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Infant nutrition: Health risks due to erucic acid are not to be expected

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Erucic acid is found in the oil-rich seeds of Brassicaceae such as rapeseed, but also in other plant families. Consequently, erucic acid is present in rapeseed oil as well as in other vegetable oils. A chronic high intake of erucic acid impairsheart muscle, called myocardial lipidosis. Accordingly, the European Food Safety Authority (EFSA) has derived an intake level for erucic acid that can be consumed orally daily over an entire lifetime without any known health risk (tolerable daily intake; TDI). In addition, the European Commission has set maximum permitted levels for erucic acid in certain foods, including infant formula and follow-on formula.

In the present opinion, the German Federal Institute for Risk Assessment has assessed potential health risks for infants through the intake of erucic acid via infant formula, follow-on formula and baby food. For this purpose, a number of models were used to investigate under which conditions the exposure for infants could exceed the EFSA-derivedTDI for erucic acid. For the exposure assessments, data on erucic acid levels from food monitoring programmes of the Federal States of Germany were included in addition to the maximum permitted levels for erucic acid in infant formula and follow-on formula set by EU law.

When considering data on actual erucic acid levels, such as provided by the food monitoring programmes of the Federal States of Germany, it is shown that erucic acid levels in infant formula and follow-on formula in Germany are considerably below the legally defined maximum permitted levels of 0.4% of total fat content according to Delegated Regulation (EU) 2019/828. Model calculations based on real erucic acid levels have shown that the intake of erucic acid via infant formula and follow-on formula, as well as industrially processed baby food, is not associated with an increased health risk for infants aged from 0 to 12 months.

Conversely, if an erucic acid level equivalent to the legal maximum permitted level for erucic acid in infant formula and follow-on formula is assumed, the exposure for infants fed exclusively infant formula (i.e. not breastfed) would exceed the value for the tolerable daily intake (TDI) of 7 mg/kg body weight per day. It is therefore recommended to examine options to limit the total intake of erucic acid via these foodstuffs to prevent an exceedance of the TDI for infants, according to the BfR's assumed worst-case model.

For infants from the age of 6 month, an intake of erucic acid can result from the consumption of infant formula and follow-on formula, as well as by consuming baby food. The addition of rapeseed oil to baby food (industrial or homemade) can also lead to a higher total intake of erucic acid. However, with an average consumption of baby food and an erucic acid content of 0.2% or less in those oils that are predominantly available on the German market, there is no elevated health risk for infants aged between 6 and 12 months if for instance a teaspoon of rapeseed oil is added to baby food. Only worst-case scenarios, considering an above-average consumption of baby food, as well as erucic acid contents of more than 0.2% in the oils added, in addition to the use of other foods containing erucic acid in preparing baby food, would in fact lead to an exposure at which the tolerable daily intake (TDI) for erucic acid could be exceeded.

In this context, the BfR noted that the total content of erucic acid as a percentage of the total fat content of infant and follow-on formula can be influenced by appropriate compositions of rapeseed oil and oils that do not naturally contain erucic acid.

1 Subject of the assessment

The German Federal Ministry of Food and Agriculture (BMEL) has asked the BfR for data and information on erucic acid in infant and follow-on formula.

The request is based on calculations of the intake levels of erucic acid via infant formula. Assuming that the diet is exclusively based on infant formula and that the maximum permitted level for erucic acid in infant formula and follow-on formula of 0.4% and 4 g/kg, respectively,of the total fat content is exhausted, infants regularly exceed the tolerable daily intake (TDI) for erucic acid of 7 mg/kg bw and day as derived by the European Food Safety Authority (EFSA).

2 Results

Assessment of the health risk to infants from the intake of erucic acid via the foods being considered

On the basis of the available data, the BfR draws the following conclusions:

- ***Erucic acid intake via products that exceed the maximum permitted level for erucic acid of 0.4% of the total fat content.***

  Assuming that infant formula and follow-on formula exhibit an erucic acid content equal to the maximum permitted value of 0.4% of the fat content specified in Delegated Regulation (EU) 2019/828, the EFSA-derived tolerable daily intake (TDI) value for erucic acid of 7 mg/kg body weight/day will be significantly exceeded.

  However, exposure assessments made on the basis of consumption data and erucic acid levels relevant to practice show that the above scenario is a worst-case model.

- ***Exposure assessment based data from food monitoring programmes of the Federal States of Germany.***

  The data from food monitoring programmes conducted by the Federal States of Germanyand transmitted by the Federal Office of Consumer Protection and Food Safety (BVL) show that the levels of erucic acid in infant formula, follow-on formula and industrially processed baby food in Germany are considerably below the legal maximum permitted level of 0.4% of the total fat content.

  Taking into account these data on erucic acid content, the tolerable daily intake (TDI) derived by EFSA is exhausted by 33 to 47 % for infants aged 0 to 6 months who are fed exclusively with infant formula.

  For infants between 6 and 12 months of age, the TDI is only slightly exceeded (up to 101%) by high consumers of infant formula, follow-on formula and baby food (P95).

  Based on the exposure assessments made, the BfR therefore comes to the conclusion that the intake of erucic acid via infant formula, follow-on formula and industrially processed baby food taking into account the existing uncertainties, is not currently associated with an increased health risk for infants from 0 to 12 months.

- ***Estimation of erucic acid intake when adding rapeseed oil to industrially produced baby food***

  The German Child Nutrition Research Unit (FKE) recommends adding rapeseed oil to baby food. Assuming that a total of one teaspoon (tsp) of rapeseed oil with an erucic acid concentration of 0.52% in the oil (*upper bound* value assumed by the EFSA expert opinion from 2016) is added to industrially produced baby food, then high consumers of baby food would exceed the TDI (121%).

  However, there is reliable evidence that in practice erucic acid levels in the oils used for baby food preparation can be assumed to be below 0.5% (EFSA 2016) or less than 0.2%, according to other sources of information. High consumers of infant and follow-on formula and baby food would exhaust the TDI (105%) under the assumptions made (addition of 1 tsp rapeseed oil with an erucic acid content of 0.2%). If more than 1 tsp rapeseed oil is added or if the erucic acid content in the oil added exceeds 0.2%, then erucic acid intake would increase correspondingly.

  In order to effectively exclude the probability of a health risk, the total intake of erucic acid, taking into account all relevant foodstuffs, should not result in the exceedance of the EFSA-derived tolerable daily intake (TDI) value.

Recommendations

- As the calculations show, the maximum erucic acid content of 0.4% of the total fat content permitted in infant formula and follow-on formula, as specified in Delegated Regulation (EU) 2019/828, would clearly exceed the TDI for erucic acid of 7 mg/kg body weight and day

  It is therefore recommended to examine whether, for example by specifying relevant legal regulations, the total intake of erucic acid via these foodstuffs can be limited in order to prevent exceeding the TDI for infants. In this context, it is stated that the legal requirements for infant formula and follow-on formula in terms of their composition can be fulfilled with appropriate formulations consisting of rapeseed oil and oils that do not naturally contain erucic acid. In this way, the total content of erucic acid of the total fat content in infant and follow-on formula can be affected by suitable compositions of rapeseed oil and erucic acid-free oils.

  For a four-month-old infant with a body weight of 6.4 kg (WHO growth standard), who consumes 800 ml of infant formula (fat content 2.6 to 4.2 g/100 ml) daily, the TDI would not be exceeded up to a maximum permitted erucic acid content of 0.1% of the total fat content.

- Beside erucic acid, other docosenoic acids (C22:1) are present in edible oils and fats as well as in foods with added oil and fat, especially cetoleic acid (C22:1, n-11) in fish oils. However, as a result of insufficient toxicological data, a comprehensive assessment of the health risks that could be potentially associated with the oral intake of other docosenoic acids is not possible at this time.

  The BfR therefore recommends improving the available toxicological data on these compounds in order to be able to consider them in future risk assessments. Furthermore, the BfR suggests including other docosenoic acids (C22:1) in addition to erucic acid in the analysis, and especially cetoleic acid (C22:1, n-11), which occurs in fish in high amounts.

3 Rationale

3.1 Risk assessment

3.1.1 Hazard identification

Erucic acid (cis-13-docosenoic acid; C 22:1, n-9) is a monounsaturated omega-9 fatty acid occurring as a glycerol ester in the oil-rich seeds of members of the brassica family (*Brassicaceae*) in particular – such as rapeseed and mustard – as well as in other plant families (*Limnanthaceae: Limnanthes alba, Boraginaceae, e.g. Borago officinalis, Fabacea, e.g. Lupinus alba*).

The seeds of rapeseed can exhibit erucic acid contents exceeding 50% of total fatty acid content. However, plant breeding techniques can reduce this level to below 2%. Rapeseed varieties are considered 'erucic acid-free' if the content in samples of their seed does not exceed 2% of total fatty acid content. Varieties of oilseed rape with low amounts of both, erucic acid and glucosinolates, known as 'Double-low (00)' varieties are nowadays cultivated for human consumption containing generally less than 0.5% or even less than 0.1% erucic acid (Low Erucic Acid Rape (LEAR) seed; 'canola') related to the total content of fatty acids. According to the Federal Plant Variety Office, no so-called erucic acid-containing varieties are currently approved for cultivation in Germany (Bickel 2012; EFSA 2016; Bundessortenamt 2019).

