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Standing Committee on Plants, Animals, Food and Feed

Section *Phytopharmaceuticals - Residues*

26 - 27 September 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/53fea3e8-ee54-4cd8-a25d-461ffc433472*

SUMMARY REPORT

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

1. Priorities under Art. 12 – updated table

The Commission presented the updated table. It raised the possibility of launching the group MRL review of dithiocarbamate substances after completion of the procedure for renewal of approval for 5 out of 6 substances, in view of the long-term stop-clock for ziram.

Two Member States reiterated their request that a decision on the confirmatory information submitted under Regulation (EC) No 1107/2009 for pyrethrins is taken before the renewal decision, to allow initiation of the maximum residue level (MRL) review as soon as possible.

2. Confirmatory data Art. 12 follow-up

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

The Commission had updated the table with the proposed follow-up actions for several substances that went through the Article 12 confirmatory data process.

At the meeting, the following actions were agreed by the Committee:

i. Bentazone, dimethomorph, fludioxonil, pyraclostrobin and teflubenzuron will be addressed by a draft Regulation, which needs to be notified through the World Trade Organisation's Sanitary and Phytosanitary Standards system (WTO-SPS).

ii. Flutolanil and imazamox will be addressed by a draft Regulation (SANTE/11822/2019) deleting all footnotes requesting confirmatory data, except for flutolanil in peppers for which the missing data had not been submitted.

iii. Spinosad will be put on hold pending the renewal decision.

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

The Commission summarised the discussion as regards tall oil crude and pitch and informed the Member States that due to insufficient toxicological data both substances would be withdrawn from Annex IV and all MRLs set to the LOQ of 0.01 mg/kg in a forthcoming draft Regulation.

A.02 Feedback from Legislation Committee

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

The Commission informed that no new active substances were under discussion in the Legislation Committee since the last meeting of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF), Section Phytopharmaceuticals – Pesticides Residues on 13-14 June 2019.

A.03 Specific substances:

1. **Propoxur**

The Commission informed the Committee about discussions with EFSA on the timing of the planned mandate on propoxur relative to other mandates and the availability of experts for both toxicity and residues.

2. **Chlorpropham**

The Netherlands, as Rapporteur Member State (RMS), gave an update on the state of play. Some Member States submitted comments in support of the on-going evaluation. The relevant stakeholders submitted additional studies and monitoring data to the RMS who is currently finalising the overall assessment, which is expected to be delivered by October 2019. Based on the available data, the RMS will propose a temporary MRL of 0.4 mg/kg to address the cross-contamination issue.

The RMS also mentioned that a draft protocol and a study with data on cleaning practices data were submitted by the applicant to be able to estimate the decline of residue levels over time. A Member State suggested that special efforts on cleaning the storage facilities should be made to limit cross-contamination as much as possible. Another Member State stressed the importance of communicating to the relevant stakeholders and growers that the substance should no longer be used to prevent non-compliances of food placed on the market when the MRL will be lowered.

3. **Copper MRLs**

The Commission introduced the topic and referred to written comments received from a Member State and the EU Copper Task Force, available on CIRCABC.

A Member State proposed to refine the calculation of background levels through more reliable monitoring data. It stated its preference for reliable consumption data from countries whose consumption data are not yet included in the PRIMo model over WHO cluster diets.

Another Member State reported its experience with authorising PPPs containing copper compounds.

EFSA referred to the ongoing revision of the uncertainty factor used to derive the ADI for copper, with an opinion expected to be finalised by May 2020. Furthermore, first biomonitoring data on copper will be available in 2019, and a model possibly by end-2020.

Member States were invited to provide their comments by 18 October 2019.

4. **Pesticides residue findings on mushrooms**

The Commission gave an overview on substances found in cultivated fungi based on the monitoring data 2015-2017 extracted by EFSA and on the feedback received from the mushroom growers. The Commission pointed out that only a few substances needed special attention and that the most important ones such as mepiquat and chlormequat, had already recently been dealt with.

