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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals – Pesticide Residues*
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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. The European Food Safety Authority (EFSA) informed that its report on the progress of the review of Maximum Residue Levels (MRLs) will be published in March 2022.

2. Confirmatory data Art. 12 follow-up

The Commission informed Member States of the recently published Reasoned Opinions on deltamethrin, metalaxyl-M and trifloxystrobin, for which EFSA reported the need for certain risk management considerations.

For deltamethrin, several data gaps were not addressed. The residue definitions (RD) for enforcement and risk assessment (RA) differ, the latter including the alpha and trans-isomers of the substance. EFSA noted that a conversion factor (CF) of 1 for recalculating the results according to the RD for enforcement to the RD for RA could be used in most cases as the isomers are unlikely to occur. Using this calculation, the data gap concerning the number of trials could be addressed. The Rapporteur Member State (RMS) for the renewal of deltamethrin confirmed a median CF of 1.09 for vegetables and fruits and that no changes to the toxicological values are foreseen.

Therefore, the Commission proposed to accept the CF of 1 (or a higher CF, when suggested by EFSA) for crops where a risk management decision was required. In case of safe Codex MRLs (CXLs), the Commission proposed to maintain/modify the existing MRL as to equal the CXL despite the wider RD for enforcement for the CXLs. For pears, the newly derived MRL would be very close to the current one, for which an acute risk for consumers was identified by EFSA with the most recent Pesticide Residues Intake Model (PRIMo rev. 3.1). Therefore, the Commission proposed lowering the MRL to the limit of quantification (LOQ).

For metalaxyl-M, the Commission proposed to accept MRLs in case fall-back Good Agricultural Practices (GAPs) are available, and if not, to lower the existing MRLs to LOQs. For soyabeans, as the proposed fall-back GAP is not in line with the use restrictions, the Commission proposed to lower the MRL to the LOQ. For herbs and edible flowers, the Commission asked to confirm if the newly proposed indoor GAP

has been authorised in any of the Member States. One Member State confirmed having authorised a use of metalaxyl-M for fresh herbs as seed treatment, and noted that no residues are expected.

For trifloxystrobin, the Commission proposed lowering MRLs to the LOQ for products for which data gaps were not addressed, with the exception of cucumbers and gherkins. For those it proposed to maintain the current MRL of 0.3 mg/kg as it reflects the CXL for cucurbits.

Member States were invited to submit their comments by 18 March 2022.

3. List of non-approved substances for follow up

The Commission presented an updated prioritisation of non-approved active substances for which existing MRLs would need to be reviewed and provided explanations on the method of assigning substances to the different priority categories. This update took into consideration the information provided by one Member State, the progress on ongoing draft measures and the publication of the latest Codex Alimentarius Committee report. Following this update, the priority for certain active substances was modified. Bifenthrin and profenofos are listed under priority 1 because they are being addressed by other measures or have temporary MRLs that need to be revised, and due to potential consumer health risks.

The Commission proposed to mandate EFSA to address the first batch of substances for which potential consumer risks were identified (i.e. azocyclotin, bifenthrin, cyhexatin, chlorfenapyr, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin, and profenofos). A second mandate to EFSA is considered, aiming to investigate whether some of the existing MRLs for the other substances included in the list were set based on CXLs that were later revoked. The Commission highlighted that EFSA's assessment could be hampered by the lack of recent studies for substances that have been non-approved since a long time and for which toxicological reference values would most likely be outdated.

A Member State supported the proposed prioritisation and noted that the MRLs for cyanides on cereals should be lowered urgently to the LOQ referring also to the contaminants Regulation (EC) No 1881/2006[1] in which MRLs for hydrocyanic acid for these products are not established and not currently under discussion. Another Member State supported the decision to address bifenthrin and profenofos in the first mandate to EFSA, and underlined the difficulty to assess consumer exposure for some of the substances in the list due to outdated studies available for them.

The Commission clarified that the current criteria offer a rough prioritisation and that including criteria such as the periodic review from Codex would be a refined but complex approach. While recognising the importance of this work, the Commission reiterated its need to take a pragmatic approach, considering its current resources and the need to continue work on other ongoing activities.

Member States were invited to submit comments by 18 March 2022.

4. Statement from EFSA for substances for which no Article 12 review is necessary

The Commission presented a table with its proposed follow up actions on the EFSA recommendations in the statement. No action is required for dimethoate, ethoprophos and methiocarb. These substances are already included in Annex V of Regulation (EC)

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1881-20220101&from=EN

No 396/2005. For didecyldimethylammonium chloride (DDAC) and nicotine, MRLs are currently being reviewed in the context of Article 16(1)(a) of the Regulation. For chlorates (incl. Mg, Na, K chlorates) no action is required at this moment. The review of those MRLs is foreseen after five years of entry into force of Regulation (EU) 2020/749[2] (i.e. 8 June 2025)

The inclusion of calcium carbonate, potassium hydrogen carbonate and carbon dioxide into Annex IV was proposed to become permanent by removing the relevant footnote in a forthcoming routine MRL proposal.

Member States were invited to submit their comments by 18 March 2022.

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

The Commission gave an overview on the outcome of the last meetings of the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation held on 1-2 December 2021 and on 27-28 January 2022. A restriction of sulfoxaflor to greenhouse uses was presented for vote in the January meeting, but got a "no opinion" and will then be referred to the Appeal Committee.

One Member State noted that for one of the active substances that were not approved, 1,3-dichloropropene, the application was withdrawn shortly before the publication of the EFSA assessment.

The Commission presented the table of active substances for which the approval had not been renewed, for which grace periods had expired or will expire soon and for which follow-up action was needed.

Furthermore the Commission mentioned that following the discussion at the last meeting of the Committee a mandate to EFSA on indoxacarb had been prepared (see Pt. A.04.03). It also highlighted that the first Conclusions of EFSA related to the assessment of endocrine disrupting properties (under clock-stop between 3 and 30 months) had been published and that for some of them follow up on MRLs would be needed. The highest number of those Conclusions will be published in 2023 and 2024, which means that follow up action on MRLs will therefore have its peak in 2025/2026 (after expiry of possible grace periods).

A.03 Specific substances:

1. Glufosinate ammonium

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

2. Glyphosate

The Commission provided an update on the ongoing renewal assessment of glyphosate.

3. Ethylene oxide – update on the state of play

The Commission reported on the outcome of the technical meeting of 20 January 2022 where the EU Member States and Norway presented an overview of their experience in applying the EU approach for the incident of ETO findings on locust

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R0749

bean gum[3]. The summary report of that meeting is available online[4] and EFSA published its Statement on the opinion of the German Federal Institute for Risk Assessment (BfR) regarding the toxicity of 2-chloroethanol[5].

4. Bacillus thuringiensis

The Commission informed that discussions on the possibility to mandate EFSA and the European Centre for Disease Prevention and Control (ECDC) to improve clarity on horizontal issues concerning dietary exposure for consumers linked to *Bacillus thuringiensis* strains are still ongoing.

