



EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2021)7479842

Standing Committee on Plants, Animals, Food and Feed
Section *Novel Food and Toxicological Safety of the Food Chain*
28 September 2021

CIRCABC Link: <https://circabc.europa.eu/w/browse/5699d7a2-a8a7-4ebd-bb3a-11297c3f2263>

SUMMARY REPORT

A.01 Feedback on the recent work of the PAFF Working Group on Food Contact Materials (FCM).

The Commission briefed the Member States on the discussions during the expert working group on food contact materials of the PAFF, which took place on 16 September 2021. The Commission explained it had informed the WG on the progress of the revision of the legislation on food contact materials, amendments to Regulation (EU) No 10/2011, and on the impact assessment to prepare a measure establishing new limits for ceramic and vitreous materials. In addition the Commission services had discussed with the PAFF working group the main concepts of a Regulation that is under preparation intended to replace Regulation (EC) No 282/2008 on recycled plastic.

A.02 Approval of the 2021 Member States' plans for the monitoring of residues in accordance with Directive 96/23/EC.

The Commission informed the Committee that the Member States' and Northern Ireland's residue monitoring plans for animals and animal products have been evaluated by DG SANTE as foreseen by Directive 96/23/EC. This evaluation also includes the review of the plans by the European Union Reference Laboratories. The Commission recommended the approval of all 27 Member States' and Northern Ireland's residue monitoring plans for 2021. Member States raised no comments during the meeting. The Commission informed that the plans will be approved if no further comments are received from Member States within 10 days, as foreseen in Article 8 of Directive 96/23/EC.

A.03 Update on topics under discussion in relation with contaminants in food.

The Commission representative provided an update on the following topics:

- the maximum levels for ochratoxin A in food: the technical discussions are now finalised with the exception of the establishment of an appropriate maximum level for date juice, taking into account the additional information received.
- the maximum levels for hydrocyanic acid: further discussion is needed on the maximum level for linseed, based on the comments and information received from a stakeholder organisation.

- the review of the maximum levels on deoxynivalenol and the establishment of maximum levels for T-2 and HT-2 toxin in cereals and cereal products: finalisation of the technical discussion is foreseen at the next WG meetings, considering the possible year-to-year variation and geographical variation of occurrence of these mycotoxins in cereal crops.
- the provisions for sampling and analysis for the control of mycotoxins in food and for the control of plant toxins in food.
- the envisaged targeted stakeholder consultation on a draft recommendation on the monitoring of glyco-alkaloids in potatoes and food products derived therefrom.
- the review of the existing benchmark levels, the setting of benchmark levels for foods not yet covered and the establishment of maximum levels for acrylamide in food. A targeted stakeholder consultation on these levels will be launched.
- the establishment of maximum levels of 3-MCPD esters and glycidyl esters in food (other than those already regulated).
- the envisaged targeted stakeholder consultation on the setting of maximum levels for dioxins and dioxin-like PCBs in foods not yet covered by legislation and the possible lowering of the maximum level for dioxins and PCBs for milk and milk products.

Member States did not raise particular comments on the information provided.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of calcium fructoborate as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft Commission Implementing Regulation (EU) authorising the placing on the market of calcium fructoborate as a novel food. The measure authorises the placing on the Union market of calcium fructoborate as a novel food for use in food supplements as defined in Directive 2002/46/EC for the adult population, excluding food supplements for pregnant and lactating women.

Belgium asked to include the following declaration in the minutes of the meeting: *‘Belgium votes against because Belgium is of the opinion that calcium fructoborate must be regarded as a new source of boron that will have to be added in Annex II to Directive 2002/46. EFSA has confirmed that boron from calcium fructoborate is bioavailable. Therefore, a reference to this Directive is needed in the authorisation. Moreover the average daily intake of 6 mg boron provided by the novel food at the proposed maximum dose of 220 mg/day would exceed twice the maximum level of boron which is allowed in our national food supplement legislation (3 mg/day). For those reasons, Belgium cannot support the authorization of calcium fructoborate with the proposed maximum level.’*

Vote taken by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of vitamin D2 mushroom powder as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft Commission Implementing Regulation (EU) authorising the placing on the market of vitamin D2 mushroom powder as a novel food. The measure authorises the placing on the Union market of vitamin D2 mushroom powder for use in a number of foods, including foods for special medical purposes as defined under Regulation (EU) No 609/2013, excluding those intended for infants, and in food supplements as defined in Directive 2002/46/EC, excluding food supplements intended for infants and young children.

The Netherlands asked to include the following statement in the minutes: *‘Our last statement in the SCoPAFF meeting of 23 June 2020 regarding point B.02, still holds as we believe that the two columns of the conditions of use in the Annex of the proposal should be replaced with the statement “To be used in compliance with Directive 2002/46/EC, Regulation (EU) No 609/2013 and/or Regulation (EC) No 1925/2006”. This would be the only adequate way to manage vitamin D intake via of all sorts of fortified foods in the diet (including food supplements) using the relevant, existing EU legislation framework. This has become even more pressing because the proposed uses of these novel food ingredients with vitamin D2 cover a really broad range of products as well as food supplements. Vitamin D (i.e. its biological active form 1,25-dihydroxy-vitamin D) has several important functions in the human body. However, due to the continued expansion of the range of foods fortified with novel vitamin D2-containing ingredients, it seems increasingly difficult to adequately manage individual vitamin D intake in consumers so that the safe upper limit is not exceeded.’*

Vote taken by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of dried fruits of *Synsepalum dulcificum* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of dried fruits of *Synsepalum dulcificum* as a novel food. The measure, which is underpinned by an EFSA opinion, authorises the use of this novel food in food supplements.

