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## **Draft of the Federal Ministry of Food and Agriculture**

### **Twenty-Second Ordinance amending the Consumer Goods Ordinance<sup>1)</sup>**

**of...2020**

The Federal Ministry of Food and Agriculture decrees the following on the basis of

- § 31(2)(1)(2), also in conjunction with § 4(2)(2), and § 46(2)(1)(1)(a) of the Food and Feed Code as promulgated on 3 June 2013 (Federal Law Gazette I p. 1426) and

- § 34(1)(2), as amended by Article 67(6) of the Ordinance of 31 August 2015 (Federal Law Gazette I p. 1474), also in conjunction with § 4(2)(2) of the Food and Feed Code as promulgated on 3 June 2013 (Federal Law Gazette I, p. 1426), in consultation with the Federal Ministry for Economic Affairs and Energy:

### **Article 1**

#### **Amendment to the Consumer Goods Ordinance**

The Consumer Goods Ordinance, as published on 23 December 1997 (Federal Law Gazette 1998 I p. 5), last amended by Article 2(1) of the Act of 15 February 2016 (Federal Law Gazette I p. 198), is amended as follows:

1. § 2 is amended as follows:

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

7. Waste paper pulp: fibre material obtained from waste paper through processing methods for the manufacture of paper, paperboard or cardboard;

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

9. Functional barriers:

- a) one or more layers or coatings of a food contact material or
- b) the wrapping of a foodstuff,

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

which ensures that certain substances from food contact materials do not migrate to the food;

10. Food simulant: Food simulant as defined by Article 3(12) of Regulation (EU) No 10/2011.'

2. The following § 6a is inserted after § 6:

§ 6a

Food contact materials made of paper, paperboard or cardboard with a proportion of recycled paper

(1) Food contact materials made of paper, paperboard or cardboard using recycled paper may only be manufactured and placed on the market if a functional barrier in accordance with § 2(9) ensures that no aromatic mineral oil hydrocarbons are transferred from the food contact materials to the food. A transfer is deemed not to have occurred if

1. the detection limit of 0.5 milligrams of the sum of aromatic mineral oil hydrocarbons per kilogram of food is not exceeded or
2. the detection limit of 0.15 milligrams of the sum of aromatic mineral oil hydrocarbons per kilogram of food simulant is not exceeded.

(2) Paragraph 1(1) does not apply if a transfer of aromatic mineral oil hydrocarbons from the food contact material to food as defined by paragraph 1(2) is precluded because

1. there are special requirements for the food contact material, in particular that there is only a low content of aromatic mineral oil hydrocarbons in the food contact article, or
2. the manufacturer or distributor of the food contact material has taken other suitable measures to prevent a transfer.

(3) In deviation from paragraph 1(1), the food contact materials described there can be manufactured and placed on the market without a functional barrier if the food business operator who brings the food contact material into contact with a food for the first time by packaging or in any other way, declares to the manufacturer or distributor of the food contact material in writing or electronically before delivery of the food contact material that he will dispense with the functional barrier pursuant to § 2(9).

(4) In the cases of paragraph 3, the food business operator using the food contact material must ensure that a transfer of aromatic mineral oil hydrocarbons from the food contact material to food as defined by paragraph 1(2) is precluded. For this purpose, he must use a functional barrier according to § 2(9)(b) or take other suitable measures. Sentence 2 does not apply if special requirements exist that prevent aromatic mineral oil hydrocarbons from migrating from the food contact material to the food as defined by paragraph 1(2), in particular due to the nature of the food that comes into contact with the food contact material, or due to the intended conditions of use of the food contact material.

(5) At the request of the competent authority, the following must be presented:

1. The compliance of the manufacturer or distributor of the food contact material with the requirements of paragraphs 2 and 3 and

2. The compliance of the food business operator with the requirements of paragraph 4.

The persons with an obligation under sentence 1 must keep documents that prove that a transfer of aromatic mineral oil hydrocarbons from the food contact material to food or food simulants as defined by paragraph 1(2) is precluded.

(6) It is forbidden to place foodstuffs on the market as foodstuffs which have been handled using a food contact article without the requirements of paragraph 1(1) or paragraph 4(1) being met.'

3. In § 7(1), '6' is replaced by '6a(4)'.

4. § 12 is amended as follows:

a) Paragraph 2 is amended as follows:

aa) In point 3, the word 'or' is replaced by a comma.

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

cc) The following points 5 and 6 are added:

'5. contrary to § 6a(1)(1) or paragraph 6, places a food contact or foodstuff on the market or

6. contrary to § 6a(4)(1), does not ensure that a transfer of aromatic mineral oil hydrocarbons is precluded.'

b) Paragraph 6 is amended as follows:

aa) The following point 1 is placed before point 1:

'1. contrary to § 6a(5)(2), fails to keep documentation, or fails to do so correctly or in full.'

bb) The previous point 1 becomes point 2.

