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Health and Food Safety Directorate General

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Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
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SUMMARY REPORT

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the presence of ethylene oxide in food additives.

The Commission presented to the Committee the draft Commission Regulation amending the Annex to Regulation (EU) No 231/2012 as regards the presence of ethylene oxide in food additives. The enforcement of the current Union law may raise difficulties, as it is difficult to establish whether the presence of ethylene oxide results from its use in the sterilisation of the food additives in breach of Regulation No 231/2012, or from any other reason. Therefore, in order to avoid those difficulties and to ensure a high level of protection of human health, the draft sets out a maximum limit for residues of ethylene oxide, irrespective of its origin, at 0,1 mg/kg (*sum of ethylene oxide and 2-chloro-ethanol expressed as ethylene oxide*) applicable to all food additives. This maximum limit might be re-examined in the future, taking into account technological progress which might result in achieving lower limits of quantification by routine methods of analysis by well-equipped laboratories across the European Union.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008.

The Commission presented the draft Regulation and its annexes. The draft Commission Regulation takes account of the comments received from Member States and stakeholders during the consultation process and previous meetings.

The Commission detailed the provisions subject to the most recent amendments:

- The Regulation requires that plastic placed on the market for food contact has been recycled with a suitable recycling technology. It may also require the authorisation of recycling processes applying a technology, and it allows for the use of so-called recycling schemes to reduce levels of contamination and

decontamination requirements. The Commission highlighted that recycled plastic must comply with Regulation (EU) No 10/2011, including as regards the migration limits.

- The new Regulation sets up three main procedures. The first establishes whether a novel recycling technology is suitable. After a demonstration of its capability to manufacture safe recycled plastics and the publication of the related report, this procedure allows novel technologies onto the market under strict conditions, in order to gather data establishing with scientific certainty their suitability for the recycling of plastic food contact materials (*chapter IV of the Regulation*). Where required for a given technology, the second procedure concerns the pre-market authorisation of recycling processes, and the third concerns the registration of recycling installations, involving the competent authorities of the Member States.
- The Regulation also places requirements on the collection of waste, as the input to recycling processes needs to be well defined; decontamination is relative: if the material that goes in is too dirty, the final material will be too dirty. Since competent authorities do not have the possibility to control this based on the official control Regulation, the new recycling Regulation requires third party certification of waste collection. The Commission noted an upcoming revision of the waste framework Directive, which might provide an extended basis for such certification in the future.

Member States welcomed in general the draft Regulation and thanked the Commission for the efforts in developing it and seeking for an EU harmonised approach. During the discussions, they raised in particular the following issues:

- The Regulation is generally perceived as complex. The Commission explained that the basis requirements are not complex, but that some of the procedures need to find a balance between legal certainty and simplicity, and are therefore sometimes detailed. In general, the need for the level of complexity is now understood and accepted. Several Member States asked for guidance and BTSF training to support its proper implementation. The Commission explained that guidance is being developed, and that training will be positively considered.
- Some Member States expressed their reticence about the possibility for recycled plastic to be present on the market when a technology has not yet been fully assessed by EFSA. The Commission explained that it had strengthened the requirements under Article 10 and that a publicly available report on the safety of the material will be required before the recycled material can be placed on the market, among other conditions and safeguard provisions.
- Some Member States raised their concern as regards the identification obligations for twenty (20) detected incidental contaminants as described under Article 13(5)(c). The Commission explained that more substances will need to be identified in practice and that this identification serves the purpose to identify the probable contamination sources and, on that basis, to reason on the likely co-occurrence of substances of concern.
- Several Member States insisted on the need to speed up the process for the authorisations Decisions for PET recycling processes. The Commission confirmed that the draft authorisation Decisions would be processed without delay after the entry into force of the Regulation. Also the Register would become operational.

- A specific discussion took place regarding the use of recycled plastic behind a functional barrier. A specific transitional provision has been added concerning these processes. A key point of this procedure is that the processors will need to demonstrate that the functional barrier is capable of functioning as such. Thereafter these processes may remain on the market if notified in accordance with Article 10, and if they are included on a specific list.

During the discussions, one Member State indicated that it could not support the proposal, as the approach where recycled plastics are allowed to be placed on the market for food contact before the final assessment of a novel technology at EU level, and where the “post-market” assessment can last for an indefinite period, cannot be considered to ensure a high-level of protection of human health. In addition, some Member States explicitly asked for a statement to be published as part of the report of the meeting:

- Belgium: *“The main objective of the legislation on food contact materials and of the competent authorities in Belgium is the protection of public health through, among other things, strict legislation and the surveillance of the food safety. We are still concerned about the "post-market" authorization procedure for novel technologies and the safeguard of the public health and we question whether this is feasible via only a documentary check in the case of a novel technology.”*

- France: *« Les autorités françaises s’abstiennent lors du vote sur ce projet de règlement bien qu’elle reconnaissent que le texte proposé par la Commission européenne constitue une avancée pour l’évaluation des procédés de recyclage. Elles auraient en effet souhaité que la procédure envisagée permette d’assurer un meilleur niveau de sécurité en ce qui concerne la mise sur le marché de matières plastiques recyclées, en prévoyant par exemple une évaluation par l’EFSA des « nouvelles technologies » de recyclage des plastiques avant leur mise sur le marché et en ne fixant pas par défaut un nombre limité de contaminants à identifier dans les rapports publiés par les opérateurs »*

- Italy : *“Italy is concerned about the "post-market" authorization procedure for novel technologies and wonders whether only a documentary check in the case of a novel technology is sufficient to guarantee the safeguard of the public health. The main objective of the competent authorities and the legislation on food contact materials is the protection of public health and food safety”.*

The Commission thanked the participants for their constructive approach and useful comments and indicated that the vote would proceed through a written procedure.

Vote taken: Favourable opinion.