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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

A.01 Exchange of views on the establishment of uniform practical arrangements for the multi annual national control plans on contaminants in food by implementing act.

The draft Regulation on control plans on contaminants builds on the repealed Council Directive 96/23/EC while its scope is extended to all contaminants, as defined in Council Regulation (EEC) No 315/93 and to food of non-animal origin. Member States should submit two plans: the risk-based control plan for food placed on the market in the Union and the risk-based control plan for food of animal origin entering the Union and intended for placing on the Union market. Both plans should contain a justification for selected contaminant/commodity combinations included in the plans, a sampling strategy and annual minimum sampling frequencies. The foreseen date of application for this Regulation is 1 January 2023. The draft Regulation will be further discussed in the corresponding working group.

A.02 EFSA Report for 2019 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products.

EFSA presented the outcome of the report to the Committee. The Commission informed Member States that the report has now been finalised by EFSA and will soon be published on the Commission website.

A.03 Feedback on the recent work of the PAFF Working Group on Food Contact Materials (FCM).

The Working Group met on 11-12 February 2021 and firstly discussed the transitional provisions under the 15th and draft 16th amendment to Regulation (EU) No 10/2011. The 15th amendment caused questions from business operators, even though similar wording was used in the past. While there are several reasons for these apparent difficulties, the main issue appears to be that it is unclear when a product is first placed on the market. In the draft 16th amendment this is addressed by explicitly stating that first placed on the market means the first marketing of a new product, which is subject to a new Declaration of Compliance (DoC). Thereafter, business operators are expected to continue to include this DoC with all consecutive products.

As long as there are no changes to a product, to its starting substances or applicable rules, requiring a re-issuing of the DoC, it should be considered the same product. This principle had been assumed in the drafting of the 15th amendment, but will become more explicit.

The 16th amendment will also allow the use of biocides in plastic food contact materials, subject to their authorisation under the biocidal product Regulation, and, if needed, the establishment of an SML under Regulation (EU) No 10/2011 itself. The approach was explained in more detail. It was mentioned that the draft text would be provided to industry, and be subject to scrutiny from the Commission services, which are on-going.

Also amendments planned for the near future were discussed:

- Styrene: A pre-cautionary limit will likely need to be established. To properly determine that limit there needs to be a consultation on the use of this substance with business operators using it in food contact materials. This consultation is now under preparation.
- A potential new Regulation on compliance documentation applicable to all FCM was favourably discussed with the experts of the Member States. Commission services will prepare a first draft to facilitate more detailed discussions in next Working Groups.
- To clarify the mandate to EFSA for risk assessment under Regulation (EU) No 10/2011 the Commission services are discussing with EFSA the introduction of a Risk Assessment Policy. When agreed this will then be introduced via an amendment to the Regulation.
- There are four substances waiting for authorisation. An amendment will be prepared to add these substances as soon as possible.

Recycling: the Commission services explained the latest draft is being prepared. This may either amend or replace Regulation (EC) No 282/2008. It should facilitate the authorisation of in particular mechanical PET recycling processes. It is now likely that this will become a re-cast, because that allows simplifying the structure of the text. Comments from the MS were taken into account.

The working group also discussed the initiative on ceramic and vitreous FCMs. The contract for a study to support the impact assessment was signed and started 1st January. SANTE confirmed the final list of metals under the initiative-to-be (*in addition to lead and cadmium, Al, As, Ba, Co, Cr and* Ni) and that the initiative would cover enamelled metals and crystal, as they are considered vitreous materials. The contractor presented the study which will focus on collecting of data, mainly from stakeholders and especially artisans, handicraft and producers of traditional and cultural articles, and the assessment of impacts from lowering current limits and introducing new limits, focusing on the feasibility, acceptability and effectiveness of provisions aimed at reducing the impacts on industry and those smaller producers. The study will run until the end of August 2021. The current timeframe is to complete the IA this year and have a measure adopted beginning 2022.

The Commission updated the Working Group on the progress being made with the overall revision of the FCM Legislation. The roadmap, which was published before Christmas for a 6 weeks feedback period, defines the main problems and broad solutions and policy options for tackling those problems and creating future legislation. A webinar with almost 800 participants took place in January to present the roadmap. Some Member States have given feedback on the roadmap. Around 300 stakeholders responded to the roadmap but this included a number of comments specifically on the revision of the legislation concerning ceramics, which is a separate action. It should be highlighted that the revision of the legislation also needs to complement other EU strategies including the CEAP and the Chemicals Strategy for Sustainability. The next steps are analysing the feedback, and the drafting of a full impact assessment which will look in closer detail at the policy options and the potential impacts of these. The FCM WG will be used as one of the channels of consultation with Member States and the Commission counts on MS to help achieve its goals. The ongoing evaluation of the FCM legislation will be finalised with a staff working document, which will help support the revision of the legislation.

