EUROPEAN COMMISSION

Health and Food Safety Directorate General

sante.ddg2.g.5(2018)5747771

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 18 SEPTEMBER 2018 - 19 SEPTEMBER 2018

(Section *Phytopharmaceuticals - Residues*)

CIRCABC Link: *https://circabc.europa.eu/w/browse/857a2351-36e2-47af-850c-0f4f20a76b96*

A.01 Proposed general approach for granting transitional periods.

Following Article 49 of Regulation (EC) No 396/2005, transition measures can only be granted when they are without prejudice to the obligation to ensure a high level of consumer protection. On the basis of the Member States' contributions to the discussion initiated at the June Standing Committee on Plants, Animals, Food and Feed, section Pesticides Residues (SC PAFF residues), a number of standard situations were discussed. It was agreed that the absence or the exceedance of a toxicological reference value, acceptable daily intake (ADI) or acute reference dose (ARfD), constitutes a risk generally preventing the granting of transitional periods. The same applies when genotoxicity of the parent compound or a metabolite is demonstrated or suspected.

However, further discussion and a case-by-case approach will be applied when the genotoxicity evaluation is not concluded, when the residue definition is obsolete and no new residue definition is available, and when a hazard is identified and triggers the human health related cut-off criteria of Regulation (EC) No 1107/2009.

It was clarified that the current practice to establish systematically a 6-month deferred application date for measures lowering maximum residue levels (MRLs) would remain unchanged. This period could however be shortened if a risk to consumers requires swift action.

A.02 Art. 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12 – updated table

   The Commission updated the table on substances prioritised under the Article 12 MRL review process and gave an overview on the state of play to the Committee.

2. Confirmatory data Art. 12 follow-up

   The Commission received extensive input from the European Food Safety Authority (EFSA) on its Working Document SANTE/E4/VW 10235/2016 relating to confirmatory data under the Article 12 MRL process. Once a stable draft is available, the Commission will distribute it to the Member States and seek their feedback.

A.03 Feedback from Legislation Committee:

The Commission informed the Committee on new active substances currently under discussion in the SC PAFF Section Legislation:

- Sodium hydrogen carbonate (currently approved as a basic substance and included in Annex IV of Regulation (EC) No 396/2005)
- Florpyrauxifen-benzyl
- BAS 750 F (mefentrifluconazole).

A.04 Specific substances:

1. Imazalil

   The Commission informed the Committee that in July 2018 it received a request for administrative review according to Article 13 of Regulation (EC) No 396/2005 referring to a recently published reasoned opinion on imazalil under Article 10 of Regulation (EC) No 396/2005 which identified new toxicological concerns for 3 metabolites. The requestor asked for withdrawal of the EFSA opinion

   The Commission informed the Committee that it rejected the claims of the requestor and concluded that there was no reason to require EFSA to withdraw its reasoned opinion.

   The Commission recalled that due to the horizontal nature of the new concerns identified by EFSA in this reasoned opinion, the Commission had asked EFSA to also revise the recently adopted Article 12 reasoned opinion for this active substance. Once this revision is available further discussions on risk management measures will be taken up.

2. Glyphosate

   The Commission outlined the envisaged approach to take the EFSA review of the existing MRLs for glyphosate according to Article 12 of Regulation (EC) No 396/2005 into account for amending the existing MRLs. Several Member States took the floor to express their views, in some cases preliminary, on the approach.

3. Propoxur

   A Member State reported recent findings of propoxur residues in beans. Propoxur has not been approved in the EU since 2002. A low ARfD of 0.0005 mg/kg body weight was set by the Canadian authorities in 2014. While propoxur falls outside the scope of Article 12 of Regulation (EC) No 396/2005, there is a need to review the MRLs in the light of this low ARfD.

   EFSA informed the Committee that they do not have sufficient data on file to perform a detailed assessment of the toxicological properties of propoxur. EFSA would welcome access to the information reviewed by the Canadian authorities.

   The Commission will reflect on the next steps, taking into account suggestions from Member States.

