

## Draft

### German Federal Ministry of Food, Agriculture and Consumer Protection

## Twenty-Second Regulation Amending the German Commodities Regulation (Bedarfsgegenständeverordnung)

### A. Object and Purpose

Foods may be contaminated with mineral oil, as has been shown by tests conducted under a research project funded by the German Federal Ministry of Food, Agriculture and Consumer Protection (Extent of migration of undesired materials from packaging made from waste paper into food – Extra Report Analysis from “119 Foodstuffs” on undesirable substances from waste paper, funding code 2809HS012). One of the main causes of this is food packaging made from paper, cardboard or paperboard, in particular packaging made from recycled paper.

Mineral oil finds its way into recycled paper through waste paper recycling. Recycled paper contains fibrous material derived from waste paper ("waste paper pulp"). Waste paper consists substantially of newspapers, advertisements, magazines, catalogues and other graphic paper, as well as packaging paper. This paper is printed using printing inks which, depending on the inks and the area of use, also contain mineral oil.

Mineral oil, which is extracted from petroleum, is a complex mixture, primarily made up of saturated (chain and ring) and aromatic (chiefly alkylated) hydrocarbons. On occasions, considerable quantities of mineral oil hydrocarbons have been detected in food, in particular mineral oil aromatic hydrocarbons (MOAH). The intake of MOAH should be minimised in the opinion of the German Federal Institute for Risk Assessment (BfR) (see, for example, BfR Statement No. 008/2010, BfR Press Release 41/2012, BfR FAQ dated 30 November 2012/26 November 2015), as it cannot be excluded that MOAH substances include those which can cause health risks in even the smallest quantities, such as, for example, cancer. In its statement from 3 May 2012 (EFSA Journal 2012;10(6):2704), the European Food Safety Authority (EFSA) raised concerns with respect to the exposure to mineral oil aromatic hydrocarbons due to their possible carcinogenic potential.

Therefore, limits must be set for the migration into food of mineral oil aromatic hydrocarbons from food contact materials and articles manufactured from paper, paperboard or cardboard using waste paper to protect consumers from potential health risks. One option for providing such a limit is by using a suitable functional barrier. For that reason, an obligation should be fundamentally imposed under this Regulation to provide food contact materials with such a functional barrier. According to this Regulation the functionality of the barrier should be determined by a detection limit of 0.5 milligrammes of MOAH per kilogramme of food/food simulant for migration from food contact materials. The obligation of the manufacturer and/or distributor of the food contact materials to fit the food contact materials with a functional barrier lapses, however, if the food business operator, who acquires the food contact material, states before the delivery that they are foregoing a functional barrier. In this case, the food business operator must take their own measures to ensure that no migration of MOAH takes place where no special requirements, for example, with regards to the quality of the foodstuffs, are provided, which exclude the migration of MOAH to the food. The obligation also lapses if the manufacturer and or the distributor of the food contact materials can guarantee in some other way than by a functional barrier that migration of MOAH to the foodstuff is prevented. This can, for example, be the case if the MOAH content in the paper, cardboard or paperboard itself is so low, that migration to the foodstuff above the detection limit should not be expected.

## **B. Solution**

This Regulation includes the provisions necessary to achieve the stated purpose.

## **C. Alternatives**

None. In order to guarantee protection of the health of consumers and a unified approach, corresponding statutory guidelines are required. Otherwise no binding and unified foundation for the detection limits to be used would be provided.

## **D. Budgetary expenditure excluding implementation costs**

Budgetary expenditure, excluding implementation costs, has no impact on public finances.

## **E. Implementation costs**

### **E.1 Implementation costs for citizens**

The citizens will not incur any implementation costs due to the Regulation.

### **E.2 Implementation costs for the industry**

The problem of contamination of food by mineral oil components from food contact materials with a waste paper component has been known for a long time. For that reason, a series of forms of packaging have been implemented, whereby, for example, inner bags, coatings or fresh fibres, rather than waste paper fibres, are used. Changes will now also become necessary for an appreciable share of food contact materials, where the exemption envisioned does not apply. For that reason, the Regulation entails additional costs for business and SMEs in particular. These costs have been estimated as follows:

*[Insert: Non-recurring/implementation costs (material and labour costs) as well as annual recurring/ongoing costs (material and labour costs) with regard to information from businesses]*

Of which bureaucratic costs due to reporting requirements

[ ]

### **E.3 Implementation costs for administration**

The *Bundesländer* (Federal States) and the municipalities have declared the following implementation costs for the Regulation:

Non-recurring labour costs and material costs: approx. € ;

Annual labour costs and material costs: approx. € .

