EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2021)1854871

Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
22 - 23 February 2021

CIRCABC Link: *https://circabc.europa.eu/w/browse/3cda1de8-5ced-44a1-9733-9c102e0c6087*

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.

2. Confirmatory data Art. 12 follow-up

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

The Commission informed that it had updated the overview table.

As regards flutriafol in beetroots, a Member State indicated that the Good Agricultural Practice (GAP) for sugar beet and fodder beet is identical in timing, number of applications and amount applied to beetroots, while the only difference is the pre-harvest interval (PHI), within the 25% rule. An extrapolation of residue data from sugar beets to beetroots is therefore possible and the Member State proposed maintaining the maximum residue level (MRL) of 0.06 mg/kg in beetroots. Another Member State supported this approach.

As regards bifenthrin in strawberries, the Commission clarified that the current MRL is based on a Codex maximum residue limit (CXL) adopted in 1995. Taking into account that the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has never received information on a GAP matching the residue trials, which were used to derive the existing CXL of 1 mg/kg, and that no alternative GAP has been provided within the last 10 years, the Commission proposes lowering the MRL in the context of the Regulation to be adopted following the non-renewal of the approval of the active substance.

Member States were invited to provide comments by 19 March 2021.

3. Residue definition for risk assessment

The Commission referred to the proposals presented to the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), section Phytopharmaceuticals – Pesticides Residues on 23/24 November 2020 and section Phyptopharmaceuticals - Legislation on 3/4 December 2020, and thanked Member States and EFSA for their written comments. Feedback was generally favourable, while some potential issues

were identified. The Commission summarised the key points raised and provided its views. It also presented a revised version of the discussion document initially shared in November/December 2020, taking into account the comments received.

In the discussion, several issues were identified that require further reflection by Member States, EFSA and the Commission, including on the impact on ongoing applications/procedures, and the requirements for submission of data where a new residue definition for risk assessment has been derived by EFSA as provisional. The Commission thus decided to present the revised version to the section Legislation of the Committee at its meeting on 24/25 March 2021, as originally planned, but to ask for endorsement of the proposed approach only at a later meeting. The Commission invited Member States to submit comments in the form of one single reply per Member State, coordinated between representatives in the two sections 'Phytopharmaceuticals – Legislation' and 'Phytopharmaceuticals – Pesticide Residues' of the Committee by 9 April 2021.

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

The Commission presented a table with its proposed follow up actions on the EFSA recommendations in the statement. No action is required for diflubenzuron and oxadiazon as these substances are already included in Annex V of Regulation (EC) No 396/2005, nor for *Gliocladium catenulatum* strain J1446 which is already in Annex IV. Flufenoxuron is in Annex II, but all MRLs except for tea are already at the Limit of Quantification (LOQ), hence no action is required for this substance either.

Inclusion of acetic acid, lime sulphur, maltodextrin and orange oil into Annex IV was proposed to be made permanent by removing the footnote indicating the temporary nature of Annex IV inclusion in a forthcoming routine MRL proposal.

On maltodextrin the authorisation holder had contacted EFSA as it could not confirm EFSA's statement that the substance was always used together with a fungicide to prevent fungal growth and possible production of mycotoxins. EFSA asked for clarification from the Member States whether they had taken any risk mitigation measures at product authorisation stage in this respect as the approval conditions of maltodextrin require that "*Member States shall pay particular attention to the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits"*. Depending on the feedback from Member States EFSA might need to revise the statement with regard to maltodextrin, however such a revision would not affect the recommended inclusion of maltodextrin into Annex IV to Regulation (EC) No 396/2005.

Aluminium sulphate, aluminium ammonium sulphate, imazaquin and fat distillation residues were proposed to be moved into Annex V with specific LOQs or the default value of 0.01 mg/kg.

One Member State asked for clarification on compounds containing aluminium and the basis for MRL setting. Aluminium is part of substances used in different sectors (food contact materials, cosmetics, PPPs, food additives, etc) and is also found naturally in the environment. A more comprehensive approach for a MRL based on aluminium would be needed in its view, taking into account all sources. The Member State also enquired about the marker compound for fat distillation residues as this information would be needed for enforcemet laboratories.

On orange oil the Rapporteur Member State (RMS) commented that the renewal of approval procedure would soon start and that they had asked to submit the additional data to confirm Annex IV inclusion and therefore questioned whether this was the right moment for a permanent inclusion into Annex IV.

The Commission indicated that on aluminium sulphate and aluminium ammonium sulphate, fat distillation residues and orange oil it will come back to the Member States with further reflections.

Member States were invited to provide comments on the table and possible use restrcitions for maltodextrin by 19 March 2021.

5. **Note Taking** of minor revisions of the MRL Guidelines and the Art. 12 confirmatory data WD (updates of links) – SANTE/ 2015/10595 Rev. 5.5. and SANTE/10235/2016 Rev.4.1

   The Commission presented the revised guidelines to reflect the new requirements in the pre-submission phase and submission application procedure brought by the Transparency Regulation and the EFSA Practical Arrangements. The SCoPAFF agreed that the new revisions will apply to all MRL applications submitted under Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009, as of 27 March 2021. For all applications submitted before 27 March 2021, all procedural steps as described in SANTE/2015/10595 Rev. 5.4 and SANTE/10235/2016 Rev. 4 continue to apply.

6. Other
   The Commission reminded the Committee that at the end of last year some Member States had problems with certain MRLs for spinetoram and fluxapyroxad which were recently assessed under Article 10 to be safe for consumers, but in the Article 12 MRL review were not taken into account as no Member State had notified any existing uses that would require those MRLs.
   This problem should be prevented by adhering to the procedures laid down in the EFSA working instructions for the Article 12 review[1] . The Commission asked the Member States to pay special attention to such situations and to also already notify uses for which authorisation is soon expected to be given. This should be done as early as possible in the process, preferably at the GAP collection step, but at the very latest during the Member State Consultation step on the draft Reasoned Opinion. The Commission stressed that there will no possibility to include additional uses after finalisation of the Reasoned Opinion. However, should this still occur, a new MRL application can always be submitted.

A.02 Feedback from Legislation Committee:

The Commission informed that in future in this section it would report back more generally on the outcome of recent meetings of the Committee's Section Legislation, while so far only new active substances had been mentioned. It gave an update on substances for which decisions had been taken in the meetings of the Committee Section – Legislation in December 2020 and January 2021.

---

[1] MRL review under article 12 of Reg. (EC) 396/2005 (https://www.efsa.europa.eu/sites/default/files/topic/01_Work%20instructions%20MRL%20review%20Article%2012.pdf)

A.03 Specific substances:

1. Glufosinate ammonium

There was no news from the Commission as regards this agenda item.

One Member State requested that the Commission present a draft Regulation lowering the MRLs to the limit of Quantification to the Committee without further delay, in view of the toxicological profile of the substance and the expiry of its approval in 2018.

