EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 16 FEBRUARY 2017 - 17 FEBRUARY 2017

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/c83227bc-67b8-4466-9b11-04194fc72498*

A.01 Exchange of views of the Committee as regards maximum residue levels (MRL) for 2- phenylphenol, bensulfuron-methyl, dimethachlor and lufenuron.

The Commission introduced the four new substances which will be included in a forthcoming Article 12 proposal. They are expected not to be controversial.

The draft of the proposal (Rev. 0) will be circulated after the meeting for comments. The goal is to vote the proposal in the next meeting of the Standing Committee on Plants, Animals, Food and Feed, section Pesticide Residues in June 2017.

A.02 Exchange of views of the Committee as regards maximum residue levels (MRL) for benthiavalicarb, fenpropidin and pymetrozine.

The Commission informed that the substance benthiavalicarb has been removed from the proposal to lower certain MRLs because the analytical standards for the benthiavalicarb isomers have been made commercially available in the meanwhile, via the Japanese distributor Kanto Chemicals. Due to the high shipping cost charged by Kanto Chemicals, the distribution of the standards will be done by Kumiai Chemical Industry, who charges a lower shipping cost. The applicant is currently also working on making the standards available via a European distributor.

For fenpropidin and pymetrozine the applicant informed the Commission, that it is working on making the required standards commercially available. However, as currently the standards for enforcement of the residue definitions for animal origin commodities are not yet available, the proposal for lowering the MRLs to the Limit of Quantification (LOQ) for animal origin commodities and for certain feed commodities, will be notified to SPS/WTO in March 2017 and it will be presented for vote during the June Standing Committee meeting.

Member States were invited to submit comments by 10 March 2017.

A.03 Update on chlorate.

Currently internal discussions are still ongoing on the most appropriate forum to have a multi-disciplinary discussion on the general approach for the issue of chlorate residues in food and drinking water. A general action plan with actions on food hygiene, food for infants and young children, pesticides and preferably also drinking water would be needed. A letter was sent by the DG SANTE (Directorate General for Health and Food Safety) Deputy Director General to the DG ENV (Directorate General for the Environment) with the request for a meeting to explore how DG ENV could contribute to reducing the exposure of children to chlorate residues via actions on drinking water. The Commission thanked two Member States who had provided some additional monitoring data for some food of plant and animal origin.

Several Member States expressed strong concerns, that internal Commission discussions had not yet resulted in any kind of concrete planning of a multidisciplinary approach to this problem that is known since 2014. The Commission informed that the planning of a multidisciplinary approach was indeed challenging but that discussions on the issue were still ongoing.

A.04 Update on *Bacillus cereus* and other *Bacillus* spp. including *Bacillus thuringiensis* in foodstuffs.

The Commission informed that further comments from the European Food Safety Authority (EFSA) and a Member State were received following the presentation of the EFSA conclusions at the last meeting and that a working group on biopesticides would be organised with participation of the Rapporteur Member States for Bt strains, EFSA and the Commission at the end of February 2017. In this working group human pathogenicity and residue aspects of Bt strains would be discussed in the context of the forthcoming renewal of approval for Bt strains. Since the renewal dossiers for Bt strains were submitted in October 2016, the Commission asked Member States to reflect whether the decision on the Annex IV inclusion should not be put on hold until the renewal decision had been taken (expected for end 2019).

Member States were invited to submit comments by 20 March 2017.

A.05 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Article 12

The Commission updated the table on substances prioritised under the Article 12 MRL review process and gave an overview to the Committee. Concerning buprofezine, the Commission informed that the conditions of approval will be restricted to ornamental plants, once the respective Commission Implementing Regulation voted at the Standing Committee, Section Plant Protection Products – Legislation on 24 January 2017 comes into force. In view of this restriction, MRLs will have to be lowered to the LOQ. In view of that, Article 12 prioritisation is no longer relevant.

Member States were invited to submit comments by 10 March 2017.

