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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 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12 – updated table

A Member State carried out a risk assessment using the recently lowered acute reference dose (ARfD) for propiconazole.

The Commission acknowledged the need to act on the maximum residue levels (MRLs) and presented different options. In view of the necessary procedures and associated timelines, it indicated its preference for a single measure regarding all MRLs for propiconazole that should be aligned with the maximum grace periods provided for in the non-renewal act. Several Member States supported the Commission's view.

Two Member States stressed that grace periods provided for in implementing acts under Regulation (EC) No 1107/2009 should be consistent with the approach taken on MRLs.

2. Confirmatory data Art. 12 follow-up

Outcome of several confirmatory data evaluations and proposed follow-up

The Commission prepared a table with proposed follow-up actions for several substances that went through the Article 12 confirmatory data process. The following agreements were reached:

For dimethomorph in blackberries and raspberries and teflubenzuron in animal products, the MRLs should be lowered to the limit of quantification (LOQ). For pyraclostrobin, the confirmatory data addressed the data gap, but the MRL for table grapes should be lowered from 1 mg/kg to 0.3 mg/kg. The latter value is safe for consumers and reflects an authorised GAP in Italy. Dimethomorph, teflubenzurone and pyraclostrobin will be addressed by a draft Regulation, which needs to be notified through the World Trade Organisation's Sanitary and Phytosanitary Standards system (SPS-WTO).

For pendimethalin and picolinafen, there is no need to lower the LOQs to lower values than the ones recommended by EU Reference Laboratories (EURLs) in the

framework of the Article 12 review. For pyraflufen-ethyl in hops, the footnote requiring confirmatory data should be kept pending the re-evaluation of the authorisations in hops, which will lead to the submission of a validated analytical method.

3. Follow up on EFSA statement on substances for which no Art. 12 review is required

The Commission outlined the proposed follow-up to the EFSA statement on substances for which no MRL is required. No further action was needed for those substances that are non-approved and for which the default MRL of 0.01 mg/kg already applies. The case of sodium silver thiocyanate was discussed. The Commission proposed to remove potassium thiocyanate, as well as tall oil, crude and pitch, from Annex IV where these substances are currently temporarily included, and apply the default level to them due to the absence of toxicological information and despite their natural occurrence. Several Member States requested to re-consider this and felt that while the sources should be further investigated the substances should remain in Annex IV, at least for the moment. EFSA confirmed that for tall oils the specification of the substances themselves was not at all clear and no residue definition could be derived. For potassium thiocyanate toxicological information was lacking. The Commission reported that for potassium thiocyanate the EURL provided some background data from a literature search, but that there were problems regarding the available analytical methods. The EURLs will invest resources to provide a method by 2020. For sodium hypochlorite a Member State proposed to consider all sources and a follow-up request to EFSA.

For fatty alcohols, 1-decanol and S-abscisic acid the Commission proposed to include them permanently in Annex IV. No comments were received on the latter.

Member States were invited to provide comments by 22 March 2019.

A.02 Feedback from Legislation Committee:

1. New active substances currently under discussion in the Legislation Committee

The Commission informed the Committee that there was only one new active substance, propanil, for which a conclusion had been published since the last meeting.

2. Update on Brexit

The Commission reported on the outcome of the “Technical expert seminar (EU27) on plant protection products and pesticide residues related matters of the UK withdrawal”, which took place on 12 December 2018.

3. Feedback from December Legislation Committee on grace periods

The Committee discussed the need to have a consistent approach to the provisions on maximum grace periods for plant protection products on one hand and transitional measures for MRLs on the other hand. A Member State referred to recent examples where it identified scope for improvement. The Commission agreed and reminded Member States to coordinate their position internally between representatives in the different sections of the Committee. Such internal co-ordination is already ensured in the Commission.

A.03 Specific substances:

1. Propoxur

EFSA has not yet received access to the studies assessed by Health Canada. A Member State suggested to contact the applicant (in Canada) directly. Should that not be successful, the Committee agreed that the Commission should mandate EFSA to review the assessment published by Health Canada.