Entries of erucic acid into the food chain arise from the use of certain vegetable fats and oils, with the highest levels of erucic acid found in oils of some mustard and rapeseed varieties. Due to the use of rapeseed meal as animal feed, erucic acid also enters products of animal origin (such as milk). Sea fish and their oils can also contribute to the intake of erucic acid. Breast milk (0.06% to 0.22% based on the total content of fatty acids) may also be a potential source of exposure for breastfed infants (EFSA 2016).

According to a 2016 exposure assessment from EFSA, however, the food group '*fine bakery wares*' is considered to be among the main sources of dietary exposure to erucic acid for young and older children. The erucic acid intake here results primarily from the use of rapeseed oil during the industrial production of pastries, cakes and biscuits, as well as the comparatively high quantity of food consumed from this product group. For infants, infant formula has been identified as the main source of dietary exposure to erucic acid (EFSA 2016).

3.1.2 Hazard characterisation

The present opinion focuses on the potential health risks arising from the intake of erucic acid via infant formula and follow-on formula, as well as baby food. For the characterisation of the potential risk, data have been used from EFSA, who published a comprehensive assessment of the potential health risks that arise from exposure to erucic acid in 2016 (EFSA 2016).

In its expert opinion, EFSA identified the heart as the primary target organ for effects following short-term and long-term exposure to erucic acid based on animal experiments in various mammalian species. Thereby, the intake of erucic acid-containing oils via the feed led to an accumulation of fats (lipids) in the heart muscle (myocardium). This so-called myocardial lipidosis, which is considered to be temporary and reversible, can reduce the contractile strength of the heart muscle. This was considered by EFSA as the most sensitive endpoint and was therefore applied to derive a health-based guidance value (HBGV). Based on a 7-

and 14-day feeding study in young rats and new-born piglets, respectively, a dose of 0.7 g erucic acid/kg body weight/day was determined as the no observed adverse effect level (NOAEL). Based on this NOAEL, a tolerable daily intake (TDI) for erucic acid was established of 7 mg/kg body weight/day (EFSA 2016).

The intake of higher doses of erucic acid also resulted in adverse effects on the liver, kidneys and skeletal muscle, as well as changes in body and testis weight in rats. In addition, mitochondrial damage and disorganisation of myofibrils as well as an increased incidence of myocardial necrosis and fibrosis were observed at higher doses of erucic acid. In studies on reproductive and developmental toxicity, no toxicologically relevant effects were observed for erucic acid. Due to the limited data available on genotoxicity and carcinogenicity, EFSA was unable to make a conclusive assessment for these endpoints (EFSA 2016).

3.1.3 Legal framework and recommendations

3.1.3.1 Definitions

In Regulation (EU) No 609/2013[1] on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, a number of terms are defined, and various compositional and informational requirements are also specified in relation to infant formula and follow-on formula:

- 'Infant formula':
  Foods intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;
- 'Follow-on formula':
  Food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants;

The Regulation also defines the terms 'baby food' and 'processed cereal-based food':

- 'Baby food'

  Food intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation to ordinary food, excluding:

  (i) processed cereal-based food; and

  (ii) milk-based drinks and similar products intended for young children;

- 'Processed cereal-based food':

  (i) intended to fulfil the particular requirements of infants in good health while they are being weaned, and of young children in good health as a supplement to their diet and/or for their progressive adaptation, to ordinary food; and

  (ii) pertaining to one of the following categories:

[1] REGULATION (EU) NO 609/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009.

a) simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids,
b) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,
c) pastas which are to be used after cooking in boiling water or other appropriate liquids, or
d) rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.

3.1.3.2 Erucic acid levels in food

Within the EU, European Commission Regulation (EU) 2019/1870[2] of 7 November 2019 sets a legal maximum permitted level of 20 g/kg (2%) erucic acid for vegetable oils and fats placed on the market for the final consumer or for use as an ingredient in food. Exceptions to this are camelina oil, mustard oil and borage oil, for which a maximum permitted level of 50 g/kg (5%) is applied.

In its scientific expert opinion published in 2016, EFSA concludes that the 95th percentile dietary exposure levels of erucic acid is especially high in infants and other children. For highly exposed children, this may pose an elevated health risk (EFSA 2016). Accordingly, stricter limits apply to infant formula and follow-on formula. In Commission Delegated Regulation (EU) 2019/828[3], the maximum level for erucic acid in infant formula and follow-on formula was reduced from the previous 1% (Delegated Regulation (EU) 2016/127[4]) to 0.4% of the total fat content.

For oils labelled as suitable for infants and young children (so-called ‘baby food oils’), no specific requirements are set in regard to the erucic acid content. In this case, the legal maximum level of 2% is applied for vegetable oils and fats.

3.1.3.3 Fatty acid levels in rapeseed oil

Compared to other edible oils, rapeseed oil is characterised by a high content of the omega-3 fatty acid alpha-linolenic acid, which is essential for human health, and alow content of saturated fatty acids. For this reason, rapeseed oil is considered to have a particularly nutritional advantage for humans, for infants and young children, and is therefore the oil that is typically used in infantand follow-on formula, and recommended for the preparation of baby food (Bührer 2014; DGE 2015; Alexy 2016).

3.1.3.4 Recommendations for the infant diet

Based on scientific findings, the FKE has developed a concept for the nutrition of infants and young children in Germany (known as the FKE ‘optimised mixed diet’ concept): which is usually intended for nutrition counselling and for consumer education. The “Dietary Schedule for

[2] COMMISSION REGULATION (EU) 2019/1870 of 7 November 2019 amending and correcting Regulation (EC) No 1881/2006 as regards maximum levels of erucic acid and hydrocyanic acid in certain foodstuffs.

[3] COMMISSION DELEGATED REGULATION (EU) 2019/828 of 14 March 2019 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula.

[4] COMMISSION DELEGATED REGULATION (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding.

the 1st year of life”included in this concept recommends that infants are exclusively breastfed or alternatively receive an industrially produced infant formula as a breast milk substitute during the first months of life. According to the "Dietary Schedule for the 1st year of life", complementary feeding is gradually introduced from the age of 5 to 7 months, and from the 10th month onwards the infant nutrition is gradually moved to the family diet (Kersting *et al.* 2017).

3.1.4 Exposure assessment

3.1.4.1 Data basis for the exposure assessment

3.1.4.1.1 Composition of infant formula and follow-on formula, and baby food

To obtain an overview of the fats and oils used in the infant formula and follow-on formula as available on the German market, research was carried out with the help of the MINTEL database (MINTEL 2016)[5]. Among other resources, this database includes information about foods and their ingredients according to product labelling information. Since MINTEL focuses on recording of new products or product changes, these results do not necessarily provide a representative picture of the market situation. In the last five years, 134 products have been recorded in the MINTEL database in the food groups of infant formula and follow-on formula in Germany. The ten fats and oils most frequently used in these products are shown in figure 1. Sunflower oil (n =131) is used in most products, followed very closely by rapeseed oil (n = 130).

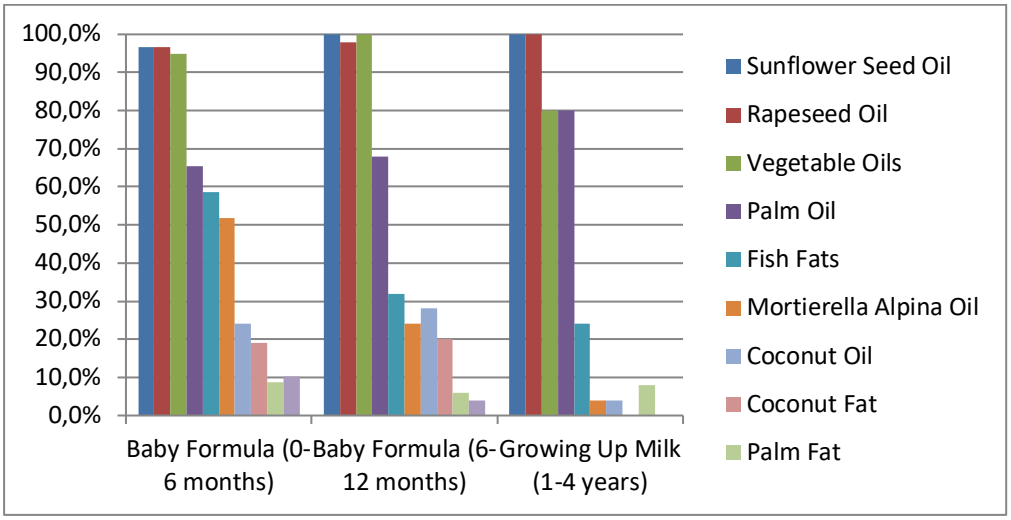

***Figure 1**. Fats and oils in infant formula and follow-on formula in MINTEL (2015–2020).*

Apart from evaluating the information supplied by MINTEL on the fats and oils used, an additional internet search was conducted on the composition of infant and follow-on formula to identify the ranking of the fats contained and to establish the importance of rapeseed oil. Although the exact proportions of the individual ingredients cannot be determined on this basis, the ranking does provide an estimate of the quantity ratios. Fifteen products were recorded as infant milk for the first 6 months, with three of these products representing special foods. A total of seven products were identified for infants from the age of 6 months and the age of 10 months. The total fat content of all infant formula and follow-on formula products is composed of several vegetable oils. For individual products, the percentage of plant oils are noted in the list of ingredients at 10% and 11.8%. Within the fat contained, rapeseed oil ranks first in only one product and is mainly in second place: in 9 out of 15 food products for infants aged under 6 months, in 6 out of 7 food products from the age of 6 monthsand onwards, and in 5 out of 7 food products from the age of 10 months(product introduction by month as stated by manufacturer). Other vegetable oils used besides rapeseed oil in infant formula