5. Fluopyram

The Evaluating Member State (EMS) informed the applicant of the discussions held by this Committee. Previously, the applicant submitted an MRL application to increase the MRLs for fluopyram in soyabeans and peanuts and to decrease the MRLs for pome fruits (apples, pears), wheat and sorghum. The applicant informed the EMS of its intention not to support the setting of lower MRLs for cereals and sorghum anymore, because, due to the Covid-19 situation, there was a backlog in Codex Alimentarius and the 2021 submission of the dossier on fluopyram in cereals was postponed. However the applicant still would like to lower the MRL for pome fruits (apples, pears) as the GAP considered during the MRL review for the US import tolerance (PHI=0 day) is not used anymore but is replaced by a new US GAP (PHI=7 days) fully supported by residue trials that lead to a lower MRL proposal and will therefore also contribute to reduce the consumer exposure in Europe.

Member States were invited to submit their comments by 18 March 2022.

6. Fosetyl/phosphonates

The Commission informed that various EFSA Reasoned Opinions on potassium phosphonates (i.e. several Article 10 applications and a joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43) were recently published. While these Opinions provide a clear rationale for the recommended MRL modifications, diverging MRL values are proposed for the same commodities in different outputs. The Commission will mandate EFSA to produce a consolidated statement clarifying which MRL should be considered in these cases. The above mentioned Opinions are currently on hold and will be addressed when the EFSA statement is available.

7. Cyanantraniliprole

A Member State questioned whether a fast-track procedure could be used to establish temporary MRLs for cyantraniliprole in raspberries, blackberries and leeks for the purpose of emergency authorisations. Some discussion on this topic took place already in the meeting of this Committee in September 2021[6].

The Member State proposes using the fast-track procedure based on the EFSA Reasoned Opinions from 2017, 2018 and 2019 that were drafted following emergency uses authorised in the UK and based on which temporary MRLs were established for those crops with a limited duration of 3 years, before being lowered

[3] https://ec.europa.eu/food/system/files/2021-07/rasff_ethylene-oxide-incident_e410_crisis-coord_sum.pdf
[4] https://ec.europa.eu/food/system/files/2022-02/rasff_ethylene-oxide-incident_e410_crisis-coord_20220120_sum.pdf
[5] https://www.efsa.europa.eu/en/efsajournal/pub/7147
[6] https://ec.europa.eu/food/system/files/2021-10/sc_phyto_20210923_ppr_sum.pdf

to the LOQ in 2021. However, the data gap for leeks regarding rotational crops is still not addressed. For raspberries and blackberries, the data gap on genotoxicity of the metabolites IN-N5M09 and IN-F6L99 will be ruled out by an EFSA Reasoned Opinion on cyantraniliprole in different crops that will be published soon.

Following these considerations, the Commission concluded that the request for a fast-track procedure could not be accepted. The aim of the fast-track procedure was to allow extrapolating data from a major crop which had been evaluated in a regular MRL procedure to a minor crop, and it was never meant to be used to bypass the need for regular applications and grant repeatedly emergency authorisations by referring back to earlier opinions on emergency authorisations. The setting of temporary MRLs in the past for this substance was done with the clear understanding that a regular and permanent MRL should be established while providing applicants with time to prepare such an application. In addition, the REFIT evaluation indicated that the number of emergency authorisations has significantly increased and the Commission is working towards increasing oversight on the use of the emergency authorisation procedure and discouraging its use where it is not justified. Therefore, the Commission will not propose to establish further temporary MRLs for cyantraniliprole. If a modification of the MRLs is needed, then applicants should apply for permanent MRLs in the frame of Article 6.

The concerned Member State took note of the Commission comment, and agreed with the provided rationale.

8. Chlorporpham

In accordance with the provisions of Commission Regulation (EU) 2021/155[7], food business operators have developed a new cleaning methodology to limit the contamination of untreated potatoes with chlorpropham, and have submitted a report on the development and implementation of cleaning practices to the Commission in December 2021. Updates to this report are to be submitted by the food operators every year.

The Commission expressed appreciation for the work done by the sector in the development of the guidelines and in the implementation of the monitoring plan.

Member States were invited to submit their comments by 18 March 2022.

9. *Spodoptera exigua nuclear polyhedrosis* virus

The approval of *Spodoptera exigua nuclear polyhedrosis virus (Florida strain)* expired in November 2017. This substance was previously listed in Annex IV, and the Commission proposed to include it in an upcoming draft Regulation moving it from Annex IV to Annex V. The Commission also highlighted that another strain of this virus species has been voted as a low-risk substance at the meeting of the Standing Committee for Plants, Animals, Food and Feed (SCoPAFF), Section Phytopharmaceuticals – Legislation of January 2022, and that its inclusion in Annex IV is foreseen by the draft Regulation SANTE/11466/2021 (under Pt. B 01.00).

The Commission inquired whether non-approved substances should be deleted from Annex IV systematically, or whether some should be maintained. In the latter

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R0155

case, the Commission asked Member States what could be the criteria for such a decision.

One Member State noted that moving a substance from Annex IV to Annex V implies requiring from the laboratories of Competent Authorities to start analysing samples to detect residues of that substance. If a substance would not pose a risk to consumers, then this additional burden of work would be unjustified.

Member States were invited to submit their comments by 18 March 2022.

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 outputs addressing 11 processes[8] had been adopted since the previous meeting of this Committee in November 2021.

Currently, outputs addressing 48 such processes are at different steps of the procedure. Out of these, 4 are to be started, 6 are under scientific assessment (5 under Regulation (EC) No 396/2005 and 1 under Regulation (EC) No 1107/2009), and 38 are currently under clock-stop as additional data had been requested (25 under Regulation (EC) No 396/2005 and 13 under Regulation (EC) No 1107/2009).

EFSA informed that, according to recent changes in its organization, the Unit responsible for Front Desk and workforce Planning (FDP) is taking over the activities of the former Applications Desk Unit (APDESK) concerning incoming dossiers. Member States are asked to use the new email address FDP@efsa.europa.eu.

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

EFSA presented the state of play of the ongoing Article 12 reviews. Since the last meeting of this Committee, MRL reviews for 11 substances have been finalised, 26 are on hold, 16 are currently being assessed at different stages of the procedure, while for 13 substances data is pending.

Dithiocarbamates

EFSA reported about the ongoing work on dithiocarbamates. The reviews for different substances are at different stages of the process. In addition to the assessment of the authorized uses, import tolerances and CXLs related to the individual active substances, data was collected to derive MRL proposals reflecting naturally occurring background carbon disulfide (CS2) residues. EFSA is currently performing the data analysis to calculate MRLs. If there is a sufficient number of results for a given commodity, the MRL proposal will be derived at the 95th percentile, otherwise it will reflect the highest statistically reliable percentile. If needed, EFSA may propose MRLs for crop groups with similar characteristics. For commodities without any data, EFSA will propose MRLs derived by extrapolation, if feasible. EFSA expects to finalise the Reasoned Opinion on the whole group of dithiocarbamates by August 2022.