2. Chlormequat in Capsicum – follow up from November meeting

The European Spice Association (ESA) informed the Chinese authorities that they should not use chlormequat on Capsicum spp. that are placed on the EU market. An Israeli distributor indicated that it is willing to supply chlormequat “free” paprika to the European market. However, the EU demand is much higher than the offer, which can only be satisfied by the Chinese production.

At the meeting it was agreed that if the Chinese authorities still intend to grant authorisations of chlormequat on Capsicum spp for the EU market, a formal request for an import tolerance should be made under Article 6(2) and (4) of Regulation (EC) No 396/2005.

3. Chlormequat and mepiquat in mushrooms

Mushroom growers submitted recent monitoring data showing that residues occur in oyster mushrooms at higher levels than the current temporary MRL set at 0.9 mg/kg for the whole group of cultivated fungi. Mushrooms are often grown on straw that had been lawfully treated with chlormequat. The mushroom growers claim that chlormequat-free straw is hardly available and that oyster mushrooms would absorb generally higher levels of chlormequat than “white mushrooms” due to the different growing media.

Some Member States acknowledged the problem and urged the Commission to find a solution. Some speculations were made also on the influence climatic conditions may have on the recent findings. A Member State mentioned that the old MRL of 10 mg/kg that had first been set in Regulation (EC) No 396/2005 had been based on monitoring data also from oyster mushrooms. However, during the Article 12 review in 2017, new monitoring data were collected, mostly on white mushrooms, leading to a temporary MRL of 0.9 mg/kg.

The Commission will reflect on whether setting a temporary MRL in accordance with Article 16 of Regulation (EC) No 396/2005 could be considered to overcome the immediate problems. It however emphasised that a temporary MRL would not solve the underlying problem and that the source of the problem must be addressed more systematically and more comprehensively.

In order to pursue the issue, the Commission will require official monitoring data collected by Member States on oyster mushrooms, as currently such data are only available from mushroom grower’s organisations and not sufficient as a basis to set a temporary MRL. It will also require an action plan both from mushroom growers as well as from manufacturers of chlormequat containing plant protection products, which should contain clear commitments on follow-up actions by a certain deadline. Actions taken by mushroom growers should comprise e.g. sourcing chlormequat-free growing materials (straw) and respective provisions in business contracts, testing of straw before using it, etc. Action taken by manufacturers should comprise e.g. labelling of plant protection products with

instructions about the use of straw from treated cereals as well as submission of relevant trials/data on mushrooms when applications are made to increase MRLs for cereals, similarly of what is required already for products of animal origin.

The Commission also clarified that the overall procedure for MRL setting needs to be followed (i.e. submission of an application, drafting of an Evaluation Report and publication of an EFSA opinion/statement). A Member State volunteered to draft the application and prepare the Evaluation Report. Other Member States volunteered to provide assistance.

As regards mepiquat, the Rapporteur Member State (RMS) is currently finalising the Evaluation Report to increase the current MRL for cultivated fungi. The Commission invited the RMS to also consider data that was recently submitted specifically on oyster mushrooms.

4. Tricyclazole/India

The Commission thanked Member States for sharing their monitoring results, which will feed into the discussions on a possible increased level of official controls under Commission Regulation (EC) No 669/2009.

Several Member States and observers indicated their willingness to provide further data.

5. Fosetyl/phosphonates

The Commission reported that in the context of the peer review for the renewal of approval of fosetyl, setting an ARfD for fosetyl has been proposed, which previously had been considered not necessary.

After commenting by the applicants for fosetyl, the RMS and EFSA reconsidered and found that no ARfD should be set. This was subsequently confirmed in an expert meeting.

EFSA will soon publish an amended Conclusion on fosetyl.

Therefore, follow-up action on the MRLs is not considered necessary at this point in time.

One Member State raised questions about the procedure of the expert consultation and reserved its position.