Member States were invited to provide comments by 12 October 2018.

A.05 News from the European Food Safety Authority:

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

EFSA informed that reasoned opinions for 7 substances are currently under preparation under the interim process of which 5 are at an advanced stage (Member States consultation already ongoing or expected in the next weeks). 21 evaluations are ongoing under the new procedure, of which 4 are at an advanced stage. Sodium hypochlorite will be addressed in a statement as no uses are currently authorised. These 21 evaluations will be finalised between now and June 2019.

Some Member States had already reacted to the table reporting the status of Article 12 confirmatory data, but reactions from more Member States are needed. EFSA invited the Member States to forward comments by 12 October 2018.

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

   So far, 34 Article 10 reasoned opinions have been finalised in 2018.

   A further 9 reasoned opinions are expected to be finalised in autumn 2018 among which 6 confirmatory data evaluations as a follow up of a previous Article 12 assessment. For 29 assessments, new clock-stops have been added. In total 54 assessments are currently in the clock-stop procedure.

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

   One reasoned opinion for acetamiprid was finalised in 2018. A mandate for an Article 43 review of imazalil had been sent to EFSA in July with a deadline of 30 September 2018.

4. EFSA work programme on Art. 12 for 2019

   The Commission introduced the draft work programme for 2019, which was developed in close collaboration with EFSA. It pointed out that due to ongoing preparations for Brexit (see agenda item A.19), the Rapporteur Member States (RMS) for meptyldinocap and novaluron were still subject to confirmation.

   Two Member States informed the Committee of a proposal to swap the launch dates for the MRL reviews for their substances to alleviate workload issues. No objections were raised.

   The Committee thus agreed to one amendment to the work programme for 2018, replacing aminopyralid (launch originally planned for December 2018) with maltodextrin. The Committee further agreed on the work programme for 2019 as introduced, with the addition of aminopyralid (launch now planned for June 2019) in place of maltodextrin.

A.06 Discussion on possible follow up to the EFSA opinion on food for infants and young children.

The Commission recalled the main conclusions of the EFSA presentation to the SC PAFF Pesticides - section Residues in June 2018 of its Scientific Opinion on pesticides in foods intended for infants and young children. The Commission informed Member States that it had consulted the EU Reference Laboratories (EU RLs) on the lowest analytical levels achievable for the quantification (LOQs) of these substances and had incorporated this information in an overview table. Findings of those pesticides in foods intended for infants and young children were also reported based on monitoring data from the years 2012 - 2016.

The Commission presented its initial view that legal action to set lower LOQs in foods for infants and young children would not be justified given the fact that there were hardly any findings in four years of monitoring, that most substances on the list were already not approved and that for many of them a lower MRL than 0.01 mg/kg was already applicable. However, it proposed to include this topic for discussion in the upcoming working group meeting of experts on pesticides monitoring to discuss whether specific substances should be suggested to be analysed in foods for infants and young children. It also proposed to consider including some of those pesticides in the work programmes of the EURLs without, however embarking into a large scale analytical development work.

A Member State supported the Commission's view and stated that further lowering of LOQs would not be reasonable, as resources should be spent in other areas rather than trying to achieve those very low levels. Moreover, if lower levels were proposed by the EURLs, these should be fully validated. This view was supported by another Member State.

Member States were invited to provide comments by 12 October 2018.

A.07 Project on data collection dithiocarbamates.

The Commission informed that the EURL Single Residue Methods (EU RL SRM) presented a report on the progress of the project (uploaded on CIRCABC) and expressed its disappointment that 6 months after the launch of the project, only 11 Official Control Laboratories (OCLs) from 3 Member States had updated the PestiPedia database, while a fourth Member State expressed its intention to update the database just before this meeting.

A Member State commented that it had little time to coordinate a sampling plan and stated that the system would be facilitated if operators/laboratories were able to upload the data themselves. It regarded the new task as an additional workload for Member States who are already carrying out inspections and report via several channels. Several Member States remarked that due to the organic nature of products to be sampled, priority given by Member States was low as most sampling programmes were risk based.