One Member State had received information on findings of anthraquinone in mushrooms and asked whether other Member States had similar findings. A Member State pointed out, that in case of dried mushrooms, drying practices could be a reason.

The Commission concluded that based on those results there was no need for a specific approach/guidance document on data requirements for mushrooms. It stressed that mushroom growers have the duty to pay special attention to raw materials, in order to avoid cross contamination in the first place.

5. **BAC/DDAC**

Temporary MRLs had been set for benzalkonium chloride (BAC) and didecyldimethylammonium chloride (DDAC) by Regulation (EU) No 1119/2014 on the basis the monitoring data available at that time. EFSA recently extracted monitoring data covering the years 2014-2017. A Member State submitted recent national monitoring data to the Commission from 2018 and the beginning of 2019.

The Commission reminded that all data that will become available by 31 December 2019 will be considered for the decision whether an extension of the validity of the current temporary MRL of 0.1 mg/kg would be needed.

6. **Clonostachys rosea strain J1446**

The Commission informed that in Regulation (EU) 2019/977 it is erroneously reported that EFSA recommended the inclusion of Clonostachys rosea strain J1446 into Annex IV to Regulation (EC) No 396/2005. The Commission intends to publish a corrigendum clarifying that EFSA did not recommended such inclusion, but that Annex IV inclusion was decided by risk managers based on the relevant Review Report (SANTE/11655/2017 Rev 3).

7. **Quizalofop/propaquizafop**

On 30 July 2019, EFSA published the Reasoned Opinion on the modification of the existing maximum residue levels for quizalofop in lettuces and salad plants[1]. The Commission clarified that the temporary MRL set in Regulation (EC) No 396/2005

[1] (EFSA Journal 2019;17(7):5747)

is higher than the one proposed in the Reasoned Opinion, because it covers a more critical Good Agricultural Practice (GAP). The Reasoned Opinion may be considered at a later stage when reviewing the temporary MRL.

8. **Chlordecone**

On 12 July 2019, the French competent authorities notified to the European Commission two emergency measures, which had been taken at national level pursuant to Article 53 of Regulation (EC) No 178/2002. Following the opinions of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France had fixed national maximum residue limits (MRLs) for chlordecone in bovine, ovine, caprine, porcine and poultry matrices at lower values than the ones currently applicable under Regulation (EC) No 396/2005 to ensure the protection of consumers in Guadeloupe and Martinique. France requested the Commission to amend the MRLs in Regulation (EC) No 396/2005 accordingly.

Another Member State enquired whether it would be possible to lower the MRLs also for products of plant origin. France clarified that according to the available monitoring data this would not be feasible at this point in time and that the ANSES review therefore only concerned products of animal origin.

The Commission will ask EFSA to review the assessments carried out by ANSES, including the one where new toxicological reference values were established.

9. **Dimethenamid-P**

EFSA had proposed new residue definitions for enforcement purposes covering also specific metabolites in the peer-review of the active substance. In that framework, EFSA had also recommended the setting of MRLs with the new residue definitions.

Member States were invited to comment by 11 October 2019 as to whether they would be in favour of changing the residue definitions in a routine MRL measure, considering that the Article 12 review had already been carried out.

10. **Glufosinate ammonium**

The Commission informed that there were no new developments since the meeting on 13/14 June 2019.

The RMS reported that it had been contacted by the main former authorisation holder who considered different strategies to ensure that MRLs relevant for imported food and feed are maintained.

One Member State stated that its food industry was concerned about the consequences that a lowering of the MRLs for glufosinate may have on the supply of livestock feed. Its industry considered that sufficient transitional periods are needed to allow the supply chain logistics to adapt.

Several Member States recalled their positions on MRL setting for active substances meeting the human health based cut-off criteria of Regulation (EC) No 1107/2009 in general.

11. **Chlorpyriphosethyl and chlorpyriphos-methyl**

On 2 August 2019, EFSA had published statements confirming that for chlorpyriphos-ethyl and chlorpyriphos-methyl serious concerns exist for human health and that a genotoxic potential could not be excluded for the two substances.

