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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*
22 June 2022

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SUMMARY REPORT

A.01 Clarification as regards the status of "Acrylamide Reducing Yeast (ARY)"

The use of asparaginase in the manufacturing process of foods is one of the available mitigation measures[1] for acrylamide reduction used by the food industry. Acrylamide is a contaminant as defined in Council Regulation (EEC) No 315/93[2] and, as such, it is a chemical hazard in the food chain. It is formed from the naturally occurring constituents asparagine and sugars in certain foods, mainly in baked or fried carbohydrate-rich foods, when prepared at temperatures typically higher than 120 °C and low in moisture.

Asparaginase (EC 3.5.1.1) is an enzyme which catalyses hydrolysis of asparagine into aspartic acid and ammonia. Several food enzymes 'asparaginase', obtained with genetically modified microorganisms, are currently available for acrylamide mitigation measures and used by the food industry. Five asparaginase applications are listed in the Register[3] of food enzymes to be considered for inclusion in the Union list of food enzymes.

Conventional baker's yeast refers to species *Saccharomyces cerevisiae* used as a characteristic food ingredient, typically at 20 g/kg of flour in baking, as a leavening agent to convert fermentable sugars present in the dough into carbon dioxide. This causes the dough to expand or rise as the carbon dioxide forms pockets or bubbles. Baker's yeast also affects aroma and taste of bakery products in which it is used. Under standard conditions, conventional baker's yeast is not capable of breaking down asparagine to such degree that would lower acrylamide levels in food[4].

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1 Commission Regulation (EU) 2017/2158 of 20 November 2017 establishing mitigation measures and benchmark levels for the reduction of the presence of acrylamide in food

2 Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 037, 13.02.1993, p. 1 -3).

3 https://ec.europa.eu/food/system/files/2020-06/fs_food-improvement-agents_enzymes_register.pdf

4 Unless used with very specific conditions and times, conventional yeast strains are ineffective at reducing acrylamide. Conventional baker's yeast is capable of degrading asparagine in order to use it as a nitrogen source only when the yeasts are starved for other nitrogen sources such as ammonia, glutamate, and glutamine.

At the request of Member States, the status of an instantaneous dry yeast, rich in asparaginase, also called "Acrylamide reducing yeast (ARY)", was discussed by the Working Group on Food Enzymes.

ARY is obtained under specific production conditions of a specific strain of *Saccharomyces cerevisiae.* The specific strain is selected on a specific media and treated with UV light to induce and enhance the asparagine-degrading cell-wall asparaginase II activity. Asparaginase activity produced is carried out by the living yeast cells. After production, the catalytic protein remains in the yeast cell wall and is not separated from it (*i.e. it is not extracted from its source*). The yeast cream is further concentrated, extruded and dried to get the commercial product with a standardised asparaginase activity level. The food additive sorbitan monostearate (E 491) is added to the yeast cells to protect it during drying and assists in the dispersion and rehydration of the product in its application.

According to the producer, ARY reduces the acrylamide levels in food requiring or not the use of a yeast by up to 93%, with no impact on taste, appearance or texture of the products in which it is used. When used in bakery products, ARY is added in small quantities to reduce acrylamide levels, e.g. up 3 g/kg flour, in addition to a conventional yeast, the latter used for leavening purposes. Despite the fact that ARY retains a reduced leavening activity, a conventional yeast is still used for this purpose, for economic reasons.

ARY is specifically used for its high level of asparaginase activity. Ammonia produced as a result of the enzymatic hydrolysis of asparagine and a certain degree of reducing sugars are consumed by the yeast cells, which also enhances its ability to reduce acrylamide in food products.