2. Glyphosate

There was no news as regards this agenda item.

3. Abamectin

In a recent mandate to EFSA, the Commission requested an updated exposure assessment for abamectin in the light of the toxicological reference values changed during the peer review process on that active substance. EFSA had agreed to deliver a Reasoned Opinion by 15 September 2021. In that context, a consultation of Member States will be conducted to identify fall-back GAPs that would lead to a safe scenario.

4. Ethylene oxide – update on the state of play

The Commission referred to the outcome of the Food and Feed Crisis Coordinators (CC) Meeting on 9 October 2020 and the discussions held at the meeting of this Committee on 23-24 November 2020. It called on Member States to act fully in line with the conclusions reached unanimously at the CC meeting, and to implement the agreed actions in a harmonised manner. The Commission stressed the need for a uniform application of the agreed approach, to ensure both a level playing field for food business operators and equal protection of consumers across the EU. It called on Member States to communicate clearly to operators in their territory, to ensure they do what is necessary under the law and in view of the agreed harmonised risk management measures.

A Member State asked about information on the root cause of the non-compliances. The Commission replied that the information available points to an intentional use of ethylene oxide in most if not all cases, with the aim of reducing or eliminating microbiological contamination.

The Commission referred to contributions received from three Member States on approaches to define a level of low concern for consumers. It also referred to the opinions of the EFSA Scientific Committee on the Margin of Exposure (MoE) approach published in 2005 and 2012. In line with the view of the Scientific Committee, the Commission stressed that the decision on the application of the MoE approach is a matter for risk managers. The Commission explained why it does not consider the application of the MoE approach appropriate in the current circumstances and asked Member States for their views. It also recalled discussions on the MoE approach in the Section Legislation of the Committee in 2016/2017, in the context of the review of the approval of the active substance diflubenzuron. Some Member States announced written comments after the meeting.

Several Member States informed the Committee on the state of play of their monitoring and enforcement activities. Those Member States reported enforcement in line with the agreed approach, i.e. withdrawal or recall of non-compliant food

products, including of composite products found to contain non-compliant ingredients, even if the relative contribution of that ingredient is small. Some food business operators are challenging this approach in Court.

Several Member States reported extension of monitoring (and findings of non-compliances with MRLs for ethylene oxide) to products from origins other than India, and to products other than sesamum seeds, and to organic products. As other Member States expressed interest to obtain more details to inform their own monitoring, the Commission invited these Member States to submit information on the occurrence of ethylene oxide in products other than sesamum seeds and/or originating from other countries than India by 19 March 2021.

A Member State informed that the degradation product 2-chloroethanol is currently being evaluated in the framework of the Biocidal Products Regulation, while another Member State enquired whether 2-chloroethanol may be generated from other sources than ethylene oxide. The EU Reference Laboratories for Residues of Pesticides (EURLs) stated that very low levels of 2-chloroethanol are probably not due to intentional treatment of food products but caused by cross-contamination.

In response to a request by a Member State for a harmonised assessment by EFSA, the Commission considered this possible in principle, provided that relevant data become available and specific questions to risk assessors are formulated, in line with EFSA's interventions at the CC meeting and the Committee meeting on 23/24 November 2020.

The Commission recalled the provisions of Commission Implementing Regulation (EU) 2020/1540, providing for special import conditions on sesamum seeds from India, and requiring those consignments to be accompanied by an official certificate and results of laboratory analysis for pesticide residues, in addition to an increased level of official controls (identity and physical checks set at 50%) upon their entry into the EU.

The Commission drew Member States' attention to its letter dated 21 January 2021 (Ref. Ares(2021)547141), informing them that based on Article 12(1) of Regulation (EC) No 178/2002, batches of sesamum seeds originating from India and withdrawn from the EU market due to exceedance of the EU-MRL for ethylene oxide may be re-exported to a third country, if compliant with the rules in place in the importing third country.

For those consignments of sesamum seeds rejected at the border, and more in general concerning measures to be taken in cases of non-compliant consignments entering the Union, there is an ongoing discussion with Member States to harmonise implementation of Articles 66(3) and 67 of the Official Controls Regulation (OCR; Regulation (EU) 2017/625), and in particular the understanding of risk associated with a consignment. Discussions are taking place in the monthly OCR working group meetings. The Commission asked Member States to provide their interpretation and raise questions related to re-export in that working group.

The Commission reminded that the EU Reference Laboratory for Single Residue Methods (EURL SRM) published on its website an analytical method for ethylene oxide on 17 December 2020 using QuOil and QuEChERS extraction methods followed by determination with GC/MS.

The EURL SRM organised an ad-hoc EU Proficiency Test (EUPT) exclusively for ethylene oxide on sesamum seeds with 26 participants. The results were overall

satisfactory. Another EUPT organised by the EURL SRM including ETO will take place mid-March 2021.

Member States were invited to submit information on findings of ethylene oxide in products other than sesamum seeds and/or originating from other countries than India, including the percentage of non-compliant samples out of all samples tested, by 19 March 2021.

5. Bacillus thuringiensis

The Commission gave an overview of the discussions that took place in the Section Legislation of the Committee of 25-26 January 2021 and the feedback received from the Member States after that. A Member State presented the outcome of a study on the "Comparative phenotypic, genotypic and genomic analyses of Bacillus thuringiensis associated with foodborne outbreaks" carried out by its risk assessment body. This study concluded that given the high degree of similarity observed between FBO-associated and some commercial Bacillus thuringensis isolates, and in the absence of contradictory evidence, it cannot be ruled out that Bacillus thuringensis used in plant protection products may have pathogenic potential.

A Member State stressed that it is the food business operator who should prove that the plant protection product is safe and that the same strict principles should apply to chemicals and micro-organisms. From the evidence provided by the study and the reports of the food business operators it concluded that there might be a risk for consumers and that more data would be needed. Taking into account the "As Low as reasonably Acheivable (ALARA)" principle, the setting of MRLs for these microorganisms would be appropriate. They further explained that they applied use restrictions to Bt strains, limiting the colony forming units to 105 cfu/g on the crop, which would effectively represent a pre-harvest interval.

Another Member State agreed to use restrictions and added that they had been studying the effects of the PHI and so far (although to be confirmed), the PHI would not have a real effect. In order to lower the exposure the dosage should be lowered.

Several Member States highlighted that setting MRLs for micro-organisms could be a reasonable option and should not be regarded as giving the substances a negative image, given that for many other pesticides safe MRLs can be established.

A Member State suggested that evaluation and decision about possible risk mitigation measures should take place at strain level and the respective data should be provided by the applicant.

The Commission clarified that it was still in the process of considering different options, taking into account all the evidence but also the existing uncertainties. A risk management decision should, however, be consistently taken between the two sections of the Committee, requiring efforts at Commission and at Member State level for coordination of positions.

Member States were requested to coordinate positions in view of the next meeting of the Section Legislation of the Committee on 24/25 March 2021. The Comission particularly invited those Membe States that had not taken position previously to share their views in order to have a better picture.