6. Chlorpropham

An acute risk to consumers had been identified by EFSA in potatoes in the framework of the renewal of the approval of the active substance. The Commission intends to lower the existing MRL for potatoes once a final decision is taken on the renewal process. A concern form will also be sent to the Codex Committee on Pesticide Residues (CCPR) in relation to the existing Codex limit.

The Commission was informed by representatives of potato trade organisations and manufacturers of chlorpropham that there is an issue of cross-contamination of untreated potatoes stored in storage facilities previously used for storage of potatoes that underwent post-harvest treatment. Even with thorough cleaning operations of these storage facilities remaining residues would not be fully avoided due to the volatility of the substance penetrating also cracks in walls and floors. While residues decline over time, they could still be present for some years. The potato industry asked whether it would be possible to set a temporary

MRL to overcome the immediate problem and give some time to find alternative storage facilities or build new ones.

At the meeting, several Member States supported the initiative, but made clear that thorough cleaning of such premises had to be the pre-condition for setting a temporary MRL, which should be set as low as possible to avoid any risk of illegal use at low doses. Furthermore, the existing MRL for chlorpropham should be lowered without undue delay given the health concerns with the existing MRL. Two Member States informed the Commission that cross-contamination might also affect cereals.

The Commission will take this up in further internal discussions. In the meantime data should already be collected and submitted to the Evaluating Member State by end of summer 2019 at the latest to avoid the drop of the MRL to the LOQ and in view of the fact that lowering must be done as soon as possible. Some preliminary data had already been submitted by the potato trade organisations coming from storage facilities where chlorpropham is no longer used. A Member State volunteered to carry out the assessment. Another Member State proposed that EFSA should foresee a consultation with Member States when developing the Reasoned Opinion. The Commission supported this idea.

7. Trifloxystrobin

EFSA published a Reasoned Opinion addressing an application to increase the current MRL for trifloxystrobin in broccoli from 0.5 mg/kg to 0.6 mg/kg. A risk management decision needs to be taken as regards the metabolites for which EFSA identified data gaps in the framework of the renewal of the approval of the active substance.

Member States were invited to provide comments by 22 March 2019.

A.04 News from the European Food Safety Authority:

EFSA informed about the recent split of the former pesticides unit and the responsibilities of the two new units dealing with pesticides peer reviews and pesticides residues. It was also clarified that the annual monitoring report (as from the data collection 2018 onwards) and the coordination of the work related to cumulative risk assessment would move to the EFSA DATA unit, while the method development for cumulative risk assessment would move to the EFSA Scientific Committee.

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

EFSA is currently working on tefluthrin and clethodim, which still fall under the interim process and another 33 substances, which fall under the new process.

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

EFSA published 68 Reasoned Opinions in 2018 and 6 in 2019. Work is on-going on 26 Reasoned Opinions. 17 new question numbers were addressed since the November SC PAFF. EFSA stressed that there are 55 question numbers on stop-the-clock due to missing information. For several of these, no information had been provided for more than a year. Member States were invited to provide feedback as to whether some applications can be withdrawn.

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

EFSA is currently working on the draft Scientific Report for preparing an EU position in the 51st Session of the Codex Committee on Pesticide Residues (CCPR). EFSA clarified that PRIMo Rev. 3.1. was used for the risk assessment.

4. Strategy for risk assessment of triazole fungicides

EFSA referred to the 2018 peer review of the pesticide risk assessment for the triazole derivative metabolites (TDMs) and introduced the proposed strategy for risk assessment of triazole fungicides. It clarified that comprehensive risk assessment for TDMs residues covering all triazole substances cannot be performed before a complete TDM residue database for all EU uses and import tolerance requests is available. The TDM strategy proposes the way forward to collect this information.

5. AOB

EFSA proposed a technical change to the reporting format for cases where LOQs need to be summed up for the reporting of the 2019 data. For the 2018 data collection only a warning would appear but no data would be rejected on that basis. It was agreed to also consult the technical experts of the EFSA networking meeting planned for 19-21 March 2019 and, if no major comments were to be received, that EFSA would go ahead with the implementation of the new format without further discussion in the SC PAFF.