The Committee endorsed the following statement (*this statement 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) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law)*:

- ARY is not considered a microbial culture traditionally used in the production of bakery products (*i.e. as baker's yeast*) which may incidentally produce enzymes. ARY is specifically produced to display and enhance enzyme asparaginase activity with a standardised level.
- The use of ARY, where its main function is to catalyse a specific biochemical reaction for a technological purpose in the food to which it is added, represents an intentional use as a food enzyme.
- Consequently, such use is deemed to meet the definition of a food enzyme and therefore it shall comply with the conditions set out in the food enzyme legislation and be labelled in accordance with the appropriate provisions for the labelling of food enzymes.
- As per Article 4 of the Regulation on Food Enzymes, from the date of application of the Union list, only food enzymes included in that list may be placed on the EU market as such and used in foods, in accordance with the specifications and conditions of use provided for in the list. Until the date of application of the Union

list of food enzymes, national provisions in force concerning the placing on the market and use of food enzymes and food produced with food enzymes continue to apply in the Member States, in accordance with Article 24 of the Regulation on Food Enzymes[5].

- Only food additives included in Annex II and Annex III to Regulation (EC) No 1333/2008 may be used in food enzymes under the conditions of use specified therein.
- Inclusion in the list of approved food enzymes or food additives may be requested by means of an application made in accordance with Regulation (EC) No 1331/2008[6].

One Member State expressed its concern on the availability of ARY on the EU Market as an acrylamide reducing tool until the first Union list of enzymes becomes effective. In that regard it was noted that, for food enzymes used as processing aids, the national legislation of the Member States applies until the establishment of the Union list.

A.02 Draft Commission Recommendation on the monitoring of perfluoroalkyl substances in food- SANTE/2021/10010 (*for endorsement*)

The Commission presented the proposal, explained its contents and opened the floor for comments. At the request of a Member State 'seaweed' was added to the scope of the Recommendation. A Member State suggested to restrict the Recommendation to food placed on the market or intended to be placed on the market, to avoid that analysis results for products from domestic/ household preparation or from biomonitoring would be considered. The Commission explained that this Recommendation aims at collecting as many data as possible on PFAS in food. The analysis of household production or the biomonitoring of animals is something that is mostly done in polluted areas, and these suspect samples need to be taken into account when establishing maximum levels (MLs). In this regard it is important that suspect samples are labelled correctly, which is explicitly mentioned in point 8(a) of the Recommendation. In addition, if a Member State would carry out representative sampling of home grown vegetables, these results could be useful for the evaluation of the occurrence of PFAS in certain products. Therefore it does not seem necessary to restrict the scope of the Recommendation.

The Commission explained that, following comments from some stakeholders, the Indicative levels for baby food were increased to 0.050 µg/kg, in order to ensure the achievability of auto controls and take into account the fact that this type of food can also contain fish or meat, which show typically higher PFAS concentrations than fruits, vegetables and cereals. The Recommendation was endorsed by the Committee.

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5 Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7–15).

6 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.

A.03 Draft Commission Recommendation on the monitoring of mercury in fish, crustaceans and molluscs- SANTE/2021/10856 (*for endorsement*)

The Commission presented the Recommendation and explained its contents. No Member State commented on the draft. The Recommendation was endorsed by the Committee.

A.04 Discussion on the EURL Guidance on minimum method performance requirements (MMPRs) for specific pharmacologically active substances in specific animal matrices (*for endorsement*)

The Commission presented the EURL Guidance document regarding the minimum method performance requirements (MMPRs) for specific pharmacologically active substances in specific animal matrices. The purpose of this technical guidance is to improve and harmonise the performance of analytical methods used for the analysis of residues, taking into account state of the art analytical methods. Member States commit to do all efforts to comply with the MMPRs set out in this guidance within reasonable time and to inform about the progress in their national control plans.

The Committee endorsed the guidance document, including a few minor amendments agreed at the meeting. The guidance document will be published on the DG SANTE website.

A.05 Information on the replacement of Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food

The Commission provided information on the replacement of Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food. Commission Regulation (EC) No 1881/2006 has been amended many times. In order to improve its readability and clarity, this new Regulation will replace Regulation (EC) No 1881/2006, and include all subsequent amendments. Consultations (*targeted stakeholder consultation and internal consultations in the Commission)* are ongoing with the aim to present the draft for opinion at a next meeting of the Committee.

