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## Erucic acid: BfR endorses proposed maximum levels, but foods with added fats should be restricted too

BfR Opinion No 044/2018 of 20 December 2018

Erucic acid occurs in vegetable oils and fats. It is a natural component of plant seeds of the *Brassicaceae* family (crucifers such as rape and mustard). Chemically, it is a long-chain, simple, unsaturated omega-9 fatty acid.

High levels of erucic acid in food can impair health. The health-damaging effects of erucic acid include fatty degeneration of the heart (myocardial lipidosis), during which fats (lipids) accumulate in the heart tissue. This may result in reduced contractility of the heart muscle which may become weaker. The lipidoses triggered by erucic acid are reversible.

The maximum levels for erucic acid in foods are regulated in EU Regulation (EC) No. 1881/2006. The maximum level is the legally established maximum permissible concentration of a substance in food, for example. It is a limit value determined by risk management which serves among other things as a trading standard and which can be achieved through good manufacturing practice. It is not a health based limit value, however, and it says nothing about whether an exceedance of the levels poses a health risk. The tolerable daily intake (TDI) is used to make a statement on health impairment, while also serving as a basis for deriving maximum levels.

The EU Commission has proposed to revise the existing maximum levels for erucic acid and to consider a reassessment of its maximum levels in foods that have not been regulated up to now. The European Food Safety Authority (EFSA) assessed the health risks posed by the consumption of foods containing erucic acid in 2016. The German Federal Institute for Risk Assessment (BfR) reviewed the proposal of the EU Commission on the basis of this data.

The EU Commission recommends the following maximum levels:

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| ➤ Vegetable oils and fats:   | 20 g/kg ( <b>currently:</b> 50 g/kg)      |
| ➤ Foods with added vegetable oils and fats (excluding infant formula and follow-on formula): | N/A ( <b>currently:</b> 50 g/kg)          |
| ➤ Infant formula and follow-on formula:  | 4 g/kg ( <b>currently:</b> 10 g/kg)       |
| ➤ Mustard:   | 30 g/kg ( <b>currently</b> no max. level) |

The BfR regards the proposed maximum levels as suitable to lower consumers' intake of erucic acid from food. The BfR also advocates the determination of a maximum level for mustard.

Contrary to the currently valid regulation, maximum levels for foods with added vegetable oils and fats, such as fine bakery wares (cakes, biscuits, muffins, waffles etc.), are no longer contained in the proposal of the EU Commission. It can be taken from the EFSA opinion on erucic acid, however, that the tolerable daily intake can be exceeded in particular by small children who consume large quantities of these foods. The BfR therefore recommends limiting the levels of erucic acid in this food category also in future.

## 1 Object of the assessment

Maximum levels currently exist for erucic acid in certain foods in line with Regulation (EC) No. 1881/2006. The EU Commission is considering a reduction of the maximum levels and the determination of maximum levels for foods not regulated up to now. The German Federal Institute for Risk Assessment (BfR) has drafted an opinion on the draft proposal of the EU Commission.

## 2 Result

The European Food Safety Authority (EFSA) assessed the health risks posed by the consumption of foods containing erucic acid in 2016 (EFSA 2016). The German Federal Institute for Risk Assessment (BfR) reviewed the proposal of the EU Commission on the basis of this data. In the view of the BfR, the proposed maximum levels are suitable to lower consumers' uptake of erucic acid from food.

### (1) *Maximum levels of erucic acid in vegetable oils and fats:*

From a toxicological point of view, the reduction of the maximum levels in vegetable oils and fats as a significant exposure source to 20 g/kg is to be considered a positive measure to reduce the probability of exceeding the tolerable daily intake (TDI<sup>1</sup>) in population groups with a high intake.

### (2) *Maximum levels of erucic acid in foods with added vegetable oils and fats (except for infant formula and follow-on formula):*

Primarily this food category, which also includes "Fine bakery wares" such as biscuits and cakes, makes a significant contribution towards exposure to erucic acid, according to estimations made by EFSA, especially in the "Other children" population group (EFSA 2016). In its statement, EFSA saw a health risk for younger population groups in particular "Young individuals" (EFSA 2016).