5. The following paragraphs 15 and 16 are added to § 16:

'(15) § 6a only applies from ... [insert: date of the first day of the thirty-seventh month following the calendar month of publication of this Ordinance].

(16) Food contact materials that have been manufactured using recycled paper in accordance with the regulations applicable up to the point in time specified in paragraph 15 may still be placed on the market and used until ... [: date of the first day of the sixty-first calendar month following the promulgation of this Ordinance].'

## **Article 2**

### **Promulgation authorisation**

The Federal Ministry of Food and Agriculture can publish the wording of the Consumer Goods Ordinance in the current version of ... [Insert: date of entry into force of this Ordinance] in the Federal Law Gazette.

## **Article 3**

### **Entry into force**

This Ordinance shall enter into force on the day following its promulgation.

Approved by the Bundesrat.

Bonn, on .....2020

The Federal Minister  
for Food and Agriculture

## **Explanatory statement**

### **A. General part**

#### **I. Objective of and need for the regulations**

Food can be contaminated with mineral oil, as has been shown inter alia by studies within the framework of a research project funded by the Federal Ministry of Food and Agriculture (extent of migration of undesirable substances from packaging materials from waste paper to food - extra report on the analysis of '119 foods' for undesirable substances from waste paper, funding code 2809HS012). In addition to other sources of entry, food packaging made of paper, paperboard or cardboard, especially when made of recycled paper, is a major cause.

Mineral oil can enter the recycled paper through the recovery of waste paper. Recycled paper contains fibre that is obtained from waste paper (known as waste paper material). Waste paper mainly consists of newspapers, advertising leaflets, magazines, catalogues and other graphic paper materials as well as packaging paper. To print on these papers, printing inks are used which, depending on the printing process and area of application, also contain mineral oil.

Mineral oil is obtained from petroleum and is a complex mixture, which mainly consists of saturated (chain and ring-shaped) and aromatic (mostly alkylated) hydrocarbons. Considerable amounts of mineral oil hydrocarbons were found in food in some cases. These also include aromatic mineral oil hydrocarbons (MOAH). In the opinion of the Federal Institute for Risk Assessment (BfR), the inclusion of MOAH should be minimised (e.g. BfR Opinion No. 008/2010, BfR Press Information 41/2012, BfR FAQ of 30 November 2012/26 November 2015), because it cannot be ruled out that the MOAH contain substances that cause harm to the health, such as cancer. The European Food Safety Authority (EFSA) also raised concerns in its opinion of 3 May 2012 (EFSA Journal 2012;10 (6):2704) with regard to exposure to MOAH due to its possible carcinogenic potential. The EFSA also found that food packaging based on waste paper stock can make a significant contribution to mineral oil hydrocarbon exposure from food.

This Ordinance is intended to significantly improve the protection of consumers against possible health hazards caused by food contact materials made of paper, paperboard or cardboard, which are manufactured using recycled paper and from which MOAH can be transferred to food.

#### **II. Main content**

The purpose of this Ordinance is to limit the migration of MOAH to foodstuffs from food contact materials made of paper, paperboard or cardboard which are manufactured using recycled paper stock to the greatest extent possible. A suitable means of introducing such a limitation is a functional barrier. A basic obligation is therefore established to equip the relevant food contact materials with such a functional barrier. According to this Ordinance, the functionality of the barrier is determined by a detection limit of 0.5 milligrams MOAH per kilogram of food for the transfer from the food contact material. When testing in food simulants, a detection limit of 0.15 milligrams MOAH per kilogram of food simulant applies. However, the obligation of the manufacturer or distributor of food contact materials to equip the food contact materials with a functional barrier does not apply if the food business operator who procures the food contact material declares to the manufacturer or distributor that it does not require a functional barrier before delivery. In

this case, the food business operator must take its own measures to ensure that a transfer from MOAH to food does not take place, unless there are special conditions, e.g. with regard to the nature of the food, which prevent the transfer of MOAH to food. The obligation to equip the food contact materials with a functional barrier also does not apply if the manufacturer or the distributor of the food contact materials can guarantee in a way other than the use of a functional barrier that a transfer from MOAH to food is precluded. This can for example be the case if the MOAH content in the paper, paperboard or cardboard itself is so low that there is no transfer from MOAH to food above the detection limit.

### **III. Alternatives**

None. In order to protect the health of consumers and to ensure uniform handling, appropriate legal requirements and the mandatory application of a detection limit for MOAH in food are required.

### **IV. Legislative powers**

The Federal Ministry of Food and Agriculture is empowered to enact this Ordinance by § 31(2)(1)(2) LFGB (Food and Feed Code), also in conjunction with § 4(2)(2) and § 46(2)(1)(1)(a) LFGB, as well as § 34(1)(2), also in conjunction with § 4(2)(2) LFGB.