6. Propoxur

The Commission referred to the recently published EFSA Reasoned Opinion for propoxur[2]. In the absence of EU data on toxicological reference values and given that no intentional uses of this non-approved substance are expected, the Commission invited Member States to provide their comments regarding toxicological reference values and the LOQ of the analytical methods for enforcement. A Member State clarified that the reasons for allocating resources for exploring LOQs lower than the level of 0.01*mg/kg should be justified by a valid necessity.

Member States were invited to provide comments by 19 March 2021.

7. Difenoconazole

EFSA recently adopted a reasoned opinion for difenoconazole in leafy brassica, where it identified a chronic intake concern. In view of the uncertainties in the assessment, EFSA proposed risk management options. The Evaluating Member State indicated that it will clarify its position in writing. Other Member States were invited to submit comments by 19 March 2021.

8. Pyrasulfotole

A Member State reported that there are currently MRLs set for pyrasulfotole in oats, bovine liver and kidneys in Regulation (EC) No 396/2005, although the substance has never been assessed at EU level. The Member State thought that the values may have been set in the past in support of import tolerance requests. EFSA commented that the MRLs were set in previous Directives and that the substance is not subject to Article 12 review as it was not approved before 2008. The Commission proposed to include the substance in the context of a forthcoming draft Regulation lowering the existing MRLs. Another Member State indicated that there are several other substances in this situation, which might also need to be addressed. The Member State will share an overview table with the Commission.

Member States were invited to provide comments by 19 March 2021.

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 48 question numbers had been addressed in 2020, 13 since the previous meeting of this Committee in November 2020.

Currently, 63 question numbers are at different steps of the procedure. Out of these, 17 relate to import tolerance applications, 5 to confirmatory data assessments and 10 to applications dealt with in the context of the renewal of approval process. 42 question numbers are currently under clock-stop. Out of these, 11 relate to import tolerance requests, 4 to confirmatory data assessments and 10 to aplications in the context of the renewal of approval process. As regards long-lasting clock-stops, EFSA repeated its earlier request to Member States to liaise with applicants and send feedback on the applications with a view to closing them.

[2] https://www.efsa.europa.eu/en/efsajournal/pub/6374

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

EFSA presented the state of play of the ongoing Article 12 reviews. 21 active substances are currently under review and at different stages of the procedure. Since the last meeting two further reviews of all existing MRLs and a statement addressing 12 question numbers had been finalised.

EFSA identified significant delays in the submission of Evaluation Reports by Member States for 5 out of the 20 substances for which the Evaluation Report had been expected in 2020.

EFSA reminded the Member States on the correct procedure to ensure that all uses would be covered in the Article 12 MRL review (see also Point A. 01.06).

EFSA also reported about the ongoing work on dithiocarbamates. The EU Refernce Laboratories had shared all data collected with EFSA. EFSA will now verify commodities for which data are not sufficient and launch a dedicated call for data only for those specific crops. By the call for data Member States are asked to submit results from control samples for trials on which no residues are expected.

The Commission presented an updated work programme for 2021, adding the MRL review for phosmet to start in July 2021, in line with the prioritisation discussed in the meeting of this Committee on 23/24 November 2020. The Committee agreed with the revision as presented.

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 reasoned opinions for spinosad, methoxyfenozide and propoxur were adopted. The Art. 43 review of fosetyl is running in parallel with the MRL review for disodium and potassium phosphonates. The launch of the Member States Consultation is expected for April 2021. The review of the toxicological properties and MRLs for benzimidazole substances carbendazim, and thiophanate-methyl will focus on import tolerances and CXLs only. For abamectin EFSA had accepted a mandate for a focused assessment on MRLs of concern considering the new Acute Reference Dose (ARfD) that was derived during the renewal of approval procedure (see also agenda item A.03.03.). The collection of Good Agricultural Practices (GAPs) is expected for March 2021.

4. Note Taking of the EFSA Administrative Guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure (SANTE/10182/2021)

The EFSA guidance describes the procedures and the associated timelines for handling applications related to pesticide active substances and for the setting of maximum residue levels, in particular to address the new provisions introduced by the Transparency Regulation amending the General Food Law and their implementation by the Practical Arrangements adopted by EFSA.

The guidance document has been presented and discussed at several meetings of the Committee (both, Section Legislation and Section - Pesticide Residues) between December 2018 and February 2021.

The Committee agreed that the EFSA guidance will apply to all applications submitted to the competent authority of a Member State as of 27 March 2021 and should be used for the preparation of applications intended to be submitted from

that date onwards. Consequently, the guidance applies to all assessment reports concerning applications submitted as of 27 March 2021.

5. Presentation of the EFSA draft annual monitoring report 2019

EFSA provided an overview of the draft monitoring report for the year 2019, showing that, overall, the pesticide residues situation is under control. EFSA explained that apart from the report, there would also be a data visualisation of the EU control programme on EFSA's website. Among its recommendations for the future, EFSA stressed the need for better reporting the country of origin of samples, given the increased percentage of samples of unknown origin reported in the last three monitoring years. In view of performing probabilistic assessments, EFSA also recommended a future review of the number of samples to be taken by Member States.

A Member State commented that for the findings concerning dimethoate the report should also consider the uncertainty associated to the residue definition which does not include omethoate and, thus, real exposure may be under-estimated. EFSA agreed to amend the report to integrate this comment.

6. Update on Cumulative Risk Assessment (CRA)

- EFSA report on cumulative dietary risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides

  EFSA provided an overview of its recently published report[3] concluding that with varying degrees of certainty, cumulative exposure to pesticides contributing to the chronic inhibition of acetylcholinesterase does not exceed the threshold for regulatory considerations established by risk managers.

- Note Taking of the EFSA-SANTE Action Plan for Cumulative Risk Assessment on pesticide residues (SANTE/10178/2021)

  The Commission reminded that in its Report to the European Parliament and the Council[4] on the REFIT evaluation[5] of the EU legislation on plant protection products[6] and pesticides residues[7] it had concluded that the development of a methodology for cumulative risk assessment covering simultaneous exposure to multiple chemicals turned out to be much more complex than initially expected and that faster progress was needed. Therefore, the Commission and EFSA developed an Action Plan with the main directions for the future.

  EFSA provided an overview of this Action Plan which focuses on four main activities: prioritisation and elaboration of new cumulative assessment groups (CAGs), performing retrospective cumulative risk assessment (CRA) for those

---

3 https://www.efsa.europa.eu/en/efsajournal/pub/6392

4 REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, COM/2020/208 final

5 https://ec.europa.eu/food/plant/pesticides/refit_en

6 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1–50

7 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, OJ L 70, 16.3.2005, p. 1–16

CAGs, further development of the methodology for the prospective CRA and integration of non-dietary exposure in the methodology.