Spain asked to include the following statement in the minutes: *‘We are of the opinion that the labelling requirement of a statement warning about the cross-reactivity with peanuts allergens must be included, based on Precautionary Principle considering EFSA opinion and due the severity of adverse reactions in the sensitive population’*

Vote taken by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of frozen and dried formulations from *Locusta migratoria* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of frozen, dried and powder (ground) forms of *Locusta migratoria* (migratory locust) on the Union market as a novel food. This is the second insect species presented for an authorisation as a novel food in the EU. The measure, which is underpinned by an EFSA opinion, authorises the placing on the EU market of the novel food to be consumed as such or as a food ingredient in a number of foods. One delegation explained that it was not in favour of the draft Regulation as there is no protein deficiency in Europe that would make insect consumption necessary as food.

The Netherlands asked to include the following statement in the minutes: *‘For the present proposal for authorization of frozen and dried formulations from Locusta migratoria the EFSA NDA panel pointed to potential cross-reactivity of Locusta migratoria proteins with proteins from crustaceans, molluscs and products thereof, and mites, and concluded that consumption of this novel food may cause allergic reactions in subjects with allergy to crustaceans, mites and molluscs. While we do not have the intention to challenge this conclusion, looking at the available information in the dossier and the EFSA opinion itself, The Netherlands doubt if this conclusion forms a sufficiently strong basis for including molluscs in the proposed allergenicity warning. We recognise that the references in the EFSA opinion to published bioinformatics data on this subject and also to other publications that highlighted cases where protein homology between more or less related arthropod species caused cross-reactivity definitely form an important starting point for an allergenicity assessment. Nevertheless, we feel that further research would be needed to demonstrate that protein homologies identified in this way are relevant for consumers with known food allergies. We are not aware of data confirming that homology between proteins in molluscs and Locusta migratoria would be clinically relevant for consumers with a known mollusc allergy. We can support the other proposed elements of the allergenicity warning labelling, since it seems that more information is available on the clinical relevance of cross-reactivity of Locusta migratoria with other arthropod species.’*

Vote taken by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of 3-fucosyllactose (3-FL) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470.

The Commission presented the draft proposal Commission Implementing Regulation (EU) authorising the placing on the market of 3-fucosyllactose (3-FL) as a novel food. The measure which is underpinned by an EFSA opinion, authorises the use of this human identical milk oligosaccharide in a number of foods, in foods for special medical purposes and in food supplements.

Vote taken by written procedure: Favourable opinion.

B.06 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 as regards the use of sodium carbonate (E 500) and potassium carbonate (E 501) in unprocessed cephalopods in unprocessed cephalopods.

The Commission presented the draft proposal Commission Regulation concerning the use of sodium carbonate (E 500) and potassium carbonate (E 501) as acidity regulators, as an alternative to phosphates, to improve the organoleptic properties of unprocessed cephalopods. The extension of use of carbonates constitutes an update of the Union list, which is not liable to have an effect on human health. Therefore, it has not been necessary to seek the opinion of the Authority.

Vote taken by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex II and Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards titanium dioxide (E 171).

The Commission presented the draft act removing the authorisation to use titanium dioxide (E 171) in foods, based on a recent scientific opinion by the European Food Safety Authority (EFSA) which concluded that titanium dioxide can no longer be considered as safe when used as a food additive. To ensure a smooth transition the proposal allows the placing on the market of foods containing titanium dioxide (E 171) in accordance with the current rules until six months after the date of entry into force of the Regulation. The proposal also contains a commitment to review the necessity to maintain titanium dioxide on the Union list of food additives for its exclusive use as a colour in medicinal products within three years after the date of entry into force. Discussions took place on the possibility of an end-date for the presence on the market of foods containing titanium dioxide, or on the duration of the transition period. The Commission services considered that the text presented a balanced compromise between all positions expressed. A question was raised by a Member State regarding the use of foods/ food ingredients containing titanium dioxide (E 171) in compound foods produced after the 6-months transition period. In reply the Commission services presented the technical view, which does not represent the binding position of the Commission as an institution, clarifying that foods which continue to be marketed in accordance with the transitional measures may not be used in the production of compound foods later than six months after the date of entry into force of the draft

Regulation, because such compound foods would not be produced in accordance with the rules applicable at the time of the production.

Belgium asked to include the following statement in the minutes: *“Belgium votes in favour of the proposed regulation, as Belgium fully supports the ban on the food use of E171, which is no longer considered safe when used as a food additive. However, Belgium is concerned about the transitional measures, as they allow foods containing E171 to be sold to consumers for many years after the ban comes into force.”*

Luxembourg asked for the following statement to be included in the minutes of the meeting: *“Luxembourg supports the proposal of the Commission in order to bring in force a Regulation at EU level prohibiting TiO₂. Luxembourg would have preferred to have besides a transition period also a specific cut-off date (2 years) after which any food products containing TiO₂ should not be marketed anymore in the EU”*

Vote taken by written procedure: Favourable opinion.