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Section *Phytopharmaceuticals - Residues*

23 - 24 November 2020

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SUMMARY REPORT

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table.

The Commission proposed to include phosmet in the table, in view of the concerns identified in the EFSA conclusions on the peer review. A Member State advised that phthalates are not only degradation products of phosmet but can also be found in plastics and certain household products, and referred to the discussions on the residue definition of folpet.

2. Confirmatory data Art. 12 follow-up

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

   The Commission informed Member States of a recently published Reasoned Opinion on flutriafol. In that framework, EFSA reported some risk management considerations in relation to food products for which the applicant has not submitted any confirmatory data. The Commission proposed to lower the MRL for beetroots to the limit of quantification (LOQ) and the MRLs for melons and watermelons to 0.3 mg/kg, corresponding to an import tolerance, which is fully supported by data.

   Member States were invited to submit their comments by 15 December 2020.

3. Residue definition for risk assessment

The Commission presented its suggestions, which include the explicit mention of the residue definition for risk assessment in the Review Report of an active substance, similarly to what is done for toxicological reference values. The Review Report is accessible through the EU Pesticides database. The Commission further presented its views on how to amend a Review Report when the residue definition for risk assessments needs to be amended, and how to manage cases where the residue definition for risk assessments is derived only provisionally.

The Commission will inform Member States' representatives in the section 'Phytopharmaceuticals – Legislation' of the Committee at the next meeting of that section.

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 – Pesticides Residues' of the Committee by 8 January 2021.

4. Overview on import tolerance requests since 2009

The Commission welcomed the contributions received from Member States and had updated the table on import tolerances requests since 2009 accordingly. The Commission clarified that the overview of import tolerances provides a useful snapshot of the existing situation, but that the current Comission's resources do not allow to regularlyupdate it.

5. OECD calculator

The Commission asked Member States whether the EFSA MRL calculator reporting also the old methodology (Rber/Rmax) is still needed. Member States confirmed that the OECD calculator is the reference tool, which should be displayed on the DG Health and Food Safety webpage. The Commission will therefore delete the EFSA MRL calculator from the website by the end of the year and invited Member States to save a copy it in case they still need to use it internally for comparison purposes.

A.02 Feedback from Legislation Committee:

1. New active substances currently under discussion in the section 'Phytopharmaceuticals – Legislation' of the Committee

The Commission informed about one new active substance for which an application for approval had been found admissible since the last meeting of the section 'Phytopharmaceuticals – Pesticides Residues' of the Committee in June 2020:

- Beauveria bassiana strain 203

A.03 Specific substances:

1. Glufosinate ammonium

There was no news as regards this agenda item.

2. Glyphosate

The Commission informed the Committee of the latest developments.

3. Mancozeb

The Commission reported on the non-renewal decision, which had been supported by a qualified majority of Member States in the section 'Phytopharmaceuticals – Legislation' of the Committee. The Commission also informed that the South African Citrus Growers Association intends to submit an import tolerance request. The Commission clarified that applicants are entitled to make such requests under the provisions of Regulation (EC) No 396/2005, even if the substance meets the cut-off criteria. The assessment will be carried out as laid down in the legislation. A risk management decision will take the assessment and all relevant factors into account.

4. Abamectin

The Commission reported on the feedback received from Member States in relation to the acute reference dose (ARfD) proposed by EFSA in the conclusions on the peer rewiev in the context of the renewal of approval procedure. The majority of Member

States confirmed that the toxicological values that were agreed by the experts during the peer review meeting should be considered. The ARfD of 0.0012 mg/kg bw should therefore be considered in the framework of the forthcoming decision on renewl/non-renewal and as well in the mandate to EFSA to review the existing MRLs.

5. Flupyradifurone and DFA

The Commission had prepared an Excel file reporting the MRLs recommended by EFSA in the framework of the Reasoned Opinion on the 'Setting of import tolerances, modification of existing maximum residue levels and evaluation of confirmatory data' following the Article 12 MRL review for flupyradifurone and difluoroacetic acid (DFA)'.

During the meeting, a Member State indicated that according to the EU Technical Guidelines on MRL setting, the MRL for pome fruits cannot be set at a higher level than the import tolerance in the exporting country. Another Member State raised concerns in relation to the methodology used by EFSA for rotational crops. EFSA explained that the relevant OECD guidelines on rotational crops were considered, but since they are not sufficiently descriptive, EFSA had to make decisions on a case-by-case basis.

Member States were invited to submit comments by 15 December 2020, in particular in relation to the risk management decisions proposed by the Commission.

6. Ethylene oxide – update on the state of play and update from the EU RLs on analytical methods

The Commission recalled the key events related to the detection of ethylene oxide residues in sesame seeds from India. Ethylene oxide is not approved as active substance in plant protection products in the EU and information to define its toxicity is not available in the context of Regulations (EC) No 1107/2009 or 396/2005. Publicly available information on the hazard profile indicates that it is a genotoxic carcinogen, for which no safety threshold can be established.