A Member State welcomed the Action plan and commented that as retrospective CRA relies on the 32 most commonly consumed commodities, representing 74% of the EU consumption[8], a review of the monitoring programme should be considered for the future. It further supported the development of the prioritisation method for more efficient allocation of resources and suggested the use of the 10% HBGV[9] as threshold to be considered for this prioritisation. EFSA reminded that as, in the future, a probabilistic approach is considered for the monitoring programme, it is expected that sampled commodities will be reviewed, while the mentioned threshold is already included in the methodology for prioritisation.

Another Member State also welcomed the Action Plan, but expressed concerns regarding its wider scope to include also non-dietary exposure. They stressed that this should not come at the expense of the ongoing work on pesticide residues, which should be the priority. The Commission clarified its commitment to speed up work in the field of pesticide residues in food/feed and invited Member States to provide further comments relating to the practical application of the methodological approach for prospective CRA in preparation of the upcoming working group meeting on CRA that will take place on 18 March 2021.

The Committee took note of the Action Plan for CRA on pesticide residues (SANTE/10178/2021) which will be made publicly available[10].

7. Other:

- update on the ongoing work on rotational crops

  EFSA informed about 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. An expert group with Member States had already taken place in December 2020 and February 2021. A discussion in a peer review expert meeting is planned for April 2021 and a draft version for the Technical report is expected for June 2021 which will be circulated to the Member States for commenting.

A.05 Note Taking of the revised Guidance Document on Pesticide Analytical methods for risk assessment and post-approval control and monitoring purposes (SANTE/12830/2020) replacing and repealing guidance documents SANCO/3029/99 Rev. 4 and SANCO/825/00 Rev. 8.1.

The Commission thanked the two Member States that took the lead in preparing the Guidance Document for their excellent work and their efforts to take into account comments from multiple commenting rounds during the preparation phase. It considered the document ready to be noted by the Committee. There were no further comments, and the Committee took note of the document (SANTE/12830/2020). It will be uploaded on the SANTE webpage and replace the two older repealed guidance documents (SANCO/3029/99 Rev. 4 and SANCO/825/00 Rev. 8.1).

---

8 https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4005

9 HBGV, Heath-Based Guidance Value

10 https://ec.europa.eu/food/plant/pesticides/max_residue_levels/cumulative_risk_en

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

The Commission made a presentation on the outcome of the feedback received from the Member States after the last meeting of the Committee on possible priorities for the collection of background data for sbstances with natural background levels above the default value of 0.01 mg/kg. The Commission noted that in addition to other previously discussed substances, cyanides (expressed as hydrogen cyanide) had also been reported as substances to be considered in that discussion. It was agreed to further explore possibilities for a project on data collection for bromide ion as first priority and indolylacetic acid as second priority in line with the comments and sugestions made by the Member States. The Commission requested the Member States to check whether they had any data on organic samples for these two substances available. This would help to define the data gaps better in view of such a possible project. The Commission also asked EFSA on the type of data available in EFSA's monitoring database and whether those data could be used as well. Member States were invited to provide comments by 12 March 2021.

A.07 Next steps for cumulative risk assessment.

The Commission reminded that during the working group on CRA for the prospective scenario that was held in June 2020, the experts discussed on EFSA's protocol describing the general principles for the design of case studies. The experts concluded that 15 case studies for CAG NAM[11] and 15 case studies for the CAG TCF[12] should be prepared by EFSA and RIVM to enable risk managers to better understand the impact of the methodological assumptions. Those case studies had in the meantime been prepared and were uploaded on CIRCA BC for commenting by Member States.

The Commission informed of an upcoming training on prospective CRA that will be held on 10 March 2021, announced a specific working group meeting on CRA that will be held on 18 March 2021 and invited Member States to nominate experts for both activities by 5 March 2021.

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

The Commission announced the intention to collect monitoring data from EFSA in relation to the temporary MRLs for mepiquat, chlormequat, profenofos and nicotine. A Member State informed the Commission that there are still findings of chlormequat and mepiquat in oyster mushrooms. The Commission invited Member States to share monitoring data within the deadlines prescribed by the respective pieces of legislation.

A.09 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission gave an update on the state of play. In December 2020, the working group had set a timeline for finalisation of the guidance document. Technical discussions within the Residue Exposure and Toxicology subgroups will continue until mid 2021. According to the planned schedule, a first draft of the guidance could be circulated in summer 2021, while a revised version could be

[11] Cumulative Assessment Group including pesticides associated with the functional alterations of the motor division of the nervous system.

[12] Cumulative Assessment Group including pesticides associated with hypothyroidism.

submitted to the OECD working group on pesticides for review and possible approval in autumn 2021. The publication of the new version and declassification of the existing one is foreseen within the first quarter of 2022.

2. OECD Honey Guidelines

One of the Member States who attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work and presented the draft flow chart for setting the MRLs for honey. The Member State explained that the base for the flow chart was taken from the EU technical guidelines[13] but there was a lot of discusson on the question whether residues are expected in honey after pesticides application. As in the different parts of the world not the same crops are used for honey production and not every country has established default MRLs, it was decided to have a modified decision tree. However, some elements have been taken over. Beside the subgroup working on the flowchart, there is another subgroup that works on the appropriate residue definitions for risk assessment and for enforcement for different substances in honey. Since more data are needed, an official call for data was launched by OECD to industry and stakeholder organisations.

A Member State raised concerns on the results from tunnel trials as it had found that during the trials the residue levels of specific substances were not above the default of 0.05 mg/kg, but that bee keepers were regularly informing them about higher levels. They proposed to carefully observe the situation and to require applicants to not only report the results of trials, but also the methodology used and detailed observations.

The next meeting of the OECD working group takes place on 24 February and 17 March 2021.

Member States were invited to submit comments by 12 March 2021.

3. Codex Alimentarius/JMPR issues- future work organisation

- CCPR 2021 - working groups and substances

  The Commission gave an overview of the content of the draft EU reply to Circular Letter (CL 2021/7-PR) on the establishment of the schedules and priority lists of pesticides for evaluation/re-evaluation by the joint FAO/WHO expert meetings on pesticide residues (JMPR). The Commission informed that the draft EU reply will be submitted to the Council Secretariat for comments with a short deadline as the deadline for submitting the comments to the Codex electronic working group is on 28 February 2021.

  The Commission summarised the work carried out over the years on the review of the IESTI equations, and the progress achieved at various levels. To inform future discussions on the way forward, the Commission invited Member States and EFSA to provide their views. EFSA informed the Committee of their work on the future release of PRIMo Rev. 4, which might have an impact on the on-going work on the IESTI equations. EFSA will send detailed information in writing after the meeting.

[13] Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 rev 9)

The Commission updated the concern form on carbendazim/benomyl/thiophanate-methyl, which was presented at this section of the Committee in June 2020, to reflect that the approval of thiophanate-methyl had in the meantime not been renewed in the EU and that EFSA was currently carrying out a combined exposure assessment for the three active substances (see agenda item A.04.03). The concern form will be circulated for comments and possible endorsement at the Council Working Party on 8 March 2021.