The issue of Bamboo flour in formaldehyde resin was further discussed. While such products cannot and could never be legally placed on the market because bamboo was never authorised through the plastic FCM Regulation (EU) N°10/2011, MS should cleary communicate to business operators that this will not be explicitly banned, to avoid that they would wait for such an explicit ban before they take these products off the market. This is also true for the use of several other potential fillers such as rice shells, as well as for the use of certain natural resins that would fit the definitions under that Regulation. It is important that business operators understand the principles of the positive list under the Regulation and that this is enforced.

In the context of the Bamboo discussion, a member stated noticed possible deficiencies with the risk assessment of formaldehyde, which could require a lower SML, as did other MS before. The Commission services consider that for the time being strict enforcement of the present limit would reduce exposure significantly. It should also be noticed that, after 23 March, new products are subject to stricter migration testing. This also underlines the importance of the Bamboo discussion. The Commission will discuss the matter with EFSA to determine the priority for its re-evaluation.

Regarding the coordinated control plan the previous WG already concluded that the first set of results for the coordinated control plan for Commission Recommendation (EU) 2019/794 indicated a high compliance rate for most materials/substances sampled with the exception of the issue for melamine-bamboo. Pending any change from this in the results for 2020, the Commission therefore pauses this exercise now, but once the revision of the EU FCM legislation is more advanced, there is clear merit in establishing a more regular formal control plan and this seems to have support from a number of Member States. The present exercise under Recommendation (EU) 2019/794 is therefore now closed. Member States who continued the exercise in 2020, should submit results using a simplified template by Wednesday 31 March 2021.

A.04 Exchange of views on the alignment to the Official Control Regulation (Regulation EU) 2017/625) of the control provisions provided in Implementing Regulation (EU) 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station. (SANTE/ 12592/2021).

The control provisions provided for in this Regulation need to be aligned to the Official Control Regulation (Regulation (EU) 2017/625). The new control provisions will be similar to the control provisions as provided in the Commission Implementing Regulation (EU) 2020/1158 on the conditions governing imports of food and feed originating in third countries following the accident at the Chernobyl nuclear power station. Since this alignment requires amendments to several articles of Implementing Regulation (EU) No 2016/6, it is appropriate for reasons of clarity to replace Implementing Regulation (EU) No 2016/6 by a new Regulation.

Furthermore, the Regulation provides that a review on the food products subject to special conditions is to be performed before 1 July 2021 taking into account

i) the results of the controls of the last two years (2019, 2020) performed by the Japanese authorities, and

ii) the outcome of controls at import.

The results of the controls for 2019 and 2020 were presented. The Committee was reminded of the criteria applied for previous reviews, i.e. a product from a certain prefecture is listed if non-compliance with the strict maximum level applicable in Japan has been found in the last year (*for Fukushima prefecture in the last 2 years*). It is thus no longer listed if no non-compliance was found in the last year (*on the condition that controls were performed*). One Member State indicated that there was no longer a need to maintain the measures while other Member States stressed the importance to continue with the approach as followed in previous reviews. The Committee was informed that a draft Regulation will be presented at a next meeting for an opinion.

A.05 Exchange of views on the maximum levels for opium alkaloids in certain foods. (SANTE/12048/2021).

Maximum levels for opium alkaloids (*morphine equivalents i.e. sum of morphine and codeine whereby to the level of codeine a factor of 0.2 is applied because of lower potency compared to morphine*) are envisaged for poppy seeds placed on the market for the final consumer and for bakery products containing poppy seeds and/or derived products thereof. It is further more provided that the food business operator supplying the poppy seeds to the food business operator manufacturing the bakery products shall provide all the necessary information, including analytical data, where appropriate, to enable the manufacturer of the bakery products to place products on market compliant with the maximum level. A delegation indicated that the wording of this provision might need some further fine-tuning. The Committee was informed that a draft Regulation will be presented at a next meeting for an opinion.

A.06 Feedback and exchange of views on topics discussed in recent meetings of the Working groups on contaminants.

The Committee was informed on the ongoing discussions in relation to certain processing contaminants, plant toxins, mycotoxins and dioxins and PCBs.