The limit of the maximum levels in this food category that has applied up to now should be regarded as a significant contribution towards reducing the likelihood of exceedance of the TDI value by the relevant population groups. From a toxicological point of view, the BfR therefore recommends that levels of erucic acid be effectively restricted for this category in future too.

### (3) *Maximum levels of erucic acid in infant formula and follow-on formula:*

The considerable reduction to 4 g/kg is endorsed by the BfR from a toxicological point of view because EFSA has estimated exceedance of the TDI particularly among "Infants" in certain exposure scenarios.

### (4) *Establishment of a maximum limit of erucic acid in mustard:*

As mustard has high levels of erucic acid, thereby making a significant contribution towards overall exposure to this compound, the BfR regards the maximum level ruling for mustard as suitable from a toxicological point of view to counteract exceedance of the TDI value by the relevant population groups, and reduce possible health risks.

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<sup>1</sup> The TDI is the estimated quantity of a substance which a person can ingest on every day of their entire life without the expectation of any health impairments.

### 3 Justification

#### 3.1 Possible hazard source (agent)

EFSA has identified the heart as the primary target organ for toxic effects of erucic acid (EFSA 2016). The health-damaging effects include myocardial lipidosis (lipid storage disease), which results in abnormal accumulation of lipids (“fatty degeneration”) in the heart tissue. Myocardial lipidoses can be associated with a reduction of the contractile power of the heart muscle. The lipidoses triggered by erucic acid are reversible.

Further examinations in various animal models also showed that exposure to high doses of erucic acid on cellular level leads to mitochondrial damage and to a disorganisation of myofibrils<sup>2</sup> which can be associated with myocardial necroses (death of cells in the heart tissue) and fibrosis (EFSA 2016). Due to the inadequate data situation, EFSA concluded that no final assessment can be made regarding a possible genotoxic<sup>3</sup> and/or carcinogenic potential of erucic acid (EFSA 2016).

The development of a lipidosis as a sensitive endpoint was used to derive a “*Health-based guidance value*”. From data of various animal studies, a maximum NOAEL (*No Observed Adverse Effect Level*) dose of 0.7 g erucic acid per kg body weight (bw) and day at which no negative effects were observed was determined for myocardial lipidosis (EFSA 2016). Based on this NOAEL, a TDI value for erucic acid of 7 mg/kg bw and day was derived using a safety factor of 100.

Based on this TDI value, EFSA evaluated in 2016 the risk which can be connected with the uptake of erucic acid via food for various population groups and in various exposure scenarios (*lower bound* (LB), *upper bound* (UB) and *medium bound* (MB)) (EFSA 2016). Data on nutrition-related exposure showed that the mean uptake of erucic acid through food is between 0.3 (LB) and 4.4 (UB) mg/kg bw and day across all age groups and therefore below the TDI. Among high consumers (95<sup>th</sup> percentile, P95), exposure was highest for “*Infants*” at 1.7 (LB) to 7.4 (UB) mg/kg bw and day and “*Other children*” at 2.1 (LB) to 9.5 (UB) mg/kg bw and day (EFSA 2016). This means that the TDI (7 mg/kg bw and day) can be exceeded by high consumers in the above-mentioned age groups. For this reason, EFSA identified a possible health risk here, especially for younger population groups “*Young individuals*” (EFSA 2016).

#### 3.2 Maximum EU Commission levels for erucic acid in food

To protect public health, the goal of Regulation (EC) No.1881/2006 is to restrict the level of contaminants (undesired substances) to toxicologically acceptable values. For contaminants with which the current exposure of the population or endangered population groups is close to or in excess of the tolerable intake level, the maximum levels must be set *as low as reasonably achievable* (ALARA) through good agricultural, fishing and manufacturing practice. The lowest maximum levels which can be achieved through the strict selection of the raw materials used in the manufacture of foods for infants and small children should be set in order to protect the health of this endangered population group.

Maximum levels of erucic acid in certain foods were established in Regulation (EU) No. 696/2014 amending Regulation (EC) No. 1881/2006 under Item 8.1 “Erucic acid”. Accordingly, the following maximum levels for

- Vegetable oils and fats: 50 g/kg

<sup>2</sup> Many myofibrils join together to form a muscle fibre.

<sup>3</sup> A genotoxic substance can alter genetic makeup.