Complexity evaluation of forthcoming Article 12 evaluations

As agreed at the meeting of this Committee in November 2021[9], the evaluation of the complexity calculator started with the support of a Member State, acting as Evaluating Member State (EMS) for phosmet. The GAP collection was immediately launched and

[8] Each process receives a so called "EFSA question number".
[9] https://ec.europa.eu/food/system/files/2021-12/sc_phyto_20211122_ppr_sum_0.pdf

EFSA, the Commission and the EMS met to discuss identified issues, re-estimate the complexity and agree on the timelines. Complexity was much lower than initially estimated, therefore the Reasoned Opinion for phosmet is expected to be finalised within 6 months. EFSA will revise the complexity calculator and present it at the next meeting of this Committee.

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

The Commission mandated EFSA to perform a targeted review of MRLs for indoxacarb. EFSA will screen existing MRLs (focusing only on import tolerances and CXLs), considering the new toxicological reference values established at the Peer Review. If there are crops for which a health concern is identified, then EFSA will request from Member States to submit fall-back import tolerances GAPs. The draft reasoned opinion will be circulated to Member States and EU Reference Laboratories (EURLs) for consultation, with the aim to finalise and deliver the reasoned opinion in 6 months.

An Art. 43 mandate for an updated consumer exposure assessment for haloxyfop-p will be submitted to EFSA in the coming weeks.

4. Other issues

Pesticides Annual Monitoring Report

The Pesticides Residues Annual Report (ARPR) 2020 has undergone consultation with the Member States and is planned to be adopted by end of February 2022. It will be presented at the next meeting of this Committee in April 2022.

International

The summary report of the Joint Meeting of the Food and Agriculture Organisation of the World Health Organisation (FAO/WHO) on Pesticides Residues (JMPR) that was held, extra-ordinarily, in May 2021 is published[10], where 27 substances are assessed. EFSA finalised the preparation of comments with the support of Member States and its draft interim report on all 27 substances was shared with the Commission in January 2022. Additionally, the report[11] of the regular JMPR meeting (September/October 2021) is published, where 19 active substances are assessed. EFSA's comments on these substances are under preparation. EFSA plans to share a draft report covering all active substances, from both the extraordinary and regular JMPR meeting, with Member States in March 2022.

Cumulative risk assessment

The work on cumulative risk assessment (CRA) for craniofacial malformations is ongoing. Due to issues with input data, the deadline for publication was postponed to the end of May 2022.

EFSA re-launched a call for 'Cooperation with EFSA in the area of cumulative risk assessment from dietary exposure to pesticides' on 19 January 2022, with a deadline set at the end of April 2022. The first specific actions foreseen under this call are a repetition of the CRA for the effects on the thyroid (e.g. to update it with more recent monitoring data) and a first CRA for the effects on kidneys.

[10] https://www.who.int/publications/m/item/joint-fao-who-meeting-on-pesticide-residues-may-and-june-2021-summary-report
[11] https://www.who.int/publications/m/item/joint-fao-who-meeting-on-pesticide-residues-september-and-october-2021-summary-report

Concerning the implementation of the prioritization method, the selection of substances has been completed, with 151 substances prioritized, and the selection of organs is expected to be completed by the end of 2022. All results will be published in an EFSA scientific report by the end of 2022.

In accordance with the EFSA/SANTE Action Plan for CRA, EFSA will perform in 2022 a "mock" assessment based on a real MRL application. This exercise will be outsourced via an existing Tasking Grant and will consider, for certain parameters, the tentative approach discussed during the Experts' meeting on CRA held on 26 May 2021 as detailed in Annex I.

EFSA Guidance on Rotational Crops

Further to previous discussions, EFSA received a mandate for the preparation of guidelines on the assessment of studies concerning pesticide residues in rotational crops. The guidelines will describe under which circumstances studies investigating the nature and magnitude of residues in rotational/succeeding crops are required, provide details on the study design, develop guidance on the interpretation of the studies for consumer risk assessments and risk mitigation measures and derive recommendations for the development of tools necessary to perform the assessment, also in alignment with the respective Guidance Document[12] of the Organisation for Economic Cooperation and Development (OECD). Following the finalisation of these specifications, a subsequent mandate will focus on the development of a corresponding tool. The draft guidelines will be submitted to the Member States and public consultation prior to finalisation, which is expected by end of January 2023.

Pesticides Steering Network/Transparency/IUCLID

The Pesticides Steering Network – IUCLID subgroup held its second meeting on 31 January 2022[13]. On 7 February 2022, a new version of IUCLID was released as an intermediate release, where identified problems were fixed. Additionally, further to the updated version of IUCLID (6.6) released on 27 October 2021, the updated "IUCLID 6.6 active substance application manual"[14] and the "IUCLID 6.6 MRL application manual"[15] were published on 21 January and 9 February 2022, respectively.

EFSA highlighted that the FDP Unit is available to provide further support or advice in performing the admissibility check in IUCLID. Member States are reminded to also notify via email the other Member States, the Commission, EFSA and the applicant on the decision on admissibility. It also gave specific recommendations to the Member States on the contents and presentation of the Evaluation report with regard to its subsequent use in IUCLID.

EFSA provided an update on the status of the first IUCLID MRLs dossiers received: 8 dossiers were declared admissible by Member States. For two, the public consultations are finished and no comments were received. The first evaluation report on copper has also been submitted.

EFSA noted that in some IUCLID dossiers declared as admissible by the RMS, personal data had not been sanitised as required. Thus, EFSA suspended the publication of those dossiers until finalization of the confidentiality assessment. EFSA has taken measures

[12] https://www.oecd.org/chemicalsafety/guidance-document-on-residues-in-rotational-crops-99457f3f-en.htm
[13] https://www.efsa.europa.eu/en/events/2nd-meeting-pesticide-steering-network-iuclid-sub-group
[14] https://zenodo.org/record/5888186#.YijXAPXMLcs
[15] https://zenodo.org/record/6020956/preview/IUCLID%206.6%20MRL%20Application%20Manual.pdf

to improve personal data management within IUCLID, e.g., contact person details are now not published by default. However, the sanitized study reports in the IUCLID dossiers often still contain names of physical persons, signatures, etc. that should be removed. Some Member States expressed the view that data sanitization is in the interest of the applicant and that they do not consider it as part of their role as RMS/EMS. The discussion will continue to further refine the process.