The Commission reminded that Member States had asked for an active role in the coordination of the data transmission but that a change of the procedure towards direct transmission of sample results from official control laboratories into the database would still be an option. Furthermore, to decrease overall workload, results from previous years could be submitted.

Two Member States stated that they intend to submit data. Another one informed that the data had already been transmitted to EFSA and that submission of duplicates should be avoided.

A Member State questioned the necessity to submit data for crops for which there were no intended uses. EFSA reminded of the purpose of this exercise to review the MRLs for dithiocarbamates in 2019 taking into account realistic background levels which could occur in crops covered by intended uses but also in crops with no intended uses. In both situations background levels would be needed to establish realistic MRLs. On the issue of duplicates, EFSA pointed out that it will include the already reported 2017 monitoring results from Member States into the database so that those data would not need re-submission. EFSA would welcome 2018 data on

crops for which not enough sample results are available yet from previous data collections.

One Member State asked about the impact of time elapsing between sampling and analysis. A Member State replied that storage conditions and sample preparation methods were essential, cryogenic milling being the best solution.

A.08 Honey - Technical guidelines for Note taking

The Commission thanked all Member States for their valuable input and explained the changes which lead to the newest revision of the Technical guidelines for determining the magnitude of pesticide residues in honey and setting maximum residue levels in honey.

The guidelines will apply as from 1 January 2020. This means that they will apply to all Article 12 reviews launched as from this data (date of EFSA data call-in on and after 1 January) and to all applications submitted by an applicant to a Member State on and after that date).

Two Member States underlined the importance of updates at regular intervals once experience is gained. The Commission confirmed that this was planned. One Member State inquired if the size of the treated plots could be detailed more precisely for field studies. This was noted as a point for a future revision.

One Member State mentioned that a working group under the Organisation for Economic Co-operation and Development (OECD) will start to work on the setting of MRLs in honey in 2019 and will use the EU guidelines as a starting point for the discussions.

The Committee took note of revision 9 of the Technical guidelines.

A.09 Cumulative risk assessment – for Note taking by the Committee of certain assumptions for retrospective scenario as discussed during the WG of experts on CRA on June 2018.

The Commission informed the Member States of the outcome of the expert working group meeting on CRA that took place on 15 June 2018 and thanked the experts for having actively contributed to its successful outcome. Experts from 20 Member States had participated and reached consensus on the parameters for certain assumptions related to risk management aspects for the retrospective (post-authorisation) scenario.

The Commission noted that these assumptions concern specific chapters of the Commission working document on CRA and refer to the margin of exposure (§3.2), the percentile of the exposure distribution (§3.2) within a whole population approach (§3.5.2.1), the handling of non-quantified residues (§3.5.3.1, §3.5.1.2), the use of processing factors (§3.5.3.3), pesticide residues in drinking water (§ 3.5.3.4), the variability factor (§ 3.5.4) and the handling of occurrence data (§ 3.5.1.1).

One Member State expressed its concerns about the proposed two-tier approach as this could raise communication issues and supported a one-tier approach. The Commission reminded that a two-tier approach had been selected as a means to save resources, but that on the basis of the discussion during the expert working group, a one-tier approach would be a future perspective.

Another Member State pointed to the communication issues that need to be addressed following the new approach.

The Committee took note on the selected aspects which can now be used for future exposure assessments. The Commission announced that as a next step risk management issues related to the prospective scenario (regulatory MRL setting scenario) would be discussed within the expert working group. The Member States welcomed that the discussion on CRA was progressing given the importance of the issue.

A.10 Work organisation for next monitoring exercise 2020, 2021, 2022.

The Commission reminded of the upcoming working group meeting of experts on monitoring of pesticide residues on 12 October 2018 for which experts had been nominated by the Member States. The Commission informed the Member States that invitations were already sent out including a provisional agenda inviting them to highlight any additional topics of interest.

