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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 Feedback on the recent work of the PAFF Expert Group on Food Contact Materials (FCM).

The Commission debriefed on the outcome of the FCM Member State Working Group (MS WG).

On the 15th amendment to Regulation (EU) 10/2011 regarding plastic food contact materials:

- The 15th Amendment was adopted on 2 September and will enter into force on Wednesday 23 September.
- Consecutive SML testing for repeat use applications is made stricter, as the Regulation now requires that subsequent results may not increase, even if below the migration limit. This rule is intended for migration testing in a laboratory, and not adapted for migration modelling by computer. In the latter case, depending on the model and parameters used, results can conclude that migration increases during subsequent test even well below the SML. In analytical tests, this situation is expected to be less likely, because of the analytical limit of detection.
- The Declaration of Compliance now has strengthened communication requirements regarding the presence of certain substances, implemented via the amendment of point 6 of Annex IV. These requirements apply also to Non Intentionally Added Substances (NIAS), which should be communicated to business operators.
- A new provision was added on the testing of whole appliances. The Commission asked for feedback on experiences with the application of this provision.
- The Commission mentioned that the guidelines are increasingly outdated following the update of legislation. Member States offered to start updating the guidelines. The Commission welcomed this suggestion and will provide the original text and a discussion forum.

- A potential issue with the transition period was discussed. The provisions state that all materials, whether final or not, may stay on the market for two years. This could lead business operators manufacturing final materials to be confronted with outdated compliance documentation if they produce new products, because their suppliers did not yet have to update the documentation.

Drafting of the 16th amendment to Regulation (EU) 10/2011 is being finalised with a vote foreseen during the Standing Committee of 17 November. Some matters may need to be postponed to the 17th amendment though. Some matters that were discussed in particular:

- Likely two substances will be proposed for authorisation
- The Commission may propose to implement the requirements of the Biocidal Products (BP) Regulation into the plastics Regulation by setting up a derogation for authorised Biocides. However, this requires still to set a migration limit and to establish the safety of the BP when used as a food contact material. ECHA and EFSA are also involved in the discussion.
- In view of a new EFSA opinion on Wood flour, that substance may now be deleted from the list, but it will continued to be allowed if an application is received. This possibility would not be applicable to Bamboo as, in the previous Committee, it was accepted that Bamboo is not authorised in plastics and such products are already illegally on the market.
- EFSA published its opinion on the prioritisation of the re-evaluation of substances without an SML. The Commission proposed to delete two of the three substances with a high priority from the list, but may continue allowing them if an application is received. For styrene, the third substance, the Commission already submitted a mandate to EFSA. It explained that EFSA however cannot decide on the safety of styrene, based on the present information. A precautionary limit based on limited exposure may be considered and would be discussed for the 16th amendment after publication of the EFSA opinion.
- The 102 medium priority substances will be further prioritised on the basis of risk management, and subsequently the same approach would be taken as for the high priority substances. Following a remark from a Member State on the deletion of the Generic migration limit (GML, late Article 11(2)) a few years ago, the Commission reminded that the OML (as expressed in Article 12) is more stringent and is applicable to those substances. Moreover, there are largely no methods to determine their specific migration.
- On phthalates. JRC asked Member States to come forward if they have issues with methods to test the current SMLs under discussion. New JRC testing work now shows that LOQ can be in the range of the new proposed SMLs. Alternatively it was suggested that Member States can set ND as limit. JRC will re-conduct a proficiency test on DBP, BBP and DEHP and asked MS if they had experience with distinguishing DINP from DIDP.

Recycling:

The Commission communicated that the recycling text is ready but still under internal consideration in the Commission.

Ceramics:

The Commission presented the state of play on the ceramics impact assessment (IA). It stated that it launched a request for services to support the IA. Offers are under evaluation. MS will be duly involved in the actual consultation work. This will include the missions the consultant should undertake to interview directly artisanal and traditional producers on the potential impact, as well as the potential benefit of mitigating measures. The overall timeline has not changed but the missions to the different artisanal and traditional producers in the Member States might be delayed due to travel restrictions related to COVID.

Accreditation:

Member states confirmed some form of derogation for FCMs was required. The Commission acknowledged the comments made that the current accreditation situation across the EU makes it difficult for smaller Member States to conduct own controls and audits, as they do not have the capacity and cannot designate laboratories in other Member States, as no overview is available of other official control laboratories, and the methods they are accredited for. Therefore, such an overview is indeed urgently needed. The Commission is discussing with JRC on how to do this.

