

Statement

on

the plan for a national

"Mineral oil regulation"

22nd regulation on the modification of the German Consumer Goods Ordinance

4th draft as at 07 March 2017

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At the beginning of March 2017, the German Federal Ministry of Food and Agriculture (*Bundesministerium für Ernährung und Landwirtschaft*, BMEL) announced the fourth draft of a 22nd regulation on the modification of the German Consumer Goods Ordinance with last edit as at 07 March 2017 for the creation of a national "mineral oil regulation".

The BMEL thus voices the political desire to treat the issue of infiltration of specific mineral oil hydrocarbons from foodstuffs or food contact materials containing recycled paper with a national regulation concept.

The modified concept of the fourth draft now plans on restricting the transfer of material of exclusively mineral oil aromatic hydrocarbons (MOAH) from foodstuffs produced with the use of recycled paper in such a way that this paper is not detectable (the current analytically permissible detection limit is 0.5 mg/kilogram of foodstuffs). These requirements should be achieved through the use of functional barriers that should be prescribed as mandatory for food contact materials (FCM) made from paper containing recycled paper, cardboard or carton.

A draft is political actionism and not a solution to the complex situation

The associations and companies organised in the German Federation for Food Law and Food Science (*Bund für Lebensmittelrecht und Lebensmittelkunde e.V.*, BLL) have expressed their disappointment with BMEL and their unilateral approach. The business communities concerned have addressed the issue since 2010 with numerous initiatives, technological developments and foundational cause analyses, and processed these successfully as a responsibility for safe products. Through the results of official food monitoring, product testers and self-inspection, it is objectively provable that the contamination situation of the undesirable mineral oil saturated hydrocarbons (MOSH) and of the mineral oil aromatic hydrocarbons (MOAH) could be reduced. In particular, the minimisation of MOAH necessary according to scientific evaluation was intensively pursued and continues to be pursued.



The current findings show that the infiltrations into the raw material, foodstuff and packaging chain, collectively referred to as the "MOSH/MOAH" issue, is much more complex and requires further research and inspection of measures. The standardisation and the validation of applied analytics, a coordinated differentiating assessment of the findings and evaluation foundations for barrier effects are mainly currently necessary to be able to start and to assess further targeted steps.

This fourth draft of a national mineral oil regulation neither provides for what has been achieved nor is it equivalent to the acknowledged complexity that goes beyond the use of barrier-optimised packaging containing recycled paper.

From the perspective of the BLL, the publication of the draft primarily represents a political gesture at this point in time. The business communities have little sympathy for this, since the draft neither contributes to legal certainty nor is a solution to open and complex issues. According to the business communities, the draft creates false expectations: barrier materials as technological solutions are at most a partial solution, and their use cannot lead to "MOAH-free" foodstuffs.

The national regulation principally damages the domestic market

As already voiced in relation to the first three drafted regulations, all the business communities vehemently oppose a national measure for the unilateral regulation of packaging materials. Specific German requirements on the use of barriers for recycled paper-based packaging materials would extremely limit the flows of goods in the European and international market. Packaging manufacturers and packing companies in the EU and in third countries would be indirectly affected, and importers to Germany discriminated and restricted in the competition. The dimensions of an interference of this kind cannot be quantitatively described; empirical data for these complex flows of goods are missing; the business communities have great concerns about the extent of the arising problems.

The European investigation has begun through monitoring

In January 2017, the European Commission published the recommendations for Europe-wide monitoring of the occurrence of mineral oil hydrocarbons in foodstuffs (RECOMMENDATION 2017/84 OF THE COMMISSION from 16 January 2017 on the monitoring of mineral oil hydrocarbons in foodstuffs and materials and items intended to come into contact with foodstuffs, Official Journal of the European Union no. L 12 as of 17 January 2017, p. 95). With the collection of data, the foundation for EFSA, the European Food Safety Authority, should be laid to carry out an exposure assessment and risk evaluation. The issue of the action required for a European regulation can be built upon this.



The national and European foodstuffs and packaging industry has embraced this step by the commission consensually and agreed to an active support of the monitoring. The urgently necessary technical guidelines on the standardised application of testing methods across Europe are currently missing.

Against this backdrop, a unilateral German regulation measure finds no foundation from a local point of view. The acceptance of a measure of such a kind - clearly damaging to the domestic market - by the other member states in the compulsory notification procedure (TRIS) is therefore highly questionable. In addition to this, the intervention of the European Commission appears to be likely due to the ongoing European monitoring.

Alternative methods: voluntary concepts and agreed action thresholds

The communities concerned from the foodstuff and packaging industry have successfully turned the numerous acquired findings into costly measures such as product and packaging development or substitutions of packaging material. Further steps on the identification of sources of infiltration and influence along the various value chains are currently being taken. Several research projects on causes of infiltration, analysis development and barrier assessment were initiated by the associations, which should result in concrete recommendations for action.

In 2016, a so-called "toolbox" was developed for the production of cocoa and chocolate which assists those responsible in making decisions on targeted minimisation approaches and in preventing risks. A "toolbox" with similar objectives is being prepared by the BLL with an up-to-date range of information on the level of knowledge on use in other food production and packaging processes, and will soon be available.

From the point of view of the business communities and with regard to the approaches, these alternative courses of action are more comprehensive, lead to adequate measures and are more targeted at minimisation than this regulation measure of the BMEL, which is unilaterally limited to the infiltration situation by recycled paper-based packaging, but is far too restrictive on the matter.