EFSA re-organisation

EFSA provided an update of its organisational changes effective as of 1 January 2022. The unit dealing with MRLs is now the Pesticides Residues & Plant Health (PLANTS) unit which is part of the Risk Assessment (ASSESS) department. The Data Management System (DMS) structure and pesticides residues mailbox have not been changed. The PLANTS Unit comprises of 5 sub-units working on: peer reviews, MRL Art 12, MRL Art 10, Plant Health (PLH) Risk assessment, and PLH monitoring.

EFSA conference 2022

EFSA informed that the "ONE – Health, Environment, Society – Conference 2022", co-organised by EFSA, the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Medicines Agency (EMA) and the European Commission's Joint Research Centre (JRC), will take place in Brussels and online on 21-24 June 2022. Registration is now open and will close, for physical participation, on 29 April 2022.

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

The Commission presented an update on the harmonisation of MRLs for pesticides that can also be used as veterinary medicinal products. A Member State had provided additional monitoring data for residues of bromide (potassium and sodium salts) in eggs showing that the existing MRL set by Regulation (EC) No 396/2005 is frequently exceeded. The Commission noted that the sample size is still not large enough to provide a robust statistical evaluation and called on Member States to collect additional data to assess the need of establishing MRLs for bromide in eggs.

Several Member States proposed that MRLs for chlorocresol also need to be aligned. Chlorocresol is a pharmacologically active substance for which MRLs are not required according to Regulation (EU) No 37/2010[16], but is also an active substance used in plant protection products (PPPs) under the name of 4-chloro-3-methylphenol with MRLs set at the LOQ in Regulation (EC) No 396/2005 at the LOQ. In addition, this substance is also approved as a biocide. The Commission will follow the developments in this area and keep the Committee updated.

Lastly, the Commission informed Member States that thiabendazole has been included in the draft Regulation SANTE/10090/2022, aligning MRL values between Regulation (EU) No 37/2010 and Regulation (EC) No 396/2005 for this active substance.

One Member State questioned whether, for chlorocresol (4-chloro-3-methylphenol), the default MRL should apply. Another Member State noted that this substance had never been used as a plant protection product but only as a biocide, and it could be considered to remove it from Annex I of Regulation (EU) No 540/2011[17], while noting

[16] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010R0037
[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011R0540

that MRLs for this substance may be needed as an acute risk for consumers of products of animal origin may arise from its biocidal use on live animals.

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

The Commission explained that methylbromide had been not approved for use in PPPs back in 2008. However, natural levels exist (mainly in the inorganic form: bromide ion) in many food and feed commodities. The natural presence of bromide ion in feed, in particular in algae and seaweed and derived products, may raise health concerns due to the possible carry over into food of animal origin.

Moreover in 2019, the European Chemicals Agency's (ECHA) opinion on the application for approval of the active substance 2,2-Dibromo-2-cyanoacetamide (DBNPA) concluded that DBNPA is considered to have endocrine-disrupting properties to humans. The conclusion is based on the observed adverse effects in the thyroid gland in the studies on rats and dogs combined with data obtained from a literature search conducted on bromide effects on the thyroid. Bromide may substitute iodide in the natrium/iodide symporter of the thyroid, thus creating a relative iodide insufficiency for further synthesis of thyroid hormones. This shows a link between the observed adverse effects in the thyroid and endocrine activity, which is relevant for humans and non-target species.

A draft mandate on bromide ion is under discussion with EFSA.

A.07 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that expire in 2022 and beyond:

1. General overview

The Commission gave an update on the state of play for the remaining substances listed in the overview table. The validity of existing temporary MRLs for nicotine in wild fungi (dried ceps and dried wild mushrooms other than ceps), profenofos in rose petals and for chlormequat in pears, cultivated fungi and oyster mushrooms will be extended by the draft Regulation SANTE/11466/2021 (for vote under Pt. B 01.00). The temporary MRLs for chlormequat and mepiquat in cultivated fungi and oyster mushrooms will be revised based on data from industry studies that are currently ongoing and that should be concluded by 2022.

The modification of temporary MRLs for the other substances/product combinations are proposed by draft Regulation SANTE/10090/2022, and are detailed under Pt. A 07.02.

2. Data analyses for decisions on temporary MRLs for profenofos, nicotine, DDAC, BAC and chlorpropham

The Commission presented its proposals as to whether the existing temporary MRLs for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), nicotine and profenofos should be maintained or lowered based on EFSA's monitoring data and on monitoring data provided by the industry. These proposals were already implemented by draft Regulation SANTE/10090/2022 (presented under Pt. C 02.00).

For nicotine and profenofos, proposed values were already presented and agreed on at the meeting of this Committee in November 2021[9].

The Commission informed the Committee that the tea industry and the Croatian Employers Association requested to reconsider the current positions for lowering current temporary MRLs for nicotine in tea and herbal infusions, as in some areas values would be much higher than the proposed revised temporary MRLs. These requests were shared with Member States in preparation of this meeting.

For BAC and DDAC, monitoring data from EFSA (2019-2020) and from the industry were analysed. For BAC, no lowering could be proposed as the LOQs for most of the analysed samples were equal of higher than the current temporary MRLs. For DDAC, for most commodities the vast majority of the samples (95-99%) had no detections or detections at levels close to LOQ, but higher occurrences were identified for products of animal origin. Thus, the Commission proposed lowering the current temporary MRL for all products of plant origin to 0.05 mg/kg, and to maintain existing temporary MRLs for products of animal origin. The Commission proposed re-assessing the temporary MRLs for BAC and DDAC in 7 years.

For chlorpropham in potatoes, monitoring data were provided both by EFSA (2019-2020) and food business operators (2020-2021). As samples from EFSA were older and the industry data indicates the effectiveness of implemented cleaning actions, the Commission decided using the industry dataset only for deriving the proposal for revising temporary MRLs. A few outliers (5) were identified and removed from the dataset. The Commission also noted that the current temporary MRLs had been set based on monitoring data, covering the 97.5th percentile (p97.5) of the data population at the 95 % confidence interval (CI). In line with this, it proposed to set the MRL at 0.35 mg/kg. The respective draft Regulation SANTE/10090/2022 is presented under Point C.02.00 of the agenda.

Member States were invited to submit comments by 11 March 2022.

A.08 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission informed about the progress made in the OECD expert group. There are still some issues related to metabolites that need to be considered and included in the draft Guidance document.

2. OECD Honey Guidelines

One of the Member States that attended the OECD working group on setting MRLs in honey gave an overview of the ongoing work. Currently four subgroups are working on the general decision tree, the study design, the non-target plants and the residue definition, respectively.

The update of the current work from both OECD working groups will be presented at the Akademie Fresenius Conference “Food Safety and Dietary Risk Assessment” which will take place on 24 March 2022.

3. Codex Alimentarius/JMPR issues

The Commission provided an update on the dates announced for the next Codex Committee on Pesticide Residues (CCPR), on the publication of the 2021 Report of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and on the developments of different electronic working groups. The Commission informed that the JMPR Report included relevant information on the way forward for the International Estimated Short-Term Intake (IESTI) equation. In order to inform further discussions on this matter,

Member States were invited to provide specific practical examples illustrating the problems with the existing equation by 03 March 2022.