The vote on the non-renewal of the approval of the active substances chlorpyrifos and chlorpyrifos-methyl is expected to take place at the meeting of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF), Section Phytopharmaceuticals – Legislation, on 6 December 2019. The draft Regulation foresees a maximum grace period of 3 months that Member States may grant for the use of stocks of the plant protection products containing the substances.

On 13 September 2019, Denmark had requested the Commission to take EU wide safeguard measures under Article 53 of Regulation (EC) No 178/2002 (General Food Law) in conjunction with Article 35 of Regulation (EC) No 396/2005 in relation to the existing MRLs for chlorpyrifos and chlorpyifos-methyl. Denmark asked to lower all MRLs for both substances to the relevant Limits of Quantification (LOQ).

At the meeting Denmark shared their concerns with the other Member States. The Commission proposed to lower the MRLs for chlorpyriphos and chlorpyriphos-methyl without delay to the relevant LOQs following the adoption of the decisions not to renew the approval of the substances and the expiry of grace periods given by Member States. It proposed a shortened deferred application of 3 months in line with the shortened grace period of 3 months proposed in the draft non-renewal decisions and clarified that a transitional period for products already on the market cannot be granted due to the serious health concerns. The EU Reference Laboratories (EU RLs) had been consulted and had confirmed that an LOQ of 0.01 mg/kg is achievable in all products.

The Committee agreed that the proposed actions would need to be carried out with high priority given the serious health risks identified by EFSA. A Member State enquired whether an immediate entry into force (no deferred application) would be an option and whether the SPS-WTO consultation period of 60 days could be shortened. The Commission confirmed that it would be possible to have no deferral of the application date, but that the 60 days for WTO-SPS consultation must be respected.

Member States were invited to comment on the following issues by 4 October 2019:

1) general approach/planning proposed by the Commission;
2) levels to be set (i.e. lower all MRLs to 0.01 mg/kg or apply the usual multiplying factors);
3) proposed length of 3 months for the deferred application date.

A.04 News from and files related to the European Food Safety Authority:

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

EFSA presented the state of play of the ongoing Article 12 reviews. 38 active substances are currently under review, 37 under the new procedure and one under the interim procedure. EFSA is also at an advanced stage of drafting a new statement on six active substances that do not require an Article 12 review.

The Commission referred to the revised work plan for MRL reviews in 2019, following discussions at the meeting of the Committee on 13/14 June 2019 and subsequent agreements from Member States for thiram (individual residue definition), cyproconazole and quinoxyfen, with the agreement of the RMS for propineb (individual residue definition) still pending. The Committee agreed to the revised work plan.

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

EFSA reported that in 2019, 32 Reasoned Opinions were issued so far and 12 new question numbers addressed since the last meeting. Although feedback on long lasting clock-stops had been received and had led to a certain reduction of the number of clock-stops, the overall number is still high (48 questions).

The most common issues are missing data in relation to the GAPs and/or missing or non-valid residue trials. Some assessments under Article 10 of Regulation (EC) No 396/2005 are merged with the assessment under the peer review process, but can be separated if the peer review results in a clock-stop (e.g. on endocrine properties).

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

One mandate under Article 43 was carried out in 2019 on chlormequat in mushrooms, but several mandates under this Article are expected shortly from the Commission.

4. **Strategy for risk assessment of triazole fungicides (TDMs)**

A discussion took place on how to handle triazole derivative metabolites (TDM) under Article 10 and Article 12. Following the comments received by Member States after the last meeting of the Committee on 13/14 June 2019, EFSA updated the strategy paper, which had been made available on CIRCABC.

The Commission informed of its intention to take note of new toxicological end-points for TDMs by end of 2019 in the SC PAFF, Section Phytopharmaceuticals – Legislation, and that further discussion on a possible monitoring programme for TDMs would take place during the meeting of the Expert Group on Pesticides Residues Monitoring on 14 October 2019. It also mentioned that according to preliminary information from the EU RLs, analytical methods and availability of analytical standards may be a problem. The Commission will follow up on both points with the EU RLs and the TDM industry task force.