Revision of the FCM legislation:

The initiative was published on the Better Regulation website and the inception impact assessment (‘roadmap’) will be published before the end of the year. It will present the different possible measures and be published for stakeholder feedback for 4 weeks.

Bamboo:

The updated note concerning the use of Bamboo flour and similar substances in plastic is now available. The material is deemed not to be legally on the market. The Commission reminded Member States of their duty to enforce. The fact that labelling may be misleading on the true content of a Bamboo containing material is separate from the fact that Bamboo is not listed as an authorised additive to plastic materials, and should be considered as a separate matter for enforcement authorities. To allow discussion helping to ensure uniform implementation of this enforcement exercise, the Commission set up a discussion forum which the FCM experts are able to participate in. Member States raised that lacking a CN code is would be difficult to control on the borders. Market controls may be necessary. The Commission will also try to raise awareness with the exporting countries, China in particular.

A.02 Approval of the 2020 Member States' plans for monitoring of residues in accordance with Directive 96/23/EC.

The Commission informed the Committee that the Member States' and UK’s residue monitoring plans for animals and animal products had 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 can recommend the approval of 26 Member States' and UK's residue monitoring plans for 2020. Malta has unfortunately not provided sufficient information for the approval in time. Given the fact that the approval of the residue monitoring plans has to be done simultaneously for all Member States, Malta was urged to provide the required information without further delay in order to be able to approve all MSs' and UK's plans, initially foreseen at this meeting of the Committee, at the next meeting of the Standing Committee.

A.03 Exchange of views on draft Regulations related to the setting of maximum levels of:

- ergot sclerotia and ergot alkaloids

- tropane alkaloids

- opium alkaloids

The Committee was informed on the status of the draft Regulations:

- reviewing the existing maximum level for ergot sclerotia in cereals and establishing maximum levels for ergot alkaloids in cereal products.
- establishing maximum levels for tropane alkaloids in buckwheat, maize, millet and sorghum and their milling products, maize for popping and herbal infusions.
- establishing maximum levels for opium alkaloids (morphine and codeine as morphine equivalents) in poppy seeds placed on the market for the final consumer and bakery products containing poppy seeds and/or derived products thereof with a specific requirement for supply chain information on the morphine equivalent content in the poppy seeds supplied to the producers of bakery products.

A.04 Exchange of views on a draft implementing Regulation related to the establishment of sampling procedures and performance criteria for methods of analysis of:

- ergot sclerotia and ergot alkaloids

- plant toxins: pyrrolizidine alkaloids, tropane alkaloids, opium alkaloids

The Committee was informed on the foreseen provisions for sampling and analysis of ergot sclerotia and ergot alkaloids. The attention was drawn in particular to the proposed procedure for visual inspection of the samples for the presence of ergot sclerotia.

As regards plant toxins, a specific Commission Implementing Regulation on the sampling and analysis of plant toxins in food is under elaboration, integrating the provisions of Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs.

A.05 Feedback and exchange of views on topics discussed in recent meetings of the Working groups on contaminants.

Following the outcome of the EFSA scientific opinion on the "Risk assessment of ochratoxin A in food" it is appropriate to review the existing maximum levels for ochratoxin A (OTA) and to establish maximum levels for OTA for foods previously not covered. The Committee did not raise objections on the suggested maximum levels for OTA in different foods, to be submitted to a targeted stakeholder consultation. The review of existing maximum levels of OTA concerns cereal products, dried vine fruit, coffee, spices and liquorice. New maximum levels for OTA are suggested in dried herbs, tea and herbal infusions, sunflower seeds, pumpkin seeds, melon seed, hemp seeds, soybeans, pistachios and cocoa powder.

Following the outcome of the EFSA opinion on the "Risk assessment of aflatoxins in food", discussions have started on possible changes/addition to the already extensive EU legislation on aflatoxins. The Committee was informed that discussions are ongoing as regards the existing maximum level for aflatoxins in almonds and spices and the possible setting up of new maximum levels for herbs and cocoa.

Following the outcome of the EFSA scientific opinion on the "Risk assessment of glycoalkaloids in feed and food, in particular in potatoes and potato- derived products", discussions are ongoing as regards a possible Commission Recommendation focussing on the monitoring of glycol-alkaloids α-solanine and α-chaconine in potatoes and potato products and on practices aimed at reducing /preventing the presence of glyco-alkaloids, with the possible establishment of indicative levels. However as the analysis appears not to be straightforward, in particular the stability of the glyco-alkaloids during extraction, the EURL has been requested to first prepare a report on the analytical aspects.

