

**Position Paper on the 22nd Ordinance Amending the German Consumer Goods Ordinance (“Mineral Oil Ordinance”), draft released on 24 February 2017 by the German Federal Ministry of Food and Agriculture (BMEL)<sup>1</sup>**

*Berlin, 6 April 2017*

**I. Summary assessment**

Mineral oil saturated hydrocarbons (MOSH) and mineral oil aromatic hydrocarbons (MOAH), as well as hundreds of other potentially harmful substances, can migrate from paper-based food-packaging materials into foods. However, there are also many other sources of food contamination with MOSH/MOAH. **The current draft ordinance fails to address this issue in a comprehensive manner.**

**The following shortcomings have been identified:**

- **The level of effectiveness required for functional barriers is inadequate** (see page 3): the draft ordinance only requires that functional barriers limit the migration of MOAH to less than 0.5 mg/kg of food. However, this requirement can be met using relatively weak barriers that do not reduce the migration of MOSH or other substances to a sufficient extent. Furthermore, the detection limit of 0.5 mg/kg for MOAH is not consistent with the current state of technological development.
- **The scope of applicability for the proposed barrier requirement is too narrow** (see page 4): the draft ordinance does not require barriers for virgin paperboard, ignoring the fact that food packaged in virgin-fibre materials can also be contaminated by substances migrating from secondary packaging. The barrier requirements also do not apply to packaging made from recycled paperboard with a low MOAH content. This exemption does not take into account that MOSH and numerous other substances can also migrate from these materials into the packaged food.
- The draft ordinance applies exclusively to MOAH contamination from packaging materials made from recycled paper and board. The federal government has failed to address the **contamination of food with MOSH/MOAH during other stages of production** (see page 5).

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<sup>1</sup> [http://www.bmel.de/SharedDocs/Downloads/Ernaehrung/Rueckstaende/MineraloelVO\\_Entwurf.pdf](http://www.bmel.de/SharedDocs/Downloads/Ernaehrung/Rueckstaende/MineraloelVO_Entwurf.pdf), last accessed 31/03/2017

**Demands:** (see pages 6-7)

- **Improve the requirements for barrier effectiveness** in the “Mineral Oil Ordinance” in order to ensure protection against the hundreds of chemicals that can migrate into food from recycled paper and board
- **Remove exemptions to barrier requirements for recycled materials and extend the scope of the ordinance to include food packaging made from virgin fibres.**
- **Establish legal limits for MOSH/MOAH in food.**

## **II. General criticism of the federal government’s approach**

As early as 2009 the German Federal Institute for Risk Assessment (BfR) began calling attention to the problems associated with the migration of mineral-oil constituents into foodstuffs based on research results from the Official Food Control Authority of the Canton of Zurich (KLZH; Kantonales Labor Zürich). In 2012 a study commissioned by the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV, now BMEL) on the migration of undesirable substances from recycled paper packaging materials into food (“Ausmaß der Migration unerwünschter Stoffe aus Verpackungsmaterialien aus Altpapier in Lebensmitteln”) concluded that, “owing to the enormous variety of potentially migrating substances (...), it is impossible to verify food safety or compliance with the relevant food law.” The report explains that **mineral oils (MOSH and MOAH<sup>2</sup>) along with hundreds of other substances** can migrate into food. Several of these substances (e.g. photoinitiators and plasticisers) are known toxins. However, numerous other compounds are of unknown toxicity, and the chemical structures of approximately one third of the substances have yet to be elucidated. **The report reaches an unequivocal conclusion: “The introduction of a barrier layer for packaging with recycled paperboard [...] appears to be absolutely essential.”**

MOSH and MOAH can also enter food unintentionally from various sources other than paper-board packaging: e.g. in the cultivation, storage and transport of the raw materials or through

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<sup>2</sup> MOSH = mineral oil saturated hydrocarbons; MOAH = mineral oil aromatic hydrocarbons. According to the European Food Safety Authority (EFSA), MOSH can accumulate in tissues of the human body, and animal testing has shown that they may cause damage to organs. MOAH are considered potentially carcinogenic. See EFSA (2012): Scientific Opinion on Mineral Oil Hydrocarbons in Food, <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2704/epdf>, last accessed 31/03/2017

the use of mineral-oil-based lubricants in food-production processes.<sup>3</sup> The European Food Safety Authority (EFSA) also described this type of contamination in its 2012 scientific opinion.<sup>4</sup>

The problem has been known for years: food is being contaminated with MOSH and MOAH from a variety of sources. In addition, hundreds of other harmful and potentially harmful substances are migrating into food products from recycled paperboard packaging. **It is imperative that the federal government recognise this problem in its entirety and establish clear objectives for its solution. In order to minimise consumer health risks to the greatest extent possible, the federal government must take action (1) to prevent the migration of hundreds of substances (including MOSH and MOAH) into food from paperboard packaging by requiring the use of functional barriers<sup>5</sup> whose effectiveness for this purpose has been demonstrated and (2) to prevent the contamination of food with MOSH and MOAH from other sources.**