### **V. Compatibility with European Union law and international treaties**

The EU law on food contact materials has not yet been fully harmonised. Regulation (EC) No. 1935/2004 does provide general requirements. However, individual measures have so far only existed for individual material groups. Article 6 of Regulation (EC) No. 1935/2004 allows the EU member states to maintain or enact national provisions for groups of materials and objects for which no individual measures have yet been taken at EU level. There are no such individual EU measures for food contact materials made of paper, cardboard or cardboard – be it either from fresh fibre or from waste paper. Consequently, it is compatible with EU law. International treaties are not affected.

### **VI. Legal consequences**

#### **1. Legal and administrative simplification**

This Ordinance does not provide for a simplification or repeal of provisions. However, the requirements with regard to the avoidance of a transfer of MOAH from food contact materials made of paper, paperboard or cardboard containing recycled paper will be standardised, thereby significantly improving legal certainty for both the competent authorities of the federal states and the businesses concerned.

#### **2. Sustainability aspects**

A sustainability review has been carried out in accordance with the fourth sentence of Section 44(1) of the Joint Rules of Procedure of the Federal Ministries (GGO). The provisions are permanently sustainable within the meaning of the national sustainability strategy. The global sustainability goal 3 is of particular relevance. 'To ensure a healthy life for people of all ages and promote their well-being'. Furthermore, the principle of sustainable development point 3) b) 'Prevent dangers and unacceptable risks to human health' is taken into account. It also contributes to global goal 12 'Ensure sustainable consumption and production patterns'. In the interests of sustainability, the use of recycling materials for food contact materials made of paper, paperboard or cardboard will

also be possible in the future, provided that the consumer protection requirements specified in this Ordinance are met. The Ordinance ensures that consumers are not adversely affected by mineral oil components from food contact materials made of paper, paperboard or cardboard that have been produced using recycled paper. The Ordinance serves the purpose of consumer health protection, contributing to sustainable development.

### 3. Budgetary expenditure exclusive of compliance costs

State budgets are not burdened with public expenditure beyond compliance costs.

### 4. Compliance costs

#### a) Administrative compliance costs

The Ordinance does not incur any additional costs for the federal administration.

Based on the information provided by the states, the administration of the states incurs the following additional compliance costs due to additional monitoring and control activities through the Ordinance:

|                          |                       |
|--------------------------|-----------------------|
| One-off material costs:  | approx. EUR 1 058 000 |
| One-off personnel costs: | approx. EUR 123 000   |
| Annual material costs    | approx. EUR 80 000    |
| Annual staff costs       | approx. EUR 292 000   |

This results in an average one-time compliance cost of EUR 236 200 and an average annual compliance cost of EUR 74 400.

These costs are made up of the following items in accordance with the individual details below jointly provided by the states. Not all states reported a cost impact from the Ordinance. This could, for instance, be due to the fact that such investigations are initially not carried out or that they are carried out in cooperation with other states.

#### Baden-Württemberg:

|                          |  |
|--------------------------|--|
| One-off material costs:  | EUR 220 000 (equipment procurement)  |
| One-off personnel costs: | EUR 35 000 (establishment of standardised analysis without measuring routine samples)  |
| Annual material costs:   | approx. EUR 10 000 (estimate) (device maintenance, consumables, repairs, etc.)   |
| Annual staff costs:      | approx. EUR 60 000 (assuming that a CTA and a laboratory manager are each deployed 50%; the actual annual personnel costs are dependent on the actual number of samples and the actual costs for the document review). |

The specified costs include the costs for the analysis and the costs for only part of the document review in the testing facility, since there is no obligation to register companies in the area of the production and placing on the market of food contact materials and

therefore no complete data on the number of those manufacturers and distributors of the food contact materials covered by the Ordinance.

Bavaria:

|                         |                     |
|-------------------------|---------------------|
| One-off material costs: | approx. EUR 200 000 |
| Annual staff costs:     | approx. EUR 72 000  |
| Annual material costs:  | approx. EUR 10 000  |

Lower Saxony:

|                         |   |
|-------------------------|---|
| One-off material costs: | Approx. EUR 1700 00 (device costs for HPLC-GC coupling)                           |
| Annual costs:           | EUR 52,000 (based on 200 samples to be examined and 40 document reviews per year) |

Schleswig-Holstein

|                          |   |
|--------------------------|---|
| One-off material costs:  | EUR 238 000 (device costs for LC-GC coupling; device was purchased in March / April 2017)       |
| One-off personnel costs: | EUR 5 000 (training)  |
| Annual staff costs:      | approx. EUR 70 000 (0.5 positions for scientific staff E14<br>1 position technical employee E9) |

Saxony:

|                          |  |
|--------------------------|--|
| One-off material costs:  | EUR 230 000 (equipment procurement)  |
| One-off personnel costs: | EUR 83 000 (0.5 FTE salary group 13+ and 1.0 FTE salary group 6 in the phase of familiarisation with the analysis equipment concerned and for the application of the method) |
| Annual material costs:   | approx. EUR 6 000 to 8 000 EUR (equipment maintenance, consumables, repairs)   |
| Annual staff costs:      | approx. EUR 90 000 (2.0 FTE pay group 6 in routine operation)  |

Saxony-Anhalt has not yet been able to quantify the one-off and recurring costs.