A.06 Update on several topics related to contaminants in food

1) Application of maximum levels for pyrrolizidine alkaloids in herbal infusions, dried herbs and food supplements:

The Commission representative informed the Committee on the request from the European Herb Growers Association (EUROPAM), representing Herb Growers and Collectors from Europe:

- to delay the implementation of Commission Regulation (EU) 2020/2040 of 11 December 2020 amending Regulation (EC) No 1881/2006 as regards maximum levels of pyrrolizidine alkaloids in certain foodstuffs , which enters into application on 1 July 2022 for a period of 5 years , and
- to establish in the meantime the same level of 400 µg/kg of pyrrolizidine alkaloids for all herbal infusions and of 1000 µg/kg for all dried herbs and food supplements

This request was done to allow research to progress further, allowing prevention measures to continue to be implemented and produce results and to avoid the loss of major plants and herbs. A representative of EUROPAM presented these

concerns at the Working Group on Agricultural Contaminants on 29 April 2022 and these concerns were then discussed with the Member States as well at the meeting of the Working Group on 15 June 2022. In advance of the WG meeting of 15 June 2022, additional information was provided confirming the request coupled with a proposal for a monitoring plan, as well as the link to the database compiled over the past months. The request for having a single maximum level of 400 µg/kg for all herbal infusions and of 1000 µg/kg for all dried herbs and food supplements was repeated in advance of this meeting of the Committee. The request was also supported by Food Supplements Europe (FSE). All information received by EUROPAM and by FSE was shared with the Member States in advance of the WG meetings and of the meeting of this Committee. The Committee confirmed that the maximum levels as laid down in Commission Regulation (EU) 2020/2040 would enter into application on 1 July 2022.

2) Update on measures related to sampling and analysis:

The Committee was informed that a targeted stakeholder consultation and internal consultation within the Commission services will be initiated on a draft Commission Implementing Regulation laying down the methods of sampling and analysis for the control of mycotoxins in food repealing Regulation (EC) No 401/2006 and on a draft Commission Implementing Regulation (EU) laying down the methods of sampling and analysis for the official control of the levels of plant toxins in food and repealing Regulation (EU) 2015/705

3) Update on maximum levels for deoxynivalenol (DON) and T-2 and H-2 toxin, criteria for physical treatment reducing aflatoxins and meeting of the Baltic Working Group:

The Committee was informed:

- on the status of the discussions on a draft Commission Regulations (EU) amending Regulation (EC) No 1881/2006 as regards maximum levels of deoxynivalenol (DON) in certain foods and as regards maximum levels of T-2 and HT-2 toxin in certain foods.
- that a working group meeting would take place to define possible criteria for plants performing a treatment involving sorting or other physical treatment to reduce aflatoxin contamination.
- that a meeting of the Baltic Working Group would be organised before September 2022 to discuss the update of the management measures provided for in Commission Recommendation (EU) 2016/688 of 2 May 2016 on the monitoring and management of the presence of dioxins and PCBs in fish and fishery products from the Baltic region and a possible change to the dioxin derogation related to the length limit for the Baltic herring from 17 cm to 19 cm.

4) Radioactivity:

Commission Recommendation 2003/274/EURATOM of 14 April 2003 on the protection and information of the public with regard to exposure resulting from the continued radioactive caesium contamination of certain wild food products as a consequence of the accident at the Chernobyl nuclear power station needs to be updated, following the expiry of Council Regulation (EC) No 733/2008 and the entry into force of Commission Implementing Regulation (EU) 2020/1158 of 5

August 2020 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station replacing Regulation (EC) No 733/2008. It is furthermore envisaged to amend within short notice the Commission Implementing Regulation (EU) 2020/1158 as regards the scope (*in particular as regards processed products*), missing footnote (*indicating that the Maximum Levels apply to the food as reconstituted*) and to update CN codes due to recent changes in the CN nomenclature, besides any other issue identified that would need to be amended.