EFSA made a presentation outlining the overall planning and the principles for the selection of active substances to be reviewed under the Article 12 future process.

The last 13 substances from the interim process will be initiated in 2017 as well as 27 substances from the future process. For prioritisation, the current principles remain valid that Article 12 should preferably be done after the renewal exercise and after assessment of any confirmatory data under Regulation (EC) No 1107/2009. The groups of dithiocarbamates and pyrethrins should be assessed together once all the substances belonging to these groups underwent the renewal exercise. Since only a few substances are already out of the renewal or confirmatory data process so far, EFSA and Commission agreed that substances from group 4(2) of the AIR IV (Annex I Renewal) project process and some new active substances should be initiated for Article 12 in 2017.

Member States were invited to submit comments on the list of substances for which the review is to be initiated by 10 March 2017.

The Commission requested EFSA proposal to launch a specific call for data on natural background levels of CS2 that can be formed during the sample preparation of vegetables high in certain natural sulphur compounds, e.g. brassica vegetables. Since the routine analytical method for dithiocarbamates cannot discriminate between the different active substances, an MRL for the sum of dithicocarbamates (based on the sum parameter CS2) is currently set. Member States are invited to get prepared and already now start collecting such data. Data collected by the EU RLs (Reference Laboratories) will also be taken into account.

Discussions took place on the appropriate timeline to review the MRLs following the renewal procedure in view of the various changes that might apply to national authorisations. Regulation (EC) No 1107/2009 provides for a period of 12 months following the renewal of the approval during which Member States shall renew, amend or withdraw the authorisations.

A Member State pointed out that requirements for submission of category 4 data might delay the process by several years.

Member States were invited to submit comments on the appropriate timeline to carry out the Article 12 review following the renewal process by 20 March 2017.

2. Follow up on interpretation of the term "produced"

The Commission emphasised that no decision had yet been taken on a possible change of the wording to be used for transitional measures in MRL proposals, in particular the term "produced". The Commission's Legal service had given its opinion on the different options on how the wording could be clarified and highlighted the main issues that would need to be considered for a legally sound solution. The Commission only received a low number of responses from the Member States on the questions raised in its discussion paper at the last meeting and stated that it would

only propose changes to the current wording if there was clear support from Member States.

Member States were divided on the way the transitional measures and the term "produced" should be interpreted. The main issues of divergening views were on whether or not a product lawfully treated under the old rules should still profit from transitional measures and whether for imported products the moment of importation whould be the decisive moment for compliance with MRLs.

Member States were invited to submit comments by 20 March 2017.

The following point was added to the agenda by the chair.

3. The Commission reminded Member States and EFSA that applications for MRL setting must be supported by a complete data package, even if certain information were identified as unavailable in an Article 12 MRL review and the subject of a footnote in the pertinent Commission Regulation.

Member States were invited to submit comments by 20 March 2017.

A.06 Specific substances:

1. Mercury

Following the recent advice from the Commission's Legal Service, the Commission will no longer propose to set mercury MRLs for products covered by Regulation (EC) No 396/2005 under contaminants legislation (Regulation (EC) No 1881/2006). The Legal Service stated that it would not be possible to move the substance out of the scope of Regulation (EC) No 396/2005 even though it acknowledged that this would have been the most coherent solution (levels for fish and dietary supplements already established under contaminants legislation).

The Commission will now prepare a draft proposal setting temporary MRLs for certain commodities under Article 16 of Regulation (EC) No 396/2005. The technical discussion on the proposed levels will however not be re-opened as the discussion was concluded by the contaminants expert group. It is planned to vote on the proposal in June 2017.

2. Cyhalothrins (lambda-cyhalothrin, gamma- cyhalothrin and cyhalothrin)

The Commission informed the Member States that a specific Article 43 mandate has been sent to EFSA to review the reasoned opinion for lambda-cyhalothrins taking into account also the GAPs (good agricultural practices) for gamma-cyhalothins, for the crops for which a concern was already expressed, as well as any possible fall back GAPs.