Thuringia announced that not inconsiderable one-off costs are likely. A detailed specification of costs is not feasible for Thuringia at this stage.

**b) Implementation costs for the trade and industry**

With respect to compliance costs for trade and industry, the Ordinance results in additional costs in particular for medium-sized companies. Since the problem of the contamination of food with mineral oil components from food commodities has been known for a long time, a number of type of packaging have already been converted by e.g. intermediate bags, coatings or virgin fibres used instead of fibres based on recycled paper. However, changes will now also be required for a significant further proportion of food contact materials, unless the planned exception applies.

An ex-ante estimate by the Federal Statistical Office resulted in one-off compliance costs (conversion costs) of around EUR 9 280 000 and annual additional compliance costs of around EUR 8 160 000. The Federal Statistical Office estimates that the two new information obligations envisaged – the written or electronic declaration when a functional barrier is waived in accordance with § 6a(3) and the obligation to provide evidence that MOAH transfer has been precluded in accordance with § 6a(5) – result in only minor costs.

**Table 1: Summary of compliance costs**

| <b>Provision</b> | <b>Requirement or information obligation</b>   | <b>Balance annual cost</b> | <b>One-time conversion costs</b> |
|------------------|--|----------------------------|----------------------------------|
| § 6a(1) and (4)  | Functional barrier for food contact materials made from recycled paper                                       | EUR 8 160 000              | EUR 9 280 000                    |
| § 6a(3)          | Written or electronic declaration on the waiver of functional barriers                                       | Minor additional costs     | -                                |
| § 6a(5)          | Obligation to provide evidence that MOAH transfer has been precluded in accordance with § 6a(1), (2) and (4) | Minor additional costs     | -                                |
|                  | <b>Total</b>   | <b>EUR 8 160 000</b>       | <b>EUR 9 280 000</b>             |

The result of the ex ante estimate is based on the following principles:

The ex-ante estimate relates to two information obligations as well as a further requirement for trade and industry, all of which are derived from the new § 6a of the Consumer Goods Ordinance:

- Recycled paper-based food contact materials may only be manufactured and put into circulation with a functional barrier (paragraph 1(1); paragraph 4). Exceptions to this rule apply if
  - in particular, there is such a low content of MOAH in the food contact material that it is not transferred to food (paragraph 2(1)).

- other suitable measures have been taken to prevent a transfer from MOAH to food (paragraph 2(2)).

- If the food business operator himself uses a functional barrier (intermediate bag or similar) or takes other measures to prevent the transfer of MOAH to food and he therefore does not require the manufacturer or distributor of the food contact article to equip the food contact article with a functional barrier, he must submit a written or electronic declaration to the manufacturer or distributor of the food contact material prior to delivery of the food contact material (paragraph 3).
- Obligation to provide evidence that MOAH transfer has been precluded (paragraph 5).

The present estimate followed the 'Guidelines for determining and presenting the compliance costs in regulatory projects of the Federal Government'<sup>1</sup>. Companies and research institutions were interviewed by telephone to estimate the number of cases as well as the time and material expenditure. The calculation of the number of cases includes data from official statistics.

### **Functional barrier for food contact materials according to § 6a(1) and (4)**

#### a) One-off conversion costs

*The reorganisation costs include personnel and material costs for the initial testing of foodstuffs and food contact materials as well as for the development, testing and commissioning of suitable packaging in accordance with § 6a.*

##### ➤ *Number of cases*

To derive the number of cases (= affected products: food plus food contact materials that come into contact with it), both data obtained from interviews and the cost structure survey in the manufacturing sector were used.<sup>2</sup> On the basis of the interviews, data on the number of products of individual companies could be obtained. The companies' sales figures were taken from publicly available sources. Based on these values, the turnover per product was determined for five companies, amounting on average to around EUR 2.5 million. The cost structure survey contains information on the number and turnover of companies in the branches of the manufacturing industry (according to the Classification of Industry Sectors, 2008 edition). On the basis of the information from the interviews, seven affected economic sectors could be identified:

Production of

- Starch and starch products
- Preserved pastry goods and cakes
- Pasta
- Confectionery
- Coffee, tea
- Ground and peeled products
- Ready meals

The total turnover of the 415 companies affected amounts to around EUR 26 billion. On the basis of the total turnover, it is estimated how many products (= food plus associated food commodity) these companies produce for the German market: with a total turnover of EUR 26 billion and a turnover of EUR 2.5 million per product, this gives

<sup>1</sup> Federal Statistical Office (2012): Guidelines for determining and presenting the compliance costs in regulatory projects of the Federal Government.

