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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Residues*
14 - 15 June 2021

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SUMMARY REPORT

A.01 Art. 12 and Art. 10 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12 – updated table

The Commission presented the updated table. Difenoconazole was added as the Article 12 review should be carried out with priority (see agenda point A.03.05).

The Article 12 reviews for phosmet is scheduled to be launched in September 2021 as agreed with the Evaluating Member State (see point A.04.2).

2. Confirmatory data Art. 12 follow-up

a) Outcome of several confirmatory data evaluations by EFSA and proposed follow up

The Commission reported on the comments submitted by Member States on flutriafol and bifenthrin. As regards flutriafol, the Commission intends to prepare a draft Regulation reviewing all maximum residue levels (MRLs), following the expiration of approval and relevant grace periods. As regards bifenthrin, the Commission has already prepared a draft Regulation to be discussed under agenda point C.04.00.

3. Residue definition for risk assessment

The Commission is currently assessing the comments recently submitted by Member States and intends to present a revised document for discussion at the next meeting of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Legislation.

4. EFSA Article 12 statement for substances for which an Art. 12 review is not necessary

The Commission presented an updated table with its proposed follow up actions based on the recommendations EFSA made in its Statement published on 15 December 2020 and amended on 21 May 2021[1].

For aluminium sulphate, aluminium ammonium sulphate and fat distillation residues, the Commission proposed to keep MRLs at the default of 0.01 mg/kg

[1] https://doi.org/10.2903/j.efsa.2020.6318

according to Article 18(1)(b) of Regulation (EC) No 396/2005. The Commission recalled the discussion at the last meeting and stated that a more comprehensive MRL review for aluminium, taking into account all sources, might need to be considered at a later stage, similarly to the approach taken for copper.

The Commission informed the Committee that for maltodextrin EFSA amended its statement on 12 May 2021 based on the discussions at the last meeting of this Committee. The amendment does not affect the recommended inclusion of maltodextrin into Annex IV to Regulation (EC) No 396/2005.

For orange oil, the Commission proposed to wait for the finalisation of the ongoing renewal of approval procedure.

5. List of non-approved substances for follow-up

The Commission thanked a Member State for its thorough analysis of substances for which existing MRLs would need to be reviewed, including those substances that were not approved before 2008 and therefore do not fall within the scope of the review under Article 12 of Regulation (EC) No 396/2005. The Commission mentioned however that other ongoing reviews of MRLs would remain priority, such as for substances the approval of which had recently not been renewed (and for which grace periods have expired), as well as the ongoing Article 12 reviews. It nevertheless invited Member States to examine the list and indicate whether any specific substances not approved before 2008 would need to be prioritised. A Member State indicated that chlofenapyr in tea might be such a case as it could lead to exceedance of the Acute Reference Dose (ARfD).

Member States were invited to submit comments by 9 July 2021.

A.02 Feedback from the Phytopharmaceuticals-Legislation section of this Committee:

The Commission presented an overview of the recently voted draft Regulations in the Legislation section of this Committee in its meetings held in March and May 2021.

A.03 Specific substances:

1. Glufosinate ammonium

The Commission informed the Committee that there were no further news on this substance.

2. Glyphosate

The Commission informed that following the submission of additional data from the applicant, EFSA will resume the assessment of an import tolerance request for soya beans.

3. Ethylene oxide (EtO) – update on the state of play

Following the Commission’s call for data on ethylene oxide (EtO) findings, several Member States had provided the results of their monitoring. Overall, 87 non-compliances were reported out of more than 650 analyses (non-compliance rate approximately 13.4%). Some more specific findings are presented in the Annex to this summary report.

The Commission informed that the new Regulation (EU) 2021/608 updating Regulation (EU) 2019/1793 on import control includes two new CN codes[2] for roasted sesame seeds.

The EU Reference Laboratory for substances amenable to Single Residue Methods (EURL SRM) provided an update on the results of the recent routine EU Proficiency Test (EUPT) that included EtO and 2-chloro ethanol (2-CE)[3]. In total, 128 laboratories participated of which 52 submitted results for EtO and 2CE. The initial statistical processing of the results indicate an overall acceptable performance considering it was the first time that those substances were included in an official EUPT.

4. Bacillus thuringiensis (Bt)

The Commission informed the Committee that since the last meeting of this section of the Committee another exchange of views on a possible renewal of approval for different strains of Bacillus thuringiensis had taken place at the Section Legislation of the Committee. The focus of the discussions was on dietary exposure as EFSA suggested not to include Bt strains into Annex IV to Regulation (EC) No 396/2005, due to the uncertainties related to dietary exposure. The Commission is currently considering further actions in order to clarify these uncertainties. This requires continued close cooperation between the Member States experts attending the Sections Legislation and Pesticides Residues of this Committee in order to come to a harmonised approach. Further discussion on the next steps will take place in the next meeting of the Legislation section of the Committee that will be held on 5-6 July 2021.

A Member State informed on a discussion with an industry task force on Bt on ways forward to keep the active substances on the market. A comprehensive testing protocol was discussed to show that Bacillus thuringiensis does not germinate and does not produce toxins in the human gut. The Member State was of the view that such a protocol should be agreed at EU level and all interested parties should be involved in this. The industry will submit a draft protocol to the Member State that will then bring it to the attention of the Commission.

The Commission welcomed the initiative.

5. Difenoconazole

The Commission clarified that EFSA had identified a chronic intake concern (exceedance of the Acceptable Daliy Intake (ADI)) in the context of the Reasoned Opinion on the modification of the MRLs for difenoconazole in leafy brassica. Moreover, EFSA had also identified additional uncertainties in relation to various metabolites. The Commission therefore proposed to put the application on hold and to address difenoconazole in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 with priority, taking into consideration the conclusions of an expert meeting that EFSA will organise in the context of the renewal of approval procedure.

EFSA proposed to carry out some refinement calculations for the chronic exposure. A Member State confirmed that it had already performed such a refinement, which still resulted in an exceedance of the ADI.

[2] CN: Combined Nomenclature for the classification of goods under the Common Customs Tariff.
[3] Also referred to as ethanol chlorhydrin (ECH).

6. Pyrasulfotole

The Commission informed the Committee that the applicant had requested to maintain the existing MRLs for oats, bovine liver and kidney, which were set in the past as import tolerances. In 2019, the applicant had submitted a dossier to the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) with a view of establishing Codex MRLs (CXLs). The Commission proposed to await the finalisation of the evaluation at international level before taking action on the MRLs, which are currently set in the EU legislation.

7. Phenmedipham

The Commission informed the Committee that the two Reasoned Opinions on the setting of MRLs for phenmedipham on strawberries and celeriac will be put on hold pending the outcomes of the on-going dicussions on the renewal of approval. In particular, in the Conclusions on the peer-review of the pesticides risk assessment in the context of the renewal procedure, EFSA had identified some data gaps in relation to the reproductive toxicity and genotoxic potential of the active substance.