The Commission clarified that at the moment it is not feasible to set any specific residue definition for cyhalothrin, a non-approved substance which has shared isomers with the approved substances lambda and gamma-cyhalothrin. The fact that

isomers are shared and that such isomers can also be formed during the analytical process itself makes unambiguous identification of the substance impossible and enforcement action difficult.

It has been decided to leave for the moment the residue definition for cyhalothrin unspecified.

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

No new active substances were discussed in the Standing Committee - section Legislation since the last update given in the November meeting of the Standing Committee, section Pesticides Residues.

4. Anthraquinone

The Commission informed about a meeting which took place with representatives of different stakeholders associations under the umbrella of Food and Drink Europe (FDE). Two new studies were presented on the possible origin of anthraquinone residues in imported products, especially in dried tea leaves, but also in dried spices. The studies gave some indication that anthraquinone could be formed during processing of food or due to environmental background levels. The stakeholders therefore requested to reconsider the MRL for tea and to possibly set a temporary MRL based on monitoring data.

The Commission outlined its reflections on the matter and stressed that in the discussions on anthraquinone the toxicological properties of the substance as well as its possible sources need careful consideration. The Commission highlighted that occurrence should be avoided/minimised by good processing practices, but that data on the substance and the mechansims/circumstances of its occurrence are still lacking.

Several proposals for further follow up were made by Member States' representatives that were welcomed by the Commission and should be further pursued. This included suggestions to wait for finalisation of the classification process in the European Chemicals Agency (ECHA), the collection of data on occurrence, formation and good practices and on possible transfer factors from tea leaves into the brewed beverage. The Commission will also seek advice from the Expert Group on contaminants as there might be similarities with polycyclic aromatic hydrocarbons (PAH).

Member States were invited to submit comments by 20 March 2017.

5. Pencycuron

A reasoned opinion on the modification of the existing maximum residue level for pencycuron in potatoes was recently published. EFSA does not recommend increasing the current MRL of 0.1 mg/kg to 0.2 mg/kg because aniline is likely to occur in processed products. The Commission questions whether immediate action should be taken on the existing MRL. At the meeting, EFSA informed the Committee that the Article 12 review of pencycuron has already been launched and is currently at the stage of consultation with Member States.

Member States were invited to submit comments by 20 March 2017.

6. Etridiazole

The item was added to the agenda by the chair.

A reasoned opinion on the modification of the existing maximum residue levels for etridiazole in cucurbits with edible peel was recently published. EFSA does not recommend increasing the current MRL of 0.1 mg/kg to 0.4 mg/kg because it claims that appropriate information on the toxicological profile and on the relevance of the major plant metabolites 5-hydroxyethoxyetridiazole acid and 3-hydroxymethyletridiazole has not been provided.

However, the section Legislation of the Standing Committee formally agreed that those metabolites are not considered toxicologically relevant (SANCO/13145/2010 - 29 May 2015). In view of such, the Commission and the Evaluating Member State believe it is appropriate to increase the MRLs for etridiazole in cucurbits with edible peel.

Member States were invited to submit comments by 20 March 2017.

A.07 Preparation Codex Committee on Pesticides Residues 49 (2017) (CCPR):

1.Priority of EU nominated substances and concern forms

The Commission informed Member States that the new Codex proposal for the new schedule of periodic review laid down in the Codex Circular Letter CL 2017/12 PR reflected the priorities proposed by the EU. The Commission clarified that the common position for this Codex agenda item will be submitted to the Codex Secretariat only after the first Council Working Party, which takes place on 29 March 2017. The second Council Working Party is scheduled on 10 April 2017.

Member States were invited to submit comments by 20 March 2017.