Member States were invited to provide their view on the way forward on the IESTI equation by 15 March 2021.

A.10 Farm to Fork Strategy/REFIT and General discussion about future priorities in the area of pesticides residues.

The Commission presented a document in which it had set out follow up actions both related to the REFIT evaluation and the Farm to Fork Strategy and assigned priorities and tentative timelines to them in line with the commitments made in the Report to the European Parliament and the Council on the REFIT evaluation of the pesticides legislation (COM/2020/208 final) and the respective Council conclusions adopted at the meeting of the Agriculture and Fisheries Council on 15-16 December 2020 [14].

A Member State highlighted that the Commission should verify the WTO compatibility of the approach for dealing with import tolerances announced in the Farm to Fork Strategy. As regards priorities, the Member State regretted that the Commission did not consider the setting of MRLs for fish a priority. They mentioned that some issues (e.g. residues of chlorate and BAC/DDAC in fish) may need to be addressed by the Commission's working group on contaminants. Two other Member States felt that it was important to address feedingstuffs, but agreed to wait for the finalisation of the classification of feed ongoing in Codex Alimentarius and the finalisation of the guidance on processed food currently under discussion in this Committee. The Commission confirmed that the approach for import tolerances announced in the Farm to Fork Strategy had been verified to be in compliance with WTO obligations and explained that the focus will on environmental issues of global concern. The Commission also clarified that discussions on substances falling under pesticides legislation should take place in this section of the Committee, even if they concerned fish for which no MRLs have yet been established.

Member States were invited to submit comments by 19 March 2021.

A.11 Guidance on processed food/feed and the use of processing factors.

The Commission gave an overview of the changes introduced to the draft Information Note on Article 20 of Regulation (EC) No 396/2005 as regards processed and composite foods. The Commission informed the Member States that it intended setting up a specific working group with Member States' experts and organising a meeting on 20 April 2021 as there are still many points that need further discussion and refinement.

The Commission invited Member States to nominate experts from their enforcement authorities with relevant experience by 19 March 2021.

[14] Document (13439/20) - https://data.consilium.europa.eu/doc/document/ST-13439-2020-INIT/en/pdf

The Commission proposed an indicative time plan and informed that after the working group with experts the Information Note will be also sent for consultation to the relevant stakeholder organisations. The aim is to finalise the document by September 2021 for Note Taking in the meeting of this Committee in September 2021.

A.12 Clarification of "Exceptional circumstances" in Article 16 of Regulation (EC) No. 396/2005.

In line with its commitment in the REFIT Report on the evaluation of the pesticides legislation (COM/2020/208 final) to "clarify the scope of what is considered 'exceptional circumstances' for setting temporary MRLs to avoid misinterpretations", the Commission presented a draft to this effect. It proposed to provide such clarification through an update of the Technical Guidelines on MRL Setting Procedures (SANTE/2015/10595 in its latest revision). The Commission invited Member States to provide feedback on the proposed form (integration in existing guidance), structure, content, and examples, including what information should be added.

EFSA proposed to include guidance on the data to be provided by applicants in support of an application for temporary MRLs (e.g. amount/type of monitoring data and/or residue trials).

A Member State referred to the example of mepiquat/chlormequat in oyster mushrooms, where the residue trials were difficult to perform, but generally supported EFSA's comment.

Another Member State stressed the need to expand the draft and derive explicit rules from the examples provided.

Member States were invited to submit comments by 19 March 2021.

A.13 Fish guidance documents.

The Commission thanked the Member State who had taken the lead in updating the documents related to data requirements on fish for its excellent work and concluded that based on the comments received from the Member States the documents were considered finalised. It proposed to retain the documents as working documents at this stage, but to publish the finalised versions on the Commission's webpage for full transparency on the contents. The documents could be transformed into guidance documents later on in the light of possible future developments on MRL setting for fish. Member States agreed to that procedure.

A Member State requested to upload also the fish dietary burden calculator on the Commission webpage and informed that there were some technical questions about this. The Commission agreed to publish the dietary burden calculator, but indicated that this would need to be checked with its IT department first.

A.14 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

No issues were reported under this agenda item.

A.15 Designation of Member States for maximum residue levels (MRL) applications.

No issues were reported under this agenda item.

A.16 Update on the Delegated acts for food for infants and young children.

The Commission informed of the on-going procedure for the preparation of the delegated acts for foods for infants and young children (IYC), which are expected to be published in the first half of this year. Some Member States expressed concerns on enforcement aspects resulting from the alignment of the regulatory framework for foods for IYC with Regulation (EC) No 396/2005, specifically on the definition of what is a "pesticide residue". The Commission reminded that this topic had already been clarified in 2013, following legal advice that from the respective service in the Commission, and that pursuant to that advice the definition included in Regulation (EC) No 396/2005 applies also for foods for IYC.

A.17 Demonstration of the new features of the EU Pesticides Database.

The Commission presented the new version of the EU Pesticide Database, which was released in November 2020. Some Member States made suggestions for further improvement, which will be considered by the Commission in the light of the on-going priorities. The main new feature relates to the possibility to visualise the evolution of the residue definitions for active substances and the type of Annex under which a substance is listed, in addition to the MRL changes, already provided in the previous version of the database. The Commission clarified that the present and future changes fo residue definitions will always be updated, while those residue definitions that changed at some stage in the past, will only be updated on a case by case basis.

A.18 Other Information points:

1) Update on measures voted in February 2020, falling under the regulatory procedure with scrutiny (PRAC)

The Commission informed the Committee about the state of play for the draft Regulations for haloxyfop, mandestrobin and flonicamid. Individual draft Regulations on haloxyfop and mandestrobin will be submitted for vote in a forthcoming meeting of the Committee, possibly in the meeting of the Section Legislation in March 2021. For the draft Regulation on flonicamid the scrutiny period will be launched soon. The Council and the European Parliament will be informed transparently about the next steps. A Member State commented that the objection against mandestrobin MRLs was particularly disappointing, as it believes that there were no concerns with this substance at all.

2) Brexit

The Commission informed that there were no news to be reported under this agenda item, but that questions from Member States would be welcome and should be sent in writing.

3) Updated Industry Roadmap on the reduction of chlorate in foods for infants and young children (IYC)

The Commission provided an overview of the latest communication from Specialised Nutrition Europe (SNE) concerning the updated version of the Industry Roadmap for the reduction of chlorate in food products, which included a brief presentation summarising the views of the Industry on the matter and a scientific paper pending publication on a BenchMark Dose (BMD) modelling exercise led by the University of Cincinnati.