The Commission shared with Member States an invitation from Crop Life International to initiate a discussion on how to address the backlog of MRL periodic reviews at Codex Alimentarius level. The Commission informed about the request from the "Coordination Committee for Latin America and the Caribbean Part" to provide information on notifications for non-compliances with MRLs for the products listed in group 14 (Assorted fruits – inedible peel) of the Guideline and on the portion of commodities to which MRLs apply and which part is analysed (CXG 41-1993).

A.09 Information Note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors and composite food and feed (SANTE/10704/2021) for endorsement by Member States:

The Commission presented the revised draft Information Note. Regarding Chapter 5.1. on the calculation of an MRL for a composite food or feed made of different ingredients, it is assumed that in the calculation of the derived MRL, the residues originate from different ingredients. However, according to a Member State, laboratories follow a worst-case scenario, that the residues originate completely from one ingredient. The Commission clarified that the part on the composite food and feed would be addressed in more detail at a later stage and highlighted that this document could be revised whenever needed. One Member State asked to modify Chapter 6.1 to provide more flexibility for the use of the analytical measurement uncertainty. The Commission agreed with the proposal and modified the text accordingly.

The Information Note was endorsed by the Members States and it was uploaded on the Commission's website[18].

A.10 Technical Guidelines on the Evaluation of Extraction Efficiency (SANTE/2017/10632) for endorsement by Member States:

The Commission provided an overview of the revised document (Revision 4) taking into consideration comments from the Member States.

The document was endorsed by the Member States and was uploaded on the Commission's website[19].

A.11 Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed (SANTE/2019/12682) (new version SANTE/2021/11312) for endorsement by Member States:

The document was endorsed by the Member States and was uploaded on the Commission's website[20].

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

No issues were raised under this agenda item.

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

No issues were raised under this agenda item.

[18] https://ec.europa.eu/food/system/files/2022-02/pesticides_mrl_guidelines_proc_imp_sante-2021-10704.pdf
[19] https://ec.europa.eu/food/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2017-10632.pdf
[20] https://ec.europa.eu/food/system/files/2022-02/pesticides_mrl_guidelines_wrkdoc_2021-11312.pdf

A.14 Forthcoming working group on RASFF procedures as regards pesticides residues:

The Commission recalled the comments and clarifications provided on the Work Instruction (WI) 2.2 of the RASFF during the meeting of this Committee in November 2021[9], namely on the evaluation of the analytical result with the MRL in consideration of the 50% default measurement uncertainty (MU) value. The WI provides that a deviation from this default value is possible if there is an exceedance of the Acute Reference Dose (ARfD); however, it does not provide clear guidance as regards the use of the MU when no toxicological reference values are available, as is the case for instance for substances that are classified as genotoxic carcinogens. Member States had therefore called for a harmonised approach through an update of the procedures.

The Commission announced the setting up of a dedicated technical working group to discuss the RASFF procedures, i.e., the Standard Operating Procedures (SOPs) and WI 2.2 and in particular the situation of substances without health-based guidance values. Member States were invited to appoint experts and forward their proposals for topics that would need to be discussed by 9 March 2022.

The working group will meet on 28 March 2022, and the Commission will subsequently discuss the outcome within this Committee.

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

The Commission informed of an exercise initiated by EFSA and one Member State to translate the codes used by the Codex Classification of Foods and Feeds to EU Codes of Annex I to Regulation (EC) No 396/2005. The harmonisation of both classification systems is important for the implementation of CXLs into EU legislation and the Commission invited Member States to express their interest in contributing to this exercise.

The Commission provided an update on the opinions received on how to deal with applications for MRLs for radish leaves when these are higher than the ones for kales. In order to capture the views of Member States, the Commission invited them to participate in an anonymous survey to select between three options:

1) include a footnote on kales indicating the specific value for radish leaves;

2) extrapolate values from radish leaves to kales setting a footnote with indications for particular situations, such as food burden calculations;

3) same as option 2 with the possibility of extrapolating values from leafy crops to radish leaves when no good agricultural practices for kales are available.

Several Member States commented on the limitations of each of the options provided, mainly due the fact that values included in footnotes are not visible when extracting the EU MRL Database into Excel spreadsheets, which is usually done by enforcement laboratories. Some Member States requested the addition of a specific row in Annex 1 to Regulation (EC) No 396/2005 to be able to set MRLs specifically for radish leaves. The Commission explained that although this option would be technically feasible in principle, it would not be acceptable for the Commission because of the high risks for the functioning of the EU pesticides database. More such cases are expected to arise in future, each time requiring an adaptation of Annex 1 and the database.

22 replies to the survey were received through the poll tool in Webex indicating the preference for the option 1 (10 replies) followed by option 3 (7 replies) and option 2 (5 replies).

Member States were invited to submit further comments by 18 March 2022.

A.16 Update on Farm to Fork/REFIT actions:

The draft Regulation lowering the MRLs for clothianidin and thiamethoxam is in the process of being consulted with the other Commission services. The Commission will distribute the draft Regulation to Member States once this procedure is concluded. In parallel the draft Regulation will be submitted for consultation of trading partners under the technical Barriers for Trade (TBT) agreement of the World Trade Organization (WTO). The vote on the draft measure will be scheduled once all procedures have been concluded.

A.17 Forthcoming draft Regulations.

The Commission informed of a forthcoming draft Regulation reviewing the MRLs for isoxaben, tetraconazole and novaluron under Article 12 of Regulation (EC) No 396/2005. EFSA published its Reasoned Opinions for these 3 substances, and the Commission intends to submit a draft Regulation for discussion at the next meeting of this Committee on 11-12 April 2022. The Commission highlighted the specific situation of novaluron, which was non-approved in the EU in 2012 further to a voluntary withdrawal of the application by the applicant, and before EFSA could finalise its assessment at the time. MRLs are currently set in Annex IIIA of Regulation (EC) No 396/2005 based on CXLs and import tolerances, and EFSA identified in its assessment various data gaps. Member States were invited to send their comments regarding novaluron by 3 March 2022.

In another forthcoming draft Regulation, the Commission will propose amendments for the MRLs of benalaxyl, chlorsulfuron, fenamiphos and epoxiconazole following the expiry of approval of these substances and the withdrawals of all authorisations in the EU. For all three substances, grace periods[21] that may have been established by Member States have expired.

The Commission also informed of the forthcoming draft Regulation lowering the MRLs for calcium phosphide, cyromazine, topramezone and triflumizole in or on certain products. Approvals of those active substances have expired and all existing authorisations for PPPs have been revoked. Grace periods have expired for all substances. The Commission will evaluate if the existing MRLs for cyromazin at 0.3 mg/kg in ovine products (except milk) could be maintained, as they were set to cover the uses as pharmacologically active substance in veterinary medicine.