Harmonised actions based on the EU legal requirements were agreed at the Food and Feed Crisis Coordinators (CC) Meeting on 9 October 2020. The Commission recalled the conclusions of the CC meeting and called on Member States to implement the agreed actions in a harmonised manner. It reported on the swift adoption of a safeguard measure (published as Commission Implementing Regulation (EU) 2020/1540) and informed Member States that an update of the CN code to which the safeguard measure applies is in preparation and intended for discussion in another section of the Committee on 17/18 December 2020.

Several Member States had submitted information on their national approach to determine the level of concern for consumers shortly before the meeting. The Commission thanked Member States and considered that new data can feed reflection but they cannot lead to a change of approach before a proper assessment is made and such change is agreed. A Member State urged to reach EU level agreement on the setting of toxicological reference values for ethylene oxide and its degradation product 2-chloroethanol. Another Member State pointed out that its national assessment had indicated that the current MRL of 0.05 mg/kg, set at the level of analytical determination, may not be sufficiently protective for some consumer groups.

The Commission also reminded Member States that Article 19 of Regulation (EC) No 396/2005 prohibits the use of non-compliant ingredients in composite products. It took

the view that Article 20 of that Regulation cannot justify the production of products compliant with the MRL for the composite product calculated in accordance with Article 20, when it is known that one of the ingredients is non-compliant with the MRL for that ingredient. Several Member States opined that for composite products a risk assessment should be carried out and the placing on the market decided based on the provisions of Regulation (EC) No 178/2002 (General Food Law), while others supported the Commission's view.

The Commission reminded Member States of the need to ensure equal treatment and a level playing field, in line with the conclusions reached unanimously at the CC meeting. All European consumers must be protected in the same way, regardless of where and when a non-compliant product was placed on the market. The Commission insisted on a uniform application of the agreed approach, not least to avoid a disincentive for food business operators to react swiftly and in line with their obligations under General Food Law.

Several Member States raised questions on the legality of re-export of batches of sesame seeds found to be non-compliant with the MRL, on actions taken by the Indian authorities, and on the distinction between withdrawal from the market and recall from consumers.

The Commission recalled Article 67 of Regulation (EU) 2017/625; pursuant to this provision, consignments presenting a risk to human health can only be either subjected to treatment in accordance with national law or be destroyed; re-export is not authorised. The Commission also indicated that harmonised application of this rule would be discussed with Member States' experts for official controls.

One Member State reported findings of ethylene oxide in food products from origins other than India, which were however compliant with the MRLs for those products. Another Member State informed about uses of ethylene oxide for sterilisation purposes in non-food areas, but also in food products other than sesame seeds.

EFSA reiterated its willingness to support risk managers, as already indicated at the CC meeting, if data becomes available and specific questions are raised.

The EU Reference Laboratories for Residues of Pesticides (EURLs) presented an overview of their work on ethylene oxide. They will run a proficiency test with interested laboratories in the EU and India in the course of December. The EURLs indicated that with the "German standard method", a limit of quantification of 0.02 mg/kg or even lower is achievable; other methods have the advantage of being faster but have lower sensitivity. The proficiency test is expected to show which method can achieve which limit of quantification under standard laboratory conditions.

7. Chlorate in white peppercorn

In light of Regulation (EU) 749/2020 setting maximum residue levels for chlorate, the European Spices Association (ESA) reported possible exceedances of the MRL for chlorate residues on white and green peppercorns due to the introduction of such residues via potable water. According to ESA, white peppercorns are derived from the processing of black peppercorns, which after washing and soaking in potable water to remove their skin are subsequently dried. Green peppercorns, prematurely harvested compared to black peppercorns, are also washed in potable water prior to drying.

ESA reported that enforcement authorities in a Member State have expressed doubts on the application of processing factors for white and green peppercorns in the sense of

footnote (A) of Regulation (EU) 749/2020 to consider those additional contributions for chlorate residues from potable water, as Annex I of Regulation (EC) 396/2005 specifies that the MRLs for peppercorns (black, green, white) are applicable to the *"dried product, whole, crushed or ground"*. Therefore, it is the view of the enforcement authorities that the peppercorn MRL of 0.07 mg/kg should be directly applied to the dry green and white peppercorns, which they consider as processed food products.

However, this could create an inconsistency in Annex I of Regulation (EC) 396/2005 which defines in its column 6 the part of the product to which MRLs apply and to which in principle Article 20(1) applies (possibility to use processing factors), since more specific MRLs for processed products have not been established (category "1300000 – Processed Food Products" is empty).