<sup>2</sup> Cost structure survey in the field of manufacturing, mining and quarrying of stones and earth (EVAS No. 42251): Employees, turnover, production value and value added of companies in the manufacturing sector, Germany 2015, economic sectors WZ08-10.

**around 10,000 products.** Only part of the product packaging actually needs to be changed, because the companies are not all equally affected: While some companies have to convert their entire product range, others only have a few products affected. However, it must be checked for all products whether the existing packaging sufficiently prevents the transfer of MOAH to the food. Food packaged exclusively in foil is also tested because these products are usually further packaged and delivered in cardboard boxes made from recycled waste paper.

➤ *Material costs*

The material costs are made up of the analysis costs for the initial testing of foodstuffs and associated food contact materials (usually packaging) as well as the development and use of new packaging. The costs arise from commissioning external laboratories for the examinations. Few companies carry out the analyses completely themselves. The total costs for all affected products of a company were requested and these total costs were allocated to the number of products of the company falling within the scope of the Ordinance.

On the basis of the interviews, it was determined that the inspection of the food and associated food contact items was around **EUR 290 per product** will cost. The costs apply to all 10 000 products.

It is assumed that the packaging has to be changed for 50% of the products tested, i.e. for 5 000 products. For this purpose, an average of **EUR 550 material costs per product** would arise.

Thus, the one-time material costs are shown by from the following calculation:

EUR 290 inspection costs x 10 000 products to be tested + EUR 550 material costs x 5 000 product packages to be converted = EUR 5 650 000.

➤ *Personnel costs*

The personnel costs consist of the time required to test the food and the associated food contact materials (usually packaging) as well as for the conversion of packaging (preparation and follow-up of the laboratory tests; the analysis itself is mainly carried out externally). The total costs for all affected products of a company were requested and these total costs were allocated to the number of products of the company falling within the scope of the Ordinance.

On the basis of the interviews, it was calculated that testing the food and associated food contact items would take around **three hours per product**. In addition to the analysis for MOAH, this also includes preparatory work such as sampling. The wage rate is set at EUR 60.50 / hour.<sup>3</sup> These costs are incurred for all 10 000 products.

The time required to convert a product packaging is approx. **six hours of work per product**. The wage rate is set at EUR 60.50 / hour.<sup>3</sup> Assuming that around 50% of all products have to be converted, labour costs are incurred for 5 000 products.

Thus, the one-time personnel costs result from the following calculation:

3 hours of testing time x EUR 60.50 wage rate x 10 000 products to be tested + 6 hours conversion costs x EUR 60.50 wage rate x 5 000 products to be converted = EUR 3 630 000.

**Table 2: Overview of the conversion costs**

| Requirement/information obligation (IP) | One-time time expenditure in | Wage rate in EUR/hour | One-time personnel costs in EUR | One-time material costs in EUR | One-time compliance costs in EUR |
|---|------------------------------|-----------------------|---------------------------------|--------------------------------|----------------------------------|
|   |                              |                       |                                 |                                |                                  |

<sup>3</sup> Wage cost tables 2017 for compliance and administrative cost measurement of the Federal Statistical Office, branch of industry C10, companies with at least 250 employees, high qualification level.

|                     |                       |              |       |           |           |                  |
|---------------------|-----------------------|--------------|-------|-----------|-----------|------------------|
|                     |                       | <b>hours</b> |       |           |           |                  |
| Functional barriers | Article 6a(1) and (4) | 60 000       | 60.50 | 3 630 000 | 5 650 000 | <b>9 280 000</b> |

b) Annual compliance costs

*The annual compliance costs include personnel and material costs for the periodic inspection and the additional costs due to the regulation-compliant packaging solution in accordance with § 6a. The periodic testing of food and packaging solutions includes sampling, analysis and evaluation.*

- *Number of cases* (= affected products: food plus food contact materials that come into contact with it)

The total number of products that are subject to the Ordinance is derived according to the number of cases for the one-time conversion cost: 10 000 products are affected in principle; the packaging must be changed for 5 000 products. The conformity of the new packaging for these 5 000 products is checked annually. According to the companies surveyed, this cost is also incurred for the products that are not to be converted. It is assumed that the test corresponds to about a third of the cost for converted products.

- *Personnel costs*

The annual compliance costs result from the personnel costs for the tasks in the area of the periodic testing of food and the associated food contact items (usually packaging) (preparation and follow-up of the laboratory tests; the analysis itself is mainly carried out externally). The total costs for all affected products of a company were requested and these total costs were allocated to the number of products of the company falling within the scope of the Ordinance.

