Rapid Risk Assessment:

What is the long-term risk of erucic acid to UK consumers if sunflower oil in food is substituted with refined rapeseed oil?

Risk Assessment Unit
Science, Evidence and Research Division, FSA

Risk Assessment Team
Science Division, FSS

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1. Executive Summary

Oilseed rape is an important oilseed crop, with the oil produced being extensively used in food and food production. Along with other species of the Brassicaceae family, rape seeds contains erucic acid, a fatty acid. Erucic acid at high levels of consumption is associated with adverse effects on the heart in several species. Cultivars of oilseed rape used commercially have been bred to contain low levels of erucic acid, and the content of erucic acid in oils including rapeseed oil is subject to maximum levels. Following a recent review by the European Food Safety Authority (EFSA) a Tolerable Daily Intake (TDI) of 7 mg/kg body weight (bw) per day was established.

Disruption to the supply chain due to the ongoing situation in the Ukraine means that the sunflower oil used in food and food manufacture may need to be wholly or partly replaced with rapeseed oil, potentially increasing consumer exposure to erucic acid.

Two exposure scenarios have been considered, in the first, more conservative, scenario it is assumed that erucic acid is present in rapeseed oil at the maximum permitted level of 2% and in the second more realistic scenario, reported occurrence data which ranges from 0.13 to 0.52% erucic acid was used. Since the latter is the most realistic scenario it has been used as the basis for this assessment

This latter exposure assessment of UK consumers shows that certain groups of high level consumers may, in a scenario where all vegetable oil is solely replaced with rapeseed oil, exceed the TDI at the upper levels of intake, by not more than 40%. However, the conservative nature of the assessment and likely exposure scenario suggests that replacement of sunflower oil with rapeseed oil is unlikely to result in adverse effect in consumers with respect to the erucic acid content.

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 adverse reactions in the general population to potential increased consumption of erucic acid from refined rapeseed oil** to be **negligible** so rare that it does not merit to be included.

It should be noted that the erucic acid content of oils, including rapeseed oil, and infant formula is specified by legislation, limiting the potential exposure to erucic acid in the diet. However for some toddlers, the age group who appear to be most sensitive to the adverse effects of erucic acid and who are also the most highly exposed, adverse effects could not be excluded since high level consumers do exceed the TDI and the effects observed in animal studies occur after a relatively short duration However, these effects are mild, transient and reversible and, taking into account the conservative nature of the exposure assessment, adverse effects are considered unlikely. It should be noted that as with all dietary components, exposure in older toddlers will decrease as their body weight increases. We therefore consider

- the **frequency of adverse reactions in the toddler age group to potential increased consumption of erucic acid from refined rapeseed oil** to be **very low** so cannot be excluded.

It is recommended that the assumptions of this risk assessment, in particular the worst case exposure assessment consumption estimates (all vegetable oils are substituted by refined rapeseed oil) are revisited post 12 months of the GB market substitutions to check the level of consumption if the substitution of sunflower oil is continuing.

Overall, we consider the potential severity of illness reported that could occur as a result of excess erucic acid exposure via rapeseed oil in general to be **medium** (for example, moderate illness, incapacitating but not usually life-threatening and of moderate duration).

We consider the **level of uncertainty** to be **medium** (for example, there are some but no complete data available). Revisiting the exposure assessment for the actual amount of sunflower seed oils substituted with rapeseed oil post market substitution may reduce this uncertainty level significantly.

2. Statement of Purpose

The aim of the risk assessment is to establish whether substitution of sunflower oil with rapeseed oil could lead to adverse health effects in consumers as a consequence of the increased exposure to erucic acid, a natural constituent of the rapeseed oil.

It has been assumed that:

- All blended vegetable oil and sunflower oil is replaced with rapeseed oil.

- All other regulatory frameworks associated with the production of food grade refined low erucic acid rapeseed oil are adhered to, including the composition of infant formula (where erucic acid content shall not exceed 0.4 % of the total fat content).

3. Background

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

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 are substituted for sunflower oil.

Oilseed rape (*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.

Rapeseed oil is considered to be a healthy type of fat and is one of the oils recommended when cooking for children (NHS, 2022)

Rapeseed oil contains erucic acid, a fatty acid which is associated with adverse effects on heart tissue, notably myocardial lipidosis. This can potentially affect the contractile force of the heart. The cultivars of oilseed rape used to provide food grade oil are bred to contain low levels of erucic acid and maximum levels of erucic acid in specific oils and in infant formula are specified by legislation. However, the

replacement of sunflower oil with rapeseed oil will lead to an increase in consumer exposure to erucic acid.