8. Trifloxystrobin

The Commission clarified that the three assessments that were put on hold by EFSA (EFSA-Q-2020-00036; EFSA-Q-2020-00037; EFSA-Q-2020-00038), will be resumed since the data identified as missing relate to new data requirements on metabolites that were set in 2018 in the context of the decision on the renewal of approval of the substance, while the MRL applications in question had been submitted before (i.e. in 2017). Therefore those new data requirements do not apply.

9. Spinetoram – fast-track procedure for purslane

A Member State made a request to use the fast-track procedure, foreseen in the Technical Guidelines on the MRL setting procedure (chapter 3.6), to set an MRL for spinetoram in purslane based on the residue trials on lettuces, which were assessed by EFSA in the framework of the review of the existing MRLs for that active substance[4].

Member States were invited to signal whether they had any objections by 30 June 2021.

10. Diquat

The Commission informed the Committee that diquat was not included in the draft Regulation SANTE/10644/2021 since some information from the applicant is still being reviewed by the Rapporteur Member State (RMS).

11. Imazalil

The Commission informed the Committee that the applicant had contacted the RMS and the Commission to update on latest developments on confirmatory data that need to be submitted by 26 September 2021. As a follow up to a single dose 90-day comparative toxicity study, a multiple dose 90-day study now becomes necessary, which will require some additional time to be carried out. The study should be then incorporated into the upcoming evaluation of the confirmatory data. The applicant will submit all available data pending the additional study ahead of the deadline of 26 September 2021.

[4] https://doi.org/10.2903/j.efsa.2020.5997

12. Prothioconazole

With reference to point C.01 and the EFSA reasoned opinion on the evaluation of confirmatory data[5], the applicant had informed the Commission on recent trial data, which confirm the large margin of safety of the conversion factors for the evaluation of Codex maximum residue limits (CXLs). The Commission invited the applicant to submit this data to EFSA under the procedure of Article 6 of Regulation (EC) No 396/2005.

A.04 News from and files related to the European Food Safety Authority:

1. Progress under Article 10 of Regulation (EC) No 396/2005

EFSA reported that the output related to 12 question numbers had been adopted since the previous meeting of this Committee in February 2021. Of these, 9 relate to import tolerance applications and 3 to uses in the EU.

Currently, 56 question numbers are at different steps of the procedure. Out of these, 13 are under scientific assessment and 40 are currently under clock-stop (31 under Regulation (EC) No 396/2005 and 9 under Regulation (EC) No 1107/2009). For clock-stops set under Art 6 of Regulation (EC) No 396/2005, in April 2021 EFSA invited the Member States to provide expected timelines for submission of the additional information required by those long lasting clock stops. EFSA was informed that certain Evaluation Reports were submitted or about to be submitted to EFSA in May/June 2021. EFSA reiterated its request to Member States to liaise with applicants and send feedback on the status of those applications with a view to close such long lasting clock-stops.

2. Progress under Article 12 of Regulation (EC) No 396/2005

EFSA presented the state of play of the ongoing Article 12 reviews. Procedures for 31 active substances are currently on hold as the procedure for the renewal of approval of the substance will need to be finalised first, 17 substances are already programmed, but not yet launched, and 27 are currently under review at different stages of the procedure. Since the last meeting, reviews of all existing MRLs for 7 substances have been finalised.

EFSA also reported about the ongoing work on dithiocarbamates. Different compounds are at different stages of the process. The EURL SRM had shared monitoring data with EFSA in March 2021. As, for some commodities, data is insufficient, EFSA plans to follow a stepwise approach to complete the dataset. Options are the grouping of data, considering data compiled in already existing Evaluation Reports or the use of data available in other databases. If data are still not complete after those steps, EFSA will launch an ad-hoc call for data to all Member States.

The Commission presented an updated work programme for 2021 The start of the MRL review for pyriproxyfen was confirmed for July 2021. The MRL review for phosmet will start in September 2021, for zoxamide in the third quarter of 2022, and for clopyralid in 2023. The Committee agreed with the revision as presented.

[5] European Food Safety Authority, "Evaluation of confirmatory datat following the Article 12 MRL review and modification of the existing maximum residue levels for prothioconazole in celeriacs and rapeseeds", EFSA Journal 2020;18(2):5999.

3. Update on Art. 43 mandates of Regulation (EC) No 396/2005

EFSA reported about the state of play of the mandates under Article 43 of Regulation (EC) No 396/2005.

The Member States consultation on the draft Reasoned Opinion (RO) for the joint Article 43 review of fosetyl, disodium phosphonates and potassium phosphonates closed in June. The RO is expected to be adopted in July 2021. The draft RO on the review of the toxicological properties and MRLs for thiophanate-methyl and carbendazim is currently under consultation with Member States and a final RO is expected to be adopted by July 2021. As regards the focussed assessment of certain MRLs of concern for abamectin, a data call for fall-back Good Agricultural Practices (GAPs) and supporting data closed in April, and the RO is expected to be adopted by September 2021.

4. EFSA draft Technical Report on Rotational Crops

EFSA presented the ongoing work on the development of a Technical Report for rotational crops to support the harmonised interpretation of the relevant OECD Guidance Documents and Test Guidelines. Meetings of an expert group with Member States had already taken place in December 2020, February 2021, and May 2021. EFSA presented a list of open questions to risk managers that require further clarification, and informed the Member States that a survey will be opened on 16 June 2021 to collect their feedback on these questions (deadline: August 2021). The finalisation of the draft Technical Report is foreseen by September 2021, after which the Member States consultation will start.

The Commission informed EFSA that it would provide its comments after having studied the report in more detail. In addition, it suggested that the risk management questions could first be addressed by an ad-hoc expert group of Member States, followed up by a discussion in a forthcoming meeting of the Committee.

A Member State highlighted that some of the points presented in the draft Technical Report would need to be further discussed (e.g. the trigger value for metabolites and the questions related to import tolerances). EFSA agreed that trigger values should be further discussed with Member States and noted that, while a calculation method had not yet been identified for import tolerances, alignment with CXLs should be guaranteed.

EFSA asked the Member States to provide comments on the draft Technical Report on Rotational Crops by 31 August 2021 to EFSA.

5. Other information from EFSA

EFSA presented an update about other mandates EFSA is currently working on and on ongoing dicussions with the EU RLs on extraction efficiency. With regard to the Pesticides Residues Annual Report 2020, EFSA highlighted that new features to the existing figures/tables can be introduced as well as new analysis tools for the existing data, and invited the Member States to send proposals by 30 June 2021. EFSA reminded the Member States that the deadline for the collection of monitoring data is 31 August 2021, but invited them to submit data by 30 June 2021, if possible.