The German Federal Ministry of Food and Agriculture (BMEL) has now put forward another draft ordinance amending the German Consumer Goods Ordinance (*Bedarfsgegenständeverordnung*), which regulates the use of food contact materials. **In its current form, the draft ordinance does little to resolve the issue, failing even to properly describe the problem or establish suitable objectives.** For example, the draft concentrates exclusively on MOAH, ignoring the hundreds of other substances that can migrate into food products. Furthermore, no consideration is given to other sources of unintentional food contamination with MOSH and MOAH. The availability of food products with minimal or no contamination is not even mentioned as an objective.

### **III. Specific criticism of the current draft ordinance**

The current draft ordinance is aimed at restricting the migration of mineral oil aromatic hydrocarbons (MOAH) into food products from food contact materials made from recycled paper and board. Essentially, the ordinance would establish guidelines requiring the use of functional barriers for these food contact materials.

In principle, this is the correct approach to solving these problems related to paperboard packaging because, at the current stage of research, functional barriers represent the only suitable

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<sup>3</sup> In addition to these unintentional sources, MOSH contamination in food can also originate from approved food additives (e.g. waxes and glazing agents). However, this position paper does not cover approved substances as sources of contamination.

<sup>4</sup> EFSA (2012): Scientific Opinion on Mineral Oil Hydrocarbons in Food, <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2704/epdf>, last accessed 31/03/2017

<sup>5</sup> A functional barrier is part of a multilayer packaging structure that prevents or reduces the migration of various substances from the packaging material into the food. See Bleisch, G. et al: *Lexikon der Verpackungstechnik*, 2014, p. 283

solution for preventing the migration of harmful or potentially harmful substances into food. However, the draft ordinance is too narrow in scope and therefore cannot adequately address the health risks associated with the migration of MOSH, MOAH and hundreds of other substances from recycled packaging into food. The shortcomings of the draft are described below:

### **1. The draft ordinance uses a detection limit of 0.5 milligrams of MOAH per kilogram of food to define the adequacy of a functional barrier.**

The text of the draft ordinance can be translated as follows: *“Food contact materials made from recycled-fibre-based paper or board may only be produced and placed on the market if a functional barrier [...] is used for ensuring that [...] no mineral oil aromatic hydrocarbons can migrate into food. Migration up to a detection limit of 0.5 milligrams of total mineral oil aromatic hydrocarbons per kilogram of food or food simulant shall be deemed not to have occurred.”* (Article 1.2)

### **These specifications for the functional barrier requirement are inadequate in several respects:**

- As early as 2012, the aforementioned study commissioned by the German Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) concluded that hundreds of other potentially harmful substances can migrate into food from recycled paperboard. However, very little is known about the toxicity of most of these compounds, and the chemical structures of approximately one third of the substances have yet to be elucidated. **In other words, MOSH and MOAH are only the tip of the iceberg. For certain types of recycled paperboard, even a relatively permeable barrier would be sufficient for keeping MOAH migration levels below 0.5 mg/kg – as required by the current draft ordinance.**<sup>6</sup> However, the 2012 study concludes that highly effective barriers are also essential for preventing other potentially highly toxic substances from migrating into food. In addition, a more effective barrier would further reduce the migration of MOAH.
- **The detection limit of 0.5 mg of MOAH per kilogram of food is much too high.** Using the methods recommended by the German Federal Institute for Risk Assessment (BfR) for the analysis of MOSH/MOAH,<sup>7</sup> it is possible to detect MOAH contamination levels as low as 0.15 milligrams per kilogram of dry food. On the first page of the draft ordinance, the ministry states that *“even exposure to minuscule amounts of some MOAH substances may cause harmful health effects, such as cancer.”* **In view of this assessment, it is unac-**

<sup>6</sup> For example, if the paperboard contains low concentrations of MOSH/MOAH but high concentrations of photoinitiators, adhesives, plasticisers and other substances whose migration into food poses health risks.

<sup>7</sup> Automated online-coupled HPLC-GC-FID, see <http://www.bfr.bund.de/cm/343/messung-von-mineraloel-kohlenwasserstoffen-in-lebensmittel-und-verpackungsmaterialien.pdf>, last accessed 31/03/2017

ceptable that the ordinance tolerates migration levels of up to 0.5 mg of MOAH per kilogram of food from packaging materials.