The most recent detailed review of erucic acid was conducted by EFSA in 2016, which forms the basis of this rapid assessment since no new data are available.

4. Hazard Identification

Erucic acid in rapeseed

Erucic acid is a fatty acid which is present at high concentrations mainly in the seeds of species of the Brassicaceae (for example, rape seed or mustard seed and also seeds from vegetable crops such as kales, cabbages and turnips).

Studies in laboratory animals

The heart is the principle target organ of erucic acid toxicity as has been demonstrated in a number of animal species including monkeys, gerbils rats and pigs follow both short and long term exposure. High doses (approximately 1-7 g/kg body weight (bw) per day of erucic acid are associated with myocardial lipidosis, an accumulation of triacylglycerols in the myocardium that appear as neutral lipid droplets. The effect is believed to be due to erucic acid being poorly β-oxidised by the heart mitochondria and erucic acid also inhibiting the mitochondrial β-oxidation of other fatty acids.

At higher dose levels (approximately 7 g/kg bw), mitochondrial damage and disorganisation of myofibrils have been reported in the heart tissue of various species. Feeding high doses of erucic acid to rats for 4 or more weeks has also been associated with myocardial necrosis and fibrosis; however, factors other than, or in addition to, the erucic acid such as fatty acid imbalance may have been responsible for these effects and were not considered by EFSA to be suitable endpoints for risk assessment. Myocardial lipidosis can reduce the contractile force of the heart muscle.

Studies in humans

There is no information on whether erucic acid causes myocardial lipidosis in humans. Epidemiological data are limited. A study in two cohorts in the USA studied the association between plasma phospholipid long-chain monounsaturated fatty acids (LCMUFAs) (20:1, 22:1 and 24:1), used as a biomarker of exposure,

and the incidence of congestive heart failure (Imamura et al., 2013). In both cohorts studied, circulating levels of 22:1 (erucic acid) and 24:1 plasma phospholipids were associated with increased risk of congestive heart failure. Dietary 22:1 is elongated to 24:1 in humans. In contrast, in another cohort study conducted in the USA, red blood cell erucic acid levels were inversely associated with coronary artery disease (Matsumoto et al., 2013).

Note: Not all C22 chain length monounsaturated fatty acids will be erucic acid; the individual acid will depend on the location of the double bond. So for example, 22:1 n-9, is erucic acid while 22:1 n-11 is cetoleic acid. The description above is as taken from EFSA (2016) or the original paper.

Therapeutic uses of Lorenzo's oil, an erucic-acid containing product used to treat Adrenoleukodystrophy (ALD), have been reported to cause haematological effects. In a clinical trial (Kickler *et al*.,1996), groups of ALD patients received no oil (n=13), glycerol trioleate (45-90 mL/day) (n = 12) or Lorenzo's oil (37.5-60 mL/day) (n=13). EFSA calculated the Lorenzo's oil doses to be equal to 0.09-0.14 g/kg bw/day erucic acid. In addition, to the three groups above, there was a further control group of 33 healthy controls consuming only their usual diets. The group receiving Lorenzo's oil showed a 1.5 fold decrease in platelets after 6 months and megathrombocytes were observed in this group, which indicates increased thrombocyte turnover. In another study, thrombocytopenia (low numbers of platelets) was reported in three out of five ALD patients receiving Lorenzo's oil for one year providing estimated intakes of erucic acid of 0.17-0.19 g/kg bw/day, calculated assuming a body weight of 70 kg. One case report described increased bleeding time, while the platelet count appeared normal, in an ALD patient receiving varied doses of Lorenzo's oil; the intakes of erucic acid are unclear. Zinkham et al., (1993) reported that of 46 patients receiving Lorenzo's oil 19 had thrombocytopenia, which persisted through the 12 months treatment period. In 6 patients with thrombocytopenia, the platelet count returned to normal 2-3 months after erucic acid was omitted from the diet; the intakes of erucic acid were not estimated.