5. **PRIMo rev. 3.1**

EFSA requested clarification on the application date for PRIMo rev. 3.1. It was agreed that the model would be applied immediately as only minor changes are expected compared to PRIMo rev. 3. If unexpectedly major differences between the two versions occurred in their risk assessments, EFSA would clearly highlight this in the respective Reasoned Opinion.

6. **EFSA reports on cumulative risk assessment and communication action**

EFSA informed of the publication on 17 September 2019 of two sets of reports: one for the acute effects on the nervous system and one for the chronic effects on the thyroid, respectively. Specifically, each of the two sets includes:

- Scientific Report on Cumulative Assessment Groups,

- Scientific Report on the Cumulative Exposure Assessment with the Monte Carlo Risk Assessment (MCRA) software,
- Scientific Report on the Cumulative Exposure Assessment with the SAS© software,
- Scientific Report on Cumulative Risk Assessment and Uncertainty analysis.

EFSA informed of the public consultation for the two Scientific Reports on Cumulative Risk Assessment and Uncertainty analysis, which is ongoing until 15 November 2019. Furthermore a stakeholder event is planned for 22 October 2019. A draft roadmap on the way ahead as regards cumulative risk assessment will be prepared by EFSA by the end of the year.

7. **Annual monitoring report**

- Follow up from the meeting in June on proposed schedules

  EFSA presented the proposed timelines regarding the 2019 monitoring report. A discussion took place regarding the deadline for data collection and timeframe for data validation in view of a timely publication of the 2019 Annual Report by the legal deadline of end February 2021. Member States were encouraged to send their monitoring data by end of June 2020 and make use of the earlier opening of the data collection exercise already in February 2020. Several Member States emphasised that an earlier closure of data collection than the legal deadline of 31 August 2020 would however not be acceptable. EFSA clarified that it was not the intention to dismiss any data submitted before the legal closure date of 31 August 2020, but that those data submitted earlier would already undergo the data validation process and thus help EFSA to speed up procedures. EFSA however made it clear that as from the reporting year 2019 onwards, submissions after the legal deadline of 31 August (so for the first time in 2020) would no longer be accepted in accordance with Article 32(3) of Regulation (EC) No 396/2005 and as agreed with the Commission. Only one round of Member States consultation will be carried out on the draft report, and the comments received published together with the final report.

- Follow up on specific recommendations made in the 2017 report

  The Commission commented on the EFSA's recommendation regarding more detailed reporting on follow-up actions and administrative actions taken by Member States when MRL exceedances occur. EFSA noted that this additional information was desirable for refining risk assessments but that the submission of such data is voluntary. EFSA encouraged Member States to provide them on a regular basis in the Standard Sampler Description (SSD) data reporting format.

A.05 Foods for infants and young children.

The Commission informed that analytical methods for most of the substances concerned have been developed by the EU RLs and that their application on infant formulae samples will commence soon. A presentation of the EU RL Animal Origin on the analytical project for foods for infants and young children had been uploaded on CIRCABC.

The Commission also provided information regarding the planned alignment of the legal framework for food for infants and young children with Regulation (EC) No 396/2005. A presentation on this topic that had been given to the Commission's Expert Group on Food Intended for Infants and Young Children and Food for Special Medical Purposes at its meeting on 25 September 2019 and had been uploaded on CIRCABC. The Commission underlined once more the importance of close involvement and co-operation in this discussion of experts on pesticides residues and on foods for infants and young children, both at Member State and at Commission level.

A.06 Transitional periods – follow up from previous meetings.

The Commission recalled the discussions at the meeting of the Committee on 13/14 June 2019 and suggested to finalise the discussion document in the version presented at that meeting. It explained why it considered further modifications not necessary at this point in time. It stressed that it is not a guidance document but only served to structure the discussions within the Committee, and to ensure consistent drafting by the Commission services. The Committee agreed to the revised discussion document and to closing the discussions on that basis.