The financial impact on the public budgets does not require counter-financing, which indirectly generates price-related effects.

### **F. Other costs**

It is impossible to totally rule out the possibility of a limited impact on unit prices, but it is not likely that there will be an impact on general price levels and in particular consumer price levels.

# **Draft by the German Federal Ministry of Food, Agriculture and Consumer Protection**

## **Twenty-second Regulation Amending the German Commodities Regulation<sup>1)</sup>**

**of ...**

The German Federal Ministry of Food, Agriculture and Consumer Protection hereby decrees on the basis of

- Section 31(2)(1)(2), also in combination with Section 4 (2)(2), and Section 46 (2)(1)(1)(a) of the German Foodstuffs and Animal Feed Code, in the version published on 3 June 2013 (German Federal Law Gazette I p. 1426) and
- Section 34 (1)(2), which has been amended by article 67 (6) of the Regulation of 31 August 2015 (German Federal Law Gazette I p. 1474), also in connection with Section 4(2)(2) of the German Foodstuffs and Animal Feed Code, in the version published on 3 June 2013 (German Federal Law Gazette I p. 1426) in concert with the German Federal Ministry of Economics and Technology:

### **Article 1**

#### **Amendment to the German Commodities Regulation**

The German Commodities Regulation in the version published on 23 December 1997 (German Federal Law Gazette 1998 I p. 5), last amended by article 2(1) of the Regulation of 15 February 2016 (German Federal Law Gazette I p. 198) is hereby amended as follows:

1. Section 2 is amended as follows:

- a) In paragraph 6, the full stop at the end is replaced by a semicolon.
- b) After paragraph 6, the following paragraphs 7 to 10 are added:

“7. Waste paper material: fibre recovered through a treatment process from waste paper for paper, cardboard or paperboard manufacture;

8. aromatic mineral hydrocarbons: highly alkylated aromatic hydrocarbons with carbon numbers C16 to C35, which contain one or more aromatic rings; these carbon numbers are linked to the elution range and/or the retention times of the corresponding n-alkanes in the gas chromatographic analysis on a separation column coated with dimethylpolysiloxane;

9. functional barriers;

- a) one or more layers or coatings on a food contact product or

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<sup>1)</sup> Notified according to Directive 2015/1535/EC of the European Parliament and the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (OJ L 241 from 17.9.2015, p. 1)

b) the coating of a food,

by which it is ensured that the specified substances from the food contact product do not migrate to the food;

10. food simulants: food simulants in the sense of article 3(12) of Regulation (EU) No. 10/2011.”

2. Under Section 6, the following Section 6a is added:

“Section 6a

Food contact materials and articles made of paper, cardboard or paperboard

(1) Food contact materials and articles made of paper, cardboard or paperboard produced using waste paper pulp only be manufactured and used if a functional barrier in accordance with Section 2(9) is ensured, so that no mineral oil aromatic hydrocarbons migrate from the food contact material to the food. Up to a detection limit of 0.5mg total mineral oil aromatic hydrocarbons per kilogramme of food or food simulant, a migration is not considered to have taken place.

(2) Paragraph 1(1) does not apply if the migration of mineral oil aromatic hydrocarbons from the food contact material to the food is excluded in the sense of Paragraph 1(2), as

1. special conditions apply, in particular there is such a low mineral oil aromatic hydrocarbon content present in the food contact material, that migration should not be expected, or

2. the manufacturer or distributor of the food contact material has taken other appropriate measures, which prevent the migration of mineral oil aromatic hydrocarbons to the food.

(3) By derogation from paragraph 1(1), food contact materials can be manufactured and distributed without a functional barrier, if the food business operator instructs the manufacturer or distributor of the food contact material in writing or electronically before delivery of the food contact material to forego the functional barrier in accordance with Section 2(9).

(4) In the cases in Paragraph 3, the responsible food business operator must ensure that a migration of mineral oil aromatic hydrocarbons from the food contact material to the food is excluded in the sense of Paragraph 1(2). For this purpose, they must take suitable measures, in particular they must use a functional barrier in accordance with Section 2(9)(b). Sentence 2 does not apply if special conditions apply, in particular on the basis of the character of the food coming into contact with the food contact material, or the conditions apply to the use of the food contact material, which exclude migration of the mineral oil aromatic hydrocarbons from the food contact material to the food in the sense of Paragraph 1(2).

(5) Documentation must be provided, which verifies that the migration of mineral oil aromatic hydrocarbons from the food contact material to the food is excluded in the sense of Paragraph 1(2):

1. in the cases in Paragraph 2 by the manufacturer or distributor of the food contact material and

2. in the cases in Paragraph 4 by the food business operator.