A.11 Screening exercise on temporary MRLs in Regulation (EC) No 396/2005 that will expire in 2018-2020.

The Commission gave an update on the state of play. Data had been submitted for all temporary MRLs expiring before 2020. The next substance to be dealt with is chlormequat for which a temporary MRL had been set for table grapes. The Commission proposed to establish a permanent MRL by taking over the Codex maximum residue limit (CXL) adopted this year by the Codex Alimentarius Commission within the routine measure taking over a range of CXLs to be voted in November 2018.

A.12 International Matters.

1. Follow-up to CCPR 2018

   The Commission informed Member States that it had received draft concern forms for diflubenzuron, iprodione and picoxystrobin. The missing draft concern form for buprofezin will be sent by the RMS soon, which will allow the Commission to send all the concern forms to the Codex secretariat.

   Regarding the concern forms already submitted for aldicarb, almitraz, azinphos-methyl, bromopropylate, dicloran, fenarimol and phosalone, following the request from the Joint FAO/WHO Meeting on Pesticides Residues (JMPR) to indicate the key studies that led to the identification of the concerns, EFSA will answer directly to JMPR and keep the Committee informed.

   Regarding the 'Discussion paper on the management of unsupported compounds', the Commission indicated that it does not intend to coordinate a position at this stage and invited Member States to provide their comments directly to the electronic working group (eWG). The Commission clarified that it would coordinate the EU position on that item after finalisation of the work of the eWG for the next meeting of the Codex Committee on Pesticides Residues (CCPR).

   Member States with a special interest in the various electronic Working Groups reported on the progress made so far in their work.

   The Member State chairing the working group on the equation of the Internationally Estimated Short Term Dietary Intake (IESTI) announced that due to internal changes it would not be in a position to continue as chair of the eWG

on the review of the IESTI equations beyond the current mandate (up to and including the 2019 CCPR).

2. Principles for EU positions

   The item was not discussed, as this point had already been concluded at the meeting of the SC PAFF pesticides – section residues on 13-14 June 2018.

3. Other International issues, e.g. developments in OECD

   The Commission provided feedback on the on-going work carried out by the OECD Residue Chemistry Expert Group on the update of its 2009 'Guidance document on the definition of residues' to also cover veterinary medicinal products. Data is currently being gathered to incorporate elements that are reported in the various guidelines that exist on the topic, among which the EFSA guidance document on the residue definition for risk assessment.

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

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

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

An application for an import tolerance request for cyflufenamid on hops had been submitted to a Member State which is not the RMS for this substance. The RMS, accepted that this Member State takes the role of Evaluating Member State for the assessment for this particular application. The Committee took note of this agreement.

A.15 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The Commission informed that the external contractor had submitted a final version of the study, which had been agreed upon previously by the Commission's Inter-Service Steering Group. Some minor amendments still need to be made before publication of the study, which is expected in October 2018.

A.16 Update on the technical guidelines for MRL setting for Note taking (SANTE/10595/2015).

The Commission informed that the Note Taking was postponed as several Member States had asked for a further opportunity to comment on the document, in particular on the section on how to handle import tolerances and Codex maximum residue limits for substances falling under the cut off criteria for which a further discussion took place.

A presentation was made on the new elements included in the document. In particular, the Commission invited Member States to reflect on a way to prevent as much as possible the use of the clock-stop procedure by EFSA to make the process more efficient.

A Member State commented that communication should be improved regarding the endorsement of new toxicological endpoints. It stressed the importance of good coordination and communication between the two relevant sections of the SC PAFF pesticides, sections residues and legislation, to minimise the time after which action is taken on the review of MRLs following the lowering of an ARfD.

Another Member State and EFSA requested that further clarification should be provided regarding the section of PAFF which is responsible for note-taking of the residue definition for risk assessment.

Member States were invited to provide comments on the MRL guidelines by 19 October 2018.