Specifically, according to the industry roadmap the baby food industry considers that it has reached its limits of what can be achieved in terms of lowering chlorate residues and that the recast of the recently adopted Drinking Water Directive (EU) 2020/2184 (DWD) is not expected to change this situation significantly given that the levels established there are still considerably higher than the default level of 0.01 mg/kg applicable to foods for IYC (0.25 mg/L in general and 0,7 mg/L in the case where water disinfection methods generate chlorate residues (e.g. method using chlorine dioxide)).

The industry position paper suggested a review of the EFSA 2015 scientific opinion[15] for chlorates as it has doubts on the toxicological reference value derived by EFSA.

The Commission clarified that both the DWD and Regulation (EU) 2020/749 on MRLs for chlorate in food were very recent and that time for implementation was needed, before any effects on actual chlorate concentrations in drinking water and food, respectively, could be observed. Moreover, the latter Regulation on chlorate MRLs in food already foresees a review of the MRLs in 2025. A review of the EFSA scientific opinion would be appropriate at that time.

4) Alignment of MRLs for pesticides with MRLs for veterinary medicinal products

The Commission presented an updated overview table with the MRLs that are set for dual use substances in the framework of Regulation (EU) No 37/2010 on veterinary medicinal products (VMPs) and Regulation (EC) No 396/2005 on pesticide residues, respectively.

The Commission intends to further align the values in the two pieces of legislation, in particular as regards those compounds which are exonerated from MRL setting in the VMP Regulation, while the default value applies in the MRL Regulation (e.g. ammonium sulfate, boric acid and borates). The Commission clarified that tryptophan and glutamic acid were notified by mistake in the framework of Directive 91/414/EEC, as explained in Regulation (EC) No 647/2007. Therefore, the default value does not apply and those substances can be deleted from the overview table. The Commission highlighted that for phoxim there are limits, which have not been re-evaluated for several years and might need further consideration by EFSA. As regards oxytetracycline, EFSA has identified concerns in relation to the limits that are currently set under the VMP Regulation. The Commission will further investigate and co-ordinate among sectors to address this issue.

Member States were invited to submit comments by 19 March 2021.

5) Phenmedipham

EFSA has recently adopted two Reasoned Opinions on the MRL setting for phenmedipham on strawberries and celeriacs, where it proposed some options for consideration by risk managers, one of them requiring further confirmatory data. The Commission informed that it intends to include the substance in a forthcoming draft Regulation to be presented at the next meeting of this Committee in June 2021 and considered that permanent MRLs could be established based on the available data. The Commission reminded that MRL applications that are submitted under Article 6 of Regulation (EC) No 396/2005 need to be fully supported by data and

[15] https://www.efsa.europa.eu/en/efsajournal/pub/4135

therefore the resulting MRLs should be set on a permanent basis, without a request of further submission of confirmatory data. If such data were needed, the stop-clock procedure should be used by EFSA.

Member States were invited to share their views as to whether the MRLs for phenmedipham could be set on a permanent basis by 19 March 2021.

6) Trifloxystrobin

The Commission had received a letter from an authorisation holder regarding the interplay between MRL procedures and the evaluation of category IV data, submitted in the context of the renewal of plant protection products authorisations, to provide residue data reflecting the amended residue definition for risk assessment. The topic has been included in the agenda of the meeting of the Post-Approval Issues (PAI) working group of the Section Legislation of the Committee on 11/12 March 2021.

The Commission asked Member States to coordinate internally their positions in view of the meeting of the PAI Working Group on 11-12 March 2021.

7) **Imazalil – withdrawal of MRL application in bananas**

The Commission informed the Committee that the applicant for an import tolerance for imazalil in bananas had withdrawn the application.

8) **Overview on substances in forthcoming Art. 12 draft Regulation**

The Commission informed the Committee that the preparation of a draft Regulation on a new Article 12 MRL review containing the substances oxyfluorfen, pyroxsulam, quinmerac and sulfuryl fluoride would be initiated soon.

Member States were invited to provide comments by 19 March 2021.

9) **Radish leaves (code 0243020-008)**

A Member State requested additional information on the trials on radish leaves that had been announced by another Member State[16]. Regulation (EU) No 2018/1049, introduced radish leaves in Part B of Annex I to Regulation (EC) No 396/2005 related to kales with a transitional period of four years (until 1 January 2022) in order to allow finalisation of those trials. After that the suitability of the MRL for kale to apply to radish leaves should be verified. The Member State in charge of those trials informed the Committee that its national plant protection service was organising meetings with interested parties to solve minor uses problems and that they were working on solutions for small radishes with leaves. Member States were invited to provide comments by 19 March 2021.

[16] https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20180226_ppr_sum.pdf

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 24-epibrassinolide, *Allium cepa* L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate 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:

- Cyflumetofen for use on citrus fruits, apricots, peaches, tomatoes, aubergines/eggplants, cucumbers and hops;
- Fludioxonil for use on elderberries;
- Fluroxypyr for use on chives, celery leaves, parsley, thyme, basil and edible flowers;
- Sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate for use on table olives and olives for oil production.

The draft Regulation also proposes the inclusion of the active substance 24-epibrassinolide and the basic substance *Allium cepa* L. bulb extract in Annex IV to Regulation (EC) No 396/2005.

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 cycloxydim, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products (Art. 10).

Following the motion for resolution adopted by the European Parliament in September 2020, the Commission had amended the draft measure by withdrawing MRLs for flonicamid, haloxyfop and mandestrobin. Moreover, in the interest of legal certainty, a retroactive application is proposed for mepiquat in cotton seeds to prevent that the current temporary MRL, valid until 30 June 2021, is lowered to the LOQ before the new permanent MRL applies.

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 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 clethodim, dazomet, hexythiazox, metam and sethoxydim in or on certain products (Art. 12).

The Commission provided clarifications on the latest revision of the draft Regulation and referred to supporting information was that had been shared with the Committee, including the comments received from members of the World Trade Organization via the Sanitary and Phytosanitary notification procedure. Additional information received

from the EU Reference Laboratories confirmed the residue definition on sethoxydim and the lack of a commercial analytical standard for sethoxydim which was indicated in a corresponding footnote "A". The Commission informed the Committee about the letters received from the applicant of clethodim via a lawfirm and the outcome of a recent meeting on the issue. The most recent letter also included new study results.

On request from a Member State, the Commission provided explanations on the differences between the specific cases on imazalil and clethodim, as this was mentioned in one of the letters received. The Rapporteur Member State confirmed receipt of the new studies and confirmed that they would be analysed in the framework of the renewal of approval process. The Commission informed that it had proposed to the applicant to submit an application under Article 6 of Regulation (EC) No 396/2005 in order to have the new data analysed in advance of the renewal procedure, but that this would not have a delaying effect on the draft Regulation on the Article 12 review in the interest of consumer protection.

Outcome of the vote by written procedure: favourable opinion.

One Member State voted against the draft Regulation and one Member State abstained. Both requested inclusion of their written declarations in the minutes of the meeting. These are presented in the Annex to this Summary report.

B.04 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 ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products (Art. 12).