EFSA confirmed that in preparing its "Guidance on Reporting pesticide residues"[1], it considered all commodities that were fitting the description of Annex I as "unprocessed" commodities even though they may have undergone treatment. This includes fermented teas, tree nuts with removed shells and dried spices.

A Member State noted that ideally a higher MRL for white peppercorns could be set on the basis of monitoring data, but also confirmed the understanding that the Annex I commodities should be considered "unprocessed" products. Another Member State agreed and recalled that when preparing Regulation (EU) 749/2020 such possible issues requiring a case-by-case approach were expected for certain Annex I commodities. The Member State believed that in this specific case, the low consumer exposure would provide flexibility to national enforcement authorities to consider residues from washing/soaking and take enforcement action based on a risk assessment. Another Member State indicated that in such cases it would apply a processing factor. A third Member State commented that if white peppercorns were derived from black peppercorns then they should be removed from Annex I.

The Commission clarified that a future amendment of Regulation (EU) 749/2020 should consider not only peppercorns but also other commodities, for which similar specific issues have been identified, and that more specific MRLs could be set when sufficient monitoring data are available for all of them. Moreover, maintaining or not white peppercorns and other similar commodities in Annex I is a question for a possible future update of Annex I of Regulation (EC) 396/2005.

Meanwhile, as a temporary compromise solution, the Committee agreed that processing factors shall be applicable for green and white peppercorns in enforcing MRLs for chlorate residues in the sense of footnote (A) of Regulation (EU) 749/2020. A Member State questioned which processing factor should be used in this case. The Commission reminded that, according to that footnote, the burden of proof lies with the food business operator and that monitoring data for the level of chlorate residues on green and white peppercorn are available.

[1] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5655

8. *Streptomyces lydicus* strain WYEC 108

The Commission drew the attention of the Committee to the outcome of the EFSA Reasoned Opinion on *Streptomyces lydicus* strain WYEC 108[2]. EFSA does not recommend to include the substance into Annex IV of Regulation (EC) No 396/2005 due to many data gaps.

The Commission announced that it intends to launch a more general discussion on risk management measures with regard to microorganisms, in particular when Annex IV inclusion is not recommended by EFSA. It expects that with the growing number of microorganisms for which applications for approval or renewal of approval are being made, these issues will become more and more important. Therefore, the discussion on points A.03.08 and A.03.09 were combined and Member States were invited to submit comments by 8 January 2021.

9. *Bacillus thuringiensis*

The Commission informed the Committee on the current status of *Bacillus thuringiensis* spp. EFSA has adopted five conclusions on different strains of *Bacillus thuringiensis* and four additional ones will be adopted in the near future. The discussions of risk managers on these conclusions will start soon. EFSA does not recommend to include those microorganisms into Annex IV of Regulation (EC) No 396/2005 due to many data gaps, however the rapporteur and co-rapppoteur Member States did not agree with these conclusions.

The Commission highlighted that the decision on renewal or non-renewal for Bacillus thuringiensis strains needs to be awaited, but that risk managers dealing with pesticides residues should reflect in parallel on the available risk management options for different possible outcomes and that very good communication of experts attending the two sections of the SCoPAFF would be needed.

Some questions were raised by the Commission by way of example to trigger further reflection, such as on possible threshold values for some micro-organisms, use of "micro-organism LOQs" in different matrices, setting pre-harvest intervals as a tool for risk management and other questions that might need to be addressed in this context. It therefore asked the Member States to reflect on issues that they consider relevant for forthcoming dicussions on this important topic, also taking into account that currently work is ongoing on an amendment of the data requirements for active substances that are micro-organisms. If specific requirements are needed for risk management purposes (e.g. the need of suitable and specific analytical methods to distinguish strains to be provided by the applicant), the window of opportunity to set them would be now.

A Member State welcomed the discussions on the setting of MRLs for micro-organisms and indicated that the threshold value of 10^5 CFU/g could be used in plant commodities for *Bacillus thuringiensis* spp.

Member States were invited to submit comments by 8 January 2021.

10. Metiram

The Commission informed on a recently published EFSA Reasoned Opinion setting import tolerances for metiram in passion fruits and pineapples. In that framework,

[2] European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels for Streptomyces lydicus strain WYEC 108 according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18 (9):6241.

EFSA identified several uncertainties and proposed risk managements options. The Commission suggested to address the Reason Opinion in the framework of the Article 12 review of the group of dithiocarbamates.

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 41 question numbers had been addressed in 2020, 6 since the previous meeting of this Committee in September 2020.

Currently, 68 question numbers are at different steps of the procedure. Out of these, 21 relate to import tolerance applications, 15 to confirmatory data assessments and 10 to applications dealt with in the context of the renewal of approval process. 46 question numbers are currently under clock-stop. Out of these, 15 relate to import tolerance requests, 7 to confirmatory data assessments and 7 to applications dealt with in the context of the renewal of approval process.