A.07 Project on data collection dithiocarbamates.

The Commission informed that work is on-going on this topic by the EU RLs and that further details would be provided at the next meeting of the Committee.

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

The Commission updated the table with the latest publications. Specific items were discussed under the relevant points of the agenda.

A.09 International Matters:

1. **OECD Guidance document on the definition for risk assessment**

   There were no news as regards this agenda point.

2. **Codex Alimentarius/JMPR issues- future work organisation**

   Several Member States reported on the ongoing work in electronic Working Groups (eWGs) established by the Codex Committee on Pesticide Residues (CCPR).

   The Commission recalled that for the following eWGs attributions of Member States were not yet agreed:

   - eWG on the management of unsupported compounds
   - eWG on the revision of guidance on mass spectrometry (Spain was erroneously mentioned in the Summary Report of the meeting of the Committee on 13/14 June 2019 due to a misunderstanding).

   The Commission invited Member States to volunteer for those eWGs.

   The Commission reiterated its call on Member States to stay actively involved in Codex related activities throughout the year.

   Regarding the designation of Member States to substances evaluated by both the extraordinary and the regular JMPR meetings in 2019, the Commission informed the Committee that co-RMS Belgium confirmed its availability to take over

mesotrione from the RMS United Kingdom after Brexit. However, for methoprene no Member State had come forward following the meeting of the Committee on 13/14 June 2019, and the Commission invited Member States to volunteer for that substance.

Croatia, which will hold the Council Presidency in the first semester of 2020, informed the Committee that three Council Working Parties will take place to prepare the EU position for CCPR 2020, on 20 January, 04 March and 16 March 2020.

Member States were invited to offer their support by 04 October 2019 on:

1) Methoprene (Acting as RMS)
2) eWG on Review of Mass Spectrometry Guidelines
3) eWG on Management of Unsupported Compounds

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

The following notifications had been made under Article 18(4) to Reg. (EC) No 396/2005:

- Cyantraniliprole on Chinese cabbage (United Kingdom)
- Cyantraniliprole on raspberries and blackberries (United Kingdom)
- Flonicamid on carrots (Finland)

The Committee took note of the notifications listed above.

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

There were no news as regards this agenda point.

A.12 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

There were no news since the last Committee meeting as regards this agenda point.

A.13 SANTE extrapolation guidelines (SANCO/7527/VI/95).

The Commission raised a question on the scope of the updated guidelines that it will prepare, in particular whether the existing guideline SANCO/7029/VI/95 should also be integrated into the document as proposed by EFSA after the last Committee meeting. A Member State commented that the guideline SANCO/7029/VI/95 was outdated and largely replaced by the OECD guideline for testing of chemicals No.509 (2009) and that it should no longer be used. EFSA clarified that some parts were not contained in the OECD guideline and could be taken on board. The Commission will look into that issue but re-iterated its comment made at the last meeting of the Committee to limit the exercise to the main purpose of aligning with the OECD Guidance Document on crop field trials[2]. Since in previous amendments the focus was on the Annexes those Annexes will not be modified this time.

A document collecting the comments submitted from Member States after the previous Standing Committee was presented. It will serve as a basis for further work on the update of the SANTE guidelines on extrapolation.

[2] ENV/JM/MONO (2011)50/REV1

Member States were invited to provide their comments by 11 October 2019 on the scope of the exercise (inclusion or not of elements of SANCO/7029/VI/95); and to comment by 31 October 2019 on the collection of comments as summarised by the Commission's summary document.

A.14 Technical Guidelines for honey.

Following a question on implementation of the guidelines for honey brought up in a recent meeting of the Inter Zonal Steering Committee, the Commission re-iterated its comment made at the last meeting of the Committee that the guidelines were drafted in a spirit to avoid unnecessary burden, thus allowing sufficient flexibility. It was clarified once again that residue trials would not be needed in all cases and that a pragmatic approach should be followed as set out in the decision tree of the guidelines. The Commission acknowledged that monitoring data could be used in addition to other relevant information (e.g. on melliferous crops, treatment before/after flowering, etc.), but clarified that an appropriate justification from the applicant was always needed for cases where trials were not carried out because they were not deemed necessary.