The Committee was also furthermore updated:

- on the mycotoxin Forum that has taken place on 4 September 2020. Stakeholders highlighted the challenges related to climate change and policy initiatives under the EU's "Farm to Fork Strategy" to mitigate the risks linked to the presence of mycotoxins in feed and food for animal and public health.
- on the presentation from EFSA of the recent scientific opinion on the "Risk to human health related to the presence of perfluoroalkyl substances (PFAS) in food" and the initial discussion on the possible regulatory follow-up to ensure a high level of public health protection
- on the ongoing review of the EU legislation on dioxins and PCBs

A.06 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: Exchange of views on certain aspects of the implementation.

It was clarified that products referred to in Article 3(3) of Implementing Regulation (EU) 2020/1158 are subject to mandatory official controls at border control posts by virtue of Article 47(1)(e) of Regulation (EU) 2017/625. This also means that:

Delegated Regulation (EU) 2019/2123 applies in relation to food and feed of non-animal origin referred to in Article 3(3) of Implementing Regulation (EU) 2020/1158. Thus, such food and feed must be subject to documentary checks at border control posts, but can also be transferred to control points for identity and physical checks in accordance with the conditions laid down in Delegated Regulation (EU) 2019/2123.

The provisions on onward transportation laid down in Delegated Regulation (EU) 2019/2124 also apply in relation to food and feed of non-animal origin referred to in Article 3(3) of Implementing Regulation (EU) 2020/1158. Such food and feed can be transferred to onward transportation facilities pending the availability of laboratory tests in accordance with the conditions laid down in Delegated Regulation (EU) 2019/2124.

Furthermore, a discussion took place on the scope as regards compound foods.

A.07 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.

The Committee was informed of the envisaged changes aimed at aligning the control provisions in Implementing Regulation (EU) 2016/6 to the Official Control Regulation (EU) 2017/625. The envisaged changes are 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

No comments were made as regards these envisaged changes.

A.08 Brexit preparedness.

The Committee was informed that the transition period provided in the EU-UK Withdrawal Agreement will come to an end on 31 December 2020 and, as a result, on 1 January 2021 the UK will leave the Internal Market and the EU Customs Union, with the exception of Northern Ireland, that will remain aligned to certain provisions of EU law.

The Commission has published on its website in the past months a number of stakeholder notices, including on food legislation falling within the remit of this section of the Standing Committee, in order to ensure that the EU is fully ready to manage this new situation (notices available at: https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/notice_for_stakeholders_food_law.pdf).

As part of the Commission's actions to ensure readiness for the UK withdrawal in the areas falling within the remit of this section of the Standing Committee, an email was sent out on 14 September 2020 to verify if there are questions or issues to be clarified. No questions were put forward or issues raised in advance or during the meeting.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods.

The Commission presented the draft Commission Implementing Regulation amending Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. The measure takes into account the fact that, at the times of adopting Commission Implementing Regulation (EU) 2018/1023, eight Commission Implementing Regulations *(EU) 2018/460 , (EU) 2018/461 , (EU) 2018/462 , (EU) 2018/469 , (EU) 2018/991 , (EU) 2018/1011 , (EU) 2018/1018 , (EU) 2018/1032* had been adopted, authorising the placing on the market of novel foods or extending the use of novel foods, respectively. However, those novel foods and extensions of use no longer appeared in the list, as replaced by Implementing Regulation (EU) 2018/1023.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee

The Committee delivered its opinion with no objections.

Vote taken by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of selenium-containing yeast (Yarrowia lipolytica) biomass 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 authorising the placing on the market of selenium-containing yeast (*Yarrowia lipolytica*) biomass 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 selenium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food for use in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and children under 4 years of age.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

Three Member States voted against and one Member State abstained because they have national maximum upper levels for selenium or because they consider that there are uncertainties relating to the Tolerable Upper Intake Level (‘UL’) for selenium set by the Scientific Committee on Food (SCF) in 2000, as it may not reflect newest scientific data.