2. IESTI (International Estimate of Short Term dietary Intake) equation

The Commission reported on the finalisation of the discussion paper of the eWG, a possible physical meeting in the margins of the CCPR (Codex Committee on Pesticides Residues) plenary, and relevant JMPR (Joint FAO/WHO Meeting on Pesticide Residues) activities. It thanked Member States for their active contribution to the work of the eWG and suggested having a detailed discussion at the upcoming Council Working Party.

3. Crop groupings

The Commission informed that they have sent the coordinated replies to the third and last groups of emails circulated by the eWG on the "Revision of the CODEX classification of food and animal feed".

Consensus has been reached in CCPR already on five of the seven items for discussion. Discussions are still open only on two issues ('Classification of the group 021 Grasses for sugar and syrup production' and 'Continue work on Table 3 Type 03 Grasses').

The Member State, who is also co-chair of the eWG, informed the Committee of comments received that would re-open the discussion on points which were already concluded at the CCPR in 2016 and advanced at step 6.

The eWG hopes to finalize a compromise solution on these issues which will be circulated before the Council Working Party on next 29 March 2017.

4. Database of national registrations for compounds listed in Table 2A and 2B of the CCPR Priority Lists

The Commission introduced the draft Codex Circular Letter (CL) on the establishment of a database of national registrations and the intention is to set up a Codex database of national registrations for compounds listed in tables 2A and 2B of the CCPR priority lists. Member States were requested to provide a complete list of only those commodities and commodity groups that are included on the registered national product labels for these compounds. The Commission thanked the Member States who already answered and recalled the Codex deadline of 30 March 2017 for submitting this information. The Commission also invited Member States to comment on this new task, on its usefulness and related workload and on the level of detail of the information to be provided, given that such a database would need regular updates and would have to be considered on top of the similar EU PPPAMS (Plant Protection Products Application Management System) database under construction.

Member States were invited to submit comments by 20 March 2017.

A.08 Number of residue trials from non-EU countries,

The Commission thanked Member States for their written comments and referred to the information available on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). It provided an overview of the different positions expressed on the acceptable number of residue trials from outside the EU. It will come back to the question of comparability at a future meeting of the Committee.

A.09 News from the European Food Safety Authority (EFSA):

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

EFSA gave an overview on the ongoing activities under Article 12 of Regulation (EC) No 396/2005. 33 substances are in the interim process, 20 of them ongoing and 13 to be initiated in 2017. A list of substances for which reasoned opinions would be issued in the coming weeks was presented. EFSA highlighted that for carboxin the data collection was ongoing and that for this substance aniline formation during processing

would be an issue as for buprofezine. A detailed overview on the state of play of the Article 12 assessment for glyphosate was given.

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

70 questions were currently open, out of which 26 in the stop-clock process. 10 reasoned opinions were in the state of drafting/publishing. The Commission and several Member States requested EFSA to re-introduce the screenshot with the PRIMO model calculations both into Article 10 and Article 12 reasoned opinion as this information was frequently used by risk managers. EFSA will discuss this internally and informed that they were currently in an intermediate state between the old and new templates.

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

EFSA has received a mandate from the Commission on MRLs of concern for lambda- and gamma-cyhalothrin.

A.10 Amendments to Annex I to Regulation (EC) No 396/2005 and Regulation (EU) No 752/2014 - state of play.

The Commission presented an updated proposal of the amendments to Annex I of Regulation (EC) No 396/2005.

The amendments/chapters from 1 to 4 have been agreed during previous Standing Committee meetings. The amendments/chapters from 5 to 8 have been accepted by the Committee during the meeting.

Member States are also invited to comment on the list of new products or varieties proposed for inclusion in the Annex I (annexed to the proposal).

Replying to a comment from one Member State on the position of the new products in Annex I, the Commission clarified that there are inevitably inconsistencies between the Codex and the EU classification, due to the fact that the revision of the CODEX classification is still on-going. When the work on classification will be completed at Codex level, an update of the EU classification will be necessary.

Member States were invited to submit comments on chapters 9-15 and on the list of new products by 10 March 2017.