[5] MINTEL (2016): Mintel GNPD – Global New Products Database. Mintel Group Ltd, 11 Pilgrim Street, London, EC4V 6RN, UK. https://portal.mintel.com/portal/login?next=/portal/.

comprise palm oil, coconut oil (coconut fat) and sunflower oil (**table 1**). Fish oil is also sometimes used as a fat source of animal origin,

Table 1: Composition of fats and ranking of rapeseed oil in the list of ingredients in selected infant formula and follow-on formula (internet research, as of March 2020)

No.	Infant formula	Fats of plant origin[2]	Position	
			Fats in list of ingredients	Rapeseed oil within other fats
	Infant milk for the first 6 months			
1	Infant milk Pre	Palm oil, rapeseed oil, coconut oil, sunflower oil	(2)	(2)
2	Infant milk 1			
3	Hypoallergenic baby food Pre	10% vegetable oils (sunflower, oilseed rape)	(2)	(2)
4	Infant milk			
5	Infant milk Pre	11.8% vegetable oils (sunflower, oilseed rape)	(3)	(2)
6	Infant milk Pre	Vegetable oils (rapeseed oil, sunflower oil, coconut oil)	(4)	(1)
7	Infant milk Pre (ready-to-drink)	Vegetable oils (palm oil, coconut oil, rapeseed oil, sunflower oil)	(4)	(3)
8	Infant milk 1	Vegetable oils (palm oil, coconut oil, rapeseed oil, sunflower oil)	(2)	(3)
9	Infant milk – special food for reflux*			
10	Infant milk – special food for cow's milk allergies*	Vegetable oils (medium-chain triglycerides (from coconut and palm oil), rapeseed oil, sunflower oil, palm oil)	(3)	(3)
11	Infant milk 1 with lactic acid cultures	Palm oil, rapeseed oil, sunflower oil	(3)	(2)
12	Organic starter milk 0+	Vegetable oils (palm oil, sunflower oil, rapeseed oil)	(3)	(3)
13	Organic infant milk	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(3)	(2)
14	Organic infant milk 1			
15	Organic infant milk from goat's milk	Vegetable oils (sunflower oil, rapeseed oil)	(3)	(2)
	Follow-on formula from month 6 onwards[1]			
1	Follow-on formula 2	Vegetable oils (palm oil, rapeseed oil, coconut oil, sunflower oil)	(3)	(2)
2	Follow-on formula 2 – special food for reflux*	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(2)	(2)
3	Follow-on formula 2	10% vegetable oils (sunflower oil, rapeseed oil)	(2)	(2)
4	Follow-on formula 2	Vegetable oils (palm oil, coconut oil, rapeseed oil, sunflower oil)	(2)	(3)
5	Organic infant milk 2	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(3)	(2)
6	Organic follow-on milk 2			
7	Organic follow-on milk 2	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(2)	(2)
	Follow-on formula from month 10 onwards[1]			
1	Follow-on milk 3	Vegetable oils (palm oil, rapeseed oil, coconut oil, sunflower oil)	(3)	(2)
2	Follow-on milk Junior 12+		(2)	(3)

3	Follow-on milk 3	Vegetableoils (palm oil, coconut oil, rapeseed oil, sunflower oil)		
4	Follow-on milk 3	10% vegetable oils (sunflower, oilseed rape)	(2)	(2)
5	Organic follow-on milk 3 – special food for reflux*	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(2)	(2)
6	Organic follow-on milk 3	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(3)	(2)
7	Organic follow-on milk 3			

[1] List of various products available on the market

[2] Fats listed in order of decreasing proportion, according packaging information

* Product is not classified as infant formula or follow-on formula, but as a food for special medical purposes for infants

The documented fat contents for infant formula range between 3.2 and 3.6 g/100 ml in relation to the ready-to-eat product. For follow-on formula (from month 6 onwards) offered as a ready-to-eat product, the fat content lies in a similar range between 3.0 and 3.5 g/100 ml in relation to the ready-to-eat product.

According to MINTEL, about a quarter of the industrially processed baby foods for both,infants and young children (88 of 363 products entered into the database over the last five years) contain vegetable fats in the form of rapeseed or sunflower oil. The use of the above-mentioned oils plays a role especially for savoury dishes. As with infant and follow-on formula, supplementary research was conducted on the internet to identify the importance of fats in baby food and the ranking of rapeseed oil (**table 2**).

Table 2: Composition of fats and ranking of rapeseed oil in the list of ingredients in selected processed cereal-based and baby food (internet search, as of May 2020)

No.	Processed cereal-based food and baby food	Fats of plant origin[2]	Position	
			Fats in list of ingredients	Rapeseed oil among other fats
	Processed cereal-based food with milk			
1	Processed cereal-based food with milk and fruit based on semolina, without added sugar (jar)	Corn oil	(3) of (1)	*
2	Processed cereal-based food with milk and apple based on oat (powder)	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(6)	(2)
3	Processed cereal-based food with milk and apple (evening meal) (powder)	Vegetable oils (sunflower oil, rapeseed oil, coconut oil)	(5)	(2)
4	Processed cereal-based food with milk and banana (Biscuit)(powder)	Vegetable oils (sunflower oil, rapeseed oil, coconut oil)	(4)	(2)
5	Processed cereal-based food with milk and cacoa (powder)			
6	Processed cereal-based food with milk based on semolina (powder)			
7	Organic processed cereal-based food with milk (powder)	Vegetable oils (palm oil, sunflower oil, rapeseed oil)	(3)	(3)
8	Processed cereal-based food with milk based on semolina (powder)	Vegetable oils (palm oil, rapeseed oil, sunflower oil)	(3)	(2)
9	Processed cereal-based food with milk based on semolina (vanilla) (jar)	Rapeseed oil, sunflower oil	(6)	(1)
10	Processed cereal-based food with milk based based on-semolina (powder)	Vegetable oils (sunflower oil, rapeseed oil)	(3) of (2)	(2)
11	Processed cereal-based food with milk based and wild berry (powder)	Vegetable oils (palm oil, rapeseed oil, coconut oil, sunflower oil)	(4)	(2)
12	Processed cereal-based food with milk (powder)			
	Baby food based on vegetables (jar or squeeze bag)			
1	White carrot with potato/parsnip	Rapeseed oil (1.1%)	(5)	(1)
2	Vegetable variety	Rapeseed oil (1.2%)	(3)	(1)
3	Vegetable rice with organic chicken	Rapeseed oil (1.7%)	(7)	(1)
4	Mediterranean vegetables with aubergine	Rapeseed oil (1.0%)	(6)	(1)
5	Sweet potato and broccoli in parsnips	Rapeseed oil (1.6%)	(3)	(1)
6	Vegetable and chicken risotto with peas	Rapeseed oil (1.8%)	(6)	(1)
7	Spaghetti bolognese	Rapeseed oil (1.4%)	(8)	(1)

8	Creamy potato soup	Rapeseed oil (2.0%)	(5)	(1)
9	Mixed potato gratin	Rapeseed oil (2.2%)	(5)	(1)
10	Carrots with potato	Rapeseed oil (organic) (1.8%)	(4)	(1)
11	Carrots with potato and beef	Rapeseed oil (organic) (1.2%)	(5)	(1)
12	Lentils with couscous	Rapeseed oil (1.1%)	(8)	(1)
13	Vegetarian menu (vegetables with millet)	Rapeseed oil (0.3%)	(10)	(1)
14	Baby carrots with potatoes	Rapeseed oil (1.0%)	(3)	(1)
15	Tasty vegetable variety	Rapeseed oil (2.0%)	(4)	(1)
16	Mashed potatoes with vegetables and minced meat	Rapeseed oil (1.0%)	(8)	(1)
17	Vegetable rice with tender turkey	Rapeseed oil (2.0%)	(6)	(1)
18	Paella with vegetables and Alaskan codfish	Rapeseed oil (1.6%)	(9)	(1)
19	Vegetable rice with turkey	Rapeseed oil, sunflower oil	(7)	(1)
20	Pasta in broccoli sauce	Rapeseed oil, sunflower oil	(9)	(1)
21	Organic broccoli with rice	No added fat	–	–
22	Organic carrots with potatoes			
23	Organic spaghetti bolognese			
24	Organic butternut squash, potato (pot)	Rapeseed oil (3.0%)	(4)	(1)
25	Organic carrot, zucchini, oat flakes (pot)	Rapeseed oil (3.0%)	(7)	(1)
26	Organic squeezy bag: carrot, apple, pumpkin, banana	No added fat	–	–
27	*Organic squeezy bag: sweet potato, spinach, zucchini*			
28	*Organic squeezy bag: carrot, spinach, peas*			

[1] List of various products available on the market

[2] Fats listed in order of decreasing proportion, according to details on packaging

** Not included*

It becomes apparent that baby food based on fruits mainly used as snacks or desserts do not contain any added fat. In contrast, a combination of various vegetable oils such as sunflower oil, palm oil, rapeseed oil or coconut oil is mostly used in processed cereal-based food with milk. In 9 of 11 products, rapeseed oil is in second-place within the vegetable oils in the list of ingredients. One product used no rapeseed oil at all, but only corn oil. In vegetable-based baby foods, rapeseed oil was the only fat used in 20 out of 22 products, with proportions ranging between 0.3% and 3%. In the other two products, sunflower oil was also used, although in each of these products rapeseed oil was the first-placed oil among the oils in the list of ingredients. In another six vegetable-based baby foods, no fats were added at all (**table 2**).