In order to get an overview on residue findings in honey the Commission had requested EFSA to extract monitoring data from their database for the years 2014-2017. One Member State had provided additional more recent data. The Commission gave an overview of these findings and concluded that only a limited number of substances were found regularly in honey and that for most of them the MRLs in honey were not exceeded in any of the samples analysed. It identified about 5 substances for which the established MRLs for honey might not always suffice and to which attention should be paid in the evaluations by Member States and EFSA. One Member State reminded the Committee of the ongoing work in the OECD on a Honey Guidance Document and proposed that EFSA monitoring data should be provided to OECD.

Member States were invited to respond by 11 October 2019 in case they would object to their monitoring data being provided to OECD by EFSA.

One Member State reported findings of residues of acetamiprid being higher in honey in those regions where rapeseed was grown.

The Commission thanked the Member States and EFSA for their valid contributions and concluded that for the time being there was no need to further discuss this issue. Once sufficient experience was gained with the implementation of the guidelines, further discussions could take place.

A.15 Pesticides database-presentation of new features.

The Commission made a presentation on the new feature provided by the future version of the EU Pesticides Database. A Member State enquired whether Member States could be involved in testing. The Commission will investigate the options.

A.16 Maximum residue levels for metam, dazomet, hexythiazox and clethodim in or on certain products (Art. 12).

Information on the four substances to be covered by a new draft Regulation under Article 12 of Regulation (EC) No. 396/2005 was presented. The Commission informed on the situation of clethodim for which EFSA did not recommend any MRLs as toxicological reference values could not be established based on the available information. The substance shares a metabolite with 1,3-dichlororpropene for which a

decision of the Committee, Section Phytopharmaceuticals - Legislation on approval as a new active substance is currently pending. The Commission informed that further information on the metabolite 3-chloroallylalcohol might be provided by the two applicants for clethodim and 1,3-dichloropropene. A Member State felt that waiting for this information would not be an option unless the information would be available shortly. The Commission asked the other Member States to examine the situation and provide their views by 18 October 2019.

A.17 Other Information points.

- *Complaint to the Ombudsman*

  The Commission informed of a recent complaint of a stakeholder organisation to the European Ombudsman against the Commission on the lowering of MRLs for buprofezin by Commission Regulation (EU) 2019/91.

- *Corrigenda*

  The Commission informed that a corrective act is under preparation regarding Commission Regulation (EU) 2019/1176.

- *Stakeholder workshop FEDIOL, COCERAL, FEFAC*

  The Commission informed that a joint stakeholder workshop by three European trade organisations, FEDIOL, COCERAL and FEFAC, would be organised on 12 November 2019, which Member States could attend.

- *Indolylacetic acid in rice*

  One Member State drew the attention of the Committee to findings of indolylacetic acid in rice and asked whether the other Member States had found such residues as well. The Commission asked the other Member States to check and report back at the next meeting.

Section B <u>Draft(s) presented for an opinion</u>

The chair informed the Member States that voting on all the draft Regulations was postponed for procedural reasons in the transition phase between the outgoing and the incoming Commission. For point B.01 the internal consultation processes are currently also on hold, the draft Regulation is not yet ready and will be tabled for vote later. The chair proposed to finalise the technical discussions on the proposed draft Regulations under agenda items B.02, B.03, B.04 and B.05 in order to put them for vote as soon as possible after internal agreement in the Commission. This may be done with shorter notice than 14 calendar days given that all documents had been timely available already for this meeting and published on the comitology register. The Member States agreed to the proposed way forward.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… 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 acequinocyl, acibenzolar-S-methyl, Bacillus subtilis strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin 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):

- acequinocyl for the use on citrus fruits;
- acibenzolar-S-methyl for the use on hazelnuts;
- emamectin for the use on kiwi and peaches;
- flonicamid for strawberries, blueberries, cranberries, currants and gooseberries;
- flutolanil for the use on beans (with pods) and globe artichokes;
- fosetyl for the use on potatoes, wheat and products of animal origin;
- imazamox for the use on peas (with pods), soyabeans, maize and rice;
- oxathiapiprolin for the use on hops.