In January 2021, EFSA initiated the development of a new revision of the Pesticide Residue Intake Model (PRIMo revision 4), which should be delivered by 2023. This revised tool will contain data for both primary and processed commodities, as well

as data for individual consumers (i.e. full distribution of consumption figures for the population). Other data input is possible to better refine calculations (e.g. processing factor, peeling factor). All of these data will be considered for the calculation of the total exposure per country and age class. The current International Estimated Short Term Intake (IESTI) equation is used for the calculation for the acute reference dose, but this algorithm could be changed in the future if needed.

Several Member States asked questions related to the use of PRIMo with regard to processed/raw products, offline access to PRIMo and the use of Limits of quantification (LOQs) in PRIMo. EFSA replied to those questions and invited to submit further ones in writing.

A Member State informed EFSA that they have new food consumption data available, and asked for clarification about the format and timing for transmission. EFSA will provide additional information.

EFSA informed that a new call for proposal 'Cooperation with EFSA in the area of cumulative risk assessment from dietary exposure to pesticides' will be launched in June 2021, and invited Member States to submit proposals.

A.05 Alignment of certain MRLs for pesticides and veterinary medicinal products:

The Commission will update the overview table to reflect the comments recently submitted by Member States and EFSA and propose future actions to further harmonise MRLs for pesticides and veterinary medicinal products at the meeting of this Committee on 23-24 September 2021.

A.06 Multiple source substances for which Annex IV inclusion is not recommended:

The Commission recalled that at the last meeting of this Committee, the Commission had asked Member States to send any data on organic samples for bromide ion and indolylacetic acid and EFSA to send the data from the monitoring database. The Commission requested EFSA to carry out further statistical data analyses together with the data submitted by the EURL which the Commission had received earlier. Based on those analyses, further steps could be discussed in the next meeting of this Committee.

A.07 Next steps for cumulative risk assessment:

The Commission provided an overview of the Workging Group meetings held on 18 March and 26 May 2021 for the prospective (MRL-setting) CRA. On the basis of the discussion paper and the 30 case studies prepared by EFSA and the Dutch National Institue for Public Health and the Environment (RIVM), experts had been invited to comment on the use of uncertainty factors in background exposure calculations, on the most appropriate scenario for probabilistic focal exposure calculations in Tier 2, on the combination of deterministic background with probabilistic focal in Tier 1 and on whether CRA should be performed if focal exposure was found to be below 10% of the toxicological reference values (TRVs) of the substance. A fifth commenting point related on the necessity or not of the use of the MRL instead of the highest residue (HR) in probabilistic focal exposure calculations in Tier 2, in line with the new IESTI equation which, if implemented, will make use of the MRL instead of the HR. While there seems to be an overall consensus for most of these points, discussion is still on-going.

A.08 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2020-2021:

The Commission had asked EFSA to extract monitoring data for profenofos, nicotine, mepiquat and chlormequat on those products for which temporary MRLs had been set in the past. This data was shared with Member States for this meeting together with additional data and/or studies submitted by Member States. The Commission intends to carry out an analysis and will make a proposal as to whether the existing temporary MRLs should be maintained or lowered.

The Commission gave an update on the state of play on the remaining susbstances listed in the overview table. In particular, the Commission informed that the temporary MRL for mepiquat in cotton seeds will be replaced by a permanent one established by Regulation (EU) 2021/976. As regards cyantraniliprole, the temporary MRLs in blackberries, raspberries and leeks, that had been set in the past in support of emergency authorisations notified by the United Kingdom, in accordance with Article 18(4) of Regulation (EC) No 396/2005, will be automatically lowered to the LOQ on 30 June 2021.

A.09 International Matters:

1. OECD Guidance document on the residue definition for risk assessment

The Commission shared a presentation on the work carried out so far by the OECD expert group outlining also the various topics and challenges. The group aims at sharing a draft guidance document by the end of 2021 for peer-review before finalisation.

2. OECD Honey Guidelines and Member States experiences with the EU guidelines

One of the Member States who attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. Several subgroups are working on different topics. A new subgroup has started on the dosing of the trials. Altough good progress had been made in those working groups, in order to be able to make sound decisions, more data were needed. Therefore early in the year a call for data was launched through the Business and Industry Advisory Committee to the OECD (BIAC) and CropLife members were invited to submit data on trials. The call had been successful with many data received. The first draft of the guidelines is planned to be ready by the beginning of 2022.

In the light of the discussions in the OECD working group the Commission invited the Member States to send comments on the implemention of the EU technical guidelines as the feedback could be helpful for the ongoing work in the OECD working group.

Member States were invited to submit comments by 16 July 2021.

3. Codex Alimentarius/Joint FAO/WHO Meetings on Pesticide Residues (JMPR) issues - future work organisation and substances

- Substances

  Member States were informed that the finalisation of the draft EU positions for the substances would take place in the Council Working Party on 28 June 2021.

- Codex Committee for Pesticides Residues (CCPR) 2021 – Electronic Working Groups (eWGs)

  In view of the exceptionally tight time schedules resulting from the postponement of the CCPR meeting to July 2021, the Commission shared with the Committee the draft EU comments on Codex Circular Letters (CLs) to facilitate the dicussion in the forthcoming Council Working Party meeting on 28 June 2021.

  - eWG on Classification: The Commission presented the draft EU comments in reply to Circular Letter CL2021/37-PR and several Member States indicated their preference to highlight the issues related to divergent classification codes for rice between the EU and Codex in the draft EU position.
  - eWG on the IESTI equation: The Commission presented the draft EU comments in reply to Circular Letter CL2021/42-PR. The Commission invited Member States to provide their views on the darft EU position by 18 June 2021, but also give their views on the way forward with the IESTI equation in the EU by 9 July 2021.
  - eWG on Management of unsupported compounds/schedules and priority lists of pesticides for evaluation by the JMPR. The Commission presented the draft EU comments in reply to Circular Letter CL2021/42-PR.

    A Member State supported the proposed draft EU position which suggested merging the eWGs on Unsupported Compounds and on the National Registration Database. This merged eWG should then give input into the dicussions on the schedules and priority list.
  - eWG on Guidelines for compounds of low public health concerns that could be exempted from the establishment of CXLs for pesticides. The Commission presented the draft EU comments in reply to Circular Letter CL 2021/38-PR.

    A Member State was not in favour of the proposed deletion of the reference to "authorised uses".
  - eWG on the Database on National Registration of Pesticides

    A Member State acting as chair of the working group informed the Committee that there had not been any developments in the Electronic working group.

  Member States were invited to submit comments on the draft EU positions by 18 June 2021.