**2. The barrier requirements proposed by the ordinance contain too many exemptions.**

**The requirements for the use of functional barriers as prescribed by the draft ordinance do not apply to virgin paperboard.** Therefore, it would still be possible to use virgin-fibre based products as food contact materials with no barrier layer. This approach ignores the proven problem of so-called cross contamination: MOSH, MOAH and hundreds of other potentially harmful substances can also migrate into food through food packaging materials made from virgin fibres – e.g., if the virgin-paperboard packages are transported in a box made from recycled paper or even if the packages are placed on the shelf next to food in recycled packaging materials. Packaging made from virgin fibres cannot guarantee the protection of food from cross contamination with MOSH/MOAH.

Furthermore, **packages made from recycled paperboard with a low MOAH content are also exempt from the barrier requirement.** This exemption ignores the fact that, given the many different grades of recycled paper, it is quite possible to produce food packaging from recycled paperboard that contains a low concentration of MOAH but nevertheless high levels of MOSH and other potentially harmful substances, which are also described in the report from the 2012 BMELV study. **The current draft ordinance allows for the use of this type of packaging with no restrictions – in spite of the fact that MOSH and hundreds of other potentially harmful substances would still be able to migrate into food products.**

**3. The draft ordinance does nothing to prevent the contamination of foodstuffs with mineral oils during other stages of production.**

The current draft ordinance focuses exclusively on minimising the unintentional contamination of food with mineral oil aromatic hydrocarbons from recycled paper and board used as food packaging. Therefore, it would not protect consumers from continued exposure to foods that are contaminated with harmful substances, such as lubricating, hydraulic and batching oils, during the production process. The federal government is ignoring the health risks associated with these sources of contamination.

#### IV. Demands

1. **Improve the requirements for barrier effectiveness in the “Mineral Oil Ordinance” in order to ensure protection against the hundreds of chemicals that can migrate into food from recycled paper and board**

**The reliable protection of consumers through effective requirements for functional barriers** must be a central objective of the “Mineral Oil Ordinance”: these barriers must provide protection from not only mineral oils but also the hundreds of other potentially harmful substances that can migrate into food from recycled food packaging and secondary packaging materials. It is not enough to define the functionality of a barrier based on a single class of compounds like MOAH: **functional barriers must effectively prevent the migration of MOAH, along with all other potentially harmful substances.** Furthermore, the requirements for functional barriers must ensure that the migration of MOAH does not exceed the technically feasible **detection limit** for the respective food group – in the case of dry foods (rice, breakfast cereals, semolina etc.) this limit is **currently 0.15 mg per kg of food.**

2. **Remove the exemptions to barrier requirements for recycled paperboard packaging, and extend the scope of the “Mineral Oil Ordinance” to include food packaging made from virgin paper and board**

The current draft ordinance contains exemptions from barrier requirements for packaging made from recycled paper and board. These exemptions must be removed. In addition, the **use of functional barriers must be obligatory** not only for food packaging made from recycled paper materials, but instead **for all food packaging made from paper or paperboard**, including virgin-fibre-based materials. This is the only way to effectively protect consumer health by preventing the migration of MOSH, MOAH and hundreds of other potentially harmful substances from both primary and secondary (e.g. transport) packaging materials. Exemptions from the mandatory use of functional barriers should only apply in cases where the properties of the food itself exclude the possibility that MOSH/MOAH or other substances could migrate into the food from the packaging.

3. **Introduce legislation that sets strict limits for MOSH/MOAH in food**

The implementation of the first two demands would still not have any influence on food contamination that occurs in other stages of production. This contamination can only be prevented if specific **limit values** are established for MOSH/MOAH **in food** and if compliance with these limits is effectively enforced.

However, specific limit values for MOSH/MOAH in food cannot be introduced through an amendment to the Consumer Goods Ordinance. Instead, the government must draft a separate piece of legislation that regulates MOSH/MOAH as contaminants and prohibits the placing on the market of any food whose content of MOSH/MOAH exceeds the established limits. Furthermore, owing to the potential carcinogenicity and mutagenicity of mineral oil aromatic hydrocarbons, these limit values must ensure that no contamination of food with MOAH is detectable using the most advanced methods of laboratory analysis available. **The current detection limit for MOAH in dry foods is 0.15 mg/kg.** Other food groups have different detection limits. The limits for MOSH contamination must be defined on the basis of the ALARA principle (as low as reasonably achievable).

#### **V. Legal background**

According to the requirements on “good manufacturing practice” (Commission Regulation EC No. 2023/2006) and the Framework Regulation for food contact materials (Regulation EC No. 1935/2004), all materials that are intended to come into contact with food must be produced in such a way “that under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health.”

However, there are still no EU regulations governing the use of paper and board as food contact materials. The basic principle formulated in the good manufacturing practice guidelines (Commission Regulation EC No. 2023/2006) has been incorporated into Section 31 of Germany’s Food and Feed Code (LFGB). However, Germany has yet to establish legal limits for mineral oils in food or to introduce guidelines requiring the use of functional barriers whenever paper or board is used as a food contact material.

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