

Message 304

Communication from the Commission - TRIS/(2020) 04079
Directive (EU) 2015/1535
Translation of the message 303
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Observations from the Commission (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

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1. MSG 304 IND 2020 0510 D EN 18-11-2020 17-11-2020 COM 5.2 18-11-2020

2. Commission

3. DG GROW/B/2 - N105 04/63

4. 2020/0510/D - C50A

5. article 5, paragraph 2, of Directive (EU) 2015/1535

6. Within the framework of the notification procedure laid down by Directive (EU) 2015/1535, the German authorities notified to the Commission on 17 August 2020 the draft "Twenty-second Ordinance amending the Consumer Goods Ordinance" (hereinafter, "the notified draft").

According to the notification message, the notified draft establishes an obligation to use a functional barrier in the production and placing on the market of food contact materials and articles made of waste paper. The aim of the notified draft is to prevent the transfer to food of mineral oil aromatic hydrocarbons (MOAH) in order to protect consumer health. This obligation is not applicable where the food business operator who uses food contact materials ensures the MOAH transfer is below a detection limit of 0.5 mg per kilogram of food, and explicitly declares a corresponding waiver to the manufacturer or entity placing it on the market.

The examination of the notified draft has prompted the Commission to issue the following comments.

The Commission recalls that all materials and articles intended to come into contact with food ('food contact materials', FCM) which are placed on the market within the European Union must comply with the requirements of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. Those requirements include, in particular, the general requirements (Article 3), special requirements for active and intelligent FCM where applicable (Article 4), requirements on labelling (Article 15) and requirements on traceability (Article 17) of Regulation (EC) 1935/2004.

Under Article 5(1) of Regulation (EC) No 1935/2004, the Commission is empowered to adopt or amend specific measures for the groups of materials and articles listed in Annex I to that Regulation. Paper and board are listed in point 9 of said Annex as a group of materials and articles which may be covered by specific measures. The Commission notes, however, that no legislation which would specifically and comprehensively cover paper and board FCM has so far been adopted at European Union level, although Commission Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food also applies to paper and board FCM. As laid down in Article 6 of Regulation (EC) No 1935/2004, the Regulation does not prevent Member States from maintaining or adopting national provisions in the absence of specific measures adopted at Union level provided they comply with the rules of the Treaty.

The Commission also recalls Commission Recommendation (EU) 2017/84 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food and the guidance developed thereunder by the European Union Reference Laboratory for Food Contact Materials. Although these documents do not possess a legally binding nature, they have relevance to the uniform application of the provisions of European Union law in the area regulated by the notified draft.

The Commission welcomes the objective of the notified draft to prevent exposure to MOAH, defined in Section 2(8) of the Consumer Goods Ordinance as introduced by Article 1(1)(b) of the notified draft, in the interest of public health. However, it takes note of the following provisions of the notified draft in particular.

Article 1(2) of the notified draft introduces Section 6a(1) in the Consumer Goods Ordinance, which lays down the general rule that FCM made of paper, paperboard or cardboard using recycled paper may only be manufactured and placed on the market if a functional barrier ensures that no MOAH are transferred from the food contact materials to the food. According to that provision, 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.'

First, the Commission is not aware at this moment in time of any scientific work which provides conclusive evidence that the use of functional barriers to prevent the transfer of MOAH from paper and board FCM is effective to protect public health by preventing exposure to MOAH. The Commission recalls that one of the principal aims of Commission Recommendation (EU) 2017/84, mentioned above, is to determine the key sources of mineral oil exposure in the supply chain and where risk management can therefore most effectively intervene in order to prevent exposure. Other potential sources of MOAH in the food chain include environmental contamination as well as oils and lubricants used in the processing and transportation of foods. A reduction of MOAH originating from

sources other than packaging could thus be defended as a more adapted measure given the large number of other sources of MOAH exposure. Therefore, the Commission kindly invites the German authorities to share scientific data which supports the view that the introduction of functional barriers as laid down in the notified draft is effective in preventing exposure to MOAH in a context of the wider potential sources of exposure.