A study was conducted in which effects on natural killer cells and lymphocytes were studied in 27 ALD patients receiving Lorenzo's oil, 14 ALD patients without treatment and 26 healthy individuals (Barmarki-Pour *et al*., 2000). The patients receiving

Lorenzo's oil received 20% of their dietary calories as Lorenzo's oil. The intake of erucic acid was not estimated but based on another paper a dose of 20% of caloric intake was estimated to correspond to approximately 0.4–0.6 g/kg bw/day erucic acid. The durations of treatment were 4.5 months to 3.2 years. Lymphocyte proliferation in response to the mitogens phytohaemagglutinin and concanavalin A were significantly increased in ALD patients receiving Lorenzo's oil.

5. Hazard Characterisation

For the purpose of establishing a TDI, EFSA identified a total of six studies in rats and one in piglets reporting on myocardial lipidosis, and which were conducted over a wide dose range and in which erucic acid was the main source of variation in the fatty acid composition of the diet. In rats the No Observed Adverse Effect Levels (NOAELs) ranged between 0.7 and 2.6 g/kg bw/day, and the Low Observed Adverse Effect Level (LOAELs) ranged between 1.0 and 7.1 g/kg bw/day. In the study in piglets the NOAEL was 0.7 g/kg bw/day and the LOAEL was 1.1 g/kg bw/day.

The lowest overall NOAEL identified in rats was from a 7-day study in male Sprague-Dawley rats. Groups of 10 rats were fed diets containing 20% mixed oil/fat by weight to give different amounts of erucic acid. Corn oil (0% erucic acid) was used as the control, mixtures of low erucic acid and high erucic acid rapeseeds oils as the low and medium doses, and high erucic acid rapeseed oil as the top dose. (There were also two other groups testing low and medium doses of erucic acid together with high amounts of saturated fatty acids). EFSA used default factors to estimate the intakes of erucic acid. Traces of myocardial lipidosis were already observed by histopathological staining in the control group, possibly due to the high fat content of the diet. There was a significant increase in severity (% area affected) in the mid-dose group receiving 2.1 g/kg bw/day erucic acid, shown histopathologically and in an accumulation of erucic acid in heart lipids. At the top dose of 10.3 g/kg bw/day, extensive lipidosis was observed, and an increase in cardiac triacylglycerol. The groups including high amounts of saturated fatty acids showed that saturated fatty acids did not affect the severity or incidence of myocardial lipidosis. The low dose of 0.7 g/kg bw/day erucic acid was considered the NOAEL.

The study in piglets was conducted in groups of 2-20 newborn male and female Yorkshire piglets fed diets containing sow's milk (control) or milk-replacer diets

containing 25% soybean oil (0% erucic acid, another control) or 25% rapeseed oil containing seven different concentrations of erucic acid. Doses of erucic acid were 0, 0.09 (sow's milk), 0.1, 0.3, 0.7, 1.1, 1.8, 3.0 or 5.1 g/kg bw/day. Myocardial lipidosis was observed in piglets receiving sow's milk but disappeared by 7 days of age. It was observed in trace amounts in the piglets receiving the soybean oil control and the erucic acid dose groups up to 0.7 g/kg bw/day. At doses of 1.1 g/kg bw/day and above there was a clear dose-related increase in lipidosis, with the maximum amounts seen after 1 week of feeding. Cardiac triacylglycerol increased in the top dose group only. There was no focal myocardial necrosis observed in any group. The NOAEL was concluded to be 0.7 g/kg bw/day. It was noted that the myocardial lipidosis observed was more severe than seen in two previous studies in weaned pigs, and it was suggested that the immature myocardium may be less able to metabolise long chain fatty acids.

EFSA applied a default uncertainty factor of 100 (10 for differences between species x 10 for inter-individual variation) to the NOAELs in the above-described studies to establish a TDI of 7 mg/kg bw/day. An extra uncertainty factor to extrapolate from subacute to chronic exposure was not applied since the myocardial lipidosis is transient and reversible. However, the TDI established is still likely to be conservative for the following reasons:

- The myocardial lipidosis was shown to be reversible in studies in rats, even after prolonged exposure to erucic acid, and it is unclear whether it is a direct mediator of any irreversible toxicity
- Studies in rats showed that the lipidosis regresses upon long term exposure to erucic acid, though it remained above the level in controls at the end of the study period. There is evidence that this is due to the induction of the peroxisomal β-oxidation system of the liver and the heart
- Although a number of other adverse effects were reported in studies in rats and pigs (changes in the liver, kidneys, skeletal muscle, adrenals, testis weight and haematological effects) the LOAELs (4-13 g/kg bw/day) were higher than for myocardial lipidosis in the same studies.