Belgium provided the following statement:
'*Unfortunately, Belgium cannot accept the maximum selenium limit set in this novel food authorization, because it is based on an EFSA UL recognized as scientifically obsolete and uncertain (the opinion dates from 2000), because it will overrule the more protective national limits applied in some Member States, such as Belgium. The maximum selenium limit that currently applies in Belgium (105 µg/day) is based on a UL (200 µg/day) that the competent Belgian Advisory Body determined in 2016 with more recent and comprehensive data. With the current conditions of use, this UL has been shown to be exceeded for different population groups. Belgium has proposed different reasonable and proportionate provisional risk management options that would have allowed for the authorization of the novel food ingredient, while ensuring a high level of health protection, in accordance with the precautionary principle (Article 7 of Regulation (EC) n°178/2002), and pending the revision of the EFSA 2000 opinion.*'

The Netherlands provided the following statement:
"*The Netherlands consider this novel food to be a new source of selenium as this Selenium-containing yeast (Yarrowia lipolytica) biomass will be used to supplement the dietary intake of selenium. In the EU, we all aim at safe intake of selenium from various sources. Therefore specific European community legislation exists to control the combined intake of vitamins and minerals to ensure that the total daily exposure remains within safe levels. Besides this, many Member States have national provisions in place in anticipation of maximum levels to be set at European level. The applicant did revise the conditions of use of its Selenium-containing yeast (Yarrowia lipolytica) biomass, so that the total daily Se-intake (including that via the background diet) meets the Upper Limit set by EFSA in 2000. We, however, feel that it is not appropriate at present to authorize the Novel Food because we should wait for EFSA's result of the re-evaluation of the safe upper level that has been requested by the Commission based on newly emerging data on selenium. In this regard, we would finally like to refer to the letter sent recently to SANTE Commissioner Ms. Kyriakides with the joint position of 19 Member States (including The Netherlands) on setting maximum levels for vitamins and minerals in food supplements and fortified foods, calling upon the European Commission to resume this work on a timely manner.* "

EFSA also, in its scientific opinion on selenium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food, noted that newly emerging data warrant a reassessment of the UL for selenium set by the SCF. Consequently, the Commission asked EFSA to re-evaluate the safety in use of selenium, and, if necessary, to provide revised tolerable upper intake levels for selenium that are unlikely to pose a risk of adverse effects, for all population groups. The deadline for delivering this scientific opinion is 12 months from acceptance of the mandate i.e. July 2021. When this scientific opinion becomes available, the Commission will review the authorisation of selenium-containing yeast (*Yarrowia lipolytica*) biomass.

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 chromium-containing yeast (Yarrowia lipolytica) biomass 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 authorising the placing on the market of chromium-containing yeast (*Yarrowia lipolytica*) biomass 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 chromium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food for use in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee

The Committee delivered its opinion with no objections.

Vote taken by written procedure: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of dried Euglena gracilis 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 authorising the placing on the market of dried *Euglena gracilis* 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 dried *Euglena gracilis* as a novel food for use in a number of foods intended for the general population, as well as in food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants, and in total diet replacement for weight control as defined by Regulation (EU) 609/2013.

Some Member States commented, considering that there is legal uncertainty as to whether food supplements for infants and young children can be marketed at all. They asked the Commission to clarify if the existence of food supplements for infants and young children is in line with principles applied in other legislative areas targeting this population group and in particular with the specific legal requirements for foods for infants and young children as well as for food supplements.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

Vote taken by written procedure: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of an extract from Panax notoginseng and Astragalus membranaceus 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 authorising the placing on the market of an extract from *Panax notoginseng* and *Astragalus membranaceus* 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 an extract from *Panax notoginseng* and *Astragalus membranaceus* as a novel food for use in food supplements as defined in Directive 2002/46/EC for the general adult population, excluding food supplements for pregnant women.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee

Four Member States abstained as they consider that there is a clear evidence of clinical interest in possible therapeutic properties of specific preparations of these plants or they expressed their reservations as, in their opinion, this product may be categorised as a medicine in their respective countries but, based on the documents provided, they were not able to conclude.

Vote taken by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of sugars obtained from cocoa (Theobroma cacao L.) pulp 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 Commission Implementing Regulation authorising the placing on the market of sugars obtained from cocoa (*Theobroma cacao* L.) pulp. The measure authorises the placing on the market of sugars obtained from cocoa (Theobroma cacao L.) pulp as a novel foods. The novel food is intended to be used in any food for the general population.

The Commission announced that it would launch the vote by written procedure in accordance with Article 3(5) of Regulation (EC) No 182/2011 shortly after the meeting of the Committee.

The Committee delivered its opinion with no objections.

Vote taken by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of heat-killed Mycobacterium setense manresensis 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 point was withdrawn from the agenda.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of 3'-sialyllactose sodium salt 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, via written procedure, the draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2470, authorising the placing on the market of 3'-Siallylactose sodium salt 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 3'-Siallylactose sodium salt to be used as a novel food in a number of foods and in food supplements intended for the general population excluding infants.