Discussion on MRL setting for herbal infusions:

A Member State had requested to take up a discussion on MRL setting for herbal infusions and how to handle own control data in this context given that there were only few official control results for these products. Issues were identified with regard to small crops included in Part B of Annex 1. The Commission signalled that the item could be taken up but should be discussed separately from the MRL guidelines. It summarised the legal situation for MRL setting under Article 16 (1) (d) of Regulation (EC) No 396/2005 and the data requirements of Regulation 283/2013 (Annex point 6.7.2. and 6.7.3.) for herbal infusions which allow temporary MRLs to be established based on monitoring data (whole population, not only positive findings) and a risk assessment by EFSA. However, the Commission underlined that this could only be done in limited and exceptional cases which would need to be well defined exemptions from the obligation to carry out residue trials and would always be of temporary nature. Further discussion is planned for a forthcoming meeting but the Commission highlighted that this was not high priority.

A Member State supported the Commission's view that the setting of MRLs on basis of monitoring data should be limited to well defined exceptional cases. Another one supported that whole datasets be used, not only positive findings as is the case currently in the FAO spices approach.

A.17 Extraction efficiency guidance document.

The agenda item was cancelled as it had been added to the draft agenda by mistake.

A.18 Exchange of experiences with EFSA PRIMo rev. 3.

Since at the last meeting the discussion on this issue had been rather short, the Commission gave the Member States the opportunity to further share experiences. Following a question from a Member State in advance of the last meeting that had come up during product authorisation, another Member State had shared its experiences and ways to handle this kind of situations. The Commission considered this exchange very useful and invited the other Member States to share their experiences as well. EFSA reported about a minor revision of the Primo model (rev. 3.1) which would fix certain bugs and would be presented at the November meeting of the SC PAFF pesticides section residues. Consumption data for infants/toddlers and the new data submitted via the Member States' surveys will be included in rev. 4 which will be a major revision. Revision 4 will translate aggregated data from the food consumption databases (with many composite products) into raw commodity consumption figures to be used for exposure assessments for pesticides residues. A Member State reported about a mistake in its consumption data for maize and will follow up on this. Another Member State asked about the new functionality for automatic import of information from the Pesticides Database that had been announced by EFSA at the last meeting. EFSA informed that it was working on this but that the work was not yet finalised. EFSA remarked that generally there was a need for further harmonisation between Commission and EFSA databases. A Member

State asked whether the variability factor of 7 used for avocado was correct. EFSA confirmed that this was the correct factor.

A.19 Preparation for Brexit.

Following the discussions in the PAFF pesticides section residues on 13-14 June 2018 and PAFF Pesticides - section Legislation on 19-20 July 2018, and subsequent comments received from Member States, the Commission presented a revised designation of Member States as back-up, for files (applications and other evaluations under Regulations (EC) No 396/2005 and 1107/2009) currently processed by the United Kingdom. It referred to the document on CIRCABC for the individual designations per file and the revisions in track changes.

Endorsement is envisaged to take place at the meeting of the Committee's section Legislation on 23-24 October 2018. Member States were invited to coordinate internally ahead of that meeting.

A.20 Dealing with non-approved basic substances.

One Member State presented its interpretation of the provisions of the pesticides legislation as regards basic substances according to which the setting of MRLs for basic substances would not be necessary. The Commission will request some legal advice on this and other issues related to basic substances.

One Member State proposed to assess the consumer exposure for non-approved basic substances, if not food, according to the Guidance document on botanical substances. The Commission presented its view that because the substances were not approved such an assessment could not be requested from the applicants for basic substances and should therefore be submitted by a Member State or third party via an Art. 6 application. Member States were invited to provide comments on this approach by 12 October 2018. If agreed, this approach would be included in the Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005 (SANCO/11188/2013).

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, clomazone, cyclaniliprole, fenazaquin, fenpicoxamid, fluoxastrobin, lambda-cyhalothrin, mepiquat, onion oil, thiacloprid and valifenalate in or on certain products (Art. 10).

The Commission introduced the draft measure and presented its content.