EFSA received a good response from the Member States on applications under clock-stop for more than 6 months and can proceed with some of them. EFSA informed that, if no response was received from the applicant despite reminders, it considers sending a final letter to the respective applicant informing of its intention to resume the assessment with a negative opinion to close the pending files.

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

- Agreement on EFSA Art. 12 Work Programme

EFSA presented the state of play of the ongoing Article 12 reviews. 25 active substances are currently under review and at different stages of the procedure. Since the last meeting one further review 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 was expected in 2020.

The Commission presented an updated work programme for 2020 with editorial corrections. The Committee agreed with the revisions as presented.

The Commission presented an updated work programme for 2021 with some changes, based on feedback received from Member States and EFSA. The Committee agreed with the work programme as presented.

The Commission called on Member States to ensure that sufficient resources are allocated for the MRL review in order to avoid significant delays. This is important as delays impact on other Member States and EFSA who plan their resources for subsequent steps according to the workflow for MRL reviews agreed in the Pesticide Steering Network and the work programmes agreed in the Committee.

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

EFSA updated the Committee on the state of play of the ongoing Article 43 mandates for methoxyfenozide, spinosad, propoxur, fosetyl/phosphonates and carbendazim/thiophanate-methyl.

The Resoned Opinion for methoxyfenozide is currently in the adoption procedure. The Commission had examined an advance copy and presented the contents of the focussed

assessment on the MRLs of concern carried out by EFSA in view of the new ARfD established for methoxyfenoxide. Overall, the current MRLs for citrus fruits are considered safe and can be maintained, the one for tomatoes could be lowered to a fall-back MRL, while the ones for apples, pears, peaches and broccoli need to be lowered to the LOQ.

For carbendazim and thiophanate-methyl, EFSA will focus on Codex maximum residue limits (CXLs) and on import tolerances and will ask Member States to notify any possible existing import tolerances in the course of December 2020.

4. Implementation of the EFSA GD on stereoisomers

The Commission informed the Committee that the SCoPAFF – section 'Phytopharmaceuticals Legislation' will take note of the document in its forthcoming meeting on 3-4 December 2020.

5. Presentation from EFSA on the Practical Arrangements to implement the new Transparency rules

EFSA gave two presentations on the content and the state of play of the three sets of Practical Arrangements to implement the new transparency rules established by Regulation (EU) 2019/1381 and about the implementation and use of IUCLID version 6.5 for submission of all applications. The Practical Arrangements are intended to be adopted by end of the year and will become applicable as from 27 March 2021. As regards IUCLID, EFSA presented the "IUCLID Hypercare" programme which will provide targeted support to Member States and applicants for using IUCLID. The programme will run one year from November 2020 until November 2021 and will focus on development of IT and technical knowledge of IUCLID for early submitters of applications for renewal of active substances and a few MRL applications.

The Commission emphasised that for MRL applications the same rules apply as for applications for new active substances or for substances in the renewal of approval process: submission in IUCLID format will be required for all MRL applications as from 27 March 2021 without exception, even though a formal implementing measure is not being prepared by the Commission. EFSA is currently preparing detailed Administrative Guidelines for applicants to explain the procedures. Applications not submitted in IUCLID format will not be processed by EFSA. The Commission asked the Member States to also clearly communicate this to applicants and other stakeholders and to also raise awareness about the IUCLID hypercare programme.

6. Other

EFSA updated the Committee on its planned Technical Report on Rotational Crops. Several Member States had signalled interest in participating in its development as requested by EFSA. A first working group will take place in December 2020 and it is expected that the Technical Report could be presented in the meeting of this Committee in February 2021.

EFSA also informed about its call for scientific and technical support and the planned public consultation on a guidance of the Scientific Committee on scientific criteria for grouping chemicals into assessment groups for cumulative risk assessment for humans. Furthermore, EFSA informed the Committee on an Excel file proposing codes for the food products covered by the EU coordinated programme for the years 2020 and reminded the Member States of the commenting deadline of 30 November 2020.

A.05 Note Taking of a Working document on pesticides to be considered for inclusion into national control programmes and other issues relating to pesticides residues monitoring.

Following the meeting of experts on the monitoring of pesticides residues on 9 October 2020, the Commission had revised the working document SANCO/12745/2013 to version 12(1).

A Member State noted an editorial mistake in relation to the evaluation period of bifenazate. Another Member State informed that its laboratories are currently facing problems with the analysis of pyridalyl. The Commission reminded that support from the EU Reference Laboratories (EU RLs) can be sought in such cases.

The Committee took note of working document SANCO/12745/2013 in its revision 12(2).

The Commission invited Member States to submit their comments by 15 December 2020 on the draft Regulation SANTE/12154/2020 concerning the EU coordinated programme for the monitoring of pesticides residues for the years 2022, 2023 and 2024.