As regards acrylamide, the following discussions are ongoing:

- review of the benchmark levels for acrylamide as established in Regulation (EU) 2017/2158 with a view to lower the levels.
- establishment of benchmark levels for acrylamide in certain foods other than those covered by Regulation (EU) 2017/2158, in particular those targeted by Commission Recommendation (EU) 2019/1888.
- establishment of maximum levels for acrylamide in certain foods.

As regards for 3-MCPD esters and glycidyl esters, the possible establishment of maximum levels in foods other than vegetable oils, fish oils, infant formula, follow-on formula and young child formula is discussed.

As regards mycotoxins and plants toxins, the following issues are currently discussed**:**

- establishment and review (lowering) of maximum levels for ochratoxin A in certain foods
- establishment of maximum levels for hydrocyanic acid in certain foods.
- review of the maximum levels for deoxynivalenol in cereal and cereal products.
- establishment of maximum levels for T2 and HT2 toxin in cereals and cereal products.
- establishment of maximum levels of Δ9-tetrahydrocannabinol in hemp seed and hemp seed derived products.
- monitoring and investigations on the presence of α-solanine and α-chaconine (glyco-alkaloids) in potatoes and potato products.
- follow-up to EFSA opinion on aflatoxins
- Amendment to Regulation (EC) No 401/2006 as regards methods of sampling and analysis for the control of the levels of ergot sclerotia and ergot alkaloids and as regards analytical performance criteria for other mycotoxins.
- Regulation 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

The Committee was furthermore informed that the draft Commission Recommendation on the monitoring of the presence of furan and alkylfurans in food and the draft Commission Recommendation on the monitoring of the presence of *Alternaria* toxins in food are to be soon adopted and published.

As regards dioxins and PCBs**,** a limited review of the maximum levels (*and if needed action levels*) for dioxins and sum of dioxins and dioxin-like PCBs (*establishment of maximum levels for new foods, review of certain existing maximum levels*) is under discussion. Furthermore, taking into account new occurrence data and experience gained with the implementation of the management recommendations for fish from the Baltic region as provided for in Commission Recommendation (EU) 2016/688 of 2 May 2016, a discussion on the review of the management recommendations is foreseen.

A.07 Brexit - implementation of the withdrawal agreement – Q&A session.

No questions were received before or during the meeting (*Note: after the meeting questions were received from the delegation of Portugal. These questions shall be addressed at the next meeting*).

The Commission announced that it would launch the votes by written procedure in accordance with Article 3(5) of Regulation (EC) No182/2011 after the meeting of the Committee

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 cadmium in certain foods.

A Member State indicated that for poppy seeds and linseeds it has national guideline levels in place, which are lower than the proposed maximum levels. The Commission explained that the maximum levels were proposed on the basis of a large EU wide data set and that also data from stakeholders were considered. It is possible that a specific national data set suggests that a lower maximum level is achievable, but it is considered that the maximum levels should be set on the basis of EU wide data, in order to be adapted to the contaminant concentrations throughout the EU.

A Member State expressed concerns that the transitional measure, which states that foodstuffs listed in the Annex that were lawfully placed on the market before the entry into force may remain on the market until 6 months after the entry into force, would not be sufficient for rice, as it has a long shelf life. The Commission explained that the proposed maximum level is set at the higher percentile of the occurrence data, so that, when taking into account also the measurement uncertainty, only a very small fraction of the produced rice risks to be non-compliant with the lowered maximum level. For this small fraction food business operators have been granted 6 extra months for placement on the market, which should be sufficient. A Member State expressed its support for the views of the Commission and commented against a prolongation of the period for the transitional measure.

Vote taken by written procedure: Favourable opinion.

B.02 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 lead in certain foods.

The Commission presented the proposal and explained the most recent changes which were made to the proposal.

A Member State commented that the proposed maximum levels for edible offal would result in a too high rejection rate for its national production. The Commission explained that the proposed maximum levels were agreed at the 2019 Codex Committee on Contaminants in Food and were supported at that time by all EU Member States. The proposed maximum levels are appropriate, when taking into account the EU wide data. Therefore the Codex maximum levels should now be implemented into EU legislation.

The European Spice Association requested to advance the application date for the proposed ML for lead in dry ginger. Due to a change (January 2020) in the pesticides

legislation (Regulation (EC) No 396/2005), on which the contaminants product classification is based, now the ML for root and tuber vegetables also applies to fresh ginger. However the ML for root and tuber vegetables does not reflect the higher lead concentration in fresh ginger. The ML for dry ginger is calculated on the basis of the ML for fresh ginger, taking into account a processing factor, which results in an unrealistically low ML. The current proposal resolves this issue by increasing the ML for fresh ginger and setting an appropriate ML for dry ginger. The European Spice Association requested to advance the application date for the proposed ML for lead in dry ginger. As this was not possible on such a short notice, the Member States agreed that in the period before the application date of the Regulation, they would not strictly apply the ML for root and tuber vegetables to ginger, but that they would only enforce when also the new higher ML is 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 amending Regulation (EC) No 333/2007 as regards the methods for sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs.