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

- oxathiapiprolin used in China on grapes and Canada and the United States on several crops.

As regards oxathiapiprolin, EFSA concluded that for Brussels sprouts and peas, the submitted data was insufficient to set new MRLs. At the meeting, it was clarified that the MRL for leeks is fully supported. A Member State suggested including the possibility to extrapolate data from spring onions to leeks in the relevant EU guidance document, which generally does not allow extrapolating data from a minor crop to a major one.

As regards fosetyl, a Member State pointed out that the value for edible offal should be set at the highest level among the other commodities listed within the same group, in line with the Commission's internal working procedures for Article 12.

The draft Regulation proposes to include *Bacillus subtilis* strain IAB/BS03 in Annex IV to Regulation (EC) No 396/2005. A Member State did not support such inclusion as it believes that the substance should not be considered as “low-risk”.

Vote postponed.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annex II 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 cherries.

The Commission introduced the draft Regulation, which proposes lowering the MRLs for dimethoate and omethoate in cherries following the non-renewal of the active substance and the expiry of the 3-month maximum grace period that Member States may grant. All existing authorisations for plant protection products containing dimethoate have been revoked in the EU in relation to uses on cherries.

In reply to the WTO notification, Canada had shared its concerns in relation to the trade of cherries and asked the EU to further clarify the risks to human health and the environment.

A Member State asked whether it is possible to shorten the deferred application date of the draft MRL measure to three months in line with the shorter grace period foreseen

by the non-renewal Regulation (EU) 2019/1090. The Commission responded that this could be considered. A Member Stated stressed the importance of communicating in advance to growers to ensure that the substance is no longer used. The Commission agreed and invited Member States to assist with this task in communication with stakeholders at national level while the Commission will do the same at EU level.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate.

The Commission introduced Revision 8 of the draft Regulation and informed the Member States that after internal consultation, footnote (A) had been updated with minor modifications. Following requests for clarity from the Member States, footnote (A) was adjusted to include reference to the specific processes included in Article 2(1)(n) of Regulation (EC) No 852/2004. As fruit juices fall under the requirement of footnote (A) concerning processed food products, the specific footnote regarding fruit juices had been removed.

A Member State questioned whether footnote (A) would be applicable in the case of frozen food products. The Commission clarified that the categories for fruits and vegetables in Annex I to Regulation (EC) No 396/2005 refer to both, fresh and frozen products. During the Experts' Group Meeting of 13 May 2019 sufficient samples of frozen food had been available in the data collection and had explicitly been included in the statistical evaluation, so that the proposed levels already take freezing processes into account. Applying footnote (A) to frozen products would therefore in general not be appropriate. The same principle applies to ready-to-eat salads where the levels concerning commodities under the category of leaf vegetables in Annex I had already been taken into consideration.

Vote postponed.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for prochloraz in or on certain products.

The Commission recalled that prochloraz had initially been included in a previous draft Regulation, but that the vote for this substance had been postponed. Two Member States had expressed concerns, one over the potential endocrine disrupting properties of the substance, the other on the version of the PRIMo Model to be used.

Some Member States stated that the strategy for the use of the new PRIMo 3 should be re-evaluated considering the difficulties encountered during the authorisation procedures.

Member States were invited to provide comments on the need to modify the current approach on the date by which PRIMo rev. 3 should be applied.

Vote postponed.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cycloxydim, epoxiconazole, flonicamid, haloxyfop, mandestrobin, mepiquat, Metschnikowia fructicola strain NRRL Y-27328 and prohexadione in or on certain products.