A.10 Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed (SANTE/10704/2021):

The Commission gave an update of the developments on the draft Information Note. The Commission proposed an updated indicative time plan and informed that it intends to send the Information Note for consultation to the relevant stakeholder organisations at the end of the summer. The aim is to present the document for endorsement in the meeting of this Committee in November 2021. The time schedule had been presented also to stakeholders represented in the Commission's Advisory Group on 7 May 2021.

Member States were invited to submit comments by 16 July 2021.

A.11 Clarification of "Exceptional circumstances" in Article 16 of Regulation (EC) No 396/2005:

The Commission had incorporated the clarification on the "exceptional circumstances" for the setting of temporary MRLs according to Article 16(1) of Regulation (EC) No 396/2005 into Chapter 3.5.1 of the Technical Guidelines on the MRL Setting Procedure (SANTE/10595/2015). As agreed in the past, the Commission further specified that where both field trials and monitoring data are available, the data from field trials should prevail (e.g. boscalid in honey). Member States were invited to submit comments by 16 July 2021.

A.12 Notifications under Article 18(4) to Reg. (EC) No 396/2005:

One Member State informed the Committee about its notification under Article 18(4) of Regulation (EC) No 396/2005 that it had re-issued an emergency authorisation for 120 days for flonicamid in carrots to control aphids. It clarified that the export of treated carrots outside its national territory is prohibited. The residue trials compliant with the Good Agricultural Practice (GAP) had been assessed by EFSA in 2018 who had recommended setting an MRL at 0.3 mg/kg. However, the adoption of the the draft Regulation (SANTE/11822/2019) that would have set this MRL was delayed due to a recent objection by the European Parliament.

A.13 Designation of Member States for maximum residue levels (MRL) applications:

Denmark is currently the Evaluating Member State for an application for setting an import tolerance for ethiprole in rice. However, in view of the extent of the evaluation, which includes a full toxicological assessment, Denmark asked if another Member State could take the lead. At the meeting, the Netherlands confirmed that it will take the role as Evaluating Member State.

A.14 Update on the Delegated acts for food for infants and young children:

In parallel to the notification to the World Trade Organization under the Technical Barriers for Trade (TBT) agreement, the Delegated Acts went through a stakeholders' consultation in the Commission's Advisory Group on the Food Chain. During the consultation certain stakeholders, while acknowledging the need for aligning the definition of "pesticide residue" between the MRL Regulation (EC) 396/2005 and the legal framework for foods for infants and young children (IYC), highlighted concerns on the possible impact of enforcement actions resulting from this alignment, specifically for dual use/multiple source substances, naturally occurring substances, e.g. bromide, and minerals, such as copper, which is also used as a pesticide, but is also a declared ingredient. Following the scrutiny procedure in the Council and the European Parliament, the two Delegated Acts are now published[6,7].

[6] Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021 amending Delegated Regulation (EU) 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.

[7] Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021 amending Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula.

A.15 Classification issues related to Annex I of Regulation (EC) No 396/2005:

The Commission shared with the Committee several written requests from companies related to classification issues in Annex I to Regulation (EC) No 396/2005:

- Dried miracle berries from *Synsepalum dulcificum* were recently evaluated as Novel Food (NF 2018/0709, EFSA-Q-2018-01032).The Commission proposed to classify them under the group "others" in subgroup (d) 'other small fruits and berries' with the code number 0154990.
- Grape seeds: the Commission shared a request from a company to reconsider the current classification for grape seeds (code number 0401150-001) linked to castor beans (code number 0401150). The requestor proposed to consider 'wine grapes' as an alternative for its classification.
- Chia seeds: the Commission shared a request from a company to reconsider the current classification of chia seeds (code number 0500020) under the group 'buckwheat and other pseudo-cereals'. MRLs for copper in chia were not sufficient to cover the natural presence of this compound and the requestor proposed to consider 'oil seeds' as an alternative for its classification.

Member States were invited to submit comments by 16 July 2021.

A.16 Other Information points:

1. Update on draft Regulations/objections within the regulatory procedure with scrutiny (PRAC)

The Commission informed about the recent objections from the European Parliament on draft Regulations setting MRLs for flonicamid and lufenuron during the scrutiny period. The Commission is currently reflecting about the next steps. It also informed that it had written a letter to a Member State who had made a statement in a recent Council meeting supporting the Parliament's concerns related to flonicamid and referring to an ongoing assessment by the US Environmental Protection Agency (US EPA) that should be awaited before setting new MRLs for flonicamid. The Commission clarified that the said assessment had been concluded and that risk mitigation measures had been taken similar to those already existing in the EU. The Commission also highlighted that the statement made in the Council meeting was inconsistent with the Member State's vote in favour of the flonicamid MRLs, the existing authorisations for flonicamid in numerous crops and its own practice to grant repeatedly emergency authorisations for the use of flonicamid on the crops to which the MRLs relate since 2017. The concerned Member State highlighted that internal dicussions were ongoing in their country and that a written reply would be provided to the Commission. Another Membe State mentioned that it was very concerned about the frequent rejections of draft MRL Regulations by the European Parliament, about the new Article on import tolerances proposed by the Parliament in the trilogues on the Common Market Organisation (CMO Regulation)(cf. Agenda item A.16.09), but also about considering environmental issues when setting MRLs. On the latter it still has doubts about the compatibility of this approach with the EU's WTO obligations.

2. Brexit

No issues were raised under this agenda item.

3. Chlorate/babyfood clarification

With reference to the comments from stakeholders and Member States regarding the impact of enforcing maximum residue levels (MRLs) of pesticides on foods for infants and young children (IYC) for dual use/multiple source substances, such as chlorate, following the alignment of the definition of a 'pesticide residue' between the regulatory framework for IYC and Regulation (EC) No 396/2005, and consequent to the Delegated Acts mentioned in point A.14, the Commission recalled the discussion held by the Committee on 22-23 April 2013 on quaternary ammonium compounds. It had then been clarified based on internal discussions among Commission services that for these compounds the default MRL of 0.01 mg/kg applies also for foods for IYC. This has, since then, been communicated to stakeholders[7] and to Member State authorities[8,9] multiple times for their consideration and enforcement. Therefore, the two Delegated Acts[10,11] that the Commission proposed and the Member States voted in favour, only formalise the already existing interpretation.

Furthermore, as discussed in several meetings of this Committee[12,13], following EFSA's publication on the risks for public health related to the presence of chlorate in food[14] in 2015, the Heads of the National Food Safety Agencies agreed on an action plan to reduce chlorate levels. In this action plan, it was confirmed that for chlorate in foods for IYC, the default MRL of 0.01 mg/kg applies.