On the basis of the interviews, it was calculated that testing the food and associated food contact items would take around **three hours per product** annually. In addition to the analysis for MOAH, this also includes preparatory work such as sampling. The wage rate is set at EUR 60.50 / hour.<sup>3</sup>

Based on the interviews, the products that have not been converted (50% of the total number, i.e. 5 000 products) are tested less intensively. The annual time expenditure corresponds accordingly to **one hour per product**. The wage rate is set at EUR 60.50 / hour.<sup>3</sup>

The annual personnel costs are: 3 hours of testing time x EUR 60.50 wage rate x 5 000 products + 1 hour testing time x EUR 60.50 wage rate x 5 000 products = EUR 1 210 000.

- *Material costs*

The material costs are made up of the costs for the periodic inspection of foodstuffs and associated food commodities (usually packaging) and the additional costs for packaging to be converted. The costs arise from commissioning external laboratories for the examinations. Few companies carry out the analyses completely themselves. In each case, the costs for all affected products of a company were requested and these total costs were allocated to the number of products of the company falling within the scope of the Ordinance.

On the basis of the interviews, it was determined that annual costs for the inspection of foodstuffs and associated food contact items of around **EUR 290 per product** will be incurred. These material costs are incurred for 5 000 products. For the less intensive testing of the foods that were not to be converted, around **EUR 100 per product** was calculated, which are incurred for 5 000 products.

The additional costs for packaging material for the 5 000 products to be converted amount to around **EUR 1 000 per product**.

The annual material costs are: EUR 290 testing costs x 5 000 products + EUR 100 testing costs x 5 000 products + EUR 1 000 material costs x 5 000 products = EUR 6 950 000.

**Table 3: Overview of ongoing compliance costs**

| Requirement/information obligation (IP) |                       | Annual time expenditure in hours | Wage rate in EUR/hour | Annual personnel costs in EUR | Material costs annually in EUR | Annual compliance costs in thousands of EUR |
|---|-----------------------|----------------------------------|-----------------------|-------------------------------|--------------------------------|---|
| Functional Barrier                      | Article 6a(1) and (4) | 20 000                           | 60.50                 | 1 210 000                     | 6 950 000                      | <b>8 160 000</b>                            |

**Written or electronic declaration on the waiver of a functional barrier as per § 6a(3)**

a) One-off conversion costs

There are no one-time conversion costs.

b) Annual compliance costs

The required additional information, i.e. the content of a waiver, will already be discussed between packaging and food manufacturers as part of the agreements on the packaging material. The additional compliance costs that arise are insignificant.

**Obligation to provide evidence that MOAH transfer has been precluded in accordance with § 6a(1), (2), and (4)**

a) One-off conversion costs

There are no one-time conversion costs.

b) Annual compliance costs

A general documentation requirement for food contact materials is already laid down in Commission Regulation (EC) No. 2231/2006 of 22 December 2006 on good manufacturing practice for materials and objects intended to come into contact with food (OJ L 384 of 29 December 2006, p. 75) (the GMP Ordinance). In addition, the initial test and the periodic tests of the food and food packaging already produce documents that can serve as evidence. The additional compliance costs that arise are insignificant.

The provisions of the Ordinance apply equally to small and medium-sized enterprises (SMEs). Special exceptions for SMEs are not possible for reasons of consumer health protection. However, the Ordinance provides for general exceptions for the use of a functional barrier, provided that the necessary conditions are met.

The one-off compliance costs for businesses resulting from the planned regulations is subject to application of the 'one-in, one-out' rule. Compensation cannot be rendered within the scope of this arrangement. The compliance costs are therefore compensated for another regulatory project.

**c) Implementation costs for citizens**

No compliance costs will be incurred by citizens as a result of this Ordinance.

## **5. Additional costs**

A minimal impact on individual prices cannot be completely ruled out; however, an impact on the general price level, in particular on the consumer price level, is not to be expected.

## **6. Other legal consequences**

The Ordinance does not contain any provisions which specifically impact the life situation of men and women. Equal consideration is given to protecting the health of men and women. Therefore, no impact on male/female equality is anticipated.

## **VII. Time limitation; evaluation**

The Ordinance is not limited in time, as the protection of consumers must be ensured over the long term.

Evaluation of the impact of this Ordinance is envisaged within five years of the application of the provisions. This is to check whether the aim of the Ordinance has been achieved, i.e. the minimisation of consumer exposure to MOAH from the food contact materials regulated in the Ordinance through the use of functional barriers or other suitable measures to prevent the transfer of MOAH (detection limit of 0.5 milligrams MOAH per kilogram of food or 0.15 milligrams MOAH per kilogram of food simulatant). The necessary data should be available on the basis of the results of the controls by the food control authorities and the conformity work of the companies concerned. Furthermore, the actual cost effects, such as the costs of the development, conversion and analytical checking of the food contact materials and affected foods, should be included in relation to the regulatory objective and any possible side effects. Developments in terms of analysis, in particular the achievable detection limits for MOAH, should also be considered.