The Commission presented the proposal and explained the most recent changes which were made to the proposal.

A Member State expressed the concern that only the LOQ requirements for lead should be loosened and not those for cadmium and arsenic. The Commission reassured that only the requirements for lead were amended.

A Member State highlighted concerns on the sampling methods for big fishes. The Commission explained that the sampling requirements for fish are intended to be updated via another Regulation.

Vote taken by written procedure: 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 as regards the use of polyols in certain energy-reduced confectionery products.

The Commission received an application for the extension of the use of polyols as a sweetener in energy-reduced hard candies and lollies, chewing candies, fruit gums and foam sugar products/marshmallows, liquorice, nougat and marzipan; strongly flavoured freshening throat pastilles and breath-freshening micro-sweet. The combination of sugar and polyols provides functionalities and organoleptic properties in those foods that cannot be achieved with other ingredients or by using polyols alone. Annex II to Regulation (EC) No 1333/2008 already allows for their use at quantum satis in food category 05.2 ‘Other confectionery including breath refreshening microsweets’ in the same types of products with no added sugars. Consequently, the authorisation of use of polyols as sweeteners in energy-reduced confectionery, alongside with their already authorised use in confectionery with no added sugars, constitutes an update of that list which is not liable to have an effect on human health. Therefore, it was not necessary to seek the opinion of the Authority. In order to ensure that consumers receive adequate information, the labelling of foods containing more than 10% added polyols authorised pursuant to Annex II of Regulation (EC) No1333/2008 must include the mandatory statement ‘*excessive*

consumption may produce laxative effects' in accordance with Annex III to Regulation (EU) No 1169/2011 of the European Parliament and of the Council. The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annex II to Regulation (EU) No 1333/2008 as regards the use of polyols in certain energy-reduced confectionery.

Vote taken by written procedure: 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 steviol glycosides (E 960) and rebaudioside M produced via enzyme modification of steviol glycosides from Stevia as a sweetener.

Steviol glycosides (E 960) is a substance authorised as a sweetener in a variety of foods in accordance with Annex II to Regulation (EC) No 1333/2008. It contains not less than 95 % of eleven named steviol glycosides: stevioside, rubusoside, dulcoside A, steviolbioside and rebaudiosides A, B, C, D, E, F and M, on a dried basis, in any combination and ratio. The Commission received an application for the amendment of the specifications of stevia glycosides (E 960) to include a new method for the production of rebaudioside M. The new process involves the bioconversion of purified stevia leaf extract (≥95% steviol glycosides) through a multistep enzymatic process with enzymes prepared at the first stage of the process. The European Food Safety Authority (EFSA) assessed this application and considered that the enzymatic step process applied for the production of rebaudioside M may result in impurities, different from those that may be present in steviol glycosides (E 960) obtained from water extraction of the leaves of the *Stevia rebaudiana* followed by recrystallisation. Furthermore, it concluded that the existing Acceptable Daily Intake (ADI) of 4 mg/kg bw per day can also be applied to rebaudioside M produced via enzyme modification of steviol glycosides. In addition EFSA concluded that rebaudioside M produced by the new process do not pose a safety concern for the same proposed uses and at the same use levels as steviol glycosides (E 960) and that separate specifications should be added to the Annex of Regulation (EU) No 231/2012. Consequently, the new food additive 'E 960c enzymatically produced steviol glycosides' should be added to the Union list of authorised food additives and the currently authorised food additive 'steviol glycosides (E 960)' should be renamed to 'steviol glycosides from Stevia (E 960a)'. As those food additives may be regulated combined, a new group for steviol glycosides, including both of them, is inserted in Part C of Annex II to Regulation (EC) No 1333/2008, and all entries for steviol glycosides (E 960) in Part E of Annex II to that Regulation should be amended accordingly. The food additive 'steviol glycosides from Stevia (E 960a)' and foods containing it may continue to be marketed as 'steviol glycosides (E 960)' during a transitional period of 18 months after the entry into force of the Regulation. The draft Regulation presented by the Commission to the Committee concerned therefore the amendment of Annexe II to Regulation (EC) No 1333/2008 as well as the Annex to Regulation (EU) No 231/2012 as regards the use of rebaudioside M produced via enzyme modification of steviol glycosides and the name of 'steviol glycosides (E 960)'.