Finally, in addition to vegetable oils, animal fats in the form of cream are also used in individual products for both processed cereal-based food with milk and baby food based on vegetables porridges. Overall, the fat content for processed cereal-based food with milk ranges from 1.5 to 2.5 g/100 g and 6.7 to 14.2 g/100 g in the ready-to-eat product and powder, respectively. In the case of baby foods with meat, fat content ranges from 0.6 to 2.9 g/100 g in

ready-to-eat products. Ready-to-eat foods containing fish have a fat content of 1.9 g/100 g. In contrast, fat content for vegetable-based baby food ranges from 0.0 to 3.4 g/100 g.

3.1.4.1.2 Information from Diätverband e.V. on the composition of infant and follow-on formula, as well as baby food

To supplement the research, information was requested from the Federal Association of Manufacturers of Foods for Special Diets (Diätverband e.V.) on the levels of rapeseed oil as a proportion of total fat content in the above-mentioned product categories of 'Infant formula', 'Follow-on formula' and 'Baby food'.

The Association responded that a relatively large variation can be found between the proportions of rapeseed oil stated in the recipes for the different food manufactured according to modern standards for infants and young children (infant and follow-on formula, and baby food), with levels ranging from 0.8% to 24% in relation to the total fat content.

For infant formula and follow-on formula products, different fat and oil compositions are used by the manufacturers in order to comply with the legal requirements for erucic acid content on the one hand, and to reduce or minimise the content of other ingredients (such as 3-MCPD fatty acid esters, glycidyl fatty acid esters, MOSH/MOAHs, and other undesirable contaminants and residues) on the other. In terms of rapeseed proportions, Diätverband e.V. distinguishes between products with 4% to 6% rapeseed oil, products with 12% to 15% rapeseed oil, and products with 15% to 19% rapeseed oil. As an exception, infant and follow-on formula based on goat's milk are mentioned, for which rapeseed oil in relation to the total fat content can be as high as 24%.

According to Diätverband e.V., rapeseed oil is also used as a fat component in the manufacture of baby food, and for processed cereal-based food with milkin particular with a distinction is made between products with 10% to 15% rapeseed oil and products with 15% to 19% rapeseed oil.

In comparison to infant formula and follow-on formula, whose fat content is defined in Delegated Regulation (EU) 2016/127 (up to a maximum of 6 g/100 kcal), the total fat content for processed cereal-based food is significantly lower. According to the German Dietetic Food Ordinance, the total fat content of cereal-based baby food must not exceed 3.3 g/100 kcal (simple cereal products, which are/must be prepared with milk or some other suitable nutritious liquid) or 4.5 g/100 kcal (cereal products with an added protein-rich food, which are/must be prepared with water or some other protein-free liquid).

The rapeseed oil content as a proportion of the total fat content for baby food products in jars is relatively low when compared to processed cereal-based food with milk, ranging between 0.8% and 2.8% related to the total fat.

3.1.4.1.3 Conclusions

From the research conducted on the composition of infant formula and follow-on formula as well as baby food, supplemented with information provided by Diätverband e.V., it can be concluded that rapeseed oil is not predominantly used as the sole source of fat in the product categories mentioned. This approach ensures the fulfilment of the legal provisions of Delegated Regulation (EU) 2016/127 with regard to the specific compositional and information requirements for infant formula and follow-on formula.

To meet requirements in terms of fat quality (fat/fatty acid content) as well as other critical ingredients (such as 3-MCPD fatty acid esters) in infant and follow-on formula, manufacturers

utilise mixtures consisting of several vegetable oils. For infant and follow-on formula, the maximum permitted rapeseed oil level of 19% of total fat was given. If these product groups are based on goat's milk, then the rapeseed oil proportion may be higher (24%).

A similar picture emerges for the product categories of processed cereal-based food and other baby food. Here too, mixtures of vegetable edible fats and oils are also used. Processedcereal-based baby foods with milk exhibit higher proportions of rapeseed oil (maximum 19% of total fat) than baby food products sold in jars that are not milk/cereal-based.

Compared to infant and follow-on formula, baby food products, especially ready-to-eat products in jars, contain less fat in general and lower levels of polyunsaturated fatty acids (n-3 fatty acid α-linolenic acid) in particular. Rapeseed oil exhibits a ratio for n-3 to n-6 fatty acids of roughly 1:2 as well as high content of α-linolenic acid. Depending on product quantity, many baby food products are therefore labelled with the instruction '*Add 1 or 2 teaspoons of baby food oil/rapeseed oil before consumption*'.

3.1.4.2 Consumption data for the exposure assessment

Since no individual consumption data are available in Germany for infants aged between 0 and 6 months, energy reference values for infants fed on infant formula according to Butte (2005) and growth reference data for the EU (van Buuren et al. 2012) were used for the scenario of interest with exclusive consumption of infant formula, so that the exposure assessments could be performed for both median (P50) and high (P95) drinking quantities.

For infants aged between 6 and 12 months, data have been applied from the VELS consumption study, which determined food intakes for infants and young children in order to estimate the acute risk of toxicity owing to the presence of residues from plant protection products (Heseker et al. 2003; Banasiak et al. 2005). This nationwide study was conducted between 2001 to 2002 in Germany, with 816 infants and young children aged from 6 months to under 5 years. The parents performed two 3-day dietary records for each child for all foods consumed. Due to the availability of consumption data for individual days, the 3-day dietary records, each collected twice, are suitable for exposure assessments that consider both acute and chronic health risks.

3.1.4.3 Erucic acid levels in foods for infants and young children

3.1.4.3.1 Data from food monitoring programmes of the Federal States of Germany

To determine the levels of erucic acid in infant and follow-on formula, a data request was submitted to the Federal Office of Consumer Protection and Food Safety (BVL), and the Federal States. Consequently, the BfR was supplied with analysis results for erucic acid of 1,158 samples from the food monitoring programmes between 2002 and 2020. The following analysis was restricted to data collected from the year 2009 onwards to ensure the currency of product composition. In addition, samples taken as complaint, suspect or prosecuted were excluded from the submitted data pool. The erucic acid content is given as a percentage in the majority of the data, and in g/100 g in the remaining data sets, which also correspond to percentage.

The samples were summarised into the groups as listed in **table 3**. In addition, the data from BVL include samples in the groups 'Desserts and puddings for infants and young children' (n = 21) and 'Desserts with milk products for infants and young children' (n = 15), in which, however, the erucic acid levels were either non-detectable or non-quantifiable in these samples. The samples of 'Milk for special diets for young children' (n = 31) exhibited a high proportion

(76%) of non-detectable or non-quantifiable values for erucic acid. The aforementioned categories represent very inhomogeneous groups and are not considered in the further evaluation.

Therefore, the following analysis is based on 818 data sets on the content of erucic acid in infant and follow-on formula, as well as baby food. In a high proportion of samples (43%), the proportion of erucic acid is given as a content of "0 %". Another 15% of samples is below the limit of detection or quantification, with the contents in these samples being set to '0' according to the *lower bound* (LB) approach due to a lack of information on fat contents or the limits of detection or quantification. An analysis using the *upper bound* (UB) approach would be associated with uncertainties due to the need for assumptions on fat content, and due to the low number of samples below these limits (15%), no significant increase in exposure would be expected.

Fat is specified as the reference parameter in 78% of samples, although details about the total fat content of the product investigated are available only in a few cases. To enable conversions to the ready-to-eat product, researched values (section 3.1.4.1.1 and **table 3**) were used in cases on missing data on fat content data and, if a range was indicated, the maximum value was used for the conversion to the ready-to-eat product.

Most data for erucic acid in infant and follow-on formula are available for the product in powder form, while research results for fat content are instead available for the ready-to-eat product. To obtain the erucic acid content in the entire product for powders with a fat content that is not stated, the content of erucic acid in the powder related to the total fat content was converted with the researched fat content in the prepared product using a factor of 8. This factor is based on internet search conducted for products offered on the German market and is in accordance to the dilution factor as recommended by EFSA for this product group (EFSA 2016). For 22% of the samples, the erucic acid contents are available for the products consumed as such for which no conversion is necessary.

Table 3: Fat contents for the various product groups (basis: results of research)

Category	Product format	Fat content[1]
Infant formula	Liquid	3.2–3.6
Follow-on formula	Liquid	3.0–3.5
Processedcereal-based food with milk	Powder	6.7–14.2
Processed cereal-based food with milk	Jar	1.5–2.5
Baby food with meat	Jar	0.6–2.9
Baby food with fish	Jar	1.9
Baby food with vegetables	Jar	0.0–3.4

[1] *Fat content details provided in g/100 ml or g/100 g.*

To determine erucic acid contents, the samples were then aggregated into the following groups: Infant and follow-on formula (powder or ready-to-eat), processed cereal-based food with milk (powder or ready-to-eat) and baby food containing a portion of meat, fish, vegetables or cereals (table 4).