Two Member States commented that they would collect data for individual components.

A.05 Discussion on possible follow up to the EFSA opinion on food for infants and young children

The Commission informed that it asked the EURLs for single residue methods and the EURL for products of animal origin to include in their 2019-2020 Work Programmes a project for developing the method of analysis to reach lower LOQs for the full residue definitions of at least the substances chlorpyrifos, emamectin, ethoprophos, fluquinconazole, gamma-cyhalothrin and alpha-cypermethrin. The project also includes the collection of samples of infant formulae and milk. Method development and validation is expected to be finalised by end of Q3 2019, while collection and analyses of samples are due by end Q4 2020.

A.06 Transitional periods – follow up from November meeting.

The Commission thanked Member States and EFSA for their comments and provided further clarifications. The Committee agreed on several cases where the granting of transitional measures can be excluded, but indicated the need to be more concrete on cases where the granting of transitional measures should be further discussed. The Commission invited Member States to make specific suggestions in writing.

Member States were invited to provide comments by 30 April 2019.

A.07 Project on data collection dithiocarbamates.

The Commission updated on the amount of samples currently included in the PestiPedia database and on EFSA's 2017 collection of data, which are to be integrated in PestiPedia. In its Work programme for 2019-2020, the EURL SRM has included a project for the collection and analysis of approximately 100 samples of organic

products. A Member State informed of its current programme for analysing organic samples, while another Member State mentioned it would upload approximately 200 samples in the database. Concerning the 2019 data, the Commission proposed that the EURLs should directly collect the data from their official control laboratories network in order to avoid delays in data transmissions by an additional step through the Member States' competent authority.

Member States were asked to react by 22 March 2019 in case they would not agree with this approach.

A.08 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2019-2020.

The Commission gave an update on the state of play. A Member State finalised the extensive assessment on flupyradifurone and difluoroacetic acid for which additional data had been submitted to fill a data gap. EFSA will shortly be mandated to assess the data.

A.09 International Matters:

1. OECD Guidance document on the definition for risk assessment

The Commission gave an update on the Workshop and Meeting of the organisation of Economic Cooperation and Development (OECD) Residue Chemistry Expert Group, held in Geneva at the World Health Organisation's (WHO) headquarters from 3 to 7 December 2018. In that framework, also experts from the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) and the FAO/WHO Joint Expert Group on Food Additives (JECFA) took part in the discussions. The relevant documents had been uploaded on CIRCABC.

Member States were invited to provide their comments in particular on those issues that could not be finalised.

2. Codex Alimentarius/JMPR issues

The Commission thanked EFSA for their work on preparing the draft Scientific Report and all Member States who provided comments on EFSA's first draft assessment on the substances/MRLs. It set out the indicative time planning for the preparation of the draft position, and urged Member States to be active in providing draft positions for points other than those covered by the JMPR Report (general considerations and proposed draft MRLs, respectively).

A Member State referred to the circular letter on the priority lists. Some points raised in the circular letter merit further discussion. The Commission invited the Member State to prepare a draft position for discussion at the first Council Working Party on 11 March 2019.

A Member State reported on the outcome of the work of the electronic Working Group (eWG) on Revision of the Classification of Food and Feed. It invited other Member States to provide comments on the changes of crop grouping for primary feed products and on the extrapolation possibility from straw to grass. Another Member State had provided input to the eWG and commented further in the Committee.

A.10 Notifications under Article 18(4) to Reg. (EC) No 396/2005.

No issues were raised under this agenda item.

A.11 Designation of Member States for maximum residue levels (MRL) applications.

No issues were raised under this agenda item.

A.12 EFSA Report on processing factors.

The Commission referred to the discussion held at the November 2018 SC PAFF Phytopharmaceuticals – Section pesticides residues and presented its view on the EFSA report. It considered the report a very useful source of information, but considered that its use in enforcement practice should not be legally binding or imposed on Member States' enforcement authorities. Where more specific processing factors are provided by food business operators, those should be preferably used in application of Article 20 of Regulation (EC) No. 396/2005. The use of default factors for certain processing operations should be left to the discretion of Member States' enforcement authorities in view of each specific case.

