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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Residues*
13 - 14 June 2019

CIRCABC Link: *https