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 a change of the conditions of use of chia seeds (Salvia hispanica) 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 to the Committee the draft proposal Commission Implementing Regulation (EU) authorising a change of the conditions of use of chia seeds (*Salvia hispanica*) 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 measure authorises a change of the conditions of use of the novel food chia seeds (*Salvia hispanica*), on the Commission's initiative. In particular, this measure removes term 'pre-packaged' from the category 'pre-packaged chia seed as such'. Therefore, this amendment of the Union list of novel foods will allow food business operators to place chia seeds as such on the Union market in both pre-packaged and non-pre-packaged (loose, bulk) forms.

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 Schizochytrium sp. (WZU477) oil 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 to the Committee the draft proposal draft Commission Implementing Regulation (EU) authorising the placing on the market of *Schizochytrium* sp. (WZU477) oil 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 measure authorises placing on the market of *Schizochytrium* sp. (WZU477) oil as a novel food for use in infant formula and follow-on formula as defined in Regulation (EU) No 609/2013.

The Netherlands asked to include the following statement

"Regarding the draft Commission Implementing Regulation (EU) authorizing the placing on the market of Schizochytrium sp. (WZU477) oil as a novel food under Regulation (EU) 2015/2283, the Netherlands remains reluctant on two issues that are not directly related to safety, but concern fundamental procedural issues. The first one concerns the discrepancy between the authorized novel food (pure Schizochytrium sp. (WZU477) oil) and the product that was assessed by EFSA, i.e. a mixture of Schizochytrium sp. (WZU477) oil and sunflower oil. In our opinion, this discrepancy should have been explained in the authorization text. The second issue regards the data protection granted for proprietary data. This data protection concerns only analytical results, which according to us clearly conflicts with the generic character of novel applications. Finally, we would like to stress that both issues mentioned would create an undesirable precedent for future authorizations."

Vote taken by written procedure: Favourable opinion.

B.08 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 ergot sclerotia and ergot alkaloids in certain foods.

The attention of the Committee was drawn to recent information received from the stakeholder organisation StarchEurope, providing a justification to consider the establishment of a higher maximum level of 400 µg/kg for ergot alkaloids in wheat gluten (*StarchEurope requested the establishment of an even higher level).* No objections were raised to this proposal.

A joint written statement from Finland and Sweden on maximum limits for ergot sclerotia and ergot alkaloids was presented :

"We welcome maximum limits for ergot alkaloids as proposed from 1 July 2021. We also welcome an assessment of the achievability in the different producing regions in the EU to be made, before the stricter levels are applied. According to recitals (7) and (8) the presence of ergot sclerotia and ergot alkaloids in cereals and cereal products can be minimized by the application of good agricultural practices and by application of sorting and cleaning techniques. However, the most efficient good agricultural practices in the context of ergot alkaloids might be contradictory to the aims of the Green Deal and Farm2Fork initiatives, the effects of which cannot yet be seen. The formation of ergot alkaloids is to a large extent dependent on weather conditions during the growing season. Such weather conditions that endanger the rye harvest might not appear during the proposed transitional period of two years. The cultivars of rye presently in use in our countries might not be able to fulfil the stricter maximum levels. Breeding is ongoing to address the problem, but as this process is time consuming, new cultivars would not be expected until about 5 years, at the earliest.

Therefore, we propose/would have preferred to delay the application of stricter levels for rye by 5-10 years, in order for the assessment to be made with more realistic results and also to allow time for the development of new cultivars. Heightened vigilance is necessary even after this, and increased cooperation through the production chain in order to reach good results and to develop the most efficient mitigation measures fitting within the scope of the Green Deal and Farm2Fork initiatives. "

To address these concerns, the foreseen application of the lower maximum levels for ergot sclerotia and ergot alkaloids in rye and rye milling products would be deferred with one additional year to enable a thorough assessment, before the stricter level applies, of the achievability in the different producing regions in the EU of the stricter level for ergot sclerotia/ergot alkaloids in rye and rye milling products by applying good practices.

Vote taken by written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1881/2006 as regards tropane alkaloids in certain foods.

The attention of the Committee was drawn to recent information received from the stakeholder organisation Tea and Herbal Infusions Europe (THIE) on the presence of tropane alkaloids in herbal infusions of seeds of fennel and anise. Although an increase of the proposed level was requested for herbal infusions of seeds of fennel

and anise, the Committee was of the opinion that only for herbal infusions of seeds of anise, an increased maximum level would be appropriate.

Vote taken by written procedure: Favourable opinion.