A.11 Honey guidance.

The Commission informed that a working group meeting was planned on 10 March 2017. Member States who wished to participate had nominated representatives and should have received an invitation. Preliminary monitoring data on honey were extracted by EFSA and uploaded on CIRCABC. The data will be published in April 2017 in the EFSA Annual monitoring report.

A.12 Screening exercise on temporary maximum residue levels (t-MRLs) in Regulation (EC) No 396/2005 that will be expiring in 2017.

The Commission gave an update on the state of play.

A.13 Inclusions in Annex IV of Regulation (EC) No 396/2005.

Substances for which an Annex IV inclusion is recommended were addressed by the routine MRL proposal reported under Agenda Point B 01.

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

No issues were raised under this agenda item.

A.15 Designation of Member States for MRL applications.

No issues were raised under this agenda item.

A.16 Information on ongoing work on endocrine disruptors.

The Commission updated the Committee on the state of play, which is also detailed on the dedicated website:
https://ec.europa.eu/health/endocrine_disruptors/next_steps_en.

Next meetings are scheduled for the 28 of February 2017: Standing Committee, section Legislation in the morning and Member State expert meeting (biocides) in the afternoon.

A.17 Information on substances falling under the hazard based criteria in Regulation (EC) No 1107/2009 and follow up on MRL side, example linuron.

The Commission explained the challenges ahead for the approach for MRL setting following decisions taken at approval/renewal stage on substances falling under the hazard based criteria (cut off criteria) of Regulation (EC) No 1107/2009, and especially the impact this could have on existing or future import tolerances. First reflections on procedural matters were shared with the Member States, including their role as first assessors in the process. Member States highlighted the difficulties that this may create at international level (Codex Alimentarius) and the issues of responsibilities for such policy decisions at their level, given their role as first evaluator in the procedure for the handling of import tolerance requests.

Member States were invited to submit comments by 20 March 2017.

A.18 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

The Commission received several contributions on the roadmap as a result of the feedback exercise. Those inputs were reflected to a certain extent in the final version of the Terms of Reference.

The Commission intends to launch the call for tenders in March 2017.

A.19 Update on the state of play of MRL setting for biocides.

The Commission informed that the interim approach for the establishment of MRLs for residues of active substances contained in biocidal product was tabled at the March meeting (15-17 March) of the competent authorities for biocidal products for discussion and endorsement.

A.20 Question referred to the Commitee by Post Annex 1 group.

The Commission updated the Committee about the on-going discussion on the terms of reference for the Post Approval Issue Group (formerly named Post Annex I Inclusion Group). This should better structure the work and information sharing between PAI Group and the two sections of the Standing Committee: Pesticides Legislation and Pesticides Residues.

The Commission committed to update regularly the Standing Committee on Pesticides Residues about the work undertaken by the PAI Group which is related to their work.

The Commission summarised the comments received on the stepwise approach for chronic risk assessment at product authorisation stage and explained how the wording was modified to take into account the comments. The Commission emphasised that the document gives some guidance, but also gives sufficient room for the Member States to take the ultimate risk management decision. The document will now be forwarded to the Post Approval Issues group for their further consideration and possible inclusion in a guidance document that would then need to be endorsed by the Standing Committee on Pesticides Residues. On a question from a Member State whether processing factors derived in an Article 12 review still in the stage of a draft, could be used for refinements of the exposure assessment, the Commission confirmed that this could be done if it was unlikely to lead to any changes between draft and final version.

A.21 Feed, Food and dual-purpose commodities (follow up on the issue of paraquat/soybean case).

The Commission clarified the status of the discussion document presented and discussed in the November 2016 meeting of the Standing Committee, section Pesticides Residues to be a thought-starter for further discussion and not a guidance document. As such it is non-binding for the Member States but could be used by Member States' authorities for their own reflections on their enforcement policy.

From the feedbacks received from five Member States on the discussion paper distributed in November, the Commission concludes that currently no further discussions at Committee level are needed.