A Member State suggested the possibility of setting a specific MRL for chlorate on foods for IYC under the legal framework for foods for IYC. The Commission made reference to the recitals of that legislation[15,16,17], which explain the rationale for defining the MRL of 0.01 mg/kg as the default value for all pesticides, with the exception of certain substances for which lower MRLs are established. More specifically, those recitals evoke the use of the precautionary principle[18] in case there is an absence of scientific information and indicate that, for foods for IYC, such an uncertainty exists due to doubts concerning the adequacy of the existing

[8] https://ec.europa.eu/food/system/files/2017-10/sc_phyto_20170921_ppr_sum.pdf

[9] https://ec.europa.eu/food/system/files/2017-12/sc_phyto_20171121_ppr_sum.pdf

[10] Commission Delegated Regulation (EU) 2021/1040 of 16 April 2021 amending Delegated Regulation (EU) 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.

[11] Commission Delegated Regulation (EU) 2021/1041 of 16 April 2021 amending Delegated Regulation (EU) 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula.

[12] https://ec.europa.eu/food/system/files/2017-10/sc_phyto_20170921_ppr_sum.pdf

[13] https://ec.europa.eu/food/system/files/2017-12/sc_phyto_20171121_ppr_sum.pdf

[14] European Food Safety Authority, "Scientific Opinon on the risks for public health related to the presence of chlorate in food", EFSA Journal 2015;13(6):4135

[15] Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC

[16] Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children

[17] Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes

[18] Article 7, Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Acceptable Daily Intakes (ADIs) to protect the health of IYC. Therefore, for this sensitive group of consumers, a level higher than the default cannot be considered.

4. Peeling factor/consumption of unpeeled food

A Member State had requested to discuss the possible follow-up to an issue that recently came up in the context of a discussion on a proposed national measure on labelling for fruits. A Member State had proposed to introduce a labelling requirement advising consumers not to eat fruit with peel for fruits that had undergone post harvest treatment with pesticides. The Commission had rejected the draft by a Regulation and informed about its reasons to do so. The Commission however agreed that the issue raised by the Member State would need some follow-up,but that this would need to be done in a harmonised way and by addressing the source of the problem, i.e. the way peeling factors are currently taken into account in the consumer risk assessment, and changed consumer attitudes towards consumption of peel for some fruits/vegetables in the light of avoiding food waste. As a first step the Commission invited Member States to submit information on fruits/vegetables that would be concerned by changes of consumer habits and to provide consumption data of such products where available. EFSA informed that for such commodities the use of peeling factors could be disabled in the risk assessment on a case by case basis. The Member States were invited to submit crops that would be concerned by 16 July to EFSA (EFSA MRL functional mailbox) with copy to the Commission.

5. Questions from several Member States on authorisations for clethodim

Several Member States had requested to discuss the way forward for dealing with national authorisations after the lowering of MRLs to the LOQ for clethodim in the context of Article 12 of Regulation (EC) No 396/2005. The applicant had proposed to maintain national authorisations that would result in levels of clethodim below the LOQ. Several Member States took the floor and expressed their views. The Commission highlighted the importance of taking a harmonised approach among Member States and presented its view that in the light of the genotoxic potential of the metabolite 3-chloroallyl alcohol (being the reason for the lowering of the MRLs to LOQ), the only logic consequence would be to withdraw the authorisations to ensure that consumers would not be exposed at all to residues of clethodim. This was supported by several Member States. The Commission also informed about the ongoing review of the substance in the framework of the renewal of approval procedure under the Plant Protection Products Regulation and referred to the planned follow up discussion on the issue with national authorisations in the context of the Committee's Working Group on Post Approval Issues (PAI).

6. Questions from a Member State related to enforcement, the Rapid Alert System for Food and Feed (RASFF) and transition periods

A Member State announced it would reconsider its position and allow taking into account measurement uncertainty (MU) on analytical results by food business operators (FBOs) for the purpose of internal controls, in alignment with the policy of other Member States which allow such use. The Commission referred to the earlier discussions on this topic under point A.20.5 of the Agenda of the meeting of this Committee on 28-29 September 2020[19] and clarified that such policy falls within the remit of the national authorities. It also reminded that for the purpose of

[19] https://ec.europa.eu/food/system/files/2020-10/sc_phyto_20200928_ppr_sum.pdf

official controls the default MU of 50% of the analytical result or a specific lower one can be used, in accordance with document SANTE/12682/2019[20] and the RASFF working instruction 2.2[21]. This MU value is determined by the outcome of the EU Proficiency Tests (EUPTs) organised throughout the years by the EU Reference Laboratories (EURLs), specifically for the Official Control Laboratories that are obliged to participate in them, in accordance with Regulation (EU) 2017/625. FBOs may use private laboratories for which MU values other than the default may apply, since they might not participate in official EUPTs organised by the EURLs. The Commission proposed to further discuss the matter, if necessary, during the meeting of the Working Group for the monitoring of pesticides residues on 15 October 2021, for which Member States were invited to nominate Experts by 09 July 2021.

7. Oxymatrine

The Commission referred to the question from a stakeholder on the MRL that should apply for oxymatrine, following recent detections of this substance and given that it has never been assessed in the EU. According to a Report[22] from the Food and Agriculture Organization (FAO) in 2015, oxymatrine, a metabolite of matrine, found in extracts of the plant Sophora spp., is registered and approved as a pesticide in certain countries in Asia. The Commisison clarified that, as for matrine[23], for oxymatrine the default MRL of 0.01 mg/kg applies.

8. Chlorate and BAC/DDAC in fish

A Member State submitted the results of its monitoring programme for pesticide residues in fish, where it had found benzalkonium chloride (BAC), didecyldimethylammonium chloride (DDAC) and chlorate. Levels of chlorate residues indicated a possible acute risk for consumers, and, therefore, the Member State proposed to establish MRLs for those substances, as currently no levels are set under Regulation (EC) No 396/2005 for fish.

The Commission recalled that for fish and fish products, footnote (8) of Annex I to the Regulation indicates that "*no MRLs are applicable until individual products have been identified and listed within this categor*y". This means that enforcement of MRLs for pesticides, while currently not applicable for this category, will start to apply once the first product is listed. The Commission clarified that, pursuant to Article 18(1)(b) of the Regulation, in such a case, the default MRL of 0.01 mg/kg would start to apply for all pesticide/fish combinations by default, except for those for which a specific level would be established.

Therefore, the Commission invited Member States to submit monitoring data of pesticide residues in fish by 31 August 2021. On the basis of the data received, further discussion will take place during the meeting of the Working Group for the monitoring of pesticides residues that will take place on 15 October 2021, where experts may explore the possible setting of indicative values for further action in order to guide national enforcement authorities in applying Article 14 of Regulation (EC) 178/2002 in a harmonised way.