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

The Commission recalled that based on the discussion on indolylacetic acid in the meeting of this Committee in June, it had been agreed to reflect on a way forward for substances for which natural background levels exist, but which are not recommended to be included in Annex IV of Regulation (EC) No 396/2005 by EFSA (no MRL necessary).

The Commission had collected information on those substances from the Member States, the EU RLs, EFSA's reasoned opinions and statements and from stakeholders. The Commission had prepared a preliminary non-exhaustive list of substances which could be considered for collection of further background data with a view of establishing more realistic maximum residue levels than the currently established default value of 0.01 mg/kg. In order to facilitate the discussions with the Member States the Commission proposed a preliminary ranking in three groups. A Member State indictated that phosphonates may be used in fertilisers (biostimulants) and therefore cannot be considered as having natural background levels. As regards glyphosate's trimethyl-sulfonium cation, which is no longer supported by the applicant, but still possibly used outside Europe, it was clarified that in such cases data should be provided by stakeholders. A Member States proposed to include anthraquinone into the list. The Commission clarified that anthraquinone was not added to the list as anthraquinone residues are coming from bad processing practices or environmental contamination and should not be considered as natural background levels. It stressed that it was not the Commission's role to provide data for such substances, nor was it the Commission's intention to consider raising the existing MRL established at the LOQ as clarified in earlier meetings.

Member States were invited to submit comments by 30 November 2020.

A.07 Next steps for cumulative risk assessment.

The Commission reminded of the work currently performed by EFSA on the case studies for the prospective scenario. As indicated in the report on the REFIT evaluation of the EU legislation on pesticides, the Commission and EFSA are working together on

the deployment of an action plan on Cumulative Risk Assessessment that will be prepared by end of 2020.

A.08 New Official Control Regulation – Commission implementing act on uniform practical arrangements for the performance of official controls on pesticides residues.

The Commission presented an overview of the differences of delegated and implementing acts, their adoption procedures and the changes made to the draft Implementing Regulation.

It summarised the dicussions held in the expert group that was organised on 24 November 2020 to discuss the Commission Delegated Regulation supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council.

The Commission introduced the proposal of one Member State to include a reference to Commission Directive 2002/63/EC establishing Community methods of sampling methods[3] into the delegated act. The reference was formerly in Art 27(2) of Regulation (EC) No 396/2005 but was deleted by the Offical Control Regulation (OCR) (Regulation (EU) N° 625/201) since Art 34(1) of the OCR generally covers sampling and analysis. The Commmission signalled that in principle a specific reference to the sampling Directive could be made, but that, due to the legal basis, this would need to be integrated in the implementing act and not in the delegated act.

Member States were invited to submit comments by 15 December 2020.

A.09 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2020-2021.

The Commission presented a revised table. It drew Member States' attention to the fact that the temporary MRLs for cyantraniliprole will drop automatically to the LOQ on 30 June 2021. A Member State reported that recent data shows that there is still an occurrence of chlormequat in pears and that the validity of the temporary MRL might need to be extended. The Commission invited the Member State to submit all relevant data by the deadline of April 2021 as prescribed by Regulation (EU) 2017/693. In addition, the Commission will also ask EFSA to share monitoring data for the past years.

A.10 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission reported on the Meeting of the OECD Residue Chemistry Expert Group (RCEG) Drafting Group on Definition of Residues, which was held as a virtual meeting on 17 and 19 November 2020. The minutes will be uploaded on CIRCABC as soon as they are available.

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. The working group had been working in 2 subgroups, in both progress has been made. The next step is to start drafting the text

[3] Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (OJ L 187, 16.7.2002, p. 30 - 43)

for the for the guideline. The next meeting of the OECD working group will take place on 16 December 2020.

3. Codex Alimentarius/JMPR issues- future work organisation

The Commission informed the Committee about the publication of the FAO study "Understanding international harmonization of pesticide maximum residue limits with Codex standards – A case study on rice", which was also presented at a side event to the WTO Committee on Sanitary and Phytosanitary Measures on 5 November 2020 that was attended by the Commission. A Member State who had also attended the side event shared its views on several aspects of relevance to the EU that were mentioned in the study and presentation.

EFSA informed the Committee that it had received input from several Member States on the publication of the WHO probabilistic exposure assessment and is still open to receive more comments.

The Member State co-chairing the Codex electronic Working Group (eWG) on the Revision of Classification of Food and Animal Feeds informed Member States that a new round of commenting has been launched. The Commission invited the Member States to contribute directly to the eWG and copy the Commission in their correspondence.

A.11 Note Taking of the SANTE extrapolation guidelines (SANTE-2019-12750), replacement of existing guidance document SANCO 7525/VI/95 Rev. 10.3).

The Commission thanked the Member States and EFSA for all the valuable contributions to the document. The Commission presented the final version of the Document SANTE/2019/12750 containing minor and editorial modifications.