The Commission presented the latest revision of the draft Regulation which had been notified to the World Trade Organization (WTO) via the Sanitary and Phytosanitary (SPS) notification procedure. It was clarified that for ametocradin the foonote of bovine and cattle requesting feeding studies was kept on request of a Member State. Another Member State explained that this feeding study was already submitted under the active substance review together with a MRL application in Ocotber 2020 to change the MRL of liver but the documents had not yet been assessed.

Outcome of the vote by written procedure: favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a coordinated multiannual control programme of the Union for 2022, 2023 and 2024 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin.

The Commission provided clarifications on revision 3 of the draft Regulation. Following comments from Member States regarding the changes made in revision 3 of the text referring to the application date, the respective text was re-aligned to the wording of previous years in revision 4.

The Commission invited Member States to maintain glyphosate in their national control programmes (NCPs) and emphasised the need to continue monitoring as many commodities as possible.

In the frame of NCPs, a Member State expressed concerns that some substances of dual use as pesticide and as veterinary medicinal product, included currently in Annex I

of Directive 96/23/EC on the monitoring of certain residues on animal products, might not be analysed any longer following its repeal by the Official Controls Regulation (EU) 625/2017 (OCR) in December 2022. The Commission reminded that Article 150 of the OCR requires that Member States shall continue to analyse samples as per Annex I of Directive 96/23/EC until 14 December 2022. The Commission informed that for the time beyond that date, an Implementing Act (IA) is currently being prepared in the field of residues of veterinary medicinal products (VMP) which makes reference to Annex I of Regulation (EU) No 37/2010. The paricipants of this section of the Committee were invited to liaise with their counterparts in the VMP residues section and provide information in case they identify discrepancies between the IA for VMPs and Annex I of Regulation (EU) No 37/2010 ahead of the next meeting of the Working Group for the Monitoring of pesticide residues that will take place later in 2021.

Outcome of the vote by written procedure: favourable opinion.

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for amisulbrom, flubendiamide, meptyldinocap (DE-126), metaflumizone, propineb in or on certain products (Art. 12).

The Commission provided an update on the status of the draft Regulation in its revision 2.

Further clarifications are expected from EFSA regarding the trials from which the proposed MRL of amisulbrom on grapes is derived.

For meptyldinocap, for both plant and animal origin commodities, the draft Regulation proposes the residue definition, as suggested by the EURLs, to include the ISO names of the compounds, i.e. sum of meptyldinocap and meptyldinocap phenol (2,4-DNMHP), expressed as meptyldinocap, although it is acknowledged that the hydrolysis step following extraction could be more laborious.

For metaflumizone, EFSA informed that the corrigendum of the Reasoned Opinion concerning the MRL on cotton seeds is already published, therefore the draft Regulation should be amended to take this into account.

For propineb, for plant commodities, the draft Regulation proposes the residue definition, as proposed by the EURLs, i.e. propineb and its reaction products that are cleaved to propane-1,2-diamine (PDA), expressed as PDA. This coincides with the current expression of the residue definition for propineb, i.e. as PDA and is also compatible with the current analytical method. In its Reasoned Opinion, EFSA proposes to determine propineb as PDA and express it as propineb. However, EFSA clarified that both expressions, either as propineb or as PDA, would be acceptable, given that PDA is not expected to be found in plant commodities, but is expected to be formed only during pasteurisation. Moreover, as the toxicological reference values for propineb were derived based on toxicological studies considering the current residue definition, i.e. expressed as PDA, no further adjustment is needed. For commodities of animal origin, the draft Regulation proposes the residue definition as propylenethiurea (PTU) free, as, according to the EURLs, inclusion of the PTU conjugates, proposed by EFSA, would require an hydrolysis step. However, no analytical method established within the EURLs would be suitable for PTU conjugates, as there are 4 different conjugates and it would be doubtful which one to target, as their relevance for all animal

commodities is doubtful. According to EFSA, free PTU may still be considered an acceptable marker for detecting illegal uses in all animal commodities, except in milk, for which the residue definition is proposed to include PTU conjugates.

Member States were invited to provide comments by 12 March 2021.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for 6-benzyladenine, aminopyralid and chlorantraniliprole in or on certain products (Art. 12).

The Commission presented the revised draft Regulation and its contents.

On 6-benzyladenine a Member State expressed its concern related to setting the MRLs at the LOQ of 0.01 mg/kg as some data from the industry indicated findings in several crops of this active substance above the default level due to its possible natural occurrence. EFSA explained that during the peer review in 2010 6-benzyladenine was initially assumed to be a naturally occurring plant hormone but there were no findings in the literature to support such natural occurrence. In the main paper that was used as a basis, other similar compounds were found, but not 6-benzyladenine. A data gap was set to keep a possibility for further data submission, but in ten years no information had been provided to fill the data gap. During the Article 12 review no comments were made either.

Based on this situation, the Commission proposed to move ahead with the proposed LOQ values. Should additional data become available at a later stage, they could be submitted through an application according to Article 6 of Regulation (EC) No 396/2005.

On aminopyralid a Member State asked for clarification on footnote "A" requiring reference standards for conjugates of aminopyralid as confirmtory data, as according to the applicant there was no need for that. It was clarified that this was the suggestion of the EURL but the Commision will verify this with the EURL.

On chlorantraniliprole a Member State requested to set the MRL for kale at the level of the CXL for radish leaves because in the EU radish leaves are classified in part B under the subgroup of kale. Currently the CXL for radish leaves is established for the subgroup of "Baby leaf crops (including brassica species)." The Commission explained that when the CXL was implemented in EU legislation in 2015, radish leaves were not explicitly mentioned in the EU legislation. Hence, it was considered as falling under the subgroup of "Baby leaf crops (including brassica species)." For this reason, in the current Article 12 MRL review, the CXL for radish leaves was proposed for "Baby leaf crops (including brassica species)" and not for kales. The Commission noted that the proposal of the Member State is based on the new classification that came into force only in 2018 and should not be applied retroactively. The Member States reiterated its view that the current classification should be used, rather than the one in place back in 2015. The Commission will further verify the request with EFSA.

Member States were invited to provide comments by 12 March 2021.

C.03 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for flupyradifurone and difluoroacetic acid in or on certain products (Art. 10).

The Commission reported on the feedback provided by Member States.

In particular, it clarified that for citrus fruits, residue trials were submitted for the four commodities (34 in total), showing that for lemons (8) and mandarins (8) an MRL of 1.5 mg/kg is sufficient, while for oranges (12) and grapefruits (6), an MRL of 3 mg/kg would adequately cover the uses in the United States. It is therefore not appropriate to extrapolate the value for oranges to the entire group, since there is sufficient information to derive separate MRL proposals, which reflect the actual residue behaviour.