## **B. Specific part**

### **Re Article 1**

#### Re (1)

The definitions for waste paper stock, aromatic mineral oil hydrocarbons (MOAH), functional barriers and food simulants are added in point (1) in light of the content of this Ordinance.

As part of the definition of the functional barrier, a differentiation is made with regard to the various forms. A functional barrier can be permanently connected to the food contact material, for example in the form of a coating (§ 2(9)(a)), or it can be separate, for example in the form of an intermediate bag (§ 2(9)(b)). Depending on the type of food contact material, the food, the conditions of use and the period of use of the food contact material, aluminium or various plastics (e.g. PET, polyacrylates, polyacetates, polyamides) are suitable as a material for coating paper, paperboard or cardboard, or as a material for an additional inner bag, for example.

#### Re (2)

(2) specifies specific provisions for food contact materials made of paper, paperboard or cardboard that are made using recycled paper.

Paragraphs 1 and 2 of § 6a contain specific requirements for the food contact materials operator (manufacturer, distributor). If the food business operator wishes to take his own

precautions that deviate from this, the requirements of paragraphs 3 and 4 addressed to him and the food contact material operator apply. Paragraph 5 is aimed at both the food contact material operator and the food business operator.

According to § 6a(1), the above-mentioned food contact materials must be equipped with a functional barrier to ensure that MOAH does not transfer to food. Manufacturers and distributors of food contact materials will usually use a functional barrier according to § 2(9)(a), i.e. a layer or coating that is firmly attached to the food contact material. If transfer to the food is measured, it is specified by law that no transfer takes place up to a detection limit of 0.5 milligrams of MOAH per kilogram of food. If the functionality of the barrier is determined using suitable food simulants, a corresponding detection limit of 0.15 milligrams of MOAH per kilogram of food simulant applies.

The analysis of mineral oil in food and the proportion of the food contact material is difficult, but great progress has been made in recent years. A long-term targeted detection limit of 0.15 milligrams per kilogram of food for the transfer of MOAH from food contact articles cannot currently be achieved in all foods. It is heavily influenced by the respective food matrix. The intended detection limit of 0.5 milligrams MOAH per kilogram of food for the transfer from food contact articles can currently be determined analytically in practice in food. If, on the other hand, food simulants (usually poly (2,6-diphenyl-p-phenylene oxide)) are used to check whether the barrier is functional to prevent the transfer of MOAH, a detection limit of 0.15 milligrams of MOAH per kilogram of food simulant is required. This is also due in particular to the fact that the effects of the food matrix that occur for MOAH do not apply, and thus MOAH can be detected in a much more sensitive manner in practice. With regard to the convention methods and the analysis methods currently mainly used, reference is made to the following publications by the Federal Institute for Risk Assessment:

- ‘Determination of hydrocarbons from mineral oil (MOSH and MOAH) or plastics (POSH, PAO) in packaging materials and dry food using solid phase extraction and GC-FID’ (available at: <http://www.bfr.bund.de/cm/343/bestimmung-von-kohlenwasserstoffen-aus-mineraloel-oder-kunststoffen.pdf>; as of: **Insert XX.YY.2020**);
- ‘Measurement of mineral oil - hydrocarbons in food and packaging materials’, compendium of the BfR and the Zurich Cantonal Laboratory (available at: <http://www.bfr.bund.de/cm/343/message-von-mineraloel-kohlenwasserstoffen-in-lebensmittel-und-verpackungsverbindungen.pdf>; as of **Insert XX.YY.2020**).

The requirements for the use of a functional barrier only apply to materials and objects made of paper, paperboard or cardboard that have been manufactured using recycled paper that fall within the scope of Article 1(2) of Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. They only apply to transport and outer boxes if the specific case involves food contact materials. An overlapping, multiple application of a functional barrier along the supply chain is generally not necessary. For example, in the case of transport boxes and outer boxes – if they are food contact materials in the specific case – a functional barrier is not necessary if the design of the actual packaging or the packaging system of the food itself (e.g. primary or secondary packaging) ensures that there is no transfer from MOAH to food. Correspondingly, as is generally the case with food contact materials, adequate communication within the supply chain is essential.

The detection limit of 0.5 milligrams MOAH per kilogram of food stipulated in this Ordinance in connection with the functional barrier only relates to a transfer from MOAH from the food contact materials covered by the scope of this Ordinance to food and does not constitute a general maximum amount of MOAH in food.