Table 4: Levels of erucic acid in infant food (basis: BVL data, 2009–2020)

		Infant and follow-on formula		Processed cereal-based food with milk		Others[2]
		Powder	Ready-to-eat	Powder	Ready-to-eat	Ready-to-eat
Samples	N	434	82	48	10	244
	Concentration = 0 or <LOD/LOQ[1] (in %)	64	44	54	30	55
Erucic acid content	Mean in %	0.013	0.002	0.009	0.001	0.026
	Median in %	0	0.002	0	0.001	0
	95th percentile in %	0.058	0.006	0.030	0.002	0.200

[1] LOD: *limit of detection,* LOQ: *limit of quantification*
[2] Ready-to-eat meal with a portion of meat, fish, vegetables or cereals

3.1.4.3.2 Information about erucic acid levels from other sources

To ensure the analysis was as representative of current practice as possible, information was requested from Diätverband e.V. what measures the manufacturers who are members of this association take in order to be in compliance with legal requirements for erucic acid contents in food for infants and young children. According to details provided by the Diätverband e.V, some manufacturers provide their suppliers with appropriate specifications or define requirements in release protocols for the finished products.

The erucic acid content must not exceed 0.1% in supplied rapeseed oil, 0.4% in supplied palm-rapeseed oil mixtures or 0.5% in supplied sunflower-rapeseed oil mixtures. Oil mixtures are not used as the only fat component within the corresponding end product. Depending on the specific recipe, these mixtures are used in varying proportions together with other oils that naturally not contain erucic acid. According to the Diätverband e.V, other manufacturers have defined a maximum erucic acid content of less than 0.1% in relation tothe total fat as an internal quality target. The erucic acid content must be below 0.3% of the total fat content in order to maintain a sufficient distance to the legal maximum permitted level of 0.4% for infant formula and follow-on formula. According to the Diätverband e.V, manufacturers take precautionary measures to ensure that the erucic acid content in a product as consumed classified as infant formula products is always below 0.1% .

Investigations conducted by Stiftung Warentest on rapeseed oils[6] have revealed erucic acid contents of up to 0.2%.

At the time of this Opinion, no representative data were available for the BfR on current erucic acid levels in oils that are used among other things, for the preparation of baby food.

However, upon request, the BVL subsequently provided a data set on erucic acid contents in rapeseed oils for the BfR. The evaluation of the individual data showed a mean value for the

[6] Stiftung Warentest, Rapsöl im Test, test 11/2018.

samples included (n = 984) of 0.26% erucic acid and a median of 0.2%, as well as erucic acid content of 0.5% and 0.62% in the 90th and 95th percentile, respectively.

Additionally, data on erucic acid levels in fish and fish products were also made available. The evaluation of salmon samples (n = 26) resulted in a mean value of 0.11% and a median of 0.08% erucic acid.

3.1.4.3.3 Conclusions

The analytical results from the food monitoring programmes and the information provided by Diätverband e.V. on erucic acid contents in infant formula and follow-on formula clearly show that the levels are significantly below the legal maximum permitted level of 0.4% in relation to the total fat content.

For processed cereal-based food and other baby food, no legal maximum permitted erucic acid levels in the end product are currently defined by law, but the data available for these product groups also indicate erucic acid levels below 0.4% of the total fat content.

According to the Diätverband e.V., manufacturers of food for infants and young children also give their upstream suppliers maximum limits for erucic acid in rapeseed oils and oil mixtures , with the aim of ensuring that legal requirements are appropriately met. The erucic acid levels are mostly below the legally defined maximum permitted level for infant and follow-on formula of 0.4% of the total fat in these products, and in any case below the maximum permitted level of 2% for vegetable oils except camelina oil, mustard oil and borage oil.

3.1.4.4 Estimation of the exposure to erucic acid considering differentmodels

In the following sections, the data available from the various sources are integrated into four model calculations, in order to estimate the potential dietary intake of erucic acid, taking into account various assumptions.

3.1.4.4.1 Model 1: Erucic acid intake via products that exhaust the maximum permitted level for erucic acid of 0.4% of the total fat content

In this first model, it is assumed that a four-month-old female infant, body weight 6.4 kg (WHO growth standard), consumes 800 ml of infant formula daily. It is further assumed that the fat content for this infant formula has a maximum erucic acid content of 0.4% of the total fat as defined in Delegated Regulation (EU) 2016/127 (2.6 to 4.2 g/100 ml). Based on these assumptions, this results in an intake of 13 to 21 mg of erucic acid per kg of body weight per day.

3.1.4.4.2 Model 2: Infants within the first half year of life fedexclusively with infant formula containing a realistic erucic acid content of the fat content

For the following exposure assessment of infants aged between 0 and 6 months, it is assumed that these are fed exclusively with infant formula. This assumption is based on the recommendation that breastfeeding alone or, as an alternative, feeding with industrially produced infant formula is considered as an adequate diet for the majority of infants during the first six months of life (Koletzko et al. 2016). Accordingly, the exposure assessment has been performed for the intake of infant formula on the basis of the mean erucic acid contents, rest on the energy requirements for infants as determined by Butte (Butte 2005), as well as the 95th percentile of body weights by sex and age (van Buuren et al. 2012) (**table 5**). It has

been avoided to present the average intake (P50) with average body weights (P50) , since the resulting intake values are identical to those for high consumers (P95).

Table 5: Derived consumption data and intake of erucic acid in infant formula for male and female infants aged up to 6 months

Sex	Age[1]	Intake of infant formula[2]	Body weight[3]	Erucic acid intake[4]
Male	1	924	5.3	3.3
	2	983	6.2	3.0
	3	1014	7.1	2.7
	4	971	7.9	2.3
	5	1044	8.6	2.3
	6	1103	9.3	2.3
Female	1	836	5	3.2
	2	895	5.8	2.9
	3	952	6.6	2.7
	4	928	7.3	2.4
	5	982	7.9	2.4
	6	1032	8.5	2.3

[1] Age in months
[2] Specified as the 95th percentile in ml/kg bw/day; based on *Butte et al. (2005)*
[3] Specified as the 95th percentile in kg; based on *van Buuren et al. (2012)*
[4] Specified in mg/kg bw/day; content according to table 4: 0.002%

Based on the assumed erucic acid content in infant formula, the erucic acid intake is between 2.3 and 3.3 mg/kg body weight/day when infants up to 6 months are exclusively fed with such a formula (**table 5**). In relation to body weight, the erucic acid intake decreases with increasing infant age, as a result of the increase in body weight over time.

3.1.4.4.3 Model 3: Infants within the second half of the first year of life fed with infant and follow-on formula and baby food, containing a realistic erucic acid content of the fat content

For children aged between 6 and 12 months, data on the consumption of infant formula and follow-on formula are available from the VELS study, which has been used for the present estimation of exposure to erucic acid. For the group of normal consumers (median of daily consumption) and high consumers (P95 of daily consumption), the intake of erucic acid based on the median erucic acid contents in the corresponding food groups is shown in **table 6**. Of the 95 children in this age group, 80 children consumed infant formula or follow-on formula resulting in a dietary intake of 0.56 mg/kg body weight/day erucic acid for normal consumers (1.20 mg/kg body weight/day for high consumers).

In addition to the consumption of infant and follow-on formula, erucic acid intake can also occur due to the consumption of baby food. As a potential erucic acid source from baby food, processed cereal-based foods with milk and baby foods containing a portion of meat, fish, vegetables or cereals were included in the analysis. The median intake of erucic acid from baby food was calculated to be 3.29 mg/kg body weight/day for normal consumers (6.73 mg/kg body weight/day for high consumers). To determine the total intake of erucic acid from infant and follow-on formula as well as baby food, the intakes of both items has been-summed up for the consumers of baby food at an individual level, since these exhibit the highest contributions to the intake. For normal consumers, a value of 3.83 mg/kg body weight/day, and 7.06 mg/kg body weight/day for high consumers has been calculated (**table 6**).

Table 6: Exposure ofof infants aged between 6 and 12 months, in mg/kg body weight/day (basis only consumers), to erucic acid from infant formula and follow-on formula, as well as baby food

	N	Erucic acid intake[1]	
		Normal consumers	High consumers
Infant and follow-on formula	80	0.56	1.20
Baby food	89	3.29	6.73
Total (basis consumers of baby food)	89	3.83	7.06

[1] Specified in mg/kg bw/day

In addition, some manufacturers recommend adding 1 or 2 teaspoons (tsp) of rapeseed oil to baby food. In order to take this additional source of exposure into account while also illustrating the variability concerning the composition of baby food given daily to the infant, a simplified estimate is made (addition of one tsp rapeseed oil is assumed).

There is reliable evidence that in practice erucic acid levels in rapeseed oils or oils labelled as suitable for the dietary needs of infants and young children (so-called 'baby food oils') can be assumed to be below 0.5% (EFSA 2016), with other sources of information placing them below 0.2% (see section 3.1.4.3.2).

In order to determine the intake of erucic acid represented by one tsp of rapeseed oil, the *upper bound* value from EFSA of 5215 mg of erucic acid per kg rapeseed oil (0.52%) was applied (EFSA 2016). According to the 'MONICA Mengenliste', which specifies weights in grams for typical household measures, a teaspoon of oil corresponds to 3 g of oil (BLE 2019). With a mean body weight of 9 kg in this age group, this would result in an additional erucic acid intake of 1.74 mg/kg body weight/day (**table 7**).

If an erucic acid content of 0.2% in rapeseed oil is assumed, the addition of one teaspoon of oil would result in an additional intake of erucic acid of 0.66 mg/kg body weight/day, assuming a mean body weight in this age group of 9 kg (median body weights according to VELS, **table 7**).