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[20] https://ec.europa.eu/food/system/files/2020-01/pesticides_mrl_guidelines_wrkdoc_2019-12682.pdf
[21] https://ec.europa.eu/food/system/files/2017-02/rasff_reg-guid_sops_wi-2-2_en.pdf
[22] Food and Agriculture Organization of the United Nations, "Progress in pesticide risk assessment and phasing-out of highly hazardous pesticides in Asia", 2015, http://www.fao.org/3/i4362e/i4362e.pdf
[23] https://ec.europa.eu/food/system/files/2019-03/sc_phyto_20190221_ppr_sum.pdf

9. MRL discussions in the context of the Common Agricutltural Policy (CAP)

The Commission gave an overview on the state of play in the ongoing trilogues on the Regulation on the Common Market Organisation (CMO Regulation) in the context of the CAP reform and outlined the current positions of the Council, the Parliament and the Commission with regard to the new Article 188a on import tolerances for pesticides proposed by the Parliament. The discussions are still ongoing. A Member State signalled that it was very worried about the developments in view of the fundamental change of principles that this would entail compared to Regulation (EC) No 396/2005. The Member State indicated it was strongly opposed to a change of Regulation (EC) No 396/2005 by the back door.

10. Enforcement action on non-compliant spices

A Member State asked about enforcement action taken by other Member States with regard to spices containing multiple (up to 30) different pesticides below the MRL, likely resulting from mixing production batches from lots of different producers. The Commission clarified that if those levels were below the respective MRLs for single substances, the samples would be compliant and that the future methodology on cumulative risk assessment would address this type of problems.

11. Banana producing countries/mancozeb

A Member State reported having received letters from banana producing countries on mancozeb. The Commission confirmed having also received such letters. The Commission recalled that EFSA's Conclusion on the risk assessment[24] for mancozeb in the context of the procedure for renewal of approval highlighted a number of critical concerns, areas that could not be finalised and data gaps. For example, mancozeb was found to be toxic to reproduction and to have endocrine disrupting properties for humans, as well as to pose risks to aquatic organisms. The risk assessment for consumers could not be finalised due to missing data. Therefore, mancozeb did not meet the approval criteria of Article 4 of Regulation (EC) No 1107/2009 and the approval could not be renewed. All the MRLs for mancozeb, including those for bananas, will be reviewed as part of a comprehensive review of the whole group of dithiocarbamate substances in accordance with Article 12 of Regulation (EC) 396/2005 and considering the natural occurrence of carbon disulphides which is the compound used as a common residue definition for all dithiocarbamate substances.

12. Specific methods to analyse dithiocarbamates – state of play

A Member State reported abut progress in developing an analytical method for dithiocarbamates that would be able to discriminate between the different substances. The work had been shared with the EURL SRM and a specific working group of laboratories had been set up. An EU proficiency test is also planned. The Commission welcomed this work which would help overcome many of the problems resulting from the current unspecific MRL for carbon disulphide.

[24] https://www.efsa.europa.eu/en/efsajournal/pub/5755

Section B Draft(s) presented for an opinion

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet Lupinus albus, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products (Art. 10).

The Commission outlined the draft Regulation and its contents.

The following MRL applications had been submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 in support of new and/or confirming existing uses in the EU:

- acibenzolar-S-methyl for use on hazelnuts/cobnuts, beans and peas (with pods);
- clopyralid for use on wheat, oat and products of animal origin, following uses of clopyralid on cereals, pastures and grasslands;
- fludioxonil for use on blueberries, cranberries, currants and gooseberries;
- fosetyl for use on almonds, chestnuts, hazelnuts/cobnuts, pistachios, walnuts, granate apples/pomegranates, herbs and edible flowers, blueberries, gooseberries, currants, garlic, shallots, wine grapes, avocados, table olives, olives for oil production, potatoes, horseradishes, flowering brassica, Chinese cabbages, kales, spinaches, wheat and products of animal origin following uses of potassium phosphonates;
- metazachlor for use on horseradishes, swedes, turnips and bovine liver;
- oxathiapiprolin for use on hops;
- tebufenozide for use on apricots and peaches;
- thiabendazole for use on citrus fruits and witloofs/Belgian endives.

The following MRL applications had been submitted in accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 in support of import tolerances:

- azoxystrobin used in the United States on sugar beet roots;
- cyflufenamid used in the United States on hops;
- fluopyram used in the United States on soyabeans;
- oxathiapiprolin used in China on grapes and in Canada and the United States on citrus fruits, blackberries, dewberries, raspberries, Chinese cabbage, basil and edible flowers, asparagus, potatoes, sweet potatoes, bulb vegetables, “Solanaceae and Malvaceae”, cucurbits, flowering brassica, Brussels sprouts, head cabbages, “lettuces and salad plants”, “spinaches and similar leaves”, peas (with and without pods), leeks and ginseng;
- thiabendazole used in the United States on sweet potatoes and in Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica on mangoes.

The draft Regulation also proposes the inclusion of the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus* in Annex IV to Regulation (EC) No 396/2005.

As regards oxathiapiprolin, EFSA concluded that for dewberries, potatoes, sweet potatoes, Brussels sprouts and peas (without pods), the submitted data was insufficient to set new MRLs. As regards fluopyram, a Member State indicated that the chronic exposure was very close to the ADI and that it would therefore abstain in the vote on the draft Regulation. The Commission clarified that EFSA had confirmed that the proposed MRL for soybean was safe for consumers and that it did not further contribute to the chronic exposure. Another Member State indicated that the draft Regulation was too extensive and that it would have appreciated an earlier sharing with Member States. The Commission explained that it must comply with the legal deadlines and internal procedures, but that it would make an effort to present future draft Regulations to the Committee earlier. Another Member State highlighted that for clopyralid in swine liver and fat, EFSA had proposed specific MRLs and not MRLs at the LOQ. The Commission modified Annex IIIA accordingly, by removing the erroneous asterisks.

Outcome of the vote by written procedure: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, acrinathrin, Bacillus pumilus QST 2808, ethirimol, penthiopyrad, picloram and Pseudomonas sp. strain DSMZ 13134 in or on certain products (Art. 10).

Following the recent objection by the European Parliament against an earlier version of the draft Regulation, the Commission had prepared an amended draft by removing MRLs for lufenuron and chlorantraniliprole. The latter substance was included in a separate draft Regulation to be voted under Point B 03. As regards lufenuron, for which the grace periods will expire by the end of June 2021, the Commission will include the substance in a forthcoming draft Regulation reviewing MRLs for substances for which grace periods expired.

Outcome of the vote by written procedure: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole in pulses (Art. 10).

Following the recent objection by the European Parliament, the Commission had prepared a separate draft Regulation to set an MRL following an application for an import tolerance for chlorantraniprole in pulses based on uses in the United States. EFSA had confirmed that the proposed MRL was fully supported by data and safe for consumers.

Outcome of the vote 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 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bentazone in peas with pods (Art. 10).