Several Member States agreed with this view and gave some more detailed explanation on how they deal with processing factors in practice, most of them do not use PFs or only use PFs to a limited extent to make decisions on non-compliances.

A.13 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The draft Staff Working Document had been presented on 30 January 2019 to the Regulatory Scrutiny Board who gave a positive opinion with comments necessitating some revisions in the draft Document. In parallel, the Commission is preparing the Report to the European Parliament and Council, which is required by legislation.

A.14 Revision of GD SANCO/3029/99 rev. 4 und SANCO/825/00 rev. 8.1.

The Member State currently working on an update of these two guidance documents reported that most likely a first draft can be presented to the June 2019 SC PAFF Phytopharmaceuticals – section Pesticide Residues.

A.15 Feedback from MS on the question on the number of trials for seed treatment raised at the last meeting.

Two Member States that had volunteered to prepare a discussion paper presented the amendments introduced in the revised document distributed to Member States. As only a limited number of Member States had commented so far, they invited the remaining Member States to comment as well, in particular on the three main questions highlighted in the document.

The Commission thanked the two Member States who proactively advanced the discussion on this topic. It noted that some actions would require a change of the data requirements (Commission Implementing Regulation (EC) No 283/2013) and could therefore not be introduced in a guidance document. Opening a discussion on changes to Regulation (EC) No 283/2013 would be possible in principle, but would be justified only if there was a number of other issues to be addressed as well.

Member States were invited to provide comments to the representatives of the two drafting Member States by 30 April 2019.

A.16 Other Information points.

- The EFSA public consultation on cumulative assessment groups for effects on the thyroid is currently ongoing with a commenting deadline of 22 March 2019.
- The Commission informed that the Parliament's Committee on the Environment, Public Health and Food Safety (COMENVI), during the scrutiny period, had adopted a draft motion for resolution objecting to the draft Regulation setting maximum residue levels for a number of substances, including clothianidin (an import tolerance request for a use on potatoes in Canada voted in the November meeting of the SC PAFF) with a large majority. The draft motion will now be debated in the March 2019 Plenary meeting of the European Parliament. A Member State expressed its concern about this course of action that becomes more frequent and that it believes could be challenged in Court by the applicant.
- The Commission informed about a vacancy for a seconded national expert from a Member State in DG SANTE in the field of pesticides, preferably pesticides residues, and invited interested experts in the Member States to apply once the post is published by the Permanent Representations of the Member States. The Commission will inform Member States by e-mail.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No .../... 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 aminopyralid, captan, cyazofamid, flutianil, kresoxim-methyl, lambda-cyhalothrin, mandipropamid, pyraclostrobin, spiromesifen, spirotetramat, teflubenzuron and tetraconazole in or on certain products (Art. 10)

The Commission introduced the draft Regulation and presented its content.

The following MRL applications had been submitted under Article 6(1) of Regulation (EC) No 396/2005 (EU uses):

- aminopyralid for the use on barley, millet, oat, rye and sorghum;
- captan for the use on cranberries and hops;
- cyazofamid for the use on potatoes, tomatoes and cucurbits;
- kresoxim-methyl for animal products following the use of the active substance on feed;
- lambda-cyhalothrin for the use on celeries, fennels, soyabeans, sunflower seeds and rice;
- mandipropamid for the use on several products;
- pyraclostrobin for the use on several products;
- spirotetramat for the use on several products;
- tetraconazole for the use on kaki, linseeds and poppy seeds.

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

- mandipropamid for the use on cocoa beans (Nigeria and Cameroon);

- pyraclostrobin for the use on rice (Indonesia), coffee beans, passion fruits and pineapples (Brazil), American persimmons and sugar canes (United States);
- spiromesifen for the use on coffee beans (Brazil);
- teflubenzuron for the use on grapefruits and mandarins (Brazil).