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

- chlorantraniliprole for the use on hops (import tolerance);
- clomazone for the use on chamomiles and plantains;
- fenazaquin: for the use on almonds (import tolerance);
- fenpicoxamid for the use on wheat and rye (EU) and bananas (import tolerance);
- fluoxastrobin for the use on garlic and oilseeds;

- mepiquat for the use on oilseeds;
- thiacloprid for the use on borage seeds and radishes;
- valifenalate for the use on various crops.

As regards lambda-cyhalothrin, a recent Regulation had erroneously lowered the MRL for rye to the limit of quantification (LOQ). The current draft measure reinstates the Codex limit for rye, which had been adopted by the Codex Alimentarius Commission in 2009. This value will be applicable as of 26 January 2019 in the interest of legal certainty.

Onion oil had recently been approved under Regulation (EC) No 1107/2009 as a basic substance. The draft measure includes the substance in Annex IV to Regulation (EC) No 396/2005.

As regards mepiquat, the draft measure extends the validity of the temporary MRL set for mushrooms. Recent monitoring data provided by Member States and stakeholders showed that mushrooms contain mepiquat at values above the LOQ. This is due to the fact that mushrooms are often grown on straw lawfully treated with mepiquat. The current MRL was recently assessed and it is safe for consumers.

Cyclaniliprole is not approved and all MRLs have already been set at the LOQ. The draft measure transfers this substance to Annex V to Regulation (EC) No 396/2005 listing non-approved substances for which all MRLs are set at the relevant LOQs. Following a comment made by some Member States, the LOQs were increased for those products which are difficult to analyse (i.e. fresh herbs, teas, hops, spices and honey).

Vote taken: Favourable opinion.

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 acetamiprid in certain products.

The draft measure had already been presented at the SC PAFF pesticides section residues in June 2018.

The Commission had received comments from non-EU countries during the WTO/SPS consultation period. They had been shared with the Member States in advance of the meeting. These comments do not affect the content of the draft measure as EFSA has identified clear risks to consumers in the Union in relation to the existing MRLs.

The only outstanding point concerned the MRL to be set for escaroles. The Committee agreed to set a temporary MRL in support of the use currently authorised in the Southern EU. Some trials still need to be performed on open-leaf varieties to set a permanent MRL. The applicant has been requested to submit the missing trials within two years from publication of the Regulation.

A consultant recently submitted information on some possible fall-back GAPs, which had not been considered by EFSA in the framework of the MRL assessment. A Member State clarified that the respective GAPs would lead to unsafe uses when considering the newly adopted ARfD.

One Member State abstained because of the wording used for transitional measures in Article 2.

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, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromadiolone, etofenprox, paclobutrazol, and penconazole (Art. 12).

The Commission informed the Committee that the footnotes accompanying the MRLs for penconazole were modified to include the request for metabolism studies for all MRLs and that no other modifications were made compared with the version discussed at the meeting of the SC PAFF pesticides section residues in June 2018.

One Member State abstained because of the wording used for transitional measures in Article 2.

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 IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben in or on certain products (Art.12).

The draft measure had already been presented at the SC PAFF pesticides section residues in June 2018.

The Commission informed that the MRL tables for carboxin and fenbutatin oxide had been updated following comments from the Member States and that the footnotes for bromuconazole related to the rotational crops field studies data gap were updated.

Following the notification under the WTO/SPS agreement, comments had been received from non-EU countries which had been shared with the Member States in advance of the meeting. The Commission summarised the key points.

One Member State pointed out that although no residues are expected for carboxin, the potential for aniline formation should be highlighted.

EFSA highlighted that the reasoned opinion for bromuconazole included data gaps related to triazole metabolites and that since the review of confirmatory data on triazoles had been published in September 2018 the same approach would be followed for future reasoned opinions on substances belonging to the triazole group.

One Member State abstained because of the wording used for transitional measures in Article 2.

Vote taken: Favourable opinion.

B.05 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 linuron.