- Foods with added vegetable oils and fats (except for infant formula and follow-on formula): 50 g/kg
- Infant formula and follow-on formula: 10 g/kg.

have applied up to now.

The EU Commission has proposed that the existing maximum levels for erucic acid be reduced and that the possibility of determining maximum levels for foods that have not been regulated up to now be examined. The proposal contains the following recommended maximum levels:

- Vegetable oils and fats: 20 g/kg
- Infant formula and follow-on formula: 4 g/kg
- Mustard: 30 g/kg (whole weight)

Maximum levels for foods with added vegetable oils and fats are no longer included in the proposal as it stands.

EFSA assessed the health risks posed by exposure to erucic acid from food in 2016 (EFSA 2016). The BfR evaluated the proposal of the EU Commission on the basis of this data. In the view of the BfR, the proposed maximum levels are suitable to lower consumers' uptake of erucic acid from food.

### 3.2.1 Maximum levels of erucic acid in vegetable oils and fats

From content data which EFSA took into consideration in its opinion, it was established that within the food group of vegetable oils and fats, the highest levels of erucic acid were found in oils of several varieties of mustard and rape (> 500 g/kg), whereas relatively low levels of 2.41 g/kg were measured in other rape varieties, such as *canola* (EFSA 2016). The contribution of edible oils, such as rapeseed oil itself, to the foodborne exposure of consumers to erucic acid was estimated to be relatively limited (EFSA 2016). However, vegetable oils and fats of this type are used in particular in the manufacture of foods which in turn make up a large proportion of overall consumer exposure to erucic acid, which include "*Fine bakery wares*" such as "*Biscuits*" and "*Pastries and cakes*". These vegetable oils and fats are also used in the manufacture of "*Food for infants and small children*" and "*Infant formulae, powder*", which again contribute to a large extent to the exposure of infants to erucic acid (EFSA 2016).

Against this background, the BfR endorses the reduction of maximum levels of erucic acid in vegetable oils and fats to 20 g/kg, as this leads to a reduction of the intake of this undesired food component among the population in general. The data provided in the EFSA assessment shows that these values can be complied with by selecting suitable *Brassicaceae* (crucifer) varieties with low levels of erucic acid (EFSA 2016). Plant varieties of this kind were developed especially for plant seed oil production and are used in most countries (also in the EU). Therefore, the newly defined maximum level for erucic acid of 20 g/kg makes good sense, especially for vegetable oils and fats widely used in large quantities in food production, e.g. rapeseed oil.

It was also pointed out in the draft that exceptions are possible in the determination of maximum levels of erucic acid in vegetable oils and fats, provided they can be justified by the suitable data. In this regard, production companies have raised the objection that several rarely used vegetable oils such as *camelina oil* and *borage oil* currently exceed the recommended highest level of erucic acid of 20 g/kg. The EU vegetable oil and proteinmeal industry association (FEDIOL) reports erucic acid levels of between 25.50 (min.) and 45.07 (max.) g/kg in camelina oil, for example.

As some data is missing which could enable an estimation of exposure from these rarely used vegetable oils, no conclusive assessment of their contribution towards overall intake can be made.

### 3.2.2 Maximum levels in foods with added vegetable oils and fats

Maximum levels for foods with added vegetable oils and fats are no longer contained in the proposal of the EU Commission as it stands.

It can be taken from the EFSA opinion on erucic acid that in particular “*Fine bakery wares*” which belong to the group of “Foods with added vegetable oils and fats” make a great contribution towards exposure to erucic acid, especially in the “*Other children*” population group (EFSA 2016). This is explained by the high consumption and great variety of this food category (e.g. as cakes, muffins, waffles, biscuits etc.). With 9.5 mg erucic acid/kg bw and day, exceedances of the TDI of 7 mg/kg bw and day also occur in these population groups, especially in scenarios for high consumers (P95) of foods with high levels of erucic acid (UB) (EFSA 2016).

The limitation of the maximum levels permitted in this food category that have applied up to now should therefore be regarded as making a significant contribution towards the avoidance of an exceedance of the TDI value for the relevant population groups. Therefore, it is recommended from a toxicological point of view when establishing maximum levels to ensure that the levels of erucic acid are also effectively limited in the future for this category.

