EUROPEAN COMMISSION

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*
30 November 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/b51e2e7a-f4bc-4d98-97f0-103e4317d9ad*

SUMMARY REPORT

A.01 Clarification as regards the use of some rice derived products.

The use of certain rice products, sometimes called 'rice concentrates' or similar, has been reported. Such products are obtained by milling non-edible parts of rice (hulls/husks) into a powder which is rich in silica (about 20 percent of silica). These products are intended to be used as anticaking agents or carriers. Powders obtained from ground rice hulls/husks have a very minor, if any, effect on the flavour of foods to which they are added. Particle size characteristics of such powders are sometimes adjusted to optimise their anticaking effect for use in different foods.

The Committee unanimously concluded the following:

- Powders obtained from the non-edible parts of rice such as hulls/husks which perform a technological effect in foods are considered neither as a substance normally consumed as a food in itself, nor as a characteristic ingredient of food.
- The intentional addition of rice husk or hull powder to food for a technological purpose, e.g. to act as an anticaking agent or carrier in foods, is deemed to meet the definition of a food additive. As a result, such powders shall comply with the conditions set out in the food additive legislation (including relevant specifications) and be labelled in accordance with the appropriate provisions for labelling of food additives.
- Only food additives listed in the Union list may be placed on the market as such and used in foods under the conditions of use specified therein. Inclusion on the list of approved food additives may be requested by means of an application made in accordance with Regulation (EC) No 1331/2008[1].

This opinion is that of the Standing Committee on Plants, Animals, Food and Feed and has not been adopted or endorsed by the European Commission. The views may not in any circumstances be regarded as stating an official position of the Commission. This opinion is intended to assist national authorities in the application of Regulation (EC)

[1] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p. 1.

No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

A.02 Exemption for cereals for the production of beer or distillates from the maximum level for cadmium, provided that the remaining cereal residue is not placed on the market as food.

In Regulation (EU) 2021/1323 on maximum levels of cadmium in certain foodstuffs, the category 3.2.12 "Cereals" is accompanied by the following footnote: "*The maximum levels do not apply to cereals used for malt for beer or distillates production, provided that the remaining malt is not placed on the market as food. In case the remaining malt is placed on the market as food, the maximum levels apply, taking into account Articles 2(1) and 2(2) of this Regulation*." A Member State and a stakeholder requested to extend this footnote to cereals for beer or distillates production, which are not converted to malt, because cadmium mainly remains in the cereal residue and the concentrations in beer are very low.

Currently a revision of Regulation (EC) 1881/2006 is under discussion, which foresees inter alia a harmonised terminology and a clearer display of the footnotes. The Member States agreed to amend the footnote for cadmium in cereals via this proposal as follows: "*The maximum levels do not apply to cereals used for the production of beer or distillates, provided that the remaining cereal residue is not placed on the market as food. In case the remaining cereal residue is placed on the market as food, the maximum levels apply, taking into account articles 2(1) and 2(2) of this Regulation*." A vote on this proposal is foreseen in the second half of 2022. In addition, awaiting the application of the revision of Regulation (EC) No 1881/2006, the Member States agreed to already take into account the revised footnote, when enforcing the ML for cadmium in cereals.

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

PFASs: following the 2020 EFSA opinion on perfluoroalkylated substances (PFASs) in food, which concluded that, for big parts of the EU population, the tolerable weekly intake is exceeded, regulatory follow up is under discussion by means of a draft Regulation on maximum levels (MLs) and a draft monitoring Recommendation. The draft Regulation proposes MLs for PFOS, PFOA, PFNA, PFHxS and the sum of these 4 PFASs in commodities, which are relevant contributors to the exposure, for which sufficient occurrence data are available, and for which there is sufficient analytical capability among the laboratories (*eggs, fish, crustaceans, molluscs, meat and offal of terrestrial animals*).

In addition, a draft Monitoring Recommendation is under discussion for:

• commodities for which data are lacking for the establishment of MLs: e.g. foods for infants and young children;

• commodities for which many laboratories are not able to analyse the low concentrations in which PFASs occur: e.g. milk, fruits, vegetables, foods for infants and young children;

• PFAS other than PFOS, PFOA, PFNA and PFHxS, in order to allow a future exposure assessment on additional PFAS substances.

For both proposals a targeted stakeholder consultation was launched between mid-October and mid-November and the comments will be further discussed in the working group on persistent organic pollutants in food. Furthermore a draft Regulation on the requirements for sampling and analytical methods for PFASs is being drafted. This Regulation will follow the general lines of Regulation (EC) No 333/2007 and the EURL will help fine-tuning the analytical method requirements.

Inorganic arsenic: by means of Commission Recommendation (EU) 2015/1381/EU Member States were recommended to monitor during 2016, 2017 and 2018 the presence of arsenic, preferably by determining the content of inorganic and total arsenic and, if possible, other relevant arsenic types, in a wide variety of foods. In 2021 EFSA published its updated dietary exposure assessment for inorganic arsenic in food and concluded that cereals, fish, vegetables and food for infants and young children are the main contributors to the exposure. Taking into account the newly available data, a draft Regulation on MLs for inorganic arsenic in food is under discussion in the working group on industrial and environmental contaminants in food. The draft Regulation proposes to lower certain MLs for rice-based products and to set new MLs for some additional rice-based products, fish, seafood and food for infants and young children and it incorporates the Codex ML for total arsenic in salt into EU legislation. The targeted stakeholder consultation on this proposal will be launched in the coming weeks. In addition an update will be drafted of Regulation (EC) No 333/2007, in order to amend the analytical method requirements (LOQ requirements) on the basis of the advice of the EURL.