The Commission outlined the draft Regulation and its contents. An MRL application had been submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 in support of a new use on peas with pods in the EU. EFSA had confirmed that the proposed MRL was fully supported by data and safe to consumers.

A Member State indicated that it would vote against the draft Regulation as there are still aspects to be clarified in relation to the toxicity of the metabolite 6-hydoxy-bentazone. It had raised the same concerns at the time of the vote on the draft Regulation renewing the approval of bentazone. The Commission referred to the decision taken by the Legislation section of the Committee on the renewal of the substance where it had been concluded that the toxicological profile of the metabolite 6-hydroxy-bentazone is comparable to that of the parent compound bentazone. Another Member State further clarified that the genotoxic potential and general toxicity of the metabolite had been fully elucidated by using read-across and quantitative structure-activity relationship (QSAR) models to fill the gaps. The Member State further stressed that animal testing should be avoided in the EU and that in this case conducting additional studies would not be accepted at national level. Another Member State suggested that the recurring discussions on the metabolite 6-hydrox-bentazone should be reported to the Legislation section of the Committee.

Outcome of the vote 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 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyprodinil in or on certain products (Art. 10).

The Commission outlined the draft Regulation and its contents. An MRL application had been submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 in support of new use on blueberries, cranberries, currants and gooseberries in the EU. EFSA had confirmed that the proposed MRLs are fully supported by data and safe for consumers.

Outcome of the vote by written procedure: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amisulbrom, flubendiamide, meptyldinocap (DE-126), metaflumizone, propineb in or on certain products (Art. 12).

The Commission informed that it had notified the draft Regulation to trading partners under the Sanitary and Phyto Sanitary (SPS) agreement to the World Trade Organization (WTO), and no comments had been received within the 60-day deadline.

In its 4th Revision, the draft Regulation maintains the current MRL of 0.5 mg/kg for amisulbrom on grapes following EFSA's revised Reasoned Opinion (RO). Additionally, for metaflumizone, EFSA revised its RO, to include one previously

omitted GAP on cotton seeds, and now recommends an MRL of 0.05 mg/kg as reflected in the draft Regulation.

Outcome of the vote by written procedure: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 6-benzyladenine and aminopyralid in or on certain products (Art. 12).

The Commission presented the latest revision of the draft Regulation which had been notified under the SPS agreement to the WTO and no comments had been received.

The Commission clarified that, based on the feedback received from Member States and the applicant, it was decided not to set a footnote (A) requesting a reference standard for conjugates of aminopyralid.

On 6-benzyladenine, the Netherlands made the following statement:

'The Netherlands votes in favour of this proposal, though it is not sure the default MRL for 6-benzyladenine will be able to cover situations in which there is a natural occurrence of 6-benzyladenine. In the near future, the Netherlands will pay special attention to levels of 6-benzyladenine in commodities in which the substance has not been approved and will come back to this if in this way more proof is gathered about the natural occurrence of the substance'.

Outcome of the vote by written procedure: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for flupyradifurone and difluoroacetic acid in or on certain products (Art. 10).

The Commission had notified the draft Regulation under the SPS agreement to the WTO, and had not received any comments from third countries. At the meeting, a Member State proposed to further discuss the extrapolation rules that would apply to witloofs in the context of a future revision of the EU Technical Guidelines on Extrapolation. Another Member State indicated that it would vote against the draft Regulation as the substance is currently under review[25]. The Member State suggested waiting for finalisation of that assessment before setting new MRLs for the substance.

Outcome of the vote by written procedure: Favourable opinion.

[25] While at the meeting it was mentioned by the Member State that this was a review under Article 21 of Regulation (EC) No 1107/2009, it needs to be clarified that the Commission – following the notification of a national measure by a Member State under Article 69 of Regulation (EC) No 1107/2009 - gave a specific mandate to EFSA to assess whether there are indications that the approval criteria in Article 4 are no longer met. Detailed information can be found in the Summary report of the meeting of the PAFF Committee, section Phytopharmaceuticals-Legislation held on 25-26 January 2021, Point A. 10.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for imidacloprid in or on certain products (Art. 12).

The Commission presented the latest revision of the draft Regulation highlighting the modifications in the text. The draft had been notified under the SPS agreement to the WTO and the Commission informed about the comment received from a third country.

A Member State indicated that it would vote against the draft Regulation since it does not agree with the proposed increase of MRLs in three commodities based on applications for setting import tolerances and considers this not to be in line with the Commission Communication on the Farm to Fork Strategy.

The Commission reminded that after the expiry of the grace periods (expiry date is June 2022), the MRLs would be revised again.

Outcome of the vote by written procedure: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) on multiannual national control programmes for pesticides residues to be established by Member States.

The Commission introduced the draft Regulation. On request of a Member State, the Commission clarified that the provisions of Article 30(3) of Regulation (EC) No 396/2005 on publication of national monitoring results and on publicly naming food business operators concerned by non-compliances in food/feed, were not reinstated in the draft Regulation since there was no legal basis for this under Regulation (EU) 2017/625 on official controls (OCR). In fact, the legal basis of the draft Regulation was limited to specific additional arrangements and specific additional contents to those provided for in Article 110 of the OCR and must therefore relate to the preparation of the relevant parts of the multi-annual national control plan (MANCP).

Furthermore, several Member States had requested to delete Article 1(3) providing for publication of multiannual national control programmes for pesticides residues by Member States 3 months before the end of each calendar year. As this requirement is already covered by Article 111(1) of the OCR, the Commission agreed to remove Article 1(3).

Outcome of the vote by written procedure: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) amending Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards radish leaves.

The Commission introduced the draft Regulation modifying a footnote in Annex I to Regulation (EC) No 396/2005 and extend the transitional period set by Regulation (EU) 2018/1049 for the application of the MRL for the commodity 'radish leaves' which was linked to the group of 'kales'. At the time of application of the Regulation, given that residue trial data had not been available to confirm whether this classification would be appropriate, a transitional period had been established for radish leaves until 31.12.2021 to enable Member States to generate such data. As the respective Member States recently informed the Commission that the generation of data was delayed, the transitional period needs to be extended to allow finalisation of the trials and their assessment.

The Commision had proposed to extend the application date set in the footnote for two more years. Some Member States indicated their preference of extending the deadline for three years which was accepted by the Commission. A draft Regulation amended accordingly was presented for vote in written procedure.

Outcome of the vote by written procedure: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Regulation correcting Commission Regulation (EU) 2021/618 of 15 April 2021 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for terbuthylazine in or on certain products.

The Commission introduced the draft Regulation, which corrects the MRLs for terbuthylazine in maize/corn, sorghum and sweet corn which are not in accordance with the EFSA Reasoned Opinion on terbuthylazine published on 30 January 2020 and were erroneously set in Commission Regulation (EU) 2021/618.

