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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*
24 April 2023

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SUMMARY REPORT

A.01 Information and exchange of views on the upcoming review of Commission Implementing Regulation (EU) 2021/1533 of 17 September 2021 imposing special conditions governing the import of feed and food originating in or dispatched from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) 2016/6.

The Committee was informed that internal consultations on the review are ongoing within the Commission. Some delegations expressed their initial views on the expected review.

A.02 Feedback of the discussions at the Working Group Agricultural Contaminants and further exchange of views on the conclusions on the different topics discussed.

An update on the issues discussed at the meeting of the Working Group on Agricultural Contaminants of 21 March 2023 was provided. It included the most recent changes as regards the maximum levels for T2 and HT2 toxin in malting barley, oat milling products and foods containing oat milling products. The comments from a stakeholder organisation on these changes were provided to the Committee for consideration.

A.03 Feedback from the 16th session of the Codex Committee on Contaminants in Foods (CCCF).

The Committee was informed of the main points discussed at the 16th session of the Codex Contaminants in Foods (CCCF) that took place from 17 to 20 April 2023. Amongst the different points mentioned, information was provided as regards the timing of the publication of the updated Toxic Equivalency Factors (TEF) for dioxins and dioxin-like PCBs agreed at the WHO expert consumption in October last year. Furthermore attention was drawn to the Circular letter on naturally occurring radionuclides for which comments are requested before 30 June 2023.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission implementing regulation authorising the change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission did not present to the Committee the draft Commission Implementing Regulation authorising the change of the conditions of use of the novel food astaxanthin-rich oleoresin from *Haematococcus pluvialis* algae as it was decided that further discussion at the PAFF Working Group meeting on novel foods was needed before it could be voted on.

Vote postponed

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) Amending Annex I to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as regards the addition of a new substance.

The Commission presented to the Committee the draft act authorising the use of an additional substance, bis(2-ethylhexyl)cyclohexane-1,4-dicarboxylate, to be used in plastic materials and articles intended to come into contact with food. The measure is underpinned by a favourable EFSA opinion.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additive stearyl tartrate (E 483).

The Commission presented to the Committee the draft Commission Regulation proposing the withdrawal of the food additive stearyl tartrate (E 483) from the Union List of food additives. EFSA, in its opinion re-evaluating the safety of stearyl tartrate (E 483), was not able to confirm its safety due to a lack of adequate toxicological data. In a public call following-up on the EFSA opinion, no business operator committed to provide the requested toxicological data. Therefore, it is appropriate to remove stearyl tartrate (E 483) from the Union list of authorised food additives. In order to enable food business operators to put alternatives in place, the draft Regulation will apply 6 months after its entry into force and foods containing stearyl tartrate (E 483) lawfully placed on the market before the date of application may continue to be marketed until their date of minimum durability or ‘use-by date’.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of buffered vinegar as a preservative and acidity regulator.

The Commission presented to the Committee the draft Commission Regulation authorising buffered vinegar as a new food additive. The proposed use was assessed by EFSA which, in July 2022, published its opinion concluding that there is no safety

concern for the use of buffered vinegar at the proposed use levels. Buffered vinegar is intended for use as an alternative to other authorised preservatives or acidity regulators, in particular to acetic acid and its salts (E 260-263). It is therefore appropriate to authorise the use of buffered vinegar as a preservative and acidity regulator and to assign E 267 as E-number to this new food additive.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additives nitrites (E 249-250) and nitrates (E 251-252).

The Commission presented to the Committee the draft Commission Regulation amending the conditions of use and specifications for the food additives nitrites (E 249-250) and nitrates (E 251-252). Nitrites and nitrates are authorised food additives used as a preservative to secure, in conjunction with other factors, the microbiological safety of foods. At the same time, the presence of nitrites and nitrates in foods can give rise to the formation of nitrosamines some of which are carcinogenic. EFSA in its 2017 opinions re-evaluating the safety of nitrites and nitrates concluded that their respective Acceptable Daily Intake values (ADIs) were not exceeded from food additive uses; however the ADIs would be exceeded if all sources of dietary exposure were to be considered together. EFSA also considered that there was some concern for the overall exposure to nitrosamines present in food although it was not possible to clearly discern the nitrosamines formed from the nitrite added as a food additive from those formed from the nitrite present in the food naturally or as a result of a contamination.