Table 7: Exposure of infants aged between 6 and 12 months, in mg/kg body weight/day (basis only consumers), to erucic acid by addition of 1 tsp rapeseed oil

	N	Erucic acid intake[1]	
		Normal consumers	High consumers
Baby foodss[2]	89	3.29	6.73
Addition of 1 tsp rapeseed oil[3] (erucic acid content 0.52%)		1.74	1.74
Addition of 1 tsp rapeseed oil[3] (erucic acid content 0.2%)		0.66	0.66

[1] Specified in mg/kg bw/day
[2] Details from table 6
[3] Assumption

3.1.4.4.4 Model 4: Infants within the second half of the first year of life fedfed with self-prepared baby food

In contrast to the exposure assessment from model 3, for which real consumption data (VELS study) and realistic data for industrially produced baby foods were taken into account

for the diets of infants aged between 6 and 12 months, another model is now applied to examine an alternative scenario, in which baby food is self-prepared. To calculate the potential erucic acid intake resulting from self-prepared baby food , recipe templates for three baby food meals have been used exemplarily from the 'Dietary schedule for the first year of life' published by the FKE (**table 8**).

Table 8: Baby food according to the dietary schedule for the first year of life from the Research Institute of Child Nutrition in Dortmund (FKE): Recipes for self-preparation (according to figure 2 in Alexy 2016)

First meal Baby food based on vegetable, potato and meat	**Second meal** Cereal-based baby food with milk	**Third meal** Cereal-based baby food with fruit
90–100 g vegetables	200 g milk	20 g cereal flakes
40–60 g potatoes	20 g cereal flakes	90 g water
15–20 g fruit juice	20 g fruit juice/puree	100 g fruit
20–**30 g** meat or **fish***		
8–**10 g rapeseed oil**		**5 g rapeseed oil**

* 1 or 2 times a week instead of meat

The FKE's recommendation to add rapeseed oil to commercial baby food products thus also applies for self-prepared baby food meals (Alexy 2016). As shown in **table 8**, 8–10 g of rapeseed oil are recommended for the baby food based on vegetable, potato and meat, and 5 g for the cereal-based baby food withfruit.

In the following scenario for self-prepared baby food, an erucic acid content of 0.2% (2 g/kg) is assumed for the rapeseed oil used (see also section 3.1.4.4.3).

For the preparation of baby food, the use of (high-fat) sea fish instead of meat once or twice a week is also recommended (Alexy 2016). In particular high-fat sea fish, such as herring, salmon and mackerel, can also contribute to the intake of erucic acid (EFSA 2016).

For the model calculation, salmon was selected as the ingredient for preparing the first meal. In its opinion, EFSA points out the lack of available data on erucic acid contents in fish and fish products. For this reason, recent analytical results of erucic acid in salmon (Atlantic salmon fillets (farmed)) were used from the 'seafood data' provided by the Institute of Marine Research (IMR). The erucic acid content in salmon (2020) is specified as 90 mg/100 g and is comparable with the *upper bound* value for *salmon spp.* (992 mg/kg) in the EFSA opinion from 2016 (EFSA 2016; IMR 2020).

Assuming that baby food is prepared according to the recommendations or recipes from the FKE ('Dietary schedule for the first year of life'), 15 g of rapeseed oil and 30 g of fish would be consumed daily through the complete feedingof the three self-prepared baby food meals (figure 2 from Alexy et al. 2016). This corresponds to an intake of 30 mg of erucic acid via the rapeseed oil, assuming an erucic acid concentration of 0.2%. Consumption of the salmon would result in the intake of 27 mg of erucic acid if the content in fish is 90 mg per 100 g. Assuming a mean body weight for the infant aged between 6 and 12 months of 9 kg, this would result in an erucic acid intake via rapeseed oil and salmon from the three self-prepared meals of 6.3 mg/kg body weight/day (**table 9**).

Table 9: Exposure ofinfants aged between 6 and 12 months in mg/kg body weight/day to erucic acid via rapeseed oil and salmon from self-prepared baby food meals according to recipe templates from the FKE (Alexy 2016).

Baby food meal[1]	Erucic acid		
	Source[2]	Content[3]	Intake[4]
First meal	10 g rapeseed oil	0.2%	2.2
	30 g fish (salmon)	0.09%	3
Second meal	–	–	
Third meal	5 g rapeseed oil	0.2%	1.1
Total erucic acid intake			6.3

[1] Cf. table 8
[2] Relevant erucic acid source in the recipe (see table 8)
[3] Assumptions according to details from 3.1.4.3.2 and 3.1.4.4.4
[4] Specified in mg/kg body weight/day

3.2 Risk characterisation

3.2.1 Model 1: Erucic acid intake via products that exhaust the maximum permitted level for erucic acid of 0.4% of the total fat content.

In the worst-case model, it was assumed that a four-month-old infant with a body weight of 6.4 kg drinks 800 ml of infant formula per day. Assuming the fat content in infant formula as specified in Delegated Regulation (EU) 2016/127 and further assuming the maximum erucic acid content of 0.4% of the total fat content, this would result in a daily erucic acid intake of 13 to 21 mg per kg body weight/day. When comparing with the tolerable daily intake (TDI) for erucic acid of 7 mg/kg body weight/day derived by EFSA, the intakes calculated here would result in exceeding the TDI by a factor of three (**table 10**).

However, exposure assessments made on the basis of consumption data and practice-relevant erucic acid contents show that the above described scenario is a worst-case model.

3.2.2 Model 2: Infants within the first half year of life fed exclusively with infant formula containing a realistic erucic acid content of the fat content

In the exposure assessment in model calculation 2,it was assumed that infants are fed exclusively with infant formula from birth to the age of 6 months.

The intake of erucic acid by the consumption of infant formula and follow-on formula ranges between 2.3 and 3.3 mg/kg body weight/day (**table 5**).The intake decreases with increasing age due to the increase in body weight. When comparing the intakespresented in table 5 with the TDI for erucic acid of 7 mg/kg body weight/day, this represents a TDI exhaustion of 33–47%.

The intakes calculated here and the resulting TDI exhaustion are significantly lower than the exposure of 13 and 21 mg/kg body weight/day as presented in model calculation 1 (**table 10**). This is based on the lower mean erucic acid content of 0.0019% from the BVL data (infant formula products), instead of assuming a value for the erucic acid content equal to the maximum permitted level of 0.4% of the total fat content (erucic acid contentr 0.134% if 0.4% in 33.6 g fat, or 0.085% if 0.4% in 21.2 g fat).

Based on the available data on the levels of erucic acid, the BfR concludes from the exposure assessment as performed in the model calculation 2, that for infants aged between 0 and 6 months, the intake of erucic acid via the foods examined and considering the existing uncertainties (cf. section 3.3) is not currently associated with an elevated health risk.

3.2.3 Model 3: Infants within the second half of the first year of life fed with infant and follow-on formula and baby food, containing a realistic erucic acid content of the total fat

For infants aged six months and older, an intake of erucic acid can result from the consumption of infant formula and follow-on formula, as well as from the consumption of baby food. The exposure assessment showed an intake of erucic acid from baby food alone of 3.3 mg/kg body weight/day for normal consumers (high consumers 6.7 mg/kg body weight/day). The total intake of erucic acid via infant and follow-on formula and baby food (total) was 3.8 mg/kg body weight/day for normal consumers and 7.1 mg/kg body weight/day for high consumers.

In the normal consumers group, the TDI for erucic acid of 7 mg/kg body weight/day is not exhausted (47% and 55%, respectively) for both exposure scenarios (baby food or infant/follow-on formula and baby food (total)). However, for high consumers of infant formula, follow-on formula and baby food (total), the TDI is slightly exceeded (7.1 mg/kg body weight/day).

If it is assumed that 1 tsp rapeseed oil with an erucic acid content of 0.52% (EFSA *upper bound*) is added to the baby food, then the erucic acid intake for normal consumers increases to 5.03 mg/kg body weight/day. This exposure would not lead to an exhaustion of the TDI (72%). For high consumers of baby food with an addition of 1 tsp of rapeseed oil would increase the erucic acid intake to 8.5 mg/kg body weight/day and thus exceeding the TDI (121%).

Assuming a more realistic erucic acid content of 0.2% in the added rapeseed oil (see 3.1.4.3.2), then the total intake of erucic acid for normal consumers and high consumers of baby food is 4 and 7.4 mg/kg body weight/day, respectively. The TDI of 7 mg/kg body weight/day would thus only be slightly exceeded by high consumers of baby food with the addition of 1 tsp rapeseed oil (105%; **table 10**).

Based on the available data for erucic acid levels, the BfR, considering the exposure assessment as performed here (model 3), concludes that for both normal consumers and high consumers of infant and follow-on formula and baby food (total) aged between 6 and 12 months, the intake of erucic acid via the foods considered and taking into account the existing uncertainties and data gaps is not currently associated with an increased health risk.

However, a health risk resulting from the intake of erucic acid can arise for infants aged between 6 and 12 months if high consumers of baby food receive an extra tsp rapeseed oil with erucic acid content of 0.2% or more in their baby food.