### 3.2.3 Maximum levels in infant formula and follow-on formula

A reduction of the maximum level of erucic acid in infant formula and follow-on formula from 10 g/kg to 4 g/kg is proposed in Item 8.1.2. (formerly 8.1.3. in Regulation (EU) No. 696/2014).

According to the exposure estimation made by EFSA, a possible health risk is seen for “*Young individuals*” in particular in connection with high exposure to erucic acid (EFSA 2016). For the population group “*Infants*”, the food group “*Food for infants and small children*” contributes the most to exposure to erucic acid (EFSA 2016). For high consumers (95<sup>th</sup> percentile) in the “*Infants*” group, daily intake is between 1.7 (LB) and 7.4 (UB) mg/kg bw and day and for “*Other children*” between 2.1 (LB) and 9.5 (UB) mg/kg bw and day. This means that the TDI can be exceeded by high consumers from these population groups through the consumption of foods with high levels of erucic acid (EFSA 2016).

This is of particular importance for the diet of children who are not or cannot be breastfed, as children in this group are fed exclusively with infant formula and follow-on formula. Infants and small children constitute a particularly vulnerable group in the population which, moreover, has a higher dietary intake in relation to body weight. For this reason, Regulation (EC) No. 1881/2006 requires that the lowest maximum limits which can be achieved through the strict selection of raw materials for the manufacture of foods for infants and small children be established in order to protect the health of this endangered population group.

For this reason, the BfR endorses the lowering of the maximum level of erucic acid in infant formula and follow-on formula from 10 g/kg to 4 g/kg as a suitable measure to limit exposure to erucic acid via foods of this kind in future, and to counteract exceedances of the TDI in the population groups mentioned.

### 3.2.4 Maximum levels in mustard

It is proposed in Item 8.1.3. that mustard is included in the maximum levels regulation as a new food group with 30 g/kg (whole weight).

Up to now, no maximum level has been established for mustard in Regulation (EC) No. 1881/2006. It can be seen from the EFSA opinion of 2016 that various mustard seeds and corresponding mustard products have particularly high levels of erucic acid (EFSA 2016). Above all, this is due to the fact that varieties with high levels of erucic acid are used for mustard seed production (EFSA 2016). Especially for adults, the consumption of condiments such as "*Mustard, mild*" contributes greatly to overall exposure to erucic acid (EFSA 2016).

In view of the potentially high contribution of mustard seeds and mustard products to erucic acid exposure, the BfR advocates the establishment of a maximum level of 30 g/kg for this food group by the EU Commission. Manufacturing associations have complained to the EU Commission that the proposed maximum limits for erucic acid cannot be complied with in the manufacture of mustard products.

It can be seen from the EFSA opinion that mustard accounts for the majority of overall exposure to erucic acid in the "*Adults*" population group (EFSA 2016). In this group, the intake of erucic acid through foods with mean levels is between 0.3 (LB) and 1.9 (UB) mg/kg bw and day. For high consumers (P95), the exposure values are between 0.9 (LB) and 4.3 (UB) mg/kg bw and day. Therefore, the estimated intake in this population group does not exceed the TDI value of 7 mg/kg bw and day.

#### More information on the topics of fats and fatty acids at the BfR website

Assessment of substance risks in foods

[https://www.bfr.bund.de/en/assessment\\_of\\_substance\\_risks\\_in\\_foods-738.html](https://www.bfr.bund.de/en/assessment_of_substance_risks_in_foods-738.html)

Assessment of fats in foods (in German)

[https://www.bfr.bund.de/de/bewertung\\_von\\_kohlenhydraten\\_fetten\\_proteinen\\_in\\_lebensmitteln-54414.html](https://www.bfr.bund.de/de/bewertung_von_kohlenhydraten_fetten_proteinen_in_lebensmitteln-54414.html)

Health assessment of fatty acids (in German)

[https://www.bfr.bund.de/de/gesundheitliche\\_bewertung\\_von\\_fettsaeuren-54422.html](https://www.bfr.bund.de/de/gesundheitliche_bewertung_von_fettsaeuren-54422.html)



BfR "Opinions app"

## 4 References

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.

### **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. It advises the Federal Government and Federal 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.

*This text version is a translation of the original German text which is the only legally binding version.*