Mercury: A draft monitoring Recommendation for mercury in fish and seafood is under discussion, which includes provisions on data collection and consumption advice. The endorsement of the Recommendation is envisaged early 2022.

Regulation (EC) No 333/2007: A Regulation aimed at updating Regulation (EC) No 333/2007 as regards the sampling requirements for metals in fish and terrestrial animals is under discussion. The vote on this proposal is targeted for early 2022.

The Committee was informed that the following **targeted stakeholder consultations** will be launched in the near future:

- on maximum levels for 3-MCPD fatty acid esters and glycidyl fatty acid esters in foods for which no maximum level has been established yet by Commission Regulation (EU) 2020/1233
- on maximum levels for dioxins and dioxin-like PCBs in foodstuffs for which no maximum level has been established yet and a lowering of the maximum level of dioxins and dioxin-like PCBs in milk and milk products.
- on acrylamide: review of the benchmark levels established by Commission Regulation (EU) 2017/2158, the establishment of benchmark levels for other foods, the establishment of maximum levels.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards maximum levels of mercury in fish and salt.

The Commission presented the proposal and explained the most recent changes. The proposal originally included a transitional measure so that the products which were lawfully placed on the market before the entry into force could remain on the market for an additional 6 months. Following a written comment requesting the extension of

this transitional measure until the date of minimum durability or use-by-date, because the shelf life of canned fish is 3 years, several Member States expressed their support for such an extension. Therefore article 2 was proposed to be rephrased to "*The foodstuffs listed in the Annex, lawfully placed on the market before the entry into force of this Regulation, may remain on the market until the date of minimum durability or use-by-date".* A Member State enquired whether this would also apply to salt, which often has no date of minimum durability or use-by date. The Commission representative confirmed that also salt which was lawfully placed on the market before the entry into force of the Regulation, might remain on the market. In case of doubt, it is for the food business operator to provide the proof of placing on the market before the entry into force of this Regulation.

Vote taken by written procedure: Favourable opinion.

B.02 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 specifications for sodium diacetate (E 262(ii)).

The Commission presented the draft proposal amending specifications for sodium diacetate (E 262(ii)). The current Union specifications lay down that sodium diacetate (E 262(ii)) shall contain 39 to 41 % of free acetic acid and 58 to 60 % of sodium acetate. The amendment allowing up to 43 % of free acetic acid enables shortening the drying time during the production, resulting in the reduction of energy needed and thus in a more sustainable production process. There are no other changes to the production process and the final product is the same, i.e. containing no other impurities than those specified in Regulation (EU) No 231/2012. The proposed amendment is considered as minor, and is not liable to have an effect on human health, thus not requiring the opinion of the Authority.

Vote taken by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.

The Commission presented the draft Regulation correcting Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. The measure is intended to correct two errors in the Union list of novel foods. The first error is related to the specifications of the authorised novel food '*Cistus incanus* L. Pandalis herb'. The specifications erroneously added detailed composition information on the novel food that the applicant had submitted as complementary information, which was not included in the opinion delivered by the Czech competent authority at the time, and is not needed for the safety assessment or the product characterisation. The second error corresponds to the novel food 'Calcium L-Methylfolate'. Its conditions of use in food supplements that were included in the Union list erroneously excluded infants and young children from the targeted users' group, whereas the original authorisation did authorise that use. In addition, there was a need to clarify the specifications limits for mercury and platinum of this novel food.

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 an extension of use of UV-treated baker's yeast (*Saccharomyces cerevisiae*) 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 Regulation (EU) authorising an extension of use of UV-treated baker's yeast (Saccharomyces cerevisiae) as a novel food. The measure authorises an extension of use of the novel food UV-treated baker's yeast (Saccharomyces cerevisiae) to a number of foods intended for the general population. The Netherlands made the following statement: "*Our arguments expressed in previous statements regarding the authorization of vitamin D mushroom powder in the SCoPAFF meeting of 23 June 2020 (point B.02) and that of 28 October (point B.01) also hold for the UV-treated baker's yeast (Saccharomyces cerevisiae). 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.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of cetylated fatty acids 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 cetylated fatty acids as a novel food. The measure authorises placing on the Union market of cetylated fatty acids as a novel food for use in food supplements as defined in Directive 2002/46/EC for the adult population.

Vote taken by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of frozen, dried and powder forms of *Tenebrio molitor* larva 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 frozen, dried and powder forms of *Tenebrio molitor* larva as a novel food. The measure authorises placing on the Union market of frozen, dried and powder forms of *Tenebrio molitor* larva as a novel food for use in a

number of foods intended for the general population. 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.

Vote taken by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of frozen, dried and powder forms of *Acheta domesticus* 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) authorizing the placing on the market of frozen, dried and powder forms of *Acheta domesticus* (house cricket) as a novel food to be used as such as snacks of as an 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.

Vote taken by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) authorising the placing on the market of pasteurised *Akkermansia muciniphila* 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) authorizing the placing on the market of pasteurised *Akkermansia muciniphila* bacteria as a novel food to be used in food supplements as defined in Directive 2002/46/EC and in foods for special medical purposes as defined in Regulation (EU) 609/2013. Both proposed uses are aimed for the adult population excluding pregnant and lactating women.

Vote taken by written procedure: Favourable opinion.