3.2.4 Model 4: Infants within the second half of the first year of life fed with self-prepared baby food

In the fourth model calculation, it was assumed that an infant with an average body weight of 9 kg consumes self-prepared baby food meals according to recipe templates from the FKE (Alexy 2016), and therefore has an erucic acid intake of 57 mg (6.3 mg/kg body weight/day) from the ingredients of salmon (30 g) and rapeseed oil (15 g). The TDI of 7 mg/kg body weight/day would thus be exhausted by 90% (**table 10**).

After considering this exemplary scenario, it can therefore not be assumed that there is an elevated health risk for infants aged between 6 and 12 months if the assumed quantities of salmon or rapeseed oil with erucic acid contents of 0.09% and 0.2% (respectively) are consumed via baby food. However, erucic acid contents in the foods considered could contribute to an exposure level exhausting or exceeding the TDI.

Table 10: Intake of erucic acid for infants aged between 0 and 12 months in mg/kg body weight/day, and exhaustion of the TDI of 7 mg/kg body weight/day using the four models calculations.

Model	Age[1]	Product group	Erucic acid content[2]	Intake[3]		Exhaustion of TDI[4]	
1	0–6	Infant and follow-on formula only	0.4% related of the total fat[5]	13–21		187–300	
2*	0–6	Infant and follow-on formula only	0.002%[6]	2.3–3.3		33–47	
3*	6–12			NC[a]	HC[b]	NC[a]	HC[b]
		Infant and follow-on formula	As per table 4	0.6	1.2	8	17
		Baby food	As per table 4	3.3	6.7	47	96
		Total (basis: consumers of baby food)	As per table 4.	3.8	7.1	55	101
		Baby food +1 tsp rapeseed oil	As per table 4 +0.52% in rapeseed oil	5.03	8.5	72	121
		Baby food +1 tsp rapeseed oil	As per table 4 +0.2% in rapeseed oil	4	7.4	57	105
4	6–12	Baby food meals with 30 g salmon and 15 g rapeseed oil	0.09% in salmon 0.2% in rapeseed oil	6.3		90	

[1] Age in months
[2] Specified in %
[3] Erucic acid intake in mg/kg body weight/day
[4] As a proportion of TDI in %, based on a TDI of 7 mg/kg body weight/day
[5] Legal maximum permitted level according to Delegated Regulation (EU) 2019/828
[6] Value according to table 4 (mean concentration of erucic acid)
[a] Normal consumers, [b] high consumers
* Consumption data included

3.3 Evaluation of the quality of available data

3.3.1 Evaluation of the data used for the exposure assessment (model 2 and 3)

At this point, it is emphasised again that only model 2 and 3 present exposure assessments based on consumption data and data on erucic acid content

For this purpose, numerous assumptions were made in regard to the fat content of infant formula and follow-on formula, as well as baby food, which could lead to both an underestimation or overestimation of erucic acid contents. However, research conducted for this Opinion has revealed only a low level of variability in the fat content of the individual food groups considered. In addition, the conservative approach of using the highest fat content in each case was chosen, meaning that an overestimation of erucic acid contents can be assumed.

EFSA has calculated levels of erucic acid in rapeseed oil from 1285 mg/kg (lb) to 5215 mg/kg (ub), although 80% of values were below the detection and quantification limits (EFSA 2016). In the food group '*Food for infants and small children*', relatively low levels of erucic acid were found, ranging from 77 (lb) and 86 (ub) mg/kg for 'Ready-to-eat meals for infants and young children' (n = 156) to 220 (lb) and 290 (ub) mg/kg for 'Infant formulas, powder' (n = 218). These data on erucic acid content in food are mainly based on data from Germany, in addition to other data from Austria, Cyprus, Czech Republic, Denmark, France, Hungary, Poland, Slovenia, Slovakia and United Kingdom. The average erucic acid exposure for infants aged from 0 to 12 months was specified as 1.8 (lb) and 2.6 (ub) mg/kg body weight/day. For frequent consumers, EFSA estimated exposure for infants at 4.1 (LB) and 5.7 (UB) mg/kg body weight/day. In comparison, the intake estimate made here for infant and follow-on formula as well as baby food for infants aged between 6 and 12 months, reveals slightly higher quantities of 3.8 mg/kg body weight/day for normal consumers and 7.1 mg/kg body weight/day for high consumers. In contrast, the intake for infants aged below 6 months in the present estimate are in similar range to those from EFSA, at 2.3 to 3.3 mg/kg body weight/day.

The exposure assessment made here for infants aged between 0 and 6 months was conducted based on energy and growth reference data from (Butte 2005) and (van Buuren et al. 2012). A consumption scenario developed by EFSA for exclusively formula-fed infants in the first four months of life (EFSA 2017) was not used due to this four-month limitation. However, if this consumption scenario from EFSA is used for the exposure assessment for infants in the first four months of life, then intake in these age groups increases marginally. In addition, the present exposure assessment relates to non breast-fed infants, whose diet consists solely of infant formula and follow-on formula. Intake may differ when breast milk or other types of foods are consumed.

In its opinion published in 2016, EFSA stated that breastmilk does contain erucic acid but at rather low levels. For Germany, a maximum content of 52.2 mg/l or 0.0052% (n = 40) was given based on work by Precht and Molkentin (1999). As a result, erucic acid intake would be higher compared to intake via infant and follow-on formula (mean erucic acid content 0.002%).

Recent studies on erucic acid contents in breast milk have revealed values from 0.1% to <0.3% in relation to the total fatty acid content depending on the milk production phase, and are thus comparable to the data from Precht and Molkentin (1999) (0.18% ±0.06% of total fatty acids) (Precht & Molkentin 1999; Thakkar et al. 2019; Yu et al. 2019; Dai et al. 2020).

Although the VELS study was carried out 16 years ago, it can be assumed that the diet of infants in Germany has not changed significantly. Evaluations of data from the DONALD study show that both the composition of baby food and total energy intake are not affected by historical trends (Hilbig & Kersting 2006; Foterek et al. 2014).

Finally, it should not be ignored that infants increasingly participate at least at normal family meals after being introduced to baby food and with increasing age. Thus, a further source for the intake of erucic acid could occur via other foodstuff as special foods for infants and young children, which have not been considered in the exposure assessment as conducted here.

In one model (model 1) considered in addition to the exposure assessments (model 2 and 3), it is assumed that the legal maximum permitted level of erucic acid of 0.4% of the total fat content in infant formula and follow-on formula is exhausted. However, the data provided by the monitoring authorities show that the erucic acid contents in product categories relevant for infant nutrition are indeed much lower. This model therefore overestimates the actual intakes. q.

In order to be able to take other sources of erucic acid into account, it was assumed in a fourth model calculation that an infant with an average body weight of 9 kg receives self-prepared baby food meals according to recipe templates s published by the FKE (Alexy 2016). The assumptions made in this model are based solely on recipe templates for self-preparing baby food. Content or consumption data are not available.

In the present calculation of erucic acid intake, only the ingredients salmon and rapeseed oil were considered, because these foods can exhibit high contents of erucic acid. The intake of erucic acid from other foods used in baby food (e.g. animal products (milk) or bakery wares(baby biscuits)) as well as breast milk is therefore also possible (EFSA 2016).

For infants aged between 6 and 12 months who would consume salmon and rapeseed oil with erucic acid contents of 0.09% and 0.2% (respectively) in self-prepared baby food, no exceedance of the TDI (90%) occurs. It can be assumed that additional sources of exposure, such as breast milk or other foods containing erucic acid, could contribute to an exhaustion of the TDI for this population group.

The erucic acid contents in fish and fish products vary depending on the type of fish, fat content and type of feed used. In this context, it should be noted that especially high-fat fish such as mackerel and herring can significantly contribute to the erucic acid intake (EFSA 2016; Sissener *et al.* 2018; IMR 2020; Vetter *et al.* 2020).

In addition, fish and fish products (e.g. fish oils) also contain cetoleic acid (C 22:1, n-11), which, as a monounsaturated fatty acid with a cis-double bond, represents an isomer of erucic acid-docosenoic acid. Relatively high levels of cetoleic acid (>1500 mg/100 g) are also found in high-fat cold-water fish (herring, mackerel and salmon), and in fish oils (IMR 2020; Vetter *et al.* 2020).

According to EFSA, the analytical separation of the docosenoic acids (C22:1) occuring in foods is often not achieved due to methodological limitations. Thus, there are uncertainties regarding the actual levels of erucic acid and other docosenoic acids (including cis and trans isomers) in foods such as fish and seafood (EFSA 2016).

3.3.2 Evaluation of the available toxicological data

The data available on the toxicology of erucic acid are very comprehensive, and a detailed toxicological assessment including any relevant uncertainties can be found in the EFSA opinion from 2016. Overall, numerous animal studies revealed pathological changes in the heart as well as other undesired effects after the intake of erucic acid (EFSA 2016).

In addition to erucic acid (C22, n-9), other docosenoic acids also exist in foods that can be consumed by infants and young children. For example, fish and fish products contain cetoleic acid, (C22:1, n-11). Results from animal experiments suggest that cetoleic acid (mostly in fish (herring) oil) can also cause undesirable effects in the heart (Beare-Rogers *et al.* 1972;

Ackman & Loew 1977; Forsyth *et al.* 1977; Loew *et al.* 1978; Schiefer *et al.* 1978; Schiefer *et al.* 1982). The available data on potential health risks of cetoleic acid in humans are insufficient and a final assessment is therefore not possible.

3.4 Recommendations for action

- As the calculations show, the exhaustion of the maximum permitted erucic acid content of 0.4% of theto total fat content in infant and follow-on formula, as specified in Delegated Regulation (EU) 2019/828, would clearly exceed the TDI for erucic acid of 7 mg/kg body weight/day .