A document containing a collection of issues for future revisions of the extrapoloation guidelines was generated and shared with Member States, including, among others, a proposal submitted by a Member State for an extrapolation from citrus to avocados applicable for treatments before and after forming the edible part. The Commission will consider the inclusion of this extrapolation in Table 3 at the next revision of the document.

The Committee took note of the guidance document SANTE/2019/12750 that will be published shortly on the DG Health and Food Safety web page.

A.12 Draft Fish guidance documents.

Germany made a presentation on the state of play in relation to the latest revisions of the three documents on the Nature of Pesticides Residues in fish, on Dietary Burden Calculations and on the Magnitude of Pesticides Residues in fish.

The Commission asked the Member States whether the three documents could be considered finalised at this stage or whether another commenting round would be necessary. Furthermore, it asked whether Member States would consider it appropriate to make them guidance documents to be noted at a forthcoming meeting of the Committee.

The Comission considered any action related to fish of lower priority than other tasks identified in the REFIT evaluation of the pesticicdes legislation and proposed a more general discussion on priorities in a fortcoming meeting, once the dicussions in the

Council on the Council Conclusions on the Commission's Report on the REFIT evaluation will have been concluded.

A Member State reminded that the data requirements for fish were applicable legislation and that in its view the format (working document or guidance document) would not matter. The Commission stated that the conclusions of the SCoPAFF meeting of 24/25 November 2014 still stand, stating that in the absence of agreed test guidelines to be published in the respective Commission Communications, the data requirements regarding fish could still be waived.

Member States were invited to submit comments by 15 December 2020.

A.13 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

There were no notifications under 18(4) of Regulation (EC) No 396/2005.

A.14 Designation of Member States for maximum residue levels (MRL) applications.

There were no new MRL applications to be attributed.

A.15 Farm to Fork Strategy/REFIT.

The Commission informed the Committee about the ongoing discussions in the Council in view of adopting Council Conclusions under the German Presidency on the REFIT evaluation of the pesticides legislation and gave the floor to the German delegation for further details on the outcome of the third Council working group that took place on 30 October 2020. A fourth and final working group meeting is planned for 27 November 2020 after which the Draft Council Conclusions will be submitted to Coreper I in view of their endorsement by the AGRIFISH Council in December 2020.

A.16 Guidance on processed food and the use of processing factors.

The Commission presented a first draft Information Note on Article 20 of Regulation (EC) No 396/2005 as regards processed and composite foods. The document describes general principles together with examples for the use of processing factors. The aim of this document is not to establish harmonised processing factors or to work towards specific MRLs for all processed products. The intention is rather to use the flexibility given by Article 20 of Regulation (EC) No 396/2005 and give some guidance to Member States on how to apply processing factors using the best information available, in order to ensure a more harmonised procedure among Member States. The format of the document is not yet decided and will depend on the final content of the document. The document is part of the Commission commitments made in the REFIT report on the evaluation of the pesticides legislation.

Member States welcomed the document. A Member State proposed to clarify the use of the terms "processing factor" or "concentration and dilution" factors. EFSA indicated that the use of processing factors for substances with MRLs set at the LOQ and the use of different residue definitions for processed/unprocessed products and composite food (containng plant and animal commodities) could be clarified in the document as well. A Member State proposed to address the use of peeling factor and to stress that a food business operator should always present a conclusion on the safety of the food. A Member State clarified that in most cases there is no issue with the different residue definitions in the composite foods. Another Member State proposed to include information on possible default drying factors for dried products (dried mushrooms,

dried goji berries, dried herbs, etc.) and proposed that for fat soluble substances a typical factor for oils based on seed/oil production yield, could also be proposed.

Member States were invited to submit comments by 8 January 2021.

A.17 Other Information points:

1) Update on PRAC measures voted in February 2020

The Commission informed that internal dicussions on the appropriate follow-up were still ongoing and that it will inform the Member States on any progress. A Member State commented as regards flonicamid that the safety of bees is taken into account when authorising plant protection products containing flonicamid at national level.

2) Readiness and preparedness for the end of the transition period set out in the UK Withdrawal Agreement

A Member State raised an issue with the Article 12 procedure and the period foreseen there for submission of Good Agricultural Practices (GAPs) in cases where authorisations were based on mutual recognition of an UK authorisation in accordance with Article 40 of Regulation (EC) No 1107/2009. It considered the timeframe of one month available for the GAP submission step in the Article 12 procedure too short to allow the Member States to liaise with their national authorisation holders, to receive and evaluate new data and to report to EFSA by means of a detailed evaluation report.