A draft Regulation setting MRLs for most of these substances had been discussed in November 2018 where it had received a favourable opinion by the Standing Committee. However, as a result of the objection raised by the European Parliament in relation to the increase of the MRL for clothianidin in potatoes – which had also been included in the draft Regulation- the Commission had now prepared a new draft Regulation without clothianidin. In addition, MRLs for epoxiconazole were withdrawn in view of the fact that France raised concerns a few days before the current meeting and the Commission needed more time to assess the implications. The Commission further clarified that the draft Regulation already reflects the new MRL for mepiquat in oyster mushrooms that had been set by the draft Regulation SANTE/10804/2019, which had received a favourable opinion of the Committee in June 2019.

As regards epoxiconazole, France clarified that it had withdrawn all authorisations of plant protection products containing the active substance, following the publication of the ANSES opinion of 19 April 2019 concerning the endocrine disrupting properties of the substance. France believes that no MRL should be raised at the current stage of the review process of the active substance under Regulation (EC) No 1107/2009. The Commission clarified procedures and reminded that EFSA recommended the setting of a new MRL for epoxiconazole in beetroots as it was considered safe for consumers. Since a decision on renewal of approval has not yet been taken, there are no grounds not to accept MRLs that were considered safe. Once a renewal decision on renewal (or not) will have been taken, the Commission will follow up on it. If then, based on the outcome, action on MRLs becomes necessary, it will be taken without delay as is already usual practice.

Two other Member States informed the Commission that they would not support any measure increasing MRLs for epoxiconazole.

Vote postponed.

Section C <u>Draft(s) presented for discussion</u>

C.01 Exchange of views of the Committee as regards maximum residue levels for sintofen, myclobutanil and napropamide (Art. 12).

Information on the draft Regulation was shared with Member States. There were no additional comments on this draft.

Member States were invited to provide their comments by 18 October 2019.

C.02 Exchange of views of the Committee as regards maximum residue levels for cyantraniliprole, cyazofamid, cyprodinil, fenpyroximate, fludioxonil, fluxapyroxad, imazalil, isofetamid, kresoxim-methyl, lufenuron, mandipropamid, propamocarb, pyraclostrobin, pyriofenone, pyriproxyfen and spinetoram in or on certain products (CXLs).

The Commission introduced the draft Regulation and presented its content.

Member States were invited to provide their comments by 18 October 2019.

C.03 Exchange of views of the Committee as regards maximum residue levels for chromafenozide, fluometuron, pencycuron, sedaxane, tau-fluvalinate and triazoxide in or on certain products (Art. 12).

Concerning chromafenozide, the Commission recalled the delay of confirmatory data assessment by the RMS. Further to the applicant's request to maintain the MRLs for pome fruits and table and wine grapes, the Commission clarified that in consistency with EFSA's Reasoned Opinion, those MRLs should be lowered to the LOQ and that the applicant would have to follow an Article 6 procedure to set new MRLs for those commodities.

For pencycuron, the Commission recalled that the metabolite pencycuron-PB-amine is found in significant levels in rotational crops and processed commodities, thus it was proposed to be included in the residue definition. Further discussion took place regarding inclusion of the margin of exposure approach for aniline in the case of pencycuron, but also in general, for MRL reviews. It was clarified that this was a risk management decision, but that earlier discussions on that topic had taken place in the Legislation Section of the SC PAFF and not resulted in a clear position.

Regarding fluometuron the Commission proposed to include free trifluoromethylaniline (TFMA) in the residue definition, as determination of the conjugated TFMA moiety would challenge the analytical limitations of most of the laboratories according to the EURLs.

Concerning triazoxide, the Commission recalled the analytical challenges encountered by the EURLs in achieving the very low LOQ of 0.001 mg/kg indicated in the EFSA Reasoned Opinion for dry and high-oil commodities and clarified that, following an EFSA calculation on consumer exposure where no risk for consumers was identified, the draft measure included a LOQ at 0.003 mg/kg for dry commodities and at 0.005 mg/kg for high-oil commodities. A Member State proposed the LOQ of 0.01 mg/kg for these commodities in case consumer exposure calculations would not raise risk concerns.

Member States were invited to provide their comments by 18 October 2019.