In their risk assessment, EFSA considered the myocardial lipidosis to be relevant to humans and established a TDI of 7 mg/kg bw/day, based on myocardial lipidosis in

young rats and newborn piglets (EFSA, 2016). EFSA noted that this TDI would also leave a large margin to the daily doses of around 100 mg/kg bw/day and above that are reported to cause haematological effects in ALD patients treated with Lorenzo's oil.

Although natural forms of rapeseed species contain high levels of erucic acid, usually more than 40%, commercially bred cultivars developed since the 1970s have been essentially free from erucic acid, i.e.<1% (EFSA, 2016). These are known as LEAR (low erucic acid rapeseed). HEAR (high erucic acid rapeseed) is used industrially.

The erucic acid content of oils is subject to legislation such that it does not exceed 2% (20 g/kg) by weight in vegetable oils and fats (REUL 1881/2006) as shown in the following table.

Table 1: Maximum level of erucic acid in the legislation

Number	Foodstuffs([1])	Maximum level (g/kg)
8.1	Erucic acid, including erucic acid bound in fat	-
8.1.1	Vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food, with the exception of camelina oil, mustard oil and borage oil	20.0
8.1.2.	Camelina oil, mustard oil (*1) and borage oil	50.0
8.1.3.	Mustard (condiment)	35.0

Maximum levels are also specified for infant formulae (REUL 2016/127). The legislation is the responsibility of DHSC and states 'The erucic acid content shall not exceed 0.4 % of the total fat content.'

Uses of refined rapeseed oil

Russia and Ukraine account for the majority of the world's sunflower oil production. The current situation is leading to shortages and finding alternative suppliers of

sunflower oil is unlikely. 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 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.

6. Exposure Assessment

Data for common cooking oils available through the National Diet and Nutrition Survey (NDNS) and the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) were considered for this assessment. The NDNS is a programme of surveys designed to assess the diet, nutrient intake and nutritional status of the general population aged 18 months and over living in private households in the UK. The DNSIYC is a single survey that was undertaken to provide detailed information on the food consumption, nutrient intakes and nutritional status of infants and young children aged 4 up to 18 months living in private households in the UK. The following four oil types were included– 1) rapeseed oil 2) sunflower oils 3) corn/peanut oil and 4) blended oils, taking into account scenarios that rapeseed oil is consumed along with other types of oils.

Two scenarios were considered – 1) a baseline scenario that takes into account erucic acid exposure from current rapeseed oil consumption and 2) a modified scenario that assumes an increased exposure to erucic acid if sunflower oil and blended oil are replaced by rapeseed oil. The baseline scenario (Table 2 and Table 3) accounts for the consumption of all four types, but with erucic acid exposure resulting from rapeseed oil only. Exposure estimates were derived using 2% which is the maximum level in vegetable oil specified by legislation – (Table 2) or actual concentrations of erucic acid in rapeseed oil reported by the EFSA Panel on Contaminants in the Food Chain (CONTAM *et al.,* 2016) (Table 3). The baseline exposure assessment shows that high consuming infants aged 4-18 months already slightly exceed the TDI if 2% erucic acid is assumed (Table 2) whereas all consumers are within the TDI when using occurrence data (Table 3).

Table 2: Chronic exposure to erucic acid - baseline consumption scenario (with recipes), assuming a 2% (20,000 mg/kg) as the concentration of erucic acid. The assessment takes into account erucic acid in rapeseed oils (2%); sunflower and blended oils (0%) and corn/peanut oil (0%)

Age group	Number of exposed respondents	Mean chronic exposure (mg/kg bw/day)	97.5th percentile chronic exposure (mg/kg bw/day)	Number of respondents in Population group
4-18 months	2172	1.7	8.4	2683
Toddlers (1.5-3 years)	1114	3.3	13	1157
19 - 64 years	4861	1.2	4.4	5094

Table 3: Chronic exposure to erucic acid- baseline consumption scenario (with recipes), using EFSA's concentration data (mean lower bound (LB)/upper bound (UB) levels of 1,285/5,215 mg/kg) applied to rapeseed oils