(6) It is forbidden to market such food as food which has been handled using food contact material,

1. which is manufactured contrary to Paragraph 1(1) or distributed, without the provisions in Paragraph 2 applying, and

2. without it being established according to Paragraph 4, that migration of mineral oil aromatic hydrocarbons from the food contact material to the food is excluded in the sense of Paragraph 1(2).”

3. In Section 7(1) the figure “6” is replaced by the figure “6a”.

4. Section 12 is amended as follows:

a) Paragraph 2 is amended as follows:

aa) in paragraph 3 the word “or” is replaced by a comma.

bb) In paragraph 4 the full stop at the end is replaced by a comma.

cc) After paragraph 4, the following paragraphs 5 to 7 are added:

“5. contrary to Section 6a(1)(1) places a food contact material on the market,

6. contrary to Section 6a(4) does not ensure that the migration of mineral oil aromatic hydrocarbons does not occur, or

7. places food on the market contrary to Section 6a(6).”

b) Paragraph 6 is amended as follows:

aa) The following paragraph 1 is appended:

“1. contrary to Section 6a(5) documents are not, not fully or not correctly submitted,”

bb) the current paragraphs 1 to 6 become paragraphs 2 to 7.

5. The following Paragraph 15 is added to Section 16:

“(15) Section 6a is to come into force only from ... [insert: the date of the first day after the nineteenth day of the calendar month following the promulgation of this Regulation]. When using food contact materials manufactured from waste paper, which were manufactured according to the provisions applying before the time specified in paragraph 1, they may still be put on sale and used after this time until stocks are used up.”

## **Article 2**

### **Permission for promulgation**

The German Federal Ministry of Food, Agriculture and Consumer Protection can promulgate the content of the Regulation Amending the German Commodities Regulation in the applicable version of [*insert: the date of effect of this Regulation*] in the Federal Law Gazette.

### **Article 3 Date of Effect**

This Regulation comes into effect the day after its promulgation.

The Federal Council has given its approval.

Bonn, ..... 2017

The Federal Minister

Food, Agriculture and Consumer Protection

## **Justification**

### **A. General Section**

#### **I. Purpose and Requirement for the Regulation**

Foods may be contaminated with mineral oil, as has been shown by tests conducted under a research project funded by the German Federal Ministry of Food, Agriculture and Consumer Protection (Extent of migration of undesired materials from packaging made from waste paper into food – Extra Report Analysis from “119 Foodstuffs” on undesirable substances from waste paper, funding code 2809HS012). One of the main causes of this is also food packaging made from paper, cardboard or paperboard, in particular such made from recycled paper.

Mineral oil finds its way into recycled paper through waste paper recycling. Recycled paper contains fibrous material derived from waste paper ("waste paper pulp"). Waste paper consists substantially of newspapers, advertisements, magazines, catalogues and other graphic paper, as well as packaging paper. This paper is printed using printing inks, which depending on the printing process and the area of use, also contain mineral oil.

Mineral oil, which is extracted from petroleum, is a complex mixture, primarily made up of saturated (chain and ring) and aromatic (chiefly alkylated) hydrocarbons. In part, considerable quantities of mineral oil hydrocarbons have been detected in food, in particular mineral oil aromatic hydrocarbons (MOAH). The intake of MOAH should be minimised in the opinion of the German Federal Institute for Risk Assessment (BfR) (see, for example, BfR Statement No. 008/2010, BfR Press Release 41/2012, BfR FAQ dated 30 November 2012/26 November 2015), as it cannot be excluded that among the MOAH substances there are those which can cause health risks health in even the smallest quantities, such as, for example, cancer. In its statement from 3 May 2012 (EFSA Journal 2012;10(6):2704), the European Food Safety Authority (EFSA) raised concerns with respect to the exposure to mineral oil aromatic hydrocarbons due to their possible carcinogenic potential. The EFSA has established that food contact materials based on waste paper can cause substantial exposure to mineral oil aromatic hydrocarbons from food.

Therefore, in this Regulation the protection for consumers from potential health risks caused by the migration into food of mineral oil aromatic hydrocarbons (MOAH), from food contact materials manufactured using waste paper, should be greatly improved.