However, on a request from a Member State, specific issues can always be discussed in the Committee as was the case with paraquat/soybeans.

One Member State requested clarification of the apparent discrepancies between Regulation (EC) No 882/2004 on Official Controls (Article 19 and 20) and Regulation (EC) No 396/2005 (Article 19). Article 19 of Regulation (EC) No 396/2005 contains the prohibition to make non-compliant commodities listed in Annex 1 to Regulation (EC) No 396/2005 compliant by processing and/or mixing with the same or other products (dilution). The Commission clarified that the provisions of Regulation (EC) No 396/2005 as lex specialis prevail.

A.22 AOB

1. New meeting date November 2017 Standing Committee on Plants Animals Food and Feed (PAFF)

The Commission informed of the changed meeting date for the November 2017 Standing Committee meeting, section Pesticides Residues, to 21-22 November 2017.

2. Ruling of the Court of Justice of 23/11/2016 in Case C-442/14 (interpretation of the concept of information on emissions in the environment)

A working group to discuss the implications of the ruling is scheduled for 13 March 2017 with the objective to draft a practical guidance for the release of studies which are considered as information on emissions in the environment. This may also relate to residues studies.

Member States were invited to appoint an expert who has good knowledge on data requirements to attend this working group. The same request was also made in the Standing Committee section Legislation in January 2017.

The following items were added to the agenda by the chair:

3. Update on chlorpyriphos/raisins

The Commission requested feedback from the Member States on their experiences with the practical enforcement level of 0.2 mg/kg for chlorpyriphos in dried raisins that some Member States operate. Several Member States replied that no major non-compliances had been encountered with this level. The few non-compliances found were from samples of different origins. In view of this, some Member States informed that they will enforce the level of 0.01 mg/kg again as from 1 January 2017, others will continue enforcing the level of 0.2 mg/kg for some time in 2017. The Commission reminded the Member States to remain vigilant on this issue and to submit any information on non-compliances (preferably all details of the results) by 20 March 2017.

4 Quinmerac

The Commission introduced the issue and a proposal for the way forward. It referred to the summary document available on CIRCABC and asked Member States to provide feedback, following internal coordination with experts from both Legislation and Pesticide Residues, on the proposed approach by 07 April 2017.

5 New comitology amendment proposal

The Commission informed Member States about the Commission proposal COM(2017) 85 final for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

6 Public consultation CAP

The Commission informed that the Consultation on modernising and simplifying the common agricultural policy (CAP) was open until May 2017 under the following link:

https://ec.europa.eu/agriculture/consultations/cap-modernising/2017_en

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation 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 benzovindiflupyr, chlorantraniliprole, deltamethrin, ethofumesate, haloxyfop, Mild Pepino Mosaic Virus isolate VC1, Mild Pepino Mosaic Virus isolate VX1, oxathiapiprolin, penthiopyrad, pyraclostrobin, spirotetramat, sunflower oil, tolclofos-methyl and trinexapac in or on certain products (Article 10).

The Commission introduced the draft and presented its contents.

Several MRL applications were submitted under Article 6(1) of Regulation (EC) No 396/2005:

- deltamethrin for the use on celeries;
- ethofumesate for the use on beetroots, sugar beet roots and chards;
- haloxyfop for the use on parsley roots and leeks;
- oxathiapiprolin for the use on table grapes, potatoes, tomatoes, aubergines, cucurbits with edible peel, melons, lettuces and grape vine leaves;
- penthiopyrad for the use on apricots, peaches, barley and oat;
- pyraclostrobin for the use on celeriacs, spinaches, chards/beet leaves, witloofs, beans and peas with pods, peas without pods, celeries and Florence fennels;
- spirotetramat for the use on pomegranates, "other root and tuber vegetables" and chicory roots;

- tolclofos-methyl for the use on potatoes.