5) Maximum Levels of Arsenic in food:

The Commission presented a draft Regulation on maximum levels for arsenic in food. The Regulation will lower the maximum levels for non-parboiled milled rice and rice and establish new maximum levels for inorganic arsenic in rice flour, rice-based drinks, fish, crustaceans, molluscs, food for infants and young children, fruit juices and nectars, and a new maximum level for total arsenic in salt. The proposal will be presented for vote at a next meeting of the Committee.

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 specifications for rebaudiosides M, D and AM produced via enzymatic conversion of purified stevia leaf extracts as a sweetener

The Commission presented the draft Commission Regulation for the specifications of rebaudioside M, D and AM produced via enzymatic conversion of purified rebaudioside A or stevioside stevia leaf extract. The new production process for E 960c was assessed by EFSA which, in August 2021, published its opinion considering that there is no safety concern for steviol glycosides with a high content of rebaudioside M, rebaudioside D and rebaudioside AM, when obtained by the process in question and concluded that the ADI of 4 mg/kg bw per day assigned to E 960a applies. It is therefore appropriate to set out specifications for rebaudioside M, D and AM produced via enzymatic conversion of purified rebaudioside A or stevioside stevia leaf extract and to assign E 960c(ii), E 960c(iii) and E 960c(iv) respectively as E-number to these new food additives.

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 iron hydroxide adipate tartrate as a novel food and amending Implementing Regulation (EU) 2017/2470

The Commission presented the draft Commission Implementing Regulation authorising the placing on the market of iron hydroxide adipate tartrate as a novel food. The measure which is underpinned by a favourable EFSA opinion, proposes the use of iron hydroxide adipate tartrate in food supplements at two concentrations, one for adults and one for children and adolescents (*4 to 18 years of age*).

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) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food *Schizochytrium* sp. oil rich in DHA and EPA

The Commission presented the draft Commission Implementing Regulation authorising changes in the conditions of use of the authorized novel food *Schizochytrium* sp. oil rich in DHA and EPA, to extent its uses in fish and meat analogues. An EFSA assessment for this extension was not necessary as the intakes from the use of this novel food in fish and meat analogues combined with the intakes from the currently authorised uses are comparable to the intakes that were deemed to be safe by EFSA in its 2014 opinion on *Schizochytrium* sp. oil rich in DHA and EPA.

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) amending Implementing Regulation (EU) 2017/2470 as regards the conditions of use of the novel food galacto-oligosaccharide

The Commission presented the draft Commission Implementing Regulation authorising changes in the conditions of use of the authorized novel food galacto-oligosaccharide to extent its uses in foods for special medical purposes as defined by Regulation (EU) No 609/2013 intended for the general population, excluding infants and young children. The measure is underpinned by a favourable EFSA opinion.

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) on uniform practical arrangements for the performance of official controls as regards the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on specific content of multi-annual national control plans and specific arrangements for their preparation

The Commission presented the draft Implementing Regulation on uniform practical arrangements for the performance of official controls as regards the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on the specific content of multi-annual national control plans and specific arrangements for their preparation. After the repeal of Council Directive 96/23/EC (*on measures to monitor certain substances and residues thereof in live animals and animal products*), it is necessary to ensure the continuity of the rules laid down in that Directive concerning the content of the multi-annual national control plans and their preparation, as well as the minimum frequency of official controls. This implementing act sets out the general requirements for the content of the national control plans, while leaving the risk-based design up to the Member States, in line with the general approach of the Official Control Regulation (EU) 2017/625 (OCR). This act defines a uniform minimum sampling frequency, additional arrangements and additional content to the Member States' multi-annual national control plan and the standard model formats for the submission of information and data. Furthermore, the proposed act will require that official controls by Member States include, in addition to

the risk-based controls, a limited number of controls implemented in a coordinated manner by each Member State and aimed at assessing compliance with the MRLs and at identifying emerging non-compliances and misuses. This surveillance based plan will be used as a basis for the design of Member States' national risk-based control plans.