The Commission introduced the draft which remained unchanged compared to the version presented in the SC PAFF pesticides section residues in June. The Commission had received comments from stakeholders which had been shared with the Member States in advance of the meeting. No comments from non-EU countries had been received during the WTO/SPS consultation period. No transition measures were proposed as a consequence of the conclusion reached under agenda item A.01 and due to the fact that the consumer risk assessment could not be finalised by EFSA.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for iprodione.

The Commission presented the draft which remained unchanged compared to the version presented in the SC PAFF pesticides section residues in June. The Commission had received comments from stakeholders as well as from non-EU countries during the SPS/WTO consultation which had been shared with the Member States in advance of the meeting. As a consequence of the conclusion reached under agenda item A.01, and due to the suspected genotoxicity of iprodione metabolite RP 30228, the Committee agreed to maintain the draft Regulation without transition measures.

Vote taken: Favourable opinion.

B.07 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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim.

The Commission introduced the draft measure and presented its content.

The Commission referred to written comments from Member States received ahead of the meeting and provided further explanation.

The Commission drew Member States' attention to the comments received from non-EU countries and stakeholders. While all comments were available to Member States, the Commission presented a summary of the key points raised.

The Commission considered that in view of the health concerns leading to the restriction of approval of buprofezin and diflubenzuron, and non-approval of picoxystrobin, a high level of consumer protection is not ensured when residues up to the current MRLs are present, regardless of the country of origin. This view is based on the latest assessment available in the EU. If interested parties have information to address the concerns identified and demonstrate a high level of consumer protection for one or more substance/commodity combinations, they should submit an application according to the pertinent articles of Regulation (EC) No 396/2005 resp. 1107/2009.

Two Member States, while not opposing the draft presented for vote, requested that the maximum length of grace periods allowed following restriction of approval or non-approval should be proportionate to the concerns identified.

One Member State abstained because of the wording used for transitional measures in Article 2.

Vote taken: Favourable opinion.

C.01 Exchange of views of the Committee 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 the draft measure and updated the Member States on comments received referring to the explanatory note revision 1 currently uploaded on CIRCA BC.

For bispyribac, following comments received, the Commission proposed a change in the residue definition to include its esters in alignment with other acidic substances. For fenoxycarb and flurochloridone the MRL table was updated.

For quizalofop-P-ethyl, quizalofop-P-tefuryl and propaquizafop, the Commission presented a detailed table of general rules on how to deal with these different esters when setting MRLs, extrapolations or the setting of confirmatory requirements. Examples on how these rules would be applied in the proposed review of MRLs were also provided. The Commission requested the Member States' views on these rules and highlighted in particular the question whether or not a footnote requesting confirmatory data should be included to indicate data gaps relating to the trials of quizalofop P esters that were not found to be supporting the most critical Good Agricultural Practice (GAP).

A Member State asked whether trials for a particular substance of this group of compounds could be used for other substances of the group. On the basis of the outcome of EFSA's Reasoned Opinion, EFSA and the Commission confirmed that this was possible. EFSA suggested that a footnote should be placed to identify the data gaps for each ester, where applicable, per crop and also supported to carry over confirmatory data requirements from the main crop to extrapolated crops. EFSA suggested that a dehydration factor should be taken into account when extrapolating from carrots to herbal infusion roots.

For tebufenozide, the Commission made reference to the comments received from a Member State on the rotational crop studies, further requiring confirmatory data since the ones that were taken into account included JMPR data for which it was not clear if the metabolite JH-1788 had been considered. The Commission also addressed the issue of data gaps for CXLs which would not be covered by confirmatory data requirements.

Member States were invited to provide comments by 12 October 2018.

C.02 Exchange of views of the Committee as regards maximum residue levels for for 2,5-dichlorobenzoic acid methylester, mandipropamid, prochloraz and profoxydim in or on certain products (Art. 12).

The Commission proposed to limit the residue definition for 2,5-dichlorobenzoic acid methylester to the parent compound only, following the advice of the EU RLs.