Two MRL applications were submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005:

- benzovindiflupyr for the use on pome fruits, wine grapes, potatoes, "tropical root and tuber vegetables", Jerusalem artichokes, solanacea, cucurbits, pulses, linseeds, poppy seeds, rapeseeds, mustard seeds, cotton seeds, gold of pleasure seeds, barley, maize, oat, rye, wheat, ginger, turmeric and to address the occurrence in liver of ruminants;

- trinexapac for the use on poppy seed.

As regards benzovindiflupyr, EFSA concluded that the submitted data were not sufficient to set new MRLs for cucurbits with inedible peel. As regards oxathiapiprolin, it is appropriate to set the MRL for table grapes also for wine grapes, in accordance with the existing guideline on extrapolation of MRLs.

As regards chlorantraniliprole, the United Kingdom granted a 120 day emergency authorisation under Article 53 of Regulation (EC) No 1107/2009 for a use on hops, due to an unexpected outbreak of Lepidoptera species. The United Kingdom submitted an application in accordance with Article 18(4) of Regulation (EC) No 396/2005 with a view to setting a temporary MRL for hops.

EFSA proposed three different MRLs to be considered by the risk managers. As there is no risk to consumers, the Committee agreed to set the MRL at 10 mg/kg, which is derived by scaling down the residue trials by a factor of 3, considering that they were overdosed in terms of number of applications and application rate. This MRL will be set as a temporary MRL valid until 31 December 2020.

For Mild Pepino Mosaic Virus isolate VC1 and Mild Pepino Mosaic Virus isolate VX1, EFSA recommended an Annex IV inclusion. For sunflower oil, the Commission proposed an Annex IV inclusion in view of its recent approval as basic substance under Regulation (EC) No 1107/2009.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation 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 fluopyram; hexachlorocyclohexane (HCH), alpha-isomer; hexachlorocyclohexane (HCH), beta-isomer; hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer; lindane (hexachlorocyclohexane (HCH), gamma-isomer); nicotine and profenofos in or on certain products.

The Commission introduced the draft and presented its contents.

Concerning hexachlorocyclohexane (HCH) isomers, several Member States commented that LOQs lower than 0.01 mg/kg were not justified in the absence of a

health risk at the level of 0.01 mg/kg. The Commission adjusted the respective MRLs to the LOQ of 0.01 mg/kg.

Concerning nicotine, one Member State indicated that the proposed MRL of 0.4 mg/kg for celery leaves would lead to an exceedance of the acute Reference Dose (ARfD) for Belgian children (body weight 17.2 kg, 102 g of celery leaves). The Commission pointed to a likely mistake in the data collection, celery stem intakes being reported for celery leaves intakes, leading to an overestimation of the exposure. Belgium confirmed and recalled that this issue was already reported to the Committee previously. EFSA also confirmed this and announced a correction of the PRIMO model before the introduction of the new revision 3 of the PRIMO model. The MRL of 0.4 mg/kg for celery leave was therefore maintained.

Concerning fluopyram, the LOQ for animal commodities was slightly corrected taking into account the residue definition which includes 2 compounds. The existing import tolerance for sugar beet roots of 0.1 mg/kg established in 2012 by Regulation (EU) No 270/2012 was maintained. As fluopyram is a highly persistent compound, significant residues are expected to be present in rotational crops, for which EFSA advised an MRL of 0.1 mg/kg and took this value into account in its exposure assessment. The MRLs for kales, other leafy brassica, kohlrabies, watercress, herbal infusions from leaves and herbs, herbal infusions from flowers and chicory roots were therefore set at 0.1 mg/kg.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residues level for achrinathrin, metalaxyl and thiabendazole (Article 12).

The Commission introduced the draft and presented the main amendments introduced in Rev. 2.