  It is therefore recommended to examine how the total intake of erucic acid via these foodstuffs can be limited in such a way that an exceedance of the TDI for infants, according to the BfR's assumed worst-case model, is prevented. In this context, it is emphasised that the legal requirements for infant formula and follow-on formula in terms of their composition can be fulfilled with appropriate formulations of rapeseed oil and oils that do not naturally contain erucic acid. In this way, the total content of erucic acid of the total fat content in infant and follow-on formula can be influenced by suitable mixtures of rapeseed oil and erucic acid-free oils.

  For a four-month-old infant with a body weight of 6.4 kg (WHO growth standard) consuming 800 ml of infant formula (fat content 2.6 to 4.2 g/100 ml) daily, the TDI would not be exceeded up to a maximum erucic acid content of 0.1% of the total fat content.

- Besides erucic acid, other docosenoic acids (C22:1), especially cetoleic acid (C22:1, n-11) in fish oils, are present in edible oils and fats as well as other foodstuffs added with oil and fat . However, due to insufficient toxicological data, a comprehensive assessment of health risks that could be potentially associated with the oral intake of other docosenoic acids is currently not possible.

  The BfR therefore recommends improving the available toxicological data on these compounds in order to be able to consider them in future risk assessments. Furthermore, the BfR suggests including other docosenoic acids (C22:1) in addition to erucic acid in the analytical analysis, especially cetoleic acid (C22:1, n-11), which is found in high amounts in fish.

Further information on the subject of erucic acid from the BfR website

Erucic acid: BfR endorses proposed maximum levels, but foods with added fats should be restricted too
BfR Opinion no. 044/2018, dated 20 December 2018

https://www.bfr.bund.de/cm/349/erucic-acid-bfr-endorses-proposed-maximum-levels-but-foods-with-added-fats-should-be-restricted-too.pdf

4 Literature

Ackman R. G. and Loew F. M. (1977). The Effects of High Levels of Fats Rich in Erucic Acid (from Rapeseed Oil) or Cetoleic and Cetelaidic Acids (from Partially Hydrogenated

Fish Oil) in a Short-Term Study in a Non-Human Primate Species II. *Fette, Seifen, Anstrichmittel* **79:** 58-69.

Alexy U.; Hilbig, A. (2016). Update Säuglingsernährung. *Ernährungs Umschau* **12**

Banasiak U., Heseker H., Sieke C., Sommerfeld C., Vohmann C. (2005). Abschätzung der Aufnahme von Pflanzenschutzmittel-Rückständen in der Nahrung mit neuen Verzehrsmengen für Kinder. *Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz* **48:** 84-98.

Beare-Rogers J. L., Nera E. A., Craig B. M. (1972). Accumulation of cardiac fatty acids in rats fed synthesized oils containing C22 fatty acids. *Lipids* **7:** 46-50.

Bickel Susanne (2012). Ölpflanzen in Europa. *Biologie in unserer Zeit* **42:** 222-231.

BLE (Bundesanstalt für Landwirtschaft und Ernährung) (2019). Monica – Mengenliste von 1984/1985. Bundeszentrum für Ernährung (BZfE).

Bührer C.; Genzel-Boroviczény, O.; Jochum, F.; Kauth, T.; Kersting, M.; Koletzko, B.; Mihatsch, W.; Przyrembel , H.; Reinehr, T.; Zimmer, P. (2014). Ernährung gesunder Säuglinge - Empfehlungen der Ernährungskommission der Deutschen Gesellschaft für Kinder- und Jugendmedizin (DGKJ). *Monatsschrift fu?r Kinderheilkunde* **6:** 527-538.

Bundessortenamt (2019). Beschreibende Sortenliste Getreide, Mais, Öl- und Faserpflanzen, Leguminosen, Rüben, Zwischenfrüchte.

Butte Nancy F. (2005). Energy requirements of infants. *Public Health Nutrition* **8:** 953-967.

Dai X., Yuan T., Zhang X., Zhou Q., Bi H., Yu R., Wei W., Wang X. (2020). Short-chain fatty acid (SCFA) and medium-chain fatty acid (MCFA) concentrations in human milk consumed by infants born at different gestational ages and the variations in concentration during lactation stages. *Food and Function* **11:** 1869-1880.

DGE (Deutsche Gesellschaft für Ernährung) (2015). Evidenzbasierte Leitlinie - Fettzufuhr und Prävention ausgewählter ernährungsmitbedingter Krankheiten **2. Version**.

EFSA (European Food Safety Authority: EFSA Scientific Committee) (2017). Guidance on the risk assessment of substances present in food intended for infants below 16 weeks of age. *EFSA Journal* **15:** e04849.

EFSA (European Food Safety Authority: Scientific Panel on Contaminants in the Food Chain (CONTAM)) (2016). Erucic acid in feed and food. *EFSA Journal* **14(11): 4593:** 1-173.

Forsyth G. W., Carter K. E., Loew F. M., Ackman R. G. (1977). Heart mitochondrial metabolism after feeding herring oil to rats and monkeys. *Lipids* **12:** 791-796.

Foterek K., Hilbig A., Alexy U. (2014). Breast-feeding and weaning practices in the DONALD study: age and time trends. *Journal of Pediatric Gastroenterology and Nutrition* **58:** 361-367.

Heseker H., Oepping A., Vohmann C. (2003). Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln (VELS). *Forschungsbericht im Auftrag des Bundesministeriums für Verbraucherschutz, Ernährung und Landwirtschaft. Universität Paderborn*.

Hilbig Annett and Kersting Mathilde (2006). Effects of age and time on energy and macronutrient intake in German infants and young children: results of the DONALD study. *Journal of Pediatric Gastroenterology and Nutrition* **43:** 518-524.

IMR (Institute of Marine Research). (2020). Seafood data. https://sjomatdata.hi.no/#search/.

Kersting M., Kalhoff H., Lücke T. (2017). Von Nährstoffen zu Lebensmitteln und Mahlzeiten: das Konzept der Optimierten Mischkost für Kinder und Jugendliche in Deutschland. *Aktuel Ernahrungsmed 2* **42:** 304-315.

Koletzko B., Bauer C.-P., Cierpka M., Cremer M., Flothkötter M., Graf C., Heindl I., Hellmers C., Kersting M., Krawinkel M., Przyrembel H., Vetter K., Weißenborn A., Wöckel A. (2016). Ernährung und Bewegung von Säuglingen und stillenden Frauen. Aktualisierte Handlungsempfehlungen von „Gesund ins Leben – Netzwerk Junge

Familie“, eine Initiative von IN FORM. *Monatsschrift fu?r Kinderheilkunde* **164:** 765-789.

Loew F. M., Schiefer B., Laxdal V. A., Prasad K., Forsyth G. W., Ackman R. G., Olfert E. D., Bell J. M. (1978). Effects of plant and animal lipids rich in docosenoic acids on the myocardium of cynomolgus monkeys. *Annals of Nutrition and Metabolism* **22:** 201-217.

Precht D. and Molkentin J. (1999). C18:1, C18:2 and C18:3 trans and cis fatty acid isomers including conjugated cis delta 9, trans delta 11 linoleic acid (CLA) as well as total fat composition of German human milk lipids. *Nahrung* **43:** 233-244.

Schiefer B., Loew F. M., Laxdal V., Prasad K., Forsyth G., Ackman R. G., Olfert E. D. (1978). Morphologic effects of dietary plant and animal lipids rich in docosenoic acids on heart and skeletal muscle of cynomolgus monkeys. *American Journal of Pathology* **90:** 551-564.

Schiefer H. B., Hancock D. S., Loew F. M. (1982). Long-term effects of partially hydrogenated herring oil on the rat myocardium. *Drug Nutr Interact* **1:** 89-102.

Sissener Nini H., Ørnsrud Robin, Sanden Monica, Frøyland Livar, Remø Sofie, Lundebye Anne-Katrine (2018). Erucic Acid (22:1n-9) in Fish Feed, Farmed, and Wild Fish and Seafood Products. *Nutrients* **10:** 1443.

Thakkar Sagar K., De Castro Carlos Antonio, Beauport Lydie, Tolsa Jean-François, Fischer Fumeaux Céline J., Affolter Michael, Giuffrida Francesca (2019). Temporal Progression of Fatty Acids in Preterm and Term Human Milk of Mothers from Switzerland. *Nutrients* **11:** 112.

van Buuren Stef, Schönbeck Yvonne, van Dommelen Paula (2012). Collection, collation and analysis of data in relation to reference heights and reference weights for female and male children and adolescents (0–18 years) in the EU, as well as in relation to the age of onset of puberty and the age at which different stages of puberty are reached in adolescents in the EU. *EFSA Supporting Publications* **9:** 255E.

Vetter W., Darwisch V., Lehnert K. (2020). Erucic acid in Brassicaceae and salmon – An evaluation of the new proposed limits of erucic acid in food. *NFS Journal* **19:** 9-15.

Yu Jiahui, Yuan Tinglan, Zhang Xinghe, Jin Qingzhe, Wei Wei, Wang Xingguo (2019). Quantification of Nervonic Acid in Human Milk in the First 30 Days of Lactation: Influence of Lactation Stages and Comparison with Infant Formulae. *Nutrients* **11:** 1892.

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the States (‘Laender’) on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.