The date of application of the Regulation has been aligned with that of Commission Regulation (EU) 2021/618 and the Regulation will apply as from 6 November 2021.

Outcome of the vote by written procedure: Favourable opinion.

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb, and silthiofam following the evaluation of Article 12 confirmatory data.

Revision 3 of the draft Regulation now excludes prothioconazole. Following comments from Member States, the applicant had confirmed that new data is available for submission to EFSA under Article 6 of Regulation (EC) No 396/2005, justifying maintaining some existing MRLs. Work on the substance will be resumed after EFSA's evaluation of this data.

For those substances for which no confirmatory data had been submitted by the applicant, the Commission is expecting an output from EFSA (e.g. a statement) to make this more transparent and will resume work on this draft Regulation after adoption of the statement.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for oxyfluorfen, pyroxsulam, quinmerac, and sulfuryl fluoride in or on certain products.

The Commission introduced the first revision of the draft Regulation and highlighthed the numerous data gaps identified by EFSA and the EURLs for the substance sulfuryl fluoride. The Commission invited Member States to submit comments by 9 July 2021.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for cyproconazole, methoxyfenozide, propoxur, spinosad and thiram in or on certain products.

The Commission presented an initial overview of the draft Regulation.

The approval of cyproconazole expired on 31 May 2021 and grace periods for sale and use of existing stocks are still on-going. Therefore the Commission considered it more appropriate to deal with the substance in a future draft Regulation and withdraw it from this draft.

Following the renewal of the approval of methoxyfenozide, a lower ARfD value had been established. EFSA's targeted assessment indicated that for citrus fruits, tomatoes, apples, pears, peaches and broccoli, consumer exposure at the current MRL values leads to exceedances of the ARfD. For citrus fruits, EFSA concluded that current MRLs are safe for consumers using the peeling factor that had been established in the EFSA Conclusion on the peer review of the risk assessment for the substance in the context of the procedure for the renewal of approval, and, therefore, they can be maintained. For tomatoes, a fall-back GAP supports lowering the MRL from 2 mg/kg to 0.6 mg/kg. For apples, pears, peaches and broccoli, no fall-back GAPs are available, therefore the Commission proposed lowering the MRLs to the LOQ of the analytical method.

For propoxur there are no toxicological reference values (TRVs) established in the EU, while EFSA could not access the assessment dossier from Health Canada setting the ARfD and ADI at 0.0005mg/kg bw and 0.0005mg/kg bw/d, respectively. The draft Regulation proposes lowering all MRLs to the LOQ of 0.01 mg/kg. The EURLs suggested that lower LOQs may be available for certain matrices. A Member State supported lowering the MRLs to the LOQ of 0.01mg/kg and the non-inclusion of the carbamate metabolite in the residue definition as there is no validated analytical method and no analytical standard for that substance. Another Member State considered that, in light of the Canadian TRVs, lower LOQs should be established and provided screening detection limits lower than the proposed LOQ of 0.01 mg/kg. Another Member State informed that its monitoring of 5.500 samples since 2016 did not reveal any findings of propoxur at an LOQ of 0.01 mg/kg. Another Member State supported using the LOQ of 0.01 mg/kg and that lower LOQs than 0.01 mg/kg should only be set where justified.

The EFSA Conclusion on the peer review of the risk assessment for spinosad in the context of the procedure for the renewal of approval had established an ARfD of 0.1 mg/kg bw. EFSA's exposure assessment indicated a risk for consumers from exposure at the current MRLs for sweet peppers/bell peppers, lettuces, escaroles/broad leaved endives, spinaches, beet leaves (chards) and witloofs. Available fall-back GAPs support lower MRLs for these crops.

For the no-longer approved substance thiram, all authorisations in Member States had been withdrawn on 30 January 2019, therefore all MRLs based on earlier EU uses should be lowered to the LOQ. For the MRLs based on import tolerances for avocados and bananas, given that no TRVs are available for thiram's metabolite M1 and that translocation of this residue cannot be excluded after peeling, the draft Regulation proposed lowering them to LOQ.

Member States were invited to submit comments by 9 July 2021.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for bifenthrin, bromopropylate, chloridazon, fenpropimorph, imazaquin and tralkoxydim in or on certain products.

The Commission introduced the draft Regulation reviewing the MRLs for the substances bifenthrin, bromopropylate, chloridazone, imazaquin, fenpropimorph and tralkoxydim following the non-renewal of their approvals. The Commission shared a

letter received from Tea & Herbal Infusions Europe (THIE) regarding the temporary MRL for bifenthrin in herbal infusions. The Commission informed that it had asked EFSA to extract monitoring data from its database for comparison.

Member States were invited to submit comments by 9 July 2021.

Annex

Overview of findings by Member States and the EURL SRM on ethylene oxide (EtO) in different foodstuffs

- ✓ A Member State reported 260 analyses of EtO during 2010-2021. For spices, out of 196 samples, 2 were non-compliant (1%). No non-compliance was identified out of 23 samples of cereals, while out of 34 samples of vegetables, 1 was non-compliant. The same Member State reported 41 analyses on sesame seeds from countries other than India, of which 6 were non-compliant.
- ✓ Another Member State reported 105 analyses (25 samples of rice, 25 samples of tea, 24 samples of spices, 9 samples of herbs and 22 samples of oilseeds). All results were below the Limit of Quantification (LOQ).
- ✓ Another Member State reported 84 non-compliances out of 272 samples (overall non-compliance rate 31%): out of 40 samples of sesame seeds from India, 21 were non-compliant (52%); out of 51 samples of sesame seeds originating in countries other than India, 10 were non-compliant (20%); out of 166 other commodities from India, 49 were non-compliant (30%), indicatively spices (e.g. black pepper, curcuma), dried vegetables (e.g. onions) and rice. Of 15 samples other than sesame seeds from countries other than India, 5 non-compliances were reported (30%) (e.g. sunflower seeds, buckwheat).
- ✓ Another Member State reported the analysis of 10 samples of commodities other than sesame seeds, peppercorn, cumin, curcuma and dried onion. All samples were below the LOQ.
- ✓ Another country reported 10 analyses on spices. All results were below the LOQ.
- ✓ Other Member States reported either fewer samples/results or that they may include EtO analyses in future monitoring programmes.
- ✓ The EURL SRM presented the outcome of 432 analyses for EtO and 2-chloroethanol (2-CE), which included samples of food supplements. Overall, there were 37 (8,6%) non-compliances (including measurement uncertainty). Main findings were on moringa, dried onions, sesame seeds and guar gum. The EURL SRM reminded that for EtO, a drying factor does not apply in dry products as it is usually applied after drying. The EURL indicated findings also in empty capsules and tablets of food supplements.