Concerning prochloraz, the Commission proposed to establish the residue definition recommended by EFSA which would include the metabolites BTS 44595 and BTS 44596. It invited Member States to reflect on the proposal from the EURLs to limit the residue definition to the parent compound only, given the low occurrence of these metabolites as well as on the possibility to maintain CXLs for some tropical fruits where no health concerns were identified. Such MRLs would be accompanied by a footnote requiring new trials based on the new residue definition or, if possible, recalculations from previous trials to establish appropriate MRLs.

Concerning profoxydim, the Commission recalled the request made by EFSA to the RMS for that active substance to specify other possible sources of the common moiety thiopyranylcyclohexenone, which is included in the proposed residue definition. The EU RLs alerted about the non specificity of the residue definition, which would cover residues of cycloxydim, and about the lack of analytical methods to enforce that residue definition. The EURLs therefore advised to limit the residue definition to the parent compound only.

Member States were invited to provide comments by 12 October 2018.

C.03 Exchange of views of the Committee as regards maximum residue levels for chlorate.

The Commission thanked EFSA for the comprehensive and speedy work on a detailed statistical analysis for the new collection of monitoring data. Statistics were calculated for the data collected between 2015 and 2017, compared with the statistics previously calculated for the period 2011 and 2015 and calculated for all pooled data.

For the commodities containing high levels of chlorate between 2011 and 2015, the more recent data show an important decrease. For example, concerning broccoli, the 90th percentile decreased from 910 µg/kg to 30 µg/kg chlorate and the 95th percentile from 2400 mg/kg to 450 mg/kg.

Overall, the new data suggest that the food industry has improved to a certain extent its manufacturing practices regarding the use of chlorinated disinfectants for the washing of fresh products or for the blanching of products to be frozen and that consumer exposure to chlorate has decreased.

On the basis of the new data collected, the Commission made new proposals for chlorate MRLs, referring to the highest 95th percentile calculated for the 2 periods 2015-2017 and 2011-2017. The Commission justified this new approach by the lower margin of manoeuvre for the food industry to further lower chlorate levels and therefore the appropriateness of the use of the 95th percentile versus the 90th percentile of all occurrence data for the setting of chlorate MRLs.

While several Member States asked for more time to analyse the new data and to consider this new proposal, some Member States already supported this new approach. One Member State did not find the choice of the 95th percentile justified in the light of the health concern at stake.

Some Member States also pointed to the need to fulfil hygiene requirements that could lead to chlorate and that the collected data were not always representative of all the production processes used in the EU.

Some Member States recalled that drinking water was by far the main contributor to chlorate intakes and that the setting of a low level for chlorate was necessary in the context of the revision of the Directive on drinking water.

The Commission invited Member States to comment on the new proposed maximum level of chlorate by 12 October 2018.

M.01 Working document on the nature of pesticides residues in fish.

The point was added to the agenda on request of one Member State. The Member State informed the Committee that it had updated the working document on the nature of pesticides residues in fish with some new chapters on the magnitude of residues and dietary burden calculations. The other Member States were invited to comment directly to that Member States with copy to the Commission by 30 October 2018.

M.02 Invitation of a number of trade organisations for an evening event on 18 September.

The Commission informed the Member States about an evening event organised by a group of trade associations on the issue of transitional periods to which Member States were invited.

M.03 Number of trials for seed treatments.

The item was added to the agenda on request of a Member State. The Member State requested a clarification on the number of trials needed for seed treatments which appear in the same column as post-harvest uses in the extrapolation guidance document (SANCO 7527/VI/95 Rev. 10.3). It is not clear whether trials from one single zone (as for post-harvest uses) would be sufficient and whether the principles laid down in the draft seed treatment guidance (SANCO/10553 2012 March 2017 rev12) would apply to MRL setting as well. Another Member State welcomed this discussion and referred to international discussions ongoing in relation to minor uses. Another Member State informed that it was currently preparing a document on this issue which would be presented in the next meeting of the SC PAFF pesticides section residues. The Commission will take this issue up in the agenda of a forthcoming meeting.