For captan, cyazofamid, kresoxim-methyl and pyraclostrobin, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005.

For flutianil, the draft Regulation sets MRLs covering the representative uses on grapes, following the approval of the active substance under Regulation (EC) No 1107/2009.

As regards teflubenzuron, an application was made to accommodate the import of broccoli from Paraguay. However, the Commission had not received a proof of an authorised use in the third country nor a reference to the establishment of a national MRL.

As regards pyraclostrobin, EFSA proposed to set different MRLs within the group of “lettuces and similar”. This issue was discussed at the meeting and several Member States indicated that a common MRL of 10 mg/kg should be set.

A Member State voted against the draft and another one abstained as both had not supported the approval of flutianil either. Another Member State abstained, because it did not receive a voting mandate on the amendments that were introduced into the draft Regulation at a late stage.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No .../... amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for ABE-IT 56, aclonifen, *Beauveria bassiana* strain PPRI 5339, *Clonostachys rosea* strain J1446, fenpyrazamine, mefentrifluconazole and penconazole in or on certain products (Art. 10)

The Commission introduced the draft Regulation and presented its content. It informed that the substance ABE-IT 56 had been taken out of the draft Regulation tabled for vote, as a decision on approval had not yet been taken in the SC PAFF Phytopharmaceuticals, Section Legislation.

The draft Regulation transposes Codex limits for fenpyrazamine and penconazole into the EU legislation and proposes the inclusion of *Beauveria bassiana* strain PPRI 5339 into Annex IV to Regulation (EC) No 396/2005. As regards, aclonifen, an application had been submitted to increase the MRL in “herbs and edible flowers”, which is fully supported by data.

As regards *Gliocladium catenulatum*, due to recent changes in taxonomic rules, the strain J1446 was transferred to the species *Clonostachys rosea*.

For mefentrifluconazole, the draft Regulation sets MRLs covering the representative uses on barley, oat, rye and wheat, following the approval of the active substance under Regulation (EC) No 1107/2009. The RMS asked whether an additional trial could be considered in support of the GAP on rye and wheat. For that purpose, an Evaluation Report was drafted and a risk assessment was carried out, leading to an

MRL of 0.05 mg/kg. At the meeting, Member States agreed to accommodate the request made by the RMS.

A Member State abstained because it did not support the inclusion of *Beauveria bassiana* strain PPRI 5339 in Annex IV to Regulation (EC) No 396/2005. Another Member State abstained because it did not receive a voting mandate on the amendments that were introduced into the draft Regulation at a late stage.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No .../... 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 bispyribac, denathonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop and tebufenozide (Art. 12)

The Commission presented revision 5 of the draft Regulation, clarifying that it integrated changes following the Commission's internal consultation procedures and the comments received from Member States.

For the esters of quizalofop-P, one Member State proposed that, since MRL values were set for all commodities within the group "0213000 (c) other root and tuber vegetables except sugar beets", the category "others" within this group should be assigned the highest value of those MRLs. The same was proposed for tebufenozide levels for the "others" category of the "leafy brassica" group. As this case is not included in the Commission Working Document and since no Member State objected to this proposal, the Commission accepted this change and prepared a revision 6 of the document.

A discussion took place on the MRL of 0.2 mg/kg proposed for spinach and the potential lowering of this MRL to 0.04 mg/kg to reflect extrapolation from lettuce open leaf varieties. However, since EFSA commented that the level of 0.04 mg/kg would not cover the more critical GAP reported for propaquizafop, the initially proposed level of 0.2 mg/kg was maintained.

A Member State proposed an increase in the level of quizalofop in potatoes and sugar beets as the highest residue reported in the trials were close to the proposed MRLs. The Commission stated that wherever possible the OECD calculator should be used and that it did not see a sound justification to divert from this rule in this case. Another Member State commented that the MRL proposal for potatoes and sugar beets were adequate.