Age group	Number of exposed respondents	Mean chronic exposure (LB-UB) (mg/kg bw/day)	97.5 th percentile chronic exposure (LB-UB) (mg/kg bw/day)	Number of respondents in Population group
4-18 months	2172	0.11 - 0.44	0.54 - 2.2	2683
Toddlers (1.5-3 years)	1114	0.21 - 0.86	0.80 - 3.3	1157
19 - 64 years	4861	0.079 - 0.32	0.28 - 1.1	5094

In a modified scenario (Table 4 and Table 5) it was assumed that rapeseed oil completely replaced sunflower and blended vegetable oils. Therefore exposure to erucic acid has been estimated based on consumption of these other oils as well as from rapeseed oil. It is not assumed that rapeseed oil will replace peanut oil. Exposures were derived using a maximum concentration of erucic acid as specified by the legislation (Table 4) and actual concentrations of erucic acid in rapeseed oil reported by the EFSA Panel on Contaminants in the Food Chain (CONTAM *et al.,* 2016) (Table 5).

Table 4: Chronic exposure to erucic acid- new modified scenario where blended oils and sunflower oils are assumed to be rapeseed oil (with recipes) assuming a 2% (20,000 mg/kg) concentration of erucic acid. The assessment takes into account erucic acid in rapeseed oils (2%); sunflower and blended oils (2%) and corn/peanut oil (0%)

Age group	Number of exposed respondents	Mean chronic exposure (mg/kg bw/day)	97.5 th percentile chronic exposure (mg/kg bw/day)	Number of respondents in Population group
4-18 months	2625	8.3	26	2683
Toddlers (1.5-3 years)	1156	15	37	1157
19 - 64 years	5088	5	13	5094

Table 5:Chronic exposure to erucic acid- new scenario where blended oils and sunflower oils are assumed to be rapeseed oil (with recipes), using EFSA's concentration data (1,285/5,215 mg/kg (lower bound (LB)/upper bound (UB)) applied to rapeseed, sunflower and blended oils

Age group	Number of exposed respondents	Mean chronic exposure (LB-UB) (mg/kg bw/day)	97.5th percentile chronic exposure (LB-UB) (mg/kg bw/day)	Number of respondents in Population group
4-18 months	2625	0.53- 2.2	1.7 - 6.9	2683
Toddlers (1.5-3 years)	1156	0.95 - 3.9	2.4 - 9.6	1157
19 - 64 years	5088	0.32 -1.3	0.82 - 3.3	5094

If a concentration of 2% erucic acid is assumed, mean and high level infant and toddler consumers exceed the TDI. Applying the range of lower-bound to upper-bound concentrations reported by EFSA for 12,444 food samples representing most of the food commodities with potential presence of erucic acid to the oil consumption data from NDNS provides the range of exposure estimates reported in Tables 3 and 5.

Table 5 provides a more plausible estimate of exposures in infants, toddlers and adults. Exposures in general are below the TDI for infants and adults, but the upper bound 97.5th percentile estimate for toddlers slightly exceeds the TDI, by less than 40%, in this assessment.

The exposure assessment focussed on consumption of refined oils in different recipes by different sub-populations. The erucic acid concentration range taken from the EFSA opinion spans a significantly higher number of food items (from multiple European countries), which may not be accurately represented in the NDNS. The use of the EFSA concentration range is likely to result in an overestimation of

exposure from refined oils, as it is being applied to a specific oil-based food group in NDNS. However, the estimated exposures to erucic acid from refined oils derived using NDNS consumption data and EFSA occurrence data are within the range of those reported by EFSA for infants, toddlers and adults from different dietary sources

7. Risk Characterisation

As described above, a TDI of 7 mg/kg bw/day was established by EFSA for erucic acid. This was based on studies in young rats and newborn piglets which reported myocardial lipidosis.

Using the most conservative assumption of an inclusion level of 2% (20,000 mg/kg) erucic acid (the maximum permitted), the TDI is exceeded by all high level consumers and by mean consumers in the 4-18 month and 18 month to 3 year age groups.

Using the occurrence data cited by EFSA (1,285- 5,215 mg/kg or 0.13 - 0.53%) results in exposures which are within the EFSA TDI for all mean consumers and for high consumers at the LB end of the range. High level consumers in the 18 month to 3 year age groups exceed the TDI, by less than 40%, at the top end of the concentration range; a concentration which would be in excess of currently permitted levels.