Some Member States commented that they consider that novel foods in general, and in this particular case 3'-Siallylactose sodium salt, should not be authorised for uses in food supplements intended for infants and young children up to 3 years of age. The vote was postponed to a later meeting, to allow for further discussions at Working Group level.

Vote Postponed

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation authorising the placing on the market of 6'-sialyllactose sodium salt 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, via written procedure, the draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2470, authorising the placing on the market of 6'-Siallylactose sodium salt 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 6'-Siallylactose sodium salt to be used as a novel food in a number of foods and in food supplements intended for the general population excluding infants.

Some Member States commented that they consider that novel foods in general, and in this particular case 6'-Siallylactose sodium salt, should not be authorised for uses in food supplements intended for infants and young children up to 3 years of age. The vote was postponed to a later meeting, to allow for further discussions at Working Group level.

Vote Postponed

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

The Commission presented the draft Commission Implementing Regulation amending Commission Regulation (EU) No 234/2011 together with the acts subject to point B.11 and B.12.

The Commission informed Member States about the outcome of the feedback consultation on this draft. The consultation period ran until 20 August 2020, during which 4 feedbacks were submitted by stakeholders. One additional feedback was also received after that deadline. The comments received raised concerns on:

- the practical implementation of the provisions of the transparency regulation in particular those concerning confidentiality provisions, and the interest of stakeholders in the practical arrangements that EFSA will adopt in respect of these provisions;
- the need to limit the administrative burden when submitting applications electronically, also in respect of possible standard data formats;
- the fact that the wording 'harm the interests of the applicant to a significant degree' as a condition for granting confidentiality is considered vague;
- the suggestion to reverse the amended points (n) and (m) of article 4 in order to acknowledge the fact that confidentiality may be claimed for certain aspects contained in the "*list of studies to support an application, including information demonstrating compliance with Article 32b*".

The Commission explained how those comments had been taken into account and presented the revised draft measure to Member States. As regards EFSA's practical arrangements, the Commission stressed its and EFSA's commitment to ensuring full transparency throughout the process of implementation of Regulation (EU) 2019/1381. The Commission acknowledged the relevance of the practical arrangements for the implementation of the provisions of the Transparency regulation. It confirmed that EFSA intends to share the practical arrangements with stakeholders for possible comments prior to discussing them at dedicated stakeholder meetings. In respect of the administrative burden, the Commission indicated that it was mindful of this aspect in the design of the e-submission system and that, as regards standard data formats, Regulation (EU) 2019/1381 itself provided that those formats should "*be user-friendly and adapted for the use by small and medium-sized enterprises*". The Commission indicated that the wording that disclosure of information could "*potentially harm* [the applicant's] *interests to a significant degree*" was taken up from Article 12 of Regulation (EC) No 1331/2008 as amended by Regulation (EU) 2019/1381 and that it may therefore not be amended in the present draft. Finally, as regards the suggested change in Article 4, the Commission indicated that the conditions for confidentiality are laid down in the relevant provisions of Regulation (EU) 2019/1381 and Regulation (EC) No 1331/2008 and that the order of points in this article listing the administrative data requirements does not have an impact on those provisions.

Following up on the presentation, a Member State indicated that it considered that risk management data, which is used in the Working Group to consider the technical need of food additives, should not be sent to EFSA nor be subject to the notification requirement. It requested that the Commission deletes the reference to the notification requirement '*and information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002'* in the amendments to Article 2(3)(c) of Regulation (EU) No 234/211. The Commission stressed that the notification requirement, in accordance with Article 32b of the Regulation (EU) No 178/2002 as amended by Regulation (EU) 2019/1381, would apply to all studies insofar as they are linked to "*applications on which Union law provides for possible scientific outputs by the Authority*". That notification requirement would therefore apply broadly to all studies commissioned or carried out in relation to applications, regardless of whether these are intended for risk assessment or risk management. For that reason, it was not considered appropriate to remove the clause referring to the notification requirement for data required for risk management.

Vote taken by written procedure: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

The Commission presented the draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2469 together with the acts subject to point B.10 and B.12.