Following the EFSA re-evaluation of nitrites and nitrates as food additives and the extensive consultation of organisations representing the relevant food business operators, consumers and experts from competent authorities of Member States, it is appropriate to reduce the maximum amounts of nitrites and nitrates that may be added to foods to keep the level of nitrosamines potentially formed due to that use as low as possible, while ensuring microbiological safety. Transitional periods will be granted to allow food business operators to adapt to the new more stringent conditions of use. It is also appropriate to amend the specifications and lower the existing maximum permitted limits for lead, mercury and arsenic in nitrites and nitrates. During the discussion several Member States intervened:

Belgium asked to include the following declaration in the report of the meeting:

“Belgium thanks the Commission for taking into account previous comments and congratulates the Standing Committee for achieving an ambitious revision for protecting the health of consumers and a first small step towards simplification. We continue to hope that in due course further steps can be taken towards clarification and simplification, and in particular a strongly reduced use of 'italics'. It is important that meat products from muscle parts such as 'filet d'Anvers' (made from beef) and smoked horse meat are included in descriptions of 'and similar products' in the guidance describing the food categories.”

France asked to include the following declaration:

“France points out that the use of these food additives is subject to a high level of attention in France because of their proven impact on health. France notes that the

interest in the use of food additives and their safety is a serious concern for citizens, as conveyed by many European consumer protection associations. The French Agency dealing with the safety of the food, environment and labour (ANSES) concluded in its opinion of 2022 that bibliographic data confirmed the existence of an association between the risk of colorectal cancer and exposure to nitrates and nitrites, whether ingested through drinking water or food, and in particular from processed meat. The Agency's assessment is thus consistent with the classification of the International Agency for Research on Cancer (IARC): consumption of processed meat (including charcuterie) is carcinogenic to humans (Group 1, i.e. sufficient indications of carcinogenicity for humans are available).

In the light of these exposure results and the known effects of exposure to nitrates and nitrites, the Agency considers that limiting the intentional addition of these compounds to food with an "as low as reasonably achievable" approach is a health objective to be pursued in order to minimise as far as possible the overall exposure of the population. Following the publication of the ANSES opinion, the French Government followed the Agency's recommendations by adopting an action plan to reduce or eliminate the use of nitric additives in all food products where this is possible without an impact on food safety and this, as soon as possible. Three phases are foreseen:

1) Immediate decreases in nitrites/nitrates additives (as of end of April 2023): they concern more than 80 % of the volumes of meat products placed on the market in France; for example, cooked hams and lardons, which account for more than 40 % of the meat products consumed in France, will see the levels of nitrites/nitrates additives decrease by 25 % and 20 % respectively in the coming weeks. This reduction will be similar for cooked sausages (knacks), pastes and rillettes, and even more than 30 % for grill sausages (chipolatas).

2) Short-term decreases (6-12 months): they concern more than 90 % of the volumes of meat products consumed in France, in particular sausages, cooked sausages, pastes, rillettes, eyelashes and douillettes, for which the reductions will be around 25 % or even more than 30 % for hams compared to the maximum levels currently in force; at the end of this period, it is even provided for the total removal of any nitrites/nitrates additives from chilling sausages. The indicated deadline will make it possible to validate the theoretical feasibility of these reductions and to check that they make it possible to control the health quality, in particular microbiological quality, of the products concerned.

3) Within 5 years: the relevant scientific institutes will be mobilised for research and development of solutions to minimise and eliminate nitrite/nitrate additives in all products of 'charcuterie' where possible.

The French authorities welcome the European Commission's efforts: the draft proposal considerably revises the regulations on nitrites and nitrates by proposing a reduction in the levels of nitrites and nitrates. However:

- the transition period by default (24 months), is still too long, given the challenges in terms of consumer protection. The French authorities would have liked this default period to be reduced to 18 months, in particular for processed meat products;

- we request that a plan be put in place at European level to achieve, in European legislation, the reduction or abolition of the use of nitrites and nitrates as additives in all food products where this is possible without health impact, as soon as possible, in line with the action plan drawn up by the French Government."

One Member State in its intervention referred to the provision for the use of nitrites in ‘*Mettwurst, Teewurst* and similar products’ introduced in the food category 08.3.4.3. outlining that there is the same need for nitrites for the corresponding products available on its market. The Commission clarified that in such case the use of nitrites would be covered by the term ‘and similar products’ and further suggested including such clarification in the Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008. A similar consideration was followed for a product corresponding to ‘dried ham’ covered by the provision ‘*dry cured ham* and similar products’ in the food category 08.3.4.2.

Another Member State requested a clarification as regards the use of nitrites in dried ham. In its reply, the Commission referred to the food category 08.3.4.2 that covers traditional dry cured products. More specifically, a reference was made to the provisions for nitrites at the maximum residual amount of 30 mg/kg permitted for ‘traditionally cured products’ and of 65 mg/kg permitted for ‘*dry cured ham* and similar products’. Further clarification may be provided in the Guidance document describing the food categories as well.

Vote taken: Favourable opinion.