3) Recently published reasoned opinions that are temporarily on hold (deltamethrin, fludioxonil, fluroxypyr)

The Commission gave an update on three Reasoned Opinions that were temporarily put on hold. The one on deltamethrin in carobs (EFSA/2020/6271), can only be addressed once the Reasoned Opinion on the Article 12 confirmatory data is finalised. This is because the latter opinion may address the exceedance of the Acceptable Daily Intake (ADI), which was identified by EFSA as being a matter of concern. The one on fludioxonil in elderberries (EFSA/2020/6175) can only be addressed in February 2021 in order to avoid anticipating the amendments brought by Regulation (EU) 2020/1633, which contains fludioxonil, and becomes applicable on 25 May 2021. The one on fluroxypyr in various crops (EFSA/2020/6273) can be addressed in February 2021, as the measure lowering the MRLs following the Article 12 confirmatory data (SANTE/12078/2020) will only be voted at a later stage.

4) Change of pesticides DB

The Commission informed on the new release of the EU Pesticides Database, which is scheduled in the coming weeks. The Commission reminded Member States on the main new features and also clarified that the overall system was completely restructured involving great efforts from the development side, which explains why it could not be released earlier.

5) Imidacloprid Article 12

The Commission informed the Committee about the first draft version of the Article 12 MRL review on imidaclorpid. Member States were invited to review the draft and submit comments by 15 December 2020.

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 aclonifen, acrinathrin, Bacillus pumilus QST 2808, chlorantraniliprole, ethirimol, lufenuron, penthiopyrad, picloram and Pseudomonas sp. strain DSMZ 13134 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:

- Aclonifen for the use on fennel seeds and caraway fruit;
- Acrinathrin for use on lettuces;
- Penthiopyrad for the use on celeries and Florence fennels;
- Picloram for the use on flowering brassica.

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

- Chlorantraniliprole used in the United States on pulses;
- Lufenuron used in Brazil on grapefruits and sugar canes.

For ethirimol, Regulation (EU) 2020/1566 lowered the MRL for ethirimol in cucumbers to 0.05 mg/kg due to a reporting error. The relevant Evaluation Reported and Reasoned Opinions were corrected and the current measure re-instates the value of 2 mg/kg, which is necessary to allow for the lawful use of bupirimate.

The draft measure also proposes the inclusion of *Bacillus pumilus* QST 2808 and *Pseudomonas sp.* strain DSMZ 13134 in Annex IV to Regulation (EC) No 396/2005, following the recommendations made by EFSA in the Reasoned Opinions in accordance with Article 12(1) of Regulation (EC) No 396/2005.

Three Member States announced that they will vote against the draft Regulation since it contains lufenuron, a non-approved substance, which is a candidate for substitution. According to them, increasing the MRLs for lufenuron to accommodate for new import tolerances would be against the spirit of the Farm to Fork Strategy.

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

Austria asked for the following statement to be recorded in the minutes of the meeting:

"SANTE/12328/2020 contains import tolerances for Lufenuron. The outdoor use of Lufenuron has been banned in the EU for more than 10 years as it fulfils two environmental cut off criteria and is therefore classified as a CfS in the EU. Meanwhile Lufenuron is not at all approved anymore. Austria is of the opinion that this import tolerances are in contradiction to Farm to Fork Strategy as part of the EU green deal, where the use and risk of pesticides should be reduced significantly by 2030 in order to

reduce CO2 emissions. In the framework of the Farm to Fork Strategy the risk of pesticides should also be reduced in third countries".

France asked for the following statement to be recorded in the minutes of the meeting:

"France is opposed to granting an import tolerance for lufenuron which is a dangerous substance for the environment in particular, now banned in the European Union and which has been banned for outdoor uses (except bait stations) for over ten years. France wishes that environmental aspects are taken into account in the assessment of requests for import tolerances as the Commission mentions in its report COM(2020) 208 of 20 May 2020 on the evaluation of Regulations (EC) No 1107/2009 and (EC) No 396/2005".

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 clethodim, dazomet, hexythiazox, metam and sethoxydim (Art. 12).

The Commission presented the latest revision of the draft Regulation which had been notified to the members of the World Trade Organisation (WTO) via the Sanitary and Phytosanitary (SPS) notification procedure. The Commission informed about comments received from the applicant and some food chain trade associations. The Commission also updated Member States about the comment from the applicant for sethoxydim on the proposed residue definition which would not be specific enough for sethoxydim and could result in false positives if clethodim was used. The Commission signalled its willingness to reconsider the use of the parent compound only as residue definition. One Member Stated expressed its agreement with this. The Commission informend Member States on a letter received from Tea and Herbal Infusion Europe (THIE) indicating the inconvenience of using methylisothiocyanate as residue definition for metam and dazomet as methylisothiocyanate would also be part of the metabolites generated by imazalil (known as R014821) and could also be naturally present in some crops, e.g. in capers.

EFSA clarified that the metabolite from imazalil R014821 does not corresponded to methylisothiocyanate.