#### **II. Significant Content of the Draft**

With this Regulation the migration of mineral oil aromatic hydrocarbons (MOAH) from food contact materials from paper, paperboard or cardboard manufactured using waste paper is limited as far as possible. One option for providing such a limit is by using a suitable functional barrier. For that reason, a fundamental obligation should be imposed under this Regulation to provide food contact materials with such a functional barrier. The functionality of the barrier according to this Regulation is described by a detection limit of 0.5 milligrammes MOAH per kilogramme of food/food simulant for migration from the food contact material. The obligation of the manufacturer and/or the distributor of the food contact materials to fit the food contact materials with a functional barrier lapses, however, if the food business operator, who acquires the food contact material, states before the delivery that they are foregoing a functional barrier. In this case the food business operator must take their own measures to ensure that migration of MOAH does not take

place or special measures, for example, with regards to the character of the foodstuffs, are provided, which prevent the migration of MOAH to the food. The obligation also lapses if the manufacturer and or the distributor of the food contact materials can guarantee in some other way than by a functional barrier that migration of MOAH to the foodstuff is prevented. This can, for example, be the case if the MOAH content in the paper, cardboard or paperboard itself is so low, that migration to the foodstuff above the detection limit should not be expected.

### **III. Alternatives**

None. In order to guarantee protection of the health of consumers and a unified approach, corresponding statutory guidelines are required. Otherwise no binding and unified foundation for the detection limits to be used would be provided.

### **IV. Impact of the Regulation**

#### **1. Gender-specific impact**

The Regulation does not contain any provisions impacting specifically on the various life situations of men or women. Equal attention has been paid to the health protection of both men and women. No impact on gender equality is therefore anticipated.

#### **2. Sustainable development**

The Regulation ensures that the health of consumers is not affected by mineral oil components from food contact materials made from paper, paperboard and cardboard manufactured from waste paper pulp. It promotes consumer health protection, thereby contributing to sustainable development.

#### **3. Budgetary expenditure excluding implementation costs**

Budgetary expenditure, excluding implementation costs, has no impact on public finances.

#### **4. Implementation costs**

The Federal government will not incur any implementation costs due to the Regulation.

The *Bundesländer* (Federal States) and the municipalities have declared the following additional costs for the Regulation:

Non-recurring labour costs and material costs: approx. € ;

Annual labour costs and material costs: approx. € .

The problem of contamination of foodstuffs by mineral oil components from food contact materials has been known for a long time. For that reason a series of forms of packaging have been implemented, whereby, for example, inner bags, coatings or fresh fibres, rather than waste paper fibres, are used. Changes will now also become necessary for an appreciable share of food contact materials, where the exemption envisioned does not apply. For that reason, the Regulation entails additional costs for business and SMEs in particular. These costs have been estimated as follows:

*[Insert: Non-recurring/implementation costs (material and labour costs) as well as annual recurring/ongoing costs (material and labour costs) with regard to information from businesses]*

Neither the citizens nor the administration will incur any implementation costs due to the Regulation.

## **5. Other costs**

It is impossible to totally rule out the possibility of a limited impact on unit prices, but it is not likely that there will be an impact on general price levels and in particular consumer price levels.

## **B. Specific Section**

### **On Article 1**

#### On paragraph 1

The definitions of waste paper material, mineral oil aromatic hydrocarbons (MOAH), functional barriers and food simulant within the framework of this Regulation are provided in paragraph 1.

In the definition of the functional barriers a differentiation is made between the various options. A functional barrier can be firmly bound to the food contact material, for example in the form of a coating, (Section 2(9)(a)) or separately, for example in the form of an inner bag (Section 2 (9)(b)). Depending on the type of the food contact material, the food, the conditions of use and duration of use, aluminium, for example, (with a layer thickness which guarantees that there are no holes) or various plastics (e.g. PET, Polyacrylate, Polyacetate, Polyamide) can be applied as a coating to the paper, paperboard or cardboard or as an additional inner bag.

#### On paragraph 2

In paragraph 2 specific regulations are set down for food contact materials made from paper, paperboard or cardboard manufactured from waste paper.

In accordance with Section 6a(1), such food contact materials must be equipped with a functional barrier against MOAH. In the manufacturing stage and the distribution of the food contact materials made from paper, paperboard and cardboard, the responsible operator must, as a rule, provide a functional barrier in accordance with Section 2(9), that is layers bonded to the food contact material or coatings. The functionality of the barriers is linked to a detection limit for migration to food of 0.5 milligrammes MOAH per kilogramme of food/food simulant.

Paragraph 2 envisages an exception to the required provision of the functional barrier on the food contact materials in question by the food contact material business operator. Where it is ensured by other means that the migration of MOAH from the food contact material at a detection limit of 0.5 milligrammes per kilogramme of food/food simulant is not demonstrable or special conditions apply, which prevent such migration, the duty to provide a barrier lapses. This can, for example, be the case if the MOAH content in the paper, cardboard or paperboard itself is already so low, that migration to the foodstuff above the detection limit should not be expected.