One Member State expressed a concern as regards the sampling requirement of casings. It was clarified that controls are necessary even if the residue control program is applied to the animal species from which the casings originate, as it cannot be excluded that prohibited antimicrobial substances have been used during processing. As regards the burden of sampling and analysis, the Commission indicated that the sampling should be risk-based and apply the risk criteria provided for in the related Delegated Regulation and that the sampling frequency might be reviewed in the future, based on experiences gained.

Vote taken by written procedure: Favourable opinion.

B.06 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 perfluoroalkyl substances in certain foodstuffs

The Commission presented the Commission Regulation and explained its contents. The maximum level for PFOA in sheep meat should be 0.20 µg/kg instead of 0.80 µg/kg, taking into account the available EFSA occurrence data. As there is still a discussion on a new provision on the part of crabs to which the maximum levels would apply, it was agree, for the time being, to keep the provision which was used in the past for other contaminants: '*for crustaceans the maximum level shall apply to muscle meat from appendages and abdomen (44). In case of crabs and crab-like crustaceans (Brachyura and Anomura) muscle meat from appendages*'.

A Member State requested to add for crab a footnote that, for canned products, the maximum levels applies to the whole content of the can. It was agreed to add such a footnote to the proposal. A Member State expressed its concerns on the feasibility of the maximum levels for game meat while another one showed concerns regarding fish from the Baltic Sea. The Commission explained that, taking into account the occurrence data, the proposed maximum levels are deemed appropriate. Several Member States requested that, when additional occurrence data become available for specific commodities, those data would be analysed to verify whether amendments of the maximum levels are needed. Belgium commented that it supports the regulation as maximum levels of PFAS in certain foodstuffs are urgently needed to protect consumer's health. Belgium requested that the working group on persistent organic pollutants in food closely examines, e.g. yearly in the coming years, all new data collected on PFAS in food placed on the market in order to review, where appropriate, the maximum levels laid down in the regulation and improve the risk management measures. The Commission confirmed that future new occurrence data will be evaluated on a regular basis and that the maximum levels would be revised, wherever needed. A Member State commented that certain maximum levels for fish meat were too high.

Vote taken by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation laying down methods of sampling and analysis for the control of perfluoroalkyl substances in certain foodstuffs

The Commission presented the draft Commission Implementing Regulation and explained its contents. A Member State asked why the provision was deleted that stated that, for controls in accordance with Regulation (EC) No 852/2004 and Regulation (EC) 853/2004, food business operators (FBOs) have to use the same methods, or equivalent ones, as those foreseen in the draft Regulation. The Commission explained that this provision was linked to Art. 4(5) of Regulation (EC) No 852/2004 and that the Commission's' Legal service considers that a link with Art. 5(4) does not provide a sufficient legal basis for these provisions. However Art.4(4) of Regulation (EC) No 852/2004 could provide such a legal basis, but it would require a separate act as the article foresees the use of a PRAC measure. Therefore the provisions on methods for FBOs have been deleted. The Commission considered that, because Art.4(4) of Regulation (EC) No 852/2004 states that FBOs may use appropriate methods which are laid down under community or national legislation and because the current Regulation sets EU rules for methods for PFAS, it is sufficiently clear that those methods should also be used by FBOs for the controls on PFAS in food under Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004. However at the request of the Member States, the Commission committed to organise a further discussion on the matter, which is relevant for all contaminants.

Vote taken by written procedure: Favourable opinion.

M.01 Any Other Business

A Member State indicated that it had received comments and requests for clarification from various stakeholders on the joint statement endorsed by Member States on 21 April 2022 regarding the presence of Mineral Oil Aromatic Hydrocarbons (MOAH) in food, including food for infants and young children. The Commission informed that a discussion would take place at the meeting of the Working Group on Industrial and Environmental Contaminants in Food scheduled on 28 June 2022, with the aim to address the stakeholders' requests for clarification and ensure a uniform interpretation of the statement by Member States.