As regards witloof, the Rapporteur Member State clarified that the cultivation of this crop takes place in two steps: a field phase of growing witloof roots and an indoor phase of forcing witloof shoots. During the cultivation of witloof roots, the crop may be exposed to difluoacetic acid (DFA) residues resulting from rotation. The RMS therefore proposed relying on the rotational crop data for lettuce and set an MRL for flupyradifurone in witloof at 0.07 mg/kg and for DFA at 0.08 mg/kg.

Member States were invited to provide comments by 12 March 2021.

C.04 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for imidacloprid in or on certain products (Art. 12).

The Commission presented the contents of the draft Regulation which was not modified since the previous meeting of this Committee. It also presented the foreseen two step procedure for the review of imidacloprid MRLs, in which first the Article 12 review would be carried out and in a second step the lowering of the MRLs to the LOQ after the expiry of the grace period in June 2022. The Commission explained that the first step (Article 12 review) is still needed since there was a possible consumer health concern with the existing MRL for kale that would need to be addressed without delay. One Member State suggested to make reference in the recitals of the draft Regulation to the fact that imidacloprid is no longer approved in the EU.

Member States were invited to provide comments by 12 March 2021.

C.05 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, prothioconazole and silthiofam following the evaluation of Article 12 confirmatory data.

The Commission provided an update on the status of the draft Regulation in its revision 2.

Following consultation with the concerned services of the Commission, it was concluded that for tentative MRLs for which confirmatory data had not been submitted by the applicant by the designated deadline, an EFSA output would be needed to justify lowering of MRLs to the LOQs. The Commission is in discussion with EFSA on the details of the way forward.

For azoxystrobin, following comments from Member States, the latest revision of the draft Regulation restores the footnotes concerning the lack of toxicological data for metabolites L1, L4 and L9 on kidneys and liver.

For fenhexamid, EFSA confirmed that in its 2014 Reasoned Opinion, setting a tentative MRL for kiwis at 15 mg/kg, the evaluation was performed with older data requirements and the request for 4 additional trials was based on the "Guidance on MRL setting and extrapolation" which, at the time, was actually asking for more trials. Therefore, the existing data should be sufficient.

For prothioconazole, some Member States supported maintaining the current MRLs for pulses, barley, oats and rye as they reflect CXLs. However, data gaps were identified in the EFSA Article 12 MRL review in 2014 which thoroughly assessed all the established older CXLs. The MRLs were implemented in a Regulation in 2016 with the respective footnotes requiring confirmatory data. Those data gaps had not been fully addressed by the applicant. The Commission therefore considered it more appropriate to lower the MRLs to the LOQ in the next revision.

Member States were invited to provide comments by 12 March 2021.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) on multiannual national control programmes for pesticides residues to be established by Member States and on sampling for the analysis of such residues (SS).

The Commission provided an overview of the revised version of the draft Regulation. A few Member States pointed out that under the current provisions of Regulation (EC) No 396/2005 only the results of the official controls were published on the national websites. The Commission clarified that this is now covered under Article 11(1) of the Official Control Regulation (EU) 2017/625[17] and therefore existing practice can remain as it is.

The Commission informed the Member States that it will present the draft Regulation for a vote at the next meeting of this Committee in June 2021. The respective Delegated act with further provisions on sampling will follow the same time schedule as the Implementing Regulation. Both will apply on the same date, in December 2022.

Member States were invited to provide comments by 19 March 2021.

[17] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 095 7.4.2017, p. 1)

Written declarations of Member States in relation to agenda item B.03:

Italy:

"One of the possible problems with the genotoxicity study is the administration mode, i.e drinking water compared with gavage, the most frequently used one.

Indeed it is stated in the OECD TG n° 474 'animals should be exposed to the test substance by an appropriate route (usually by gavage)'. However, other routes of exposure such as dietary or drinking water can be justified depending on the anticipated route of human exposure or scientific reasons, as indicated in the same OECD TG.

The difference among the two modes is the Cmax, which is higher following the gavage (corresponding to a bolus dose) with respect to the drinking water administration in which the same dose is fractioned over the day. This was clearly shown also by the PBPK modelling provided by the applicant. The higher Cmax implies that, for a given dose level, hepatic toxicity is likely to be higher by oral gavage than by drinking water. Indeed lethality from dosing of 3-CAA by aqueous oral gavage at a dose of 75 mg/kg/day for two days was previously reported (Liberacki 1999). In order to avoid possible confounding in genotoxicity assessment due to high liver toxicity, the administration via drinking water can be acceptable, also considering that the same modelling showed that concentrations of 3-CAA in the blood (as represented by the area under the blood concentration curve, AUC) would be similar for administration by oral gavage or in drinking water . The only observation is that the modelling was parametrised by considering the biotransformation of the 3-CAA being catalysed only by ALD, ignoring other possible metabolic reaction, which can be relevant considering that 3-CAA toxicity is mediated by metabolism.

The TG also indicates that the study should aim to identify the maximum tolerated dose (MTD), defined as the highest dose that will be tolerated without evidence of study limiting toxicity. An MTD was achieved at the highest dose in the TGR study (100 mg/kg/day nominal, 83.9 mg consumed/kg/day), based on overall mean body weight gain was significantly lower compared to the vehicle control group. evidence of increased relative liver weights. In this line it is indicated in the TG that MTD can be indicated by body weight depression or hematopoietic system cytotoxicity, but not death or evidence of pain, suffering or distress necessitating humane euthanasia.

The only residual point is if the demonstration of the target tissue (bone marrow) exposure.

To verify systemic exposure of rats (thus including bone marrow) in the Big Blue assay, in silico evaluations of oral absorption of 3CAL from the drinking water route were conducted. The predicted absorption was consistent with prior pharmacokinetic data for 3CAL by the oral route, showing high absorption of this test material with systemic exposure to plasma and tissues, which are expected to be well distributed to tissues, including liver and bone marrow.

Based on the above considerations, there is no reason for not considering the results coming for the submitted genotoxicity test on 3-CAA, giving negative results."

Portugal:

"PT ABSTAINS if clethodim remains in the proposal, and the main reasons are the following:

- EFSA considered as inconclusive the information on genotoxicity potential of the metabolite 3-chloroallyl alcohol (3-CAA);
- there are no identified consumer risks that would justify such a rushed decision on lowering the MRLs to the LOD, especially considering that the new study concluded on the lack of genotoxicity of the metabolite, even if specific methodological elements would need to be clarified, once the AIR evaluation of clethodim will be in place in a near future;
- that the lowering of the MRLs also implies severe economic negative consequences in the EU (it is authorized in AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK, according to the information on the EU Pesticides data base) and with regards to third countries exporting to the EU. In PT it is authorized in potatoes, carrots, onions and sunflower, being an important missing;
- So, PT is of the opinion that the MRLs in force should remain valid and not set at the LOD as proposed, till a Peer Review of the requested vertebrate study for the metabolite 3-CAA, submitted to EFSA in August 2020, and also of the new already submitted information regarding residue trials with the residue values of this metabolite."