Member States were invited to submit their comments by 15 December 2020.

C.02 Exchange of views of the Committee on a draft Commission Regulation as regards maximum residue levels for ametoctradin, bixafen, fenazaquin, spinetoram, tefluthrin and thiencarbazone-methyl in or on certain products (Art. 12).

The Commission reported on the comments received by Member States and provided Revision 3 of the draft Regulation. This version had been notified to the members of the World Trade Organisation (WTO) via the Sanitary and Phytosanitary (SPS) notification procedure. A proposal from one Member State to use a default value of 0.01 mg/kg instead of the achievable LOQ of 0.002 mg/kg for tefluthrin in animal commodities was discussed. According to Commission Working Document for drafting Article 12 measures, lower LOQs than the default value of 0.01 mg/kg should only be established if considered necessary, e.g. in particular cases, where a high risk has been

identified in relation to the default value of 0.01 mg/kg. EFSA explained that it had proposed low LOQ values due to low toxicological reference values for tefluthrin, but that 0.01 mg/kg in animal commodities would be safe for consumers. It was clarified that in this case, the value of 0.01 mg/kg should be established without the asterisk as it does not correspond to the actual LOQ.

Member States were invited to submit comments by 15 December 2020.

C.03 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 overview of the text and annexes of the draft Regulation and made reference to the accompanying Explanatory Note.

For flubendiamide, it proposed lowering the Codex-based MRLs for head cabbages and lettuces from 4 mg/kg and 7 mg/kg, respectively, to the LOQ of the analytical method for this matrix (0.01*mg/kg), as EFSA had identified a possible consumer health risk.

For meptyldinocap (DE-126), the EURLs suggested a residue definition that makes reference to the ISO names of the compounds, i.e. sum of meptyldinocap and meptyldinocap phenol (2,4-DNMHP), expressed as meptyldinocap, compared to the suggested residue definition in EFSA's Reasoned Opinion. The EURLs also proposed a differentiated residue definition for commodities of animal origin.

For metaflumizone, the draft Regulation proposes lowering of the MRLs for broccoli and escaroles to the LOQ as EFSA had identified a possible consumer health risk. For cotton seeds, there is no data available in the EFSA Reasoned Opinion concerning any authorised use, therefore, the MRL is proposed to be set at the LOQ. However, EFSA notified the Commission of its on-going communication with a Member State regarding an authorised use for cotton seeds that may be included in a corrigendum of the Reasoned Opinion.

For propineb, the proposed LOQs are pending confirmation by the EURLs. It was clarified that the draft Regulation amends the column of Annex II and III B of Regulation (EC) 396/2005 for propineb expressed as propylenediamite, without updating the corresponding column for dithiocarbamates in which propineb is also included among the other substances of that group. A Member State suggested that the values of the latter column indicating use of propineb, which are listed with a "pr" in brackets, should also be modified otherwise there would be a conflict of values. EFSA supported this view. However, until EFSA publishes its Article 12 reasoned opinion for the whole dithiocarbamate group, Article 12 reviews for individual substances belonging to the group (e.g. ziram) will trigger changes of the column which may create confusion.

Member States were invited to submit comments by 15 December 2020.

C.04 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 draft Regulation and its contents.

The Commission clarified that for the MRL of chlorantraniliprole in pulses, the Article 12 EFSA Reasoned Opinion establishing the MRL of 0.01 mg/kg was published before

the Article 10 Reasoned Opinion, recommendeding an MRL of 3 mg/kg. Therefore, in order to avoid inconsistencies before presenting this draft Regulation for a vote in one of the forthcoming Committee meetings, it is necessary to wait for the outcome of the scrutiny of the European Parliament on the draft Regulation SANTE/12328/2020 that is scheduled for vote in written procedure after this Committee meeting (point B.01 of this agenda) and adapt the proposed MRL accordingly.

Member States were invited to submit comments by 15 December 2020.

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 presented the text and Annexes of the draft Regulation.

Specifically for fenhexamid in and on kiwi, it proposes lowering the MRL from 15 mg/kg to 0.01* mg/kg as the data gap on residue trials indicated in the respective footnote of Regulation (EU) 2018/1514 had not been addressed. According to a Member State and EFSA this data gap should be waived as it concerns a post-harvest treatment of kiwi.

For azoxystrobin on commodities of animal origin, the draft Regulation proposes to maintain the current MRLs and remove the respective footnote concerning the lack of toxicological data for metabolites L1, L4 and L9. In its evaluation supporting this position, a Member State justified a large margin of consumer safety by assuming the same toxicological reference value for the metabolites as for the parent compound. Another Member State questioned if this read-across is feasible.

For prothioconazole, two Member States expressed concerns for lowering the MRLs for barley and rye as the specific data gaps on residue trials are addressed in the renewal process.

Member States we invited to submit comments by 4 December 2020.