One Member State voted against the draft as quizalofop-P-tefuryl meets the exclusion criteria of Regulation (EC) No 1107/2009 and some MRLs for the substance were proposed to be increased. Another Member State abstained due to the wording used for transitional measures. One Member State had no voting mandate for the revised version and abstained.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No .../... 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 2,5-dichlorobenzoic acid methylester, mandipropamid, prochloraz and profoxydim in or on certain products (Art. 12)

The Commission presented comments received from Member States. Regarding prochloraz, a Member State raised its concerns for maintaining the CXLs for certain tropical fruits arguing that EFSA's calculations were based on PRIMo model revision 2, whereas using PRIMo model revision 3 would result in exceedances of the ARfD in some cases. The Commission reminded that in line with what had been discussed in the meetings of the Committee in November 2017 and February 2018 the correct PRIMo model revision to be used was indeed revision 2, as EFSA's call for data on prochloraz ended in 2016, thus prior to 1 February 2018, which was set as the cut-off date. Nevertheless, that Member State announced that it would abstain in the vote on the draft Regulation.

Another Member State voiced its concern that prochloraz had been included among the substances, potentially categorised as an endocrine disruptor, following the report on the screening of individual substances according to different options in the context of the impact assessment¹ that had been prepared to accompany the proposal for setting criteria to identify substances with endocrine disrupting properties and, therefore, announced to vote against the draft.

A third Member State announced that it would abstain due to the wording of the transitional measures indicated in Article 2 of the draft, while a fourth Member State announced to abstain as it had no voting mandate on the revised text.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee concerning a coordinated multi-annual control programme of the Union for 2020, 2021 and 2022 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

After providing a brief overview of the comments received from Member States and EFSA, the Commission informed of the rice industry's concerns regarding the use of a numerical value for the rice processing factor (PF) included in the draft Regulation as a means for enforcement action. The Commission reminded that those values were indicative, providing a guidance, and that it falls under the merit of national authorities to decide which values to use.

Certain Member States shared their concerns about the possible misconceptions entailed by maintaining PF values in the draft Regulation and three Member States proposed the deletion of the PF value for rice in footnote 2, while another Member State proposed deletion of all PF values in the text. It was agreed to remove all references to processing factors.

A Member State questioned the inclusion of liver in the programme. Another Member State informed that the methods for analysis of glyphosate on animal commodities

¹ https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_study_en.pdf

would need more attention as there are indications that they do not provide reliable results. According to another Member State, glyphosate should be removed from the programme altogether. The Commission reminded that inclusion of glyphosate in the monitoring Regulation and inclusion of the matrix liver had been discussed in the Working Group meeting of October 2018 and confirmed in the SC PAFF meeting of 26-27 November 2018. The Commission stressed that inclusion of glyphosate in the programme for a wide variety of matrices (including animal products) is necessary to ensure that stringent enforcement action can be taken by Member States and that updated and comprehensive information on human exposure is always available. It also reminded that the EURL had developed a method for the analysis of glyphosate on commodities of animal origin and that a proficiency test on bovine liver was currently being organised in which official control labs will be invited to participate.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee as regards maximum residue levels for chlorate

The Commission provided an initial overview of the outcomes of the feedback mechanism and informed the Committee of the tentative planning for a vote on chlorate MRLs scheduled in Q2 or Q3 2019. A short summary on the outcome of the feedback mechanism will follow once all contributions have been thoroughly assessed.

The Commission stressed the importance to find a compromise solution that would address the health concerns for children and provide a basis for enforcement action taken by Member States as the alternative would be that Member States take enforcement action on the basis of the existing default level of 0.01 mg/kg, which had posed problems at the onset of the discussion on chlorate MRLs.

Several Member States expressed their view that the comments received in the feedback mechanism should be addressed and reflected in the draft Regulation and felt that further discussion was particularly needed on the issue of processed products. It was proposed to address this point in a Working Group meeting. A Member State voiced its opinion that since those temporary MRLs will be reviewed in the future, setting them towards the higher end would be preferable.