The Commission informed Member States about the outcome of the feedback consultation on this draft. The consultation period ran until 20 August 2020, during which 6 feedbacks were submitted by different stakeholders. The comments received raised concerns on:

- the practical implementation of the provisions of the transparency regulation in particular those concerning confidentiality provisions, the notification of studies and the provision of pre-submission advice by EFSA, and the interest of stakeholders in the practical arrangements that EFSA will adopt in respect of these provisions;
- the need to limit the administrative burden when submitting applications electronically, also in respect of possible standard data formats;
- the fact that the wording 'harm the interests of the applicant to a significant degree' as a condition for granting confidentiality is considered vague by some stakeholders;
- the lack of references to measurement results obtained by experimental tests and their comparability which would prevent metrological aspects from being applied;
- the suggestion to amend Article 5 of Implementing Regulation (EU) 2017/2469 to insert a reference to the need to avoid toxicology studies involving live animals and to avoid duplication of animal testing.

The Commission explained how those comments had been taken into account and presented the revised draft measure to Member States. As regards EFSA's practical arrangements, the Commission stressed its and EFSA's commitment to ensuring full transparency throughout the process of implementation of Regulation (EU) 2019/1381. The Commission acknowledged the relevance of the practical arrangements for the implementation of the provisions of the Transparency regulation. It confirmed that EFSA intends to share the practical arrangements with stakeholders for possible comments prior to discussing them at dedicated stakeholder meetings. In respect of the administrative burden, the Commission indicated that it was mindful of this aspect in the design of the e-submission system and that, as regards standard data formats, regulation (EU) 2019/1381 itself provided that those formats should "*be user-friendly and adapted for the use by small and medium-sized enterprises*". The Commission indicated that the wording that disclosure of information could "*potentially harm* [the applicant's] *interests to a significant degree*" was taken up from Article 12 of Regulation (EC) No 1331/2008 as amended by Regulation (EU) 2019/1381 and that it may therefore not be amended in the present draft. As concerns the request to insert a reference to metrological aspects, Article 5 of Commission Implementing Regulation (EU) 2017/2469 lays down general requirements in respect of scientific data. As the scientific data requirements laid down in Article 5 have not been directly affected by the provisions of Regulation (EU) 2019/1381, the Commission is of the view that it should not be amended by the present amending act. As regards the suggestion to amend Article 5 to stress the need to avoid studies involving live animals and avoid duplication of animal testing, the recitals of both Regulation (EU) 2015/2283 and Regulation (EU) 2019/1381 refer to Directive 2010/63/EU and the need to avoid animal testing where possible. As the scientific data requirements laid down in Article 5 have not been directly affected by the provisions of Regulation (EU) 2019/1381, the Commission is of the view that it should not be amended by the present act.

The Committee delivered its opinion with no objections.

Vote taken by written procedure: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods.

The Commission presented the draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2468 together with the acts subject to point B.10 and B.11.

The Commission informed Member States about the outcome of the feedback consultation on this draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2017/2468. The consultation period ran until 20 August 2020, during which 3 feedbacks were submitted by different stakeholders. The comments received raised concerns on:

- the practical implementation of the provisions of the transparency regulation in particular those concerning confidentiality provisions, the notification of studies and the provision of pre-submission advice by EFSA, and the interest of stakeholders in the practical arrangements that EFSA will adopt in respect of these provisions;
- the need to limit the administrative burden when submitting applications electronically, also in respect of possible standard data formats;
- he lack of references to measurement results obtained by experimental tests and their comparability which would prevent metrological aspects from being applied.

The Commission explained how those comments had been taken into account and presented the revised draft measure to Member States. As regards EFSA's practical arrangements, the Commission stressed its and EFSA's commitment to ensuring full transparency throughout the process of implementation of Regulation (EU) 2019/1381. The Commission acknowledges the relevance of the practical arrangements for the implementation of the provisions of the Transparency regulation. It confirmed that EFSA intends to share the practical arrangements with stakeholders for possible comments prior to discussing them at dedicated stakeholder meetings. In respect of the administrative burden, the Commission indicated that it was mindful of this aspect in the design of the e-submission system and that, as regards standard data formats, regulation (EU) 2019/1381 itself provided that those formats should "*be user-friendly and adapted for the use by small and medium-sized enterprises*". As concerns the request to insert a reference to metrological aspects, Article 6 of Commission Implementing Regulation (EU) 2017/2468 lays down general requirements in respect of scientific data. As the scientific data requirements laid down in Article 6 have not been directly affected by the provisions of Regulation (EU) 2019/1381, the Commission is of the view that it should not be amended by the present amending act

The Committee delivered its opinion with no objections.

Vote taken by written procedure: Favourable opinion.