Paragraph 2 provides for exceptions to the mandatory equipping of the food contact materials in question with a functional barrier by the food contact materials operator: If there are special requirements that prevent the transfer of MOAH to food, or if other measures ensure that the transfer of MOAH from the food contact material is not detectable with a detection limit of 0.5 milligrams MOAH per kilogram of food (or 0.15 milligrams MOAH per kilogram of food simulant), there is no obligation to use a functional barrier. For example, the former may be the case if the MOAH content in the paper, paperboard or cardboard itself is already so low that it cannot be transferred to food above the detection limit. Examples of the latter, i.e. other suitable measures as defined by (2) include measures applying to the food contact material, such as the incorporation of adsorbents (activated carbon or similar) in the paper, paperboard or cardboard, which prevent MOAH from being transferred to the food.

According to § 6a(3), in deviation from § 6a(1), taking into account paragraph 4, the relevant food contact materials may be manufactured and placed on the market without a functional barrier that is permanently connected to the food contact material. However, this is only permissible if the food business operator declares (in written or electronic form) to the manufacturer or distributor of this food contact material that he will dispense with a functional barrier before delivery of a food contact material. This declaration must be kept by the manufacturer or the person placing the food contact material on the market in order to be able to prove to the competent authority that the provision of § 6a(1)(1) could be deviated from due to the waiver by the food business operator.

The provision of § 6a(3) covers food business operators who, in their area of responsibility, bring food contact materials that have been manufactured using recycled paper into direct or indirect contact with food, i.e. wrap or package food, or bring food into contact with a food contact material for the first time in another way. However, the obligation under § 6a(3) does not apply, for example, to food business operators who only purchase previously packaged food (including from another EU member state or a non-member state) and for whom the packaging process is beyond their control. In this case, however, the food business operator must ensure, as part of his general duty of care, that the products in question meet the requirements relating to the impermissible transfer of MOAH.

In the cases of § 6a(3), the food business operator himself must take appropriate measures in accordance with § 6a(4) to preclude transfer of MOAH from the food contact material to the food. Thus, the food business operator can use an intermediate bag or similar which serves as a functional barrier while filling the food, for example (see § 2(9)(b)). The requirements for the detection limit apply accordingly.

However, the use of a functional barrier is not the only way to ensure that no transfer of MOAH from the food contact material to the food takes place or that no such transfer is detectable. In particular, there is no obligation to take appropriate measures if, due to the nature of the food (e.g. table salt) or the conditions of use (e.g. in the case of frozen food or short-term contact with dry food), a transfer from MOAH to food does not take place or is not above the detection limit and is therefore considered undetectable.

As part of the general provisions on food contact materials, the responsible entrepreneur in question – e.g. the manufacturer, the distributor or the food packager – must, in fulfilling his due diligence duty, ensure that the food contact materials in or used in his area of responsibility meet the relevant requirements. Reference is made, for example, to § 30(3) of the Food, Consumer Goods and Feed Code (LFGB) and Regulation (EC) No. 2023/2006. According to Regulation (EC) No. 2023/2006, certain documentation requirements (among other things) must be fulfilled. With regard to this Ordinance, this is relevant for the question of the barrier to be used or for the application of the exemption, because the documents that are drawn up as part of these obligations can also serve as evidence that the barrier has the required functionality with regard to MOAH for the

intended purpose, or, if no functional barrier is used, that a transfer from MOAH from the food contact material to food cannot be detected, i.e. does not exceed the detection limit.

The manufacturer or distributor of the food contact material and the food business operator are obliged to explain to the competent authority the conditions or circumstances on which an exception is based. § 6a(5) also contains an obligation (which clarifies the provisions above) for the manufacturers or the distributors of food contact materials and the responsible food business operators to provide documents that prove how the respective responsible person ensures that there is no transfer from MOAH to food.

§ 6a(6) contains prohibitions on trade in foodstuffs to protect consumers from possible health hazards caused by the transfer of MOAH from food contact materials. The prohibitions on trade apply to food that has been handled with food contact materials that do not comply with § 6a(1)(1) or § 6a(4)(1), without one of the relevant exceptions under § 6a(2) or § 6a(4)(3) applying.

### Re (3)

(3) regulates the ban on the use of food contact materials that do not meet the requirements of § 6a.

### Re (4)

(4) establishes the enforcement of infringements of the provisions under § 6 of the Consumer Goods Ordinance.

### Re (5)

(5) establishes that the provisions are only to be applied after a three-year transition period.

(5) also stipulates that food contact materials that were manufactured in accordance with the provisions in effect before the date of application of the Ordinance may also be placed on the market and used for a further two years after this date.

### **Re Article 2**

Article 2 contains the publication permit for the Consumer Goods Ordinance.

### **Re Article 3**

Article 3 lays down the entry into force of the Ordinance.