The Commission clarified once again that Regulation (EC) 396/2005 is the only legal framework in which limits for chlorate can be established and that removing a substance formerly or currently used as a pesticide from the scope of the Regulation is legally not possible. This was previously discussed and clarified by the Commission's Legal Service also in a similar case on mercury. While the Commission welcomed the idea of a Working Group meeting, Member States were invited to constructively contribute to the discussion with very concrete cases on which the Working Group should focus.

A Member State reminded of the problem currently faced and that a solution needs to be found, but stressed that it is important to understand how biocide residues should be regulated.

C.02 Exchange of views of the Committee as regards maximum residue levels for imazalil

The Commission referred to comments received since the last meeting from Member States, the applicant, stakeholder associations and a non-EU country.

The Commission outlined the regulatory history of imazalil in the EU and the decisions taken in procedures under Regulation (EC) No 1107/2009. It pointed to the new information available from recent procedures under Regulation (EC) No 396/2005 and discussed the degree of concern associated with genotoxicity studies that are all negative except for one equivocal result.

The Commission invited Member States to reflect on the possibility to set or maintain MRLs for commodities where no acute consumer risk was identified at or near the existing levels. It clarified that such a possibility could not be considered for commodities where an acute consumer risk was identified and no information on a safe fall-back use was available.

Several Member States provided initial reactions but intended to reflect further on their position.

Member States were invited to provide comments by the 31 March 2019.

C.03 Exchange of views of the Committee as regards maximum residue levels for cyflufenamid, fenbuconazole, fluquinconazole, and tembotrione in or on certain products (Art. 12)

The Commission presented a first version of the draft Regulation and gave an overview of the comments received.

For cyflufenamid, a Member State proposed a change of the LOQ for animal commodities from 0.03 mg/kg to 0.02 mg/kg to take into account the different metabolites and isomers included in the residue definition consistently and in line with products of plant origin. The Commission clarified that in its draft it had also taken into account the differences in analytical methods (gaschromatography coupled with mass spectrometry for plant products and liquid chromatography coupled with mass spectrometry for animal origin products), leading to a different number of peaks in the chromatography for animal and plant commodities. Therefore, the proposed LOQ of 0.03 mg/kg should be maintained for animal products. Another Member State proposed 0.06 mg/kg for the category “0140990 Others” in the group of stone fruits, however, the Commission requested clarification as this level is not the highest non-LOQ MRL proposed for the individual crops within the group.

For fenbuconazole, a Member State proposed to remove the footnote requiring additional trials for apricots and plums. The five applications with which trials had been carried out on plums are more than the three applications specified in the GAP, but according to the Member State it is possible that the first two applications might not have any effect on the residue level. The same argument was considered for apricots. Member States were requested to provide their input.

Member States were invited to provide comments by 22 March 2019.

C.04 Exchange of views of the Committee as regards maximum residue levels for amitrole, fipronil, flufenoxuron, flupyrsulfuron-methyl, imazosulfuron, isoproturon, orthosulfamuron and triasulfuron in or on certain products

The Commission introduced the draft Regulation and presented its content.

The eight substances had been either not approved, not renewed or their approval had expired. The draft Regulation would lower the existing MRLs for all substances except for flufenoxuron in tea for which an import tolerance request had been made by the applicant based on a Japanese GAP. It is proposed to grant transitional measures for the lowering of all existing MRLs, as they had recently been assessed by EFSA either in the framework of the Article 12 review or in separate assessment and found to be safe for consumers.

Member States were invited to provide comments by 15 March 2019.

M.01 Findings on matrine

The point was added on request of a Member State who had received questions about findings of matrine, a plant extract that had never been approved in the EU as a pesticide but seems to be used as an insecticide. It asked other Member States whether they had received similar questions. One other Member State affirmed.

The Commission clarified that the default MRL of 0.01 mg/kg applies to matrine. Some evidence was provided showing that this product was placed on the market as a fertiliser and not as a plant protection product. Member States were advised to liaise with their colleagues attending the section Pesticides Legislation of the SC PAFF, since the delineation fertilisers-PPP falls within their remit.

Member States were invited to submit further comments by 22 March 2019.