Second, the Commission considers it unclear from the definition in Section 2(9) to be introduced in the Consumer Goods Ordinance by Article 1(1)(b) of the notified draft, or from any other provision thereof, which types of barrier materials would be sufficiently effective in preventing such migration. Whilst the Commission takes note of examples of suitable materials provided in the notification message, the German authorities are invited to consider further specifying these types of barrier materials within the text of the notified draft. Doing so would clarify the consequences of observing MOAH in food which has been packed in recycled paper and board using a functional barrier, where the possibility of a failure of the functional barrier may exist in addition to MOAH potentially being present in the food prior to its packaging.

Third, in the explanatory statement to the notified draft, reference is made to two methods of analysis, namely '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' and 'Measurement of mineral oil - hydrocarbons in food and packaging materials'.

The Commission considers, taking into account the available information on the current state of analysis of MOAH in foods, that the current analytical capabilities are insufficient in order to reliably measure for all foods the proposed limits of 0.5 mg/kg for the sum of MOAH in food and 0.15 mg for the sum of MOAH in food simulant as defined in the notified draft.

The Commission would like to refer in this regard to the guidance issued by the Commission's Joint Research Centre as European Reference Laboratory for food contact materials on sampling, analysis and data reporting for the monitoring of mineral oil hydrocarbons in food and food contact materials ('Guidance Document') in the context of Commission Recommendation (EU) 2017/84. As explained in the Guidance Document, it is intended for use by all stakeholders involved in the determination of mineral oil hydrocarbons in food and FCM, including food inspectors, official control laboratories, laboratories in industry and laboratories of non-governmental organisations. Table II of the Guidance Document contains the recommended performance criteria for MOAH analysis with maximum and target limit of quantification (LOQ) for each so-called C-fraction in different food categories (dependent on fat content). It can be observed from that table that the recommended target LOQ for each C-fraction in fats and oils is 0.5 mg/kg. This level corresponds to the maximum level provided for in section 6a(1)(1) to be introduced in the Consumer Goods Ordinance by Article 1(2) of the notified draft for the sum of MOAH in food.

The Commission notes that the methods of analysis mentioned in the notification message do not contain or refer to validation data demonstrating that the limits of 0.5 mg/kg food or 0.15 mg/kg food simulant are achievable. Given that reliable measurement is required in order to assess compliance with the provisions of the notified draft, the Commission kindly invites the German authorities to consider whether there is validation data demonstrating that the level for the sum of MOAH as reflected by those limits can be reliably measured for all categories of food, and to inform the Commission of such data. Without reliable analytical methods to assess compliance, the stated aim of the notified draft to protect public health may not be effectively achieved due to its reduced enforceability which, given that the notified draft is understood to apply also to FCM originating from other Member States, may also disturb the effective functioning of the internal market.

Finally, the Commission notes that Article 1(2) of the notified draft introduces Paragraph 3 of Section 6a in the Consumer Goods Ordinance, which provides for a derogation from paragraph 1 of that Section under which the FCM concerned can be manufactured and placed on the market without a functional barrier if the food business operator who brings the FCM into contact with a food for the first time declares to the manufacturer or distributor of the FCM before delivery thereof that he or she will dispense with the functional barrier. It is stated in the explanatory statement of the draft Ordinance that obligation to use a functional barrier when placing on the market FCM made of waste paper 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". It is further stated that "[i]n 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."

The Commission would like to point out that it has not been clarified how a food business operator may ensure that the products in question meet the requirements of the notified draft when using FCM originating from another Member State which are not subject to the requirements of the notified draft. It is also unclear how this obligation would affect manufacturers or distributors of FCM in other Member States, including where they do not intentionally market their products in Germany, but whose products are nevertheless used by food business operators in Germany for reasons beyond their control. To avoid disturbance to the effective functioning of the internal market, the German authorities are invited to clarify these elements of the notified draft.

The Commission invites the German authorities to take the above-mentioned comments into account.

The Commission furthermore recalls that once the definitive text has been adopted, it must be communicated to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

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