Another step for which the business communities have expressed fundamental support would be a value concept to be agreed between associations and supervisory bodies that follows the ALARA principles. By agreeing on temporary action thresholds (reference values/ target values) as a common reference basis, procedure and assessment safety could generally be created in a manner compliant with practice.

The BLL, as an umbrella association indicates towards the federal states (Bundesländer) (working group of the Federal Committee on Consumer Protection "Food, consumer goods, wine and cosmetics (ALB)) that it strives for this collaboration and takes on communication in value chains.



Notes on the draft in detail:

Subject to the above listed general points of criticism on the state of affairs and on the approach of the federal government, below are the BLL estimates that specifically refer to the formulations in the fourth draft:

- Specification for recycled paper packaging materials and barrier duty

Through sec. 6a, which is to be newly included in the German Consumer Goods Ordinance, food contact materials made from paper, cardboard or carton with recycled paper produced and placed on the market in Germany are legally specified. These are exclusively fitted with a functional barrier ("one or several coatings of food contact materials or wrapping of foodstuffs") that is suited to prevent the detectable transfer of material of mineral oil aromatic hydrocarbons MOAH.

The focus of the regulation on MOAH is fundamentally correct and, even from a scientific point of view, only justifiable based on the fact that there are health concerns toward this group of substances (see EFSA statement from 2012). Overlooking MOSH facilitates the observation of specifications due to the analytically unavoidable "false positive findings". Nevertheless, the minimisation of MOAH must not be separated from MOSH which is classified as undesirable (and effectively stemming from mineral oil), since the sources of infiltration as a rule are identical.

The regulation should be set aside on a single parameter regarding the condition of recycled paper-based packaging materials or their combination with materials or other coatings acting as barriers. The total load of undesirable substances from the recycled paper cycle is irrelevant, as are its causes. The regulation therefore only has an end-of-the-pipe approach and does not target the causes, which is not proportionate from the point of view of the packing companies.

- Exemption from barrier duty and waivers

Exemptions for the manufacture and placing on the market of food contact material from recycled paper material are provided in case of respectively low output load in which a detectable migration of MOAH is not expected, in case of the adoption of "other suitable measures", or in case of an explicit waiver. So long as the food business operator as a buyer releases the manufacturer or distributor of the food contact materials from the obligation to deliver a legally compliant item in a way that can be proven, he is obligated as an alternative to introduce suitable measures to establish compliance with the law at his level.

This regulation would be a novelty; it is extremely questionable from a legal point of view and interferes in the customary information flow in the supply chain, since it disregards the established concept of declarations of conformity, documentation obligations according to good manufacturing practice and valid accountability at every



stage of the process. In relation to the provided storage and submission obligations for customer declarations, the regulation is bureaucratic and impractical.

From the point of view of the business communities, a concept of such a kind and implemented nationally cannot reach the target of the desired information of local authorities and of transparency in the complex supply chains, which include suppliers from all member states and from third countries.

- Limit value for MOAH

The transfer of MOAH over 0.5 mg/kg of foodstuffs or food simulant from food contact material does not classify as evidence of the functionality of an obligatory barrier concept in case of the use of materials containing recycled paper. According to official justification, this corresponds to the current detection limit and is therefore a performance criterion for available analysis. These performance limits are variable and depend on many intrinsic and exterior factors.

There is also the risk that 0.5 mg/kg of foodstuffs are treated as a toxicologically derived migration limit value and, in this respect, that also MOAH findings stemming from other unavoidable sources are respectively assessed analogously.

Regardless of this, a sanctioned provision that relies on the detection limit of a non-validated method, only applicable with great fluctuation margins, leads to great legal uncertainty and to implementation problems.

- Trade ban and importation

The ban of marketing planned for foodstuffs which are "treated" with non-compliant food contact material (see sec. 6a (6)), is unacceptable from the point of view of business communities. This creates an extensive and especially discriminating state of affairs that in the end would lead to the ban of food contact materials containing recycled paper in the process stage of the value chains, irrespective of the issue of the effectively identifiable effect. Even the import of foodstuffs with unclear contact with materials in the course of their handling would fall under the ban.

Effects of the law and sustainability aspects

The draft dutifully poses the question of implementation costs also to the business communities. Considerations of costs are not possible in the context of this regulation. As stated above, the identification and the minimisation of mineral oil infiltrations is treated extensively by the business communities with projects and measures that have hitherto been very costly. It is already known today through the introduced barrier-optimised materials available on the market that they are significantly more expensive than the conventional ones, and that the conversions bring additional costs.



The introduction of a barrier duty and the related permanent additional testing, certification and communication duties can be assigned a considerable implementation cost that will necessarily impact the consumer prices.

In the context of the effects of the law, BMEL also stated that the regulation contributes under sustainability aspects to a "sustainable development". From the point of view of the business communities, this supposition must be firmly rejected. Due to the demand of a barrier, this regulation leads to counter-productive development, since the additional cost at issue for resources and use of materials is inconsistent with the sustainability targets. Adequate barrier materials are, as a rule, combinations from materials on a recycled paper basis in conjunction with plastic materials, metals, foils, absorption media and fresh fibre paper, and in this respect more expensive in the production process and more critical with regard to separation and recyclability.

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