According to Section 6a(3), the food contact materials indicated may, in deviation from Section 6a(1) also be manufactured and placed on sale without a functional barrier (bonded to the food contact material). This is, however, only permitted, if the food business operator, who, for example, intends to use the food contact materials to pack foods, explicitly instructs the manufacturer or distributor of the food contact materials electronically or in writing to forego a functional barrier. This instruction must be retained both by the instructing food business operator and the manufacturer or distributor of the food contact materials for submission to the responsible authority on request.

In these instances, the food business operator must provide suitable measures under Section 6a(4) to prevent migrations of MOAH from the food contact material to the food. To do so, the food business operator can, for example, when filling the foodstuff use an inner bag to serve as a functional barrier or the like (see Section 2(9)(b)). The corresponding requirements for the detection limit apply.

The use of a functional barrier must not, however, be the only option for ensuring that no migration of MOAH from the food contact material to the food takes place and/or that such migration is not demonstrable. This also becomes the case, for example, when it can be verified that on the basis of the character of the food (e.g. table salt) or the conditions of use (e.g. in case of frozen foods or brief contact with dry food) that no migration of MOAH from the food contact material to the food takes place and/or that it is below the detection limit and as a result special requirements as per Section 6a(4) apply.

The mineral oil analyses of food and the analysis of the component arising from the food contact material are demanding, but have made considerable progress in recent years. A long-term target detection limit of 0.15 milligrams per kilogram of food/food simulant for the migration of MOAH from food contact materials cannot, at present, be achieved for all foodstuffs. It is strongly influenced by the respective food matrix. The now stipulated limit value of 0.5 milligrammes per kilogramme of food/food simulant for the migration should currently be generally analytically detectable in foodstuffs and food simulants. When food simulants are used, it must be ensured that the test conditions and the results obtained from them reflect conditions at least as strictly as a test of the migration of MOAH into food.

It should be pointed out that the provisions applying to the use of a functional barrier only for such materials and objects from paper, paperboard and cardboard that have been manufactured using waste paper, fall within the scope of application of article 1(2) of (EC) Regulation No. 1935/2004 on materials and objects, which are intended to come into contact with foods and repealing directives 80/590/EEC and 89/109/EEC. Applicability, for example, to covering boxes, transport boxes or the like can, accordingly, then only occur, if in a specific case it relates to food contact materials. The detection limits set down in connection with functional barriers in this Regulation of 0.5 mg/kg of food relate only to the migration of MOAH from food contact objects to food covered by the scope of application of this Regulation and presents no general maximum quantity for MOAH in food.

Under the general food contact material statutory provisions the relevant responsible operator – e.g. the manufacturer, distributor, food packaging filler – in fulfilment of their duty of care must ensure, that food contact materials located or used within their sphere of responsibility satisfy the applicable requirements. Reference is made, for example, to Section 30(3) of the LFGB (Foods, Consumer Goods and Feedstuffs Code) and Regulation (EC) No. 2023/2006 dated 22 December 2006 on good manufacturing practice for materials and objects, which are designed to come into contact with food (OJ. L 384 from 29.12.2006, p. 75). As a result, among other things, the documentation requirements set in accordance with Regulation (EC) No. 2023/2006 must be met. In regard to this Regulation this relates to the question of whether the use of barriers or the application of an exemption is relevant. In this way, it can be guaranteed and verified that the barrier provides the required functionality with regards to MOAH or that a migration of MOAH

from the food contact material to food also lies below the detection limit where no functional barrier is used.

Section 6a(5) includes, therefore, an obligation for the manufacturer or distributor of the food contact materials and also the responsible food business operator to retain documents showing how it has been ensured by the responsible person that migration of MOAH to the food does not occur.

Section 6a(6) includes a ban on the sale of food, which is handled with food contact materials without the requirements of Section 6a(1-4) to protect consumers against possible health hazards from the migration of MOAH food contact materials being satisfied.

#### On paragraph 3

Paragraph 3 sets out the ban on the use of food contact materials, which do not meet the requirements under Section 6a.

#### On paragraph 4

Paragraph 4 sets out the enforcement of breaches against the provisions of Section 6a of the Regulation Amending the German Commodities Regulation.

#### On paragraph 5

Paragraph 5 determines that the provisions should only apply on the first day after the nineteenth day of the calendar month after the promulgation of the Regulation. Paragraph 5 also determines that food contact materials, which have been manufactured according to provisions applicable before this date, may be placed on sale and used after this day until the stockpile is used up ("free sale").

#### **On article 2**

Article 2 sets out the permission to promulgate the Regulation Amending the German Commodities Regulation.

#### **On article 3**

Article 3 sets out the date of effect of the Regulation.