting risks to disruption of the food supply chain relating to sunflower oil. Around 80% of the UK's sunflower oil comes from Ukraine with Russia making up a significant portion of the remaining 20%.

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. The proposed mitigation is that alternative food grade oils, such as refined rapeseed oil, are substituted 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

Allergens in rapeseed

Food allergy involves an adverse immune reaction triggered by normally harmless protein antigens in food. 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 (celery, cereals containing gluten, crustaceans, eggs, fish, lupin, milk, molluscs, mustard, nuts, peanuts, sesame seeds, soya and sulphur dioxide). These 14 must be labelled on food and they make up the majority of foods that people may experience an allergic reaction to. Rapeseed is not included in the list of 14 allergens. However theoretically any food that contains protein could elicit an allergenic response in a sensitised individual, and this would include rapeseed oil.

Rapeseeds contain approximately 40% oil and 17-26% protein (Aider and Barbana, 2011). Several allergenic proteins have been identified and characterised in rapeseed pollen, such as Bra n1, Bra n4, Bra n7, Bra n8, Bra n PG and cruciferin (Fiocchi et al., 2016, EFSA Journal, 2020). However, rapeseed is mainly consumed as an oil and other studies reported that rapeseed oil contain only small amounts of protein allergens as these are removed during the refining process (Verhoeckx et al., 2015, Fiocchi et al., 2016).

Food allergy to rapeseed and oilseed rape has been reported to occur (Poikonen et al., 2008, Puumalanen et al., 2015). Indications of cross-reactivity between rapeseed proteins and other food proteins, particularly those of mustard have been described (Hauser et al., 2008). An EFSA opinion on the allergenicity of rapeseed protein isolates has been published and the Panel on Dietetic Products, Nutrition and Allergies (NDA) considered that the risk of sensitisation to rapeseed cannot be excluded and that it is likely that rapeseed can trigger allergic reactions in mustard allergic subjects (EFSA NDA Panel, 2013, EFSA Journal, 2020).

5. Hazard Characterisation

Uses of refined rapeseed oil

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. The proposed mitigation plan is that alternative vegetable oils, such as refined rapeseed oil, will be used as substitutes. Therefore, refined

rapeseed oil is likely to be used more widely in the food industry as an ingredient 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 (e.g. jarred pasta sauces) and vegetable suet.

Prevalence of rapeseed oil protein allergy

The worldwide literature on rapeseed oil protein allergy is limited and true prevalence is unknown in the UK, although generally it is regarded as a very rare allergy 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 has involved a community survey of participants aged 18-70. Interim results indicate that of the 1673 respondents, only 1 reported adverse reactions to rapeseed oil (clinical confirmation of this person's allergy 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 statistically is 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 rapeseed allergy. Data on the prevalence of rapeseed oil protein allergy for children in the UK are therefore not available in FSA-funded research.

There are some reports in the grey literature on the internet ([Identify the dangers of rapeseed oil as a major allergen - Change.org](#), [Allergy/intolerance to rapeseed oil - Facebook](#)) of consumers indicating they have experienced allergic reactions or intolerances in relation to rapeseed oil, although it is not clear if these relate to refined rather than unrefined rapeseed oil and whether these illnesses have been clinically confirmed rather than self-reported.

FSA and FSS contacted three leading UK allergy specialists, including 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 rapeseed allergy. They are not aware of reactions to refined rapeseed oil in the UK during their careers working in the allergy field spanning more than 10 or 20 years. This suggests that the allergy to refined rapeseed oil in the UK is very rare in the UK in both adults and children.

Severity of rapeseed oil allergy

The data in the literature on symptoms caused by rapeseed oil protein allergy is very limited. Symptoms reported include facial urticaria and abdominal symptoms and may suggest that oilseed rape could trigger an allergic response in young children with atopic dermatitis (Fiocchi et al., 2016). We are not aware of reports of serious illness associated with rapeseed oil.

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 these deaths were associated with rapeseed oil. There were no reports of hospital admissions or anaphylaxis due to rapeseed oil consumption reported in the paper although we cannot account for the 'other' or 'unknown' food category (Baseggio Conrado et al., 2020).

We have not found any information in the literature regarding hospitalisation or deaths linked to the consumption of rapeseed oil outside the UK.

A few peer-reviewed papers describe that rapeseed can trigger allergic reactions in mustard allergic subjects (Palomares et al., 2002, EFSA Journal, 2013).

The majority of the symptoms associated with rapeseed oil described in the literature are linked to the presence of erucic acid which is a naturally occurring contaminant present in several vegetable oils. Erucic acid is not taken into account in this risk assessment as this will be covered in a separate toxicological risk assessment which has been commissioned.

6. Exposure Assessment

Effects of processing on rapeseed proteins

Rapeseed is mainly consumed as an oil and highly refined vegetable oils contain very low concentrations of residual proteins from their source (EFSA Journal, 2007, Rigby et al., 2011, Blom et al., 2017)

The production of highly refined rapeseed oil involves several steps. According to [FEDIOL](#) (the edible oil refiners European trade association), there are two main refining processes used on crude oils, it can be done using a chemical/alkali or physical refining, which differ principally 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).

Exposure assessment limitations

Exposure assessment for allergens in ingredient 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 (i.e. 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 refined rapeseed oil, or the amounts of unrefined rapeseed oil that may be included in finished products and consumed on a single eating occasion when substituted for sunflower oil. The ability to carry out exposure assessment is further limited by the lack of an eliciting dose for rapeseed proteins to compare likely doses with in order to determine whether susceptible individuals may react at any given dose.

We note that rapeseed oil has not been subject to research to test whether it is safe for people with rapeseed allergy. The lack of clinically verified reports of allergic reactions to refined rapeseed oil by UK consumers suggests that the level of protein in refined rapeseed oil 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 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.

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

- the **frequency of allergic reactions to refined rapeseed oil** to be **very low** (i.e. very rare but cannot be excluded).
- the severity of illness reported in relation to allergic reactions to rapeseed in general to be **low** (i.e. mild illness, not usually life-threatening, normally short duration, symptoms are self-limiting) and the **severity of illness in relation to allergic reactions to refined rapeseed oil** to be **negligible** (i.e. 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** (i.e. there are some but no complete data available). The key remaining sources of uncertainty are listed in the next section.

8. Key sources of uncertainty

- The degree to which the refining process removes proteins from rapeseed oil (and whether there are variations of refinement leading to variations in protein content).
- The amount of rapeseed protein that would be included in servings of final food products that would be eaten on a single eating occasion refined rapeseed oil is substituted for sunflower oil.
- The amount of allergenic rapeseed protein that needs to be consumed in order to elicit an allergic reaction.
- Whether the lack of confirmed clinical data on allergic reactions to refined rapeseed oil or rapeseed more generally in the UK could be due to under-reporting.

9. References

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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 (e.g. transient diarrhoea)
Medium	Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (e.g. diarrhoea requiring hospitalisation)
High	Severe illness: causing life-threatening or substantial sequelae or illness of long duration (e.g. 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 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