A.18 Other Information points*:*

1. Update on PRAC measures/objections

The Commission informed about an announced motion for resolution in the Committee on the Environment, Public Health and Food Safety of the European Parliament during the scrutiny period for the draft Regulation setting MRLs for flutianil to address import tolerance requests, for which this Committee had given a favourable opinion with unanimity after the meeting in November 2021. Actions will be taken to raise awareness of the objectives of the draft Regulation and of the safety of the proposed MRLs.

2. Brexit

No issues were raised under this agenda item.

[21] Grace periods may have been established by Member States for using up and selling off of existing stocks.

3. Prosulfocarb

The point was added to the agenda on request of a Member State informing about prosulfocarb in apples.

Prosulfocarb had been found in apples as a consequence of cross-contamination from lawful uses on neighbouring crops and possible spray drift. As prosulfocarb is not authorised for use in apples, the MRL is set as the default value of 0.01 mg/kg. Risk mitigation measures were put in place (500 m buffer zones to neighbouring crops, night-time application, apply at low temperature, low wind, and 75% wind reducing nozzles) and after a temporary improvement of the situation, a new case emerged in autumn 2021, causing severe losses to farmers. As the measures applied proved insufficient, the Member State enquired whether other Member States encountered similar issues and how they controlled the situation. It mentioned that an applicant suggested an Article 6 application for setting an MRL for prosulfocarb in apples. Lastly, it requested the Commission if the possibility of applying for a temporary MRL in accordance with Article 16 of Regulation (EC) No 396/2005 could be considered.

Several other Member States reported similar cases of cross-contamination from prosulfocarb in apples and other crops that they had in their territories, however risk mitigation measures were only partially effective. An application for setting MRLs for prosulfocarb in apples would not be feasible, as there are no GAPs for this substance on apples. One Member State proposed collecting monitoring data.

A similar issue of prosulfocarb cross-contamination, in olives, was already discussed by the Committee in 2017[22] and 2018[23]. In that case, it was agreed that setting a temporary MRL would not be appropriate as other tools for managing cross-contamination were available.

The Commission noted that the current situation may differ, as risk mitigation measures have already been taken and invited Member States to submit monitoring data by 11 March 2022. Further discussion may be needed at the next meeting of this Committee.

4. Guidance values for fish

During the Working Group meeting of Experts on the Monitoring of pesticide residues held on 15 October 2021, the Commission presented indicative values of residues of chlorates, BAC and DDAC in fish based on the statistical evaluation of the monitoring data submitted by EFSA, Member States and other European Countries. However, in performing a consumer exposure assessment based on these values, a Member State indicated possible health risks for its population and, therefore, called for an EU consumer exposure assessment by EFSA.

The Commission recalled that, currently, MRLs for fish are not available and that, in the absence of MRLs on fish, indicative values were proposed as a reference for further enforcement action by the Member States and that a consumer exposure assessment based on these values had indeed not been performed. The Commission proposed to prepare a mandate for EFSA to perform this assessment but, meanwhile, invited Member States to provide their comments on whether or not such a mandate was necessary by 18 March 2022.

[22] https://ec.europa.eu/food/system/files/2017-12/sc_phyto_20171121_ppr_sum.pdf
[23] https://ec.europa.eu/food/system/files/2018-03/sc_phyto_20180226_ppr_sum.pdf

5. Matrine in liquorice

The Commission informed of a study[24] provided by the Association of Confectionery Industries in Europe (CAOBISCO) claiming that findings of matrine in raw liquorice from Iran is not caused by the use of the substance as a pesticide, but rather due to the accidental and unavoidable harvesting of liquorice roots with roots of the *Sophora* species that naturally contain matrine. The stakeholder suggested that liquorice should be excluded from the default MRL of 0.01mg/kg because such residues, being unavoidable and accidental, are exempted from the definition of what is a 'pesticide residue' under Regulation (EC) No 396/2005.

The Commission recalled that Article 3(2)(c) of the MRL Regulation refers to residues which may arise 'in particular' as a result of the use of a substance in plant protection, in veterinary medicine and as a biocide, therefore does not exclude its presence due to other sources (including natural occurrence). The default MRL of 0.01mg/kg for matrine on raw liquorice applies, while efforts should focus on training programmes at harvest, quality control at reception of raw liquorice roots in processing facilities and on exploring processing factors applicable in accordance with Article 20 of the MRL Regulation. Interested parties can apply for establishing a MRL for matrine on raw liquorice under Article 6 of Regulation (EC) No 396/2005.

6. Substances for Human BioMonitoring (HBM)

The Commission informed that in the frame of the Horizon 2020 research programme 'HBM4EU'[25], human biomonitoring studies currently focus on the analysis of urine samples for pyrethroids, chlorpyrifos, chlorpyrifos-methyl, dimethoate, glyphosate (including polyethoxylate tallow amine), and fipronil and invited Member States to provide their suggestions for any other substances that could be prioritised in the programme by 24 February 2022.

Section B Draft(s) presented for an opinion

The Commission informed the Member States that its intention was to finalise the technical discussion on points under section B of the agenda and that voting would take place by written procedure after the meeting. It asked the Member States to signal whether they had any objections as regards a vote by written procedure. None of the Member States had any objections.

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 ametoctradin, chlormequat, dodine, nicotine, profenofos and *Spodoptera exigua multicapsid nucleopolyhedorvirus* (SeMNPV) isolate BV-0004.
(SANTE/11466/2021)

The Commission provided clarifications on revision 4 of the draft Regulation and its Annexes. This version contains editorial changes that were suggested by one Member State and corrections on footnotes.

[24] Schultz J., Raters M., Wittig M., Christall B., Heckel F. (2021), "Analysis and occurrence of matrine in liquorice raw materials – Exclusion of its application as pesticide", Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2021.2005261

[25] https://www.hbm4eu.eu/

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:

– ametoctradin on crops that might be attractive to bees and that might result in residues in honey;

– dodine on citrus fruits.

EFSA had confirmed that the proposed MRLs are fully supported by data and safe for consumers.

For the following active substance/product combinations, MRLs had been set earlier as temporary MRLs, pending the submission of monitoring data on the occurrence of these substances in the concerned products:

– chlormequat in cultivated fungi, oyster mushrooms and pears;

– nicotine in wild fungi (dried ceps and dried wild mushrooms other than ceps);

– profenofos in rose petals.

Recent monitoring data show that residues of these substances still occur at levels higher than the LOQ in these products. Thus, this Regulation proposes to extend the validity of the temporary MRL for chlormequat in cultivated fungi and oyster mushrooms for one year, as new data from the industry are expected by 2022, and for seven years for the other substance/product combinations.