The footnotes for metalaxyl were modified to specify whether data is missing for metalaxyl or metalaxyl-M. The MRLs of radishes and head cabbages for metalxyl have been corrected following the OECD calculator. The use on rhubarb in metalxyl was not considered as the data were mentioned but not fully evaluated in the Evaluation Report prepared by the Evaluating Member State. Similarly, only the uses of acrinathrin in lettuces and other salad plants have been considered, as other uses were already covered by the PRIMO model used by EFSA.

As regards acrinathrin, the Commission reminded Member States of the current restrictions set under Regulation (EC) No 1107/2009 and the need to adapt the existing national authorisations.

As regard metalaxyl on pepper corn, the Commission informed the Committee about the reactions from several third countries on the proposal to lower the current MRL to the LOQ. The European Spice Association (ESA) also expressed its concern on the

negative impact that this could have on the availability of pepper corns on the European market.

The Commission clarified that there are no EU authorisations nor import tolerance requests for pepper corns. Since the 2018 WHO/FAO Joint Meeting on Pesticides Residues (JMPR) will assess monitoring data to set a new CXLs in pepper corn and other spices and since there is no health risk to consumers, the Committee decided to maintain the MRL for a limited period of time pending the JMPR evaluation.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

The Commission introduced the draft and presented its contents. No comments were made by the Member States.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for tricyclazole in or on certain products.

The Commission introduced the draft and presented its contents. SPS comments from Thailand and India were discussed.

A Member State indicated that it would abstain during the vote because it believes that full transitional measure should be granted because there is no clear proof that a human health concern might occur.

On the other hand, another Member State indicated that the MRL for rice should be lowered without any transitional measures, because there is no proof available that this MRL is safe for consumers.

Several Member States expressed their support to the proposal. A Member State suggested to limit in time the provision that the existing MRL continues to apply to products placed on the market or imported before the application date. Although this suggestion was supported by another Member State, the Commission considered it not appropriate to make such a last minute change to the proposal.

The Rapporteur Member State informed that it had received an import tolerance request to support an MRL for rice of 0.4 mg/kg. The Commission clarified that even though some new studies were available, the full data package was not yet submitted, as long term rat studies are still being carried out.

The Member States requested clarifications on the interpretation of the term 'placed on the market'. The Commission explained that the definition of this term is laid down in Article 3(8) of Regulation (EC) No 178/2002 on the general principles and requirements of food law. Further discussions on this item took place under agenda item A. 05.02.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation 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 dimethoate and omethoate in or on certain products.

The Commission introduced the draft and presented its contents. A Member State requested an estimate of the consumer risk assessment, taking into account all dimethoate metabolites and assuming a toxicity equal to the one of omethoate. However, EFSA indicated this was not possible due to the lack of residue trial data.

For oats and barley EFSA had only trial data available for a more critical Good Agricultural Practice (GAP) than the one that is currently authorised, which would result in higher MRLs than the existing one. As it was confirmed that the existing MRL for dimethoate and omethoate separately would cover the residues from the critical GAP, it was decided to keep the existing MRL in place, instead of increasing it.

A comment was received from THIE (Tea and Herbal Infusions Europe) on the lowering of the MRL for dimethoate for rose flowers for herbal infusions, supported by monitoring data from third country samples. The proposal was amended to keep the current MRL for 2 years with a footnote that additional monitoring data need to be submitted. In order to maintain this MRL, an application under Article 6 of Regulation (EC) No 396/2005 supported by a full data package, would need to be submitted.

SPS comments from Turkey and the United States were discussed.

A Member Sate considered it is not appropriate to change the residue definition, when some toxicological data on certain metabolites are still missing. Despite previous agreement among the Member States, to use the existing version of the IESTI equation using the highest residue from supervised field trials, the Member Sate expressed concerns on a possible health risk with the proposed MRLs for cherries, when using the MRL as an input parameter in the calculation.

The Commission explained that EFSA identified no health risk for cherries with the existing version of the IESTI equation and re-confirmed that possible changes to the equation can only be considered once an agreement will be reached during the ongoing discussions on this topic at an international level.

Vote taken: Favourable opinion.