The TDI is a level of intake that is without significant risk to health over a life time – thus occasional exceedance of the TDI, whilst undesirable, would not be expected to result in an increased risk of adverse effects. The risk of adverse effects increases with the degree and duration of the exceedance. In this instance, the key adverse effect in animals occurs within a short period of time but is both transient and reversible. Myocardial lipidosis has not been reported in humans, but adverse changes in haematological parameters were reported in ALS patients taking Lorenzo's oil for 1 year as an estimated dose of 170-190 mg/kg bw/day. Given the conservative nature of the exposure assessment, and the likely nature and level of the exceedance, substitution of sunflower oil with rape seed oil would not be expected to result in adverse effects.

To present this risk assessment in a qualitative form, the 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) was used.

This is described in Figure 1 below.

1) The probability of an adverse event occurring per serving

A qualitative scale for the frequency of occurrence of foodborne risks (EFSA 2006):

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

Increased exposure to erucic acid would not be expected to affect consumers following a single serving and equates to a generic category of Negligible risk. It should be noted that the erucic acid content of oils, including rapeseed oil, and infant formula is specified by legislation limiting the potential exposure to erucic acid in the diet.

However for some toddlers, the age group who may, if comparable to laboratory species, be most sensitive to the adverse effects of erucic acid and who are also the most highly exposed, adverse effects could not be completely excluded. It is noted that the TDI is based on effects observed in young animals, the most sensitive group, which may be attributable to immature metabolism in the heart and/or liver. Laboratory studies indicate that effects in animals occur following a short duration of treatment. Therefore, in this group, the risk category, would equate to very low. It is recommended that the assumptions of this risk assessment, in particular the exposure assessment consumption estimates are revisited post 12 months of the GB market substitutions to check the level of consumption is substitution is still ongoing.

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 adverse reactions in the general population to potential increased consumption of erucic acid from refined rapeseed oil** to be **negligible** so rare that it does not merit to be included.
- the **frequency of adverse reactions in the toddler age group to potential increased consumption of erucic acid from refined rapeseed oil** to be **very low),** so cannot be excluded.

2) Severity of detriment

A qualitative scale for the severity of detriments of foodborne risks (ICMSF 2002):

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)

The myocardial lipidosis associated with excess erucic acid could, if sufficiently severe, affect the contractile force of the heart muscle. The effects of erucic are reversible but could be long lasting. There are limited human data available; haematological changes have been observed in patients taking Lorenzo's oil (which contains significantly more erucic acid than would occur in the diet even at the maximum exposure levels estimated) but it is unknown whether the lipidosis and other adverse effects observed in the heart tissue in animal studies is replicated in humans. Thus, there is uncertainty associated with the surveillance and differential diagnosis needed to detect cases due to high exposures to erucic acid.

Overall, we consider the severity of illness that could potentially occur as a result of excess erucic acid exposure to be **medium** (i.e. moderate illness, incapacitating but not usually life-threatening and of moderate duration.

3) An assessment of quality of data

A qualitative scale for the level of uncertainty in food risk assessment:

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

The data from experimental animals show a consistent pattern of adverse effects in heart tissue. The key effect of myocardial lipidosis has not been observed in humans but the limited human data available suggests changes to haematological parameters at doses significantly in excess of the TDI. There are no chronic human or reliable animal data available. Interpretation of the database is consistent between assessments completed by regulatory bodies including FSANZ, EFSA and Bfr.

The large data gaps are in exposure assessment and in particular how the GB food industry substitutes sunflower oil for oils other than oilseed rape in general food products, noting that maximum erucic acid levels are specified by legislation for rapeseed oil and infant formula.

Uncertainty in the exposure assessment could be decreased by revisiting the diet in 12 months post substitutions to gain a better dataset.

Overall, we consider the **level of uncertainty** to be **medium** (for example, 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

- Occurrence data for erucic acid. In the absence of a specific concentration of erucic acid in refined oils for use in the exposure assessment the range reported by EFSA for a significantly larger number of food items or the maximum value allowed by the legislation were used in the exposure scenarios. Both approaches are likely to overestimate exposure.

- It is unknown which food groups are driving the exposure – however, the EFSA exposure assessment, which includes UK data, suggests that “Fine bakery wares” (including “pastries and cakes” and “cookies”) was the main source.
- There is a lack of chronic data. The key animal studies in young rats and piglets has only a short duration but the consistency effects in different species are noted)
- Although young animals appear to be more sensitive to the effects of erucic acid, it is unknown whether this would also apply to humans.
- Limited human data are available. The key effect in animals has not been observed in humans but was considered relevant.

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