The draft Regulation also proposes including the active substance *Spodoptera exigua multicapsid nucleopolyhedorvirus (SeMNPV) isolate BV-0004* in Annex IV to Regulation (EC) No 396/2005. This substance was voted as a low-risk substance at the last meeting of the SCoPAFF, Section Phytopharmaceuticals – Legislation, in January 2022.

One Member State commented that as profenofos is a non-approved substance, MRLs should be lowered whenever possible. The Commission highlighted that all decreases of MRLs that were possible based on monitoring data will be proposed by an upcoming measure (SANTE/10090/2022), that is for discussion under Agenda Pt. C 02.00.

Another Member State noted that, for nicotine, no MRL values are reported in the EU MRL database for many products and recommended filling this gap by adding the default MRL of 0.01 mg/kg. The Commission proposed addressing this issue with the above-mentioned measure SANTE/10090/2022, which also includes nicotine.

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 Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid in or on certain products.
(SANTE/11278/2021)

The Commission outlined the draft Regulation in its Revision 1 and provided clarifications on its Annexes, which contain editorial changes (i.e. in the previous version, some of the values were erroneously marked in bold).

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 for

acetamiprid in plums, granate apples/pomegranates, sweet peppers/bell peppers, aubergines/eggplants, cucumbers, courgettes, "other cucurbits with edible peel", poppy seeds, mustard seeds and "honey and other apiculture products". EFSA confirmed that the proposed MRLs are fully supported by data and safe for consumers.

A Member State informed that as it had enacted a national ban of all products containing neonicotinoids (including acetamiprid), it is not in favour of increasing the MRLs for this substance and will vote against this draft measure.

Another Member State informed that it would abstain as it has concerns about two already existing MRLs (not subject to this measure), that were however considered safe by EFSA with the consumer exposure model applicable at the time of assessment.

Post – meeting Note: In addition, a third Member States abstained during the written procedure due to general concerns related to neonicotinoids.

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 II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fludioxonyl in or on certain products.
(SANTE/11464/2021)

The Commission outlined the draft Regulation and its contents. An MRL application in support of import tolerances for fludioxonil used in the United States on sugar beet roots, and in Guatemala, Honduras and Colombia on bananas had been submitted in accordance with Articles 6(2) and (4) of Regulation (EC) No 396/2005. 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.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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products.
(SANTE/10016/2022)

The Commission provided clarifications on Revision 2 of the draft Regulation and its Annexes, which contain some minor amendments following the comments received by other Commission services during the internal consultation procedures and by Member States. The Commission highlighted that, while it was previously proposed to raise the current MRL for isofetamid in elderberries to 4 mg/kg as to adapt the Codex MRL (CXL) for the subgroup of 'bush berries', this proposal was withdrawn in Revision 2 as elderberries do not belong to that group but to the subgroup 'large shrub/tree berries'. In the revised version, no MRL modification is therefore proposed for isofetamid in elderberries.

The Commission outlined the draft Regulation which proposes to implement into EU legislation the CXLs for benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin,

spirotetramat, thiabendazole and tolclofos-methyl, since the EU had not reserved its position in the Codex Committee for Pesticides Residues (CCPR). All MRLs were assessed by EFSA and are safe for consumers.

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 Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fluoride ion, oxyfluorfen, pyroxsulam, quinmerac and sulfuryl fluoride in or on certain products.
(SANTE/10218/2021)

The Commission provided an overview of the draft Regulation in its Revision 3 and informed the Committee of the comments received from the United States following the consultation of trading partners under the Sanitary and Phytosanitary (SPS) agreement of the WTO with regard to the MRLs of oxyfluorfen on almonds and wine grapes.

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 methoxyfenozide, propoxur, spinosad and thiram in or on certain products.
(SANTE/10552/2021)

The Commission outlined Revision 4 of the draft Regulation which took into account the comments from Member States on the LOQs for propoxur and thiram. For thiram, MRLs for herbs, edible flowers and cereals were proposed at the LOQ of 0.05*mg/kg. For propoxur, MRLs for products with high fat content and complex matrices were proposed at the LOQ of 0.01*mg/kg and for products with high water content, acidic and dry products at the LOQ of 0.005*mg/kg due to the high toxicity of the substance.

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, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, bromopropylate, chloridazone, fenpropimorph, imazaquin and tralkoxydim in or on certain products.
(SANTE/10644/2021)

The Commission informed that certain elements of the draft Regulation would need to be reviewed following relevant comments that were received very late. The vote on this draft Regulation was therefore postponed to a forthcoming meeting of this Committee. One Member State indicated its intention not to support the draft Regulation in its current version, due to concerns on the MRL values for bifenthrin and possible consumer risks.

Vote postponed.

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 1,4-dimethylnaphthalene, 8-hydroxyquinoline, pinoxaden and valifenalate in or on certain products.
(SANTE/10776/2021)

The Commission presented the latest revision of the draft Regulation (Revision 3) highlighting modifications in the text following the discussion at the meeting of the Committee in November 2021, and made reference to the Explanatory Note Rev. 3.

For 1,4-dimethylnaphthalene, temporary MRLs were proposed to be set at 0.05 mg/kg for all products of plant origin except potatoes, pending the submission of further monitoring data. For 8-hydroxyquinoline, the footnote concerning data gaps for strawberries was deleted since the MRL for this product is already at the LOQ. For pinoxaden, footnote (A) was added to highlight the lack of a commercial standard for the metabolite M5. For valifenalate, a footnote clarifying that the residue definition for products of animal origin does not apply to honey and other apiculture products was added.

The draft Regulation Revision 2 had been notified to trading partners under the SPS agreement of the WTO, and no comments were received.

A Member State considered that, for 1,4-dimethylnaphthalene, the proposed temporary MRL of 0.05 mg/kg for all products of plant origin except potatoes might not be sufficient to account for natural levels and informed the Commission of a monitoring plan to assess the natural occurrence of this substance aiming to collect data for a possible future modification of the MRL.

Outcome of the vote by written procedure: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) .../... as regards a coordinated multiannual control programme of the Union for 2023, 2024 and 2025 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.
(SANTE/11190/2021)

The Commission presented Revision 5 of the draft Regulation which maintains broccoli as commodity to be sampled, noting that EFSA had initially proposed to replace broccoli with zucchinis. However, this would need to be supported by further data.

EFSA clarified that a review of the selection of products included in the EU coordinated monitoring programme would, nevertheless, be necessary in the future when the update of EU consumption data will be finalised.

Outcome of the vote by written procedure: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for acequinocyl, chlorantraniliprole and emamectin in or on certain products (Art. 12).
(SANTE/11314/2021)

The Commission provided clarifications on Revision 2 of the draft Regulation and its Annexes. This version contains editorial changes and corrections of the footnotes. The

Commission clarified that with regard to subgroup "Others" for certain product categories, for chlorantraniliprole and emamectin, the previous MRLs had been maintained as the authorisations granted by Member States for those specific product categories also cover the subgroup "Others".

The Commission shared a letter received from the trade association "Tea & Herbal Infusions Europe (THIE)" regarding concerns on the proposed decreases of MRLs for emamectin in fresh rose hips and in "Herbal infusions from flowers". THIE proposed to keep the LOQ of 0.02* mg/kg for "Herbal infusions from flowers" and of 0.01* mg/kg for fresh rose hips in view of analytical feasibility.

The Commission explained that according to the European Reference Laboratories (EURL) the LOQ of 0.002* mg/kg was achievable for fresh rose hips and a level of 0.01* mg/kg for "Herbal infusions from flowers". In proposing the level for fresh rose hips the Commission had also taken the effects of drying into account which would result in a concentration of residues in the dried product, and had considered that the proposed level for fresh rose hips would ensure consistency with the proposed level for the overall group "Herbal infusions from flowers".

The Committee agreed on the MRLs for rose hips and herbal infusions as proposed in the draft Regulation.

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 II to Regulation (EC) No 396/2005 of the European Parliament and of the Council 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.
(SANTE/12078/2020)

According to a Member State the MRLs for garlic, shallots, leeks, cereals (barley, maize/corn, oat, rye, sorghum, wheat), herbal infusions from flowers and sugar canes should be maintained, because the 2017 Review Report of the substance sufficiently addresses the data gap for the analytical methods for these products. The Member State recalled the discussion held under Agenda item A.01.02 a) of the meeting of the Committee on 28-29 September 2020[26], where risk managers had agreed on this approach.

The Commission presented Revision 7 of the draft Regulation which took into account this comment and the wording suggestions provided by another Member State.

Outcome of the vote by written procedure: Favourable opinion.

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

Section C Draft(s) presented for discussion

C.01 Exchange of views of the Committee on a draft Commission regulation (EU) .../... as regards maximum residue levels for 1-methyl-3-(trifluoromethyl)-1H-pyrazole-4-carboxamide, beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad in or on certain products.

(SANTE/11128/2021)

The Commission introduced the draft Regulation reviewing the MRLs for the substances beta-cyfluthrin, cycloxydim, cyflumetofen, cyfluthrin, metobromuron and penthiopyrad.

Member States were invited to submit their comments by 18 March 2022.

C.02 Exchange of views of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for benzalkonium chloride (BAC), chlorpropham, didecyldimethylammonium chloride (DDAC), flutriafol, metazachlor, nicotine, profenofos, quizalofop-P, sodium aluminium silicate, thiabendazole and triadimenol in or on certain products.

(SANTE/10090/2022)

The Commission introduced the substances covered by the draft Regulation which is still in an early stage of preparation. This measure intends to amend MRLs for a number of active substances for various reasons including expiry of approval, lowering previously established tentative MRLs following confirmatory data assessments, modifying MRLs based on Article 6 applications, and lowering temporary MRLs based on monitoring data. The rationale for the proposed changes to temporary MRLs for BAC, chlorpropham, DDAC, nicotine and profenofos is provided under Agenda Pt. A 07.02.

For flutriafol, this draft Regulation intends to increase MRLs for cucurbits with inedible peel following an application for an import tolerance, and to implement EFSA recommendations following confirmatory data assessments. At the meeting of this Committee of 14-15 June 2021, it was agreed to maintain the MRL of 0.06 mg/kg in beetroots since an extrapolation from sugar beets was possible.

For metazachlor, this draft Regulation follows up the risk management decision taken by this Committee in June 2020, for lowering existing MRLs for radishes, flowering brassica and kales, while confirming the MRLs for head cabbages and kohlrabies.

For quizalofop-P, this draft Regulation intends lowering the existing MRLs in caraway based on an application for an EU use in accordance with EFSA's conclusion.

For sodium aluminium silicate, currently included in Annex IV, the approval expired on 31 August 2019, and all authorisations for plant protection products (PPP) containing this active substance were revoked. This draft Regulation intends to lower all existing MRLs to the LOQ of 0.01 mg/kg and to move this substance to Annex V.

For thiabendazole, this draft regulation intends modifying existing MRLs for products of animal origin based on an EFSA Opinion. For cases were CXLs exist but are not sufficiently supported by data the Commission proposed lowering the MRL to the respective LOQs. In addition, this proposal modifies the MRLs for cattle and goat products as to align them with the MRLs of Regulation (EU) No 37/2010.

For triadimenol, the approval expired on 31 August 2019, and all authorisations for PPPs containing this active substance were revoked. This draft Regulation intends to lower all existing MRLs to the LOQ, with exception of the existing CXLs (i.e., for grapes, cucurbits with inedible peel and globe artichokes). As two of these CXL s were established before 2011 (i.e. no ESFA assessment were performed on those) the Commission enquired with Member States if those should be maintained or if the MRL should be lowered to the LOQ. The Commission also noted that some products had MRLs already set at LOQ, but the LOQs were not consistently established throughout Annex 1 and would need lowering in some cases.

One Member State commented that for profenofos the existing CXL for tomatoes might pose a risk for consumers. The Commission noted that this draft Regulation is only addressing temporary MRLs modifications, and that reassessment of CXLs should be done in the framework of the activities on non-approved-substances (see Pt. A 01.03).

Member States were invited to submit their comments by 11 March 2022.

C.03 Exchange of views of the Committee on a draft Commission Regulation (EU) .../... as regards maximum residue levels for for abamectin in or on certain products. (SANTE/11316/2021)

The Commission presented an overview of the draft Regulation, which intends to amend certain MRLs for abamectin by taking into account the EFSA Reasoned Opinions on the evaluation of confirmatory data following the Article 12 MRL review and on the modification of MRLs for abamectin in various commodities considering import tolerances and the focussed assessment of certain MRLs under Article 43 of Regulation (EC) No 396/2005.

Member States were invited to submit their comments by 18 March 2022.

Annex I. Tentative approach regarding certain parameters for EFSA's 'MRL-Setting using CRA – Mock Exercise 2022'

(see point **A.04.04** - *Cumulative Risk Assessment*)

This *'tentative approach'* for some parameters is the outcome of an initial exchange and convergence of ideas expressed during the Experts' meetings. **The approaches listed below only serve the purpose of supporting the execution of the 'mock' exercise from EFSA**. **They are subject to review and update from the Experts following the results of the exercise**, in order to further fine-tune the approach.

#	Parameter	Tentative Approach	Status
1	Uncertainty of background exposure	Use uncertainty factors at the 99.9P in Tier 1 and Tier 2.	Consensus
2	Tier 1	PRIMo estimates to be summed with the 99.9th percentile of the background exposure distribution	No agreement. Awaiting results from 'mock' exercise.
3	Tier 2	GAP-scenario including the 20% use frequency.	Consensus
4	Condition to trigger CRA?	If focal exposure >10% ADI/ARfD	No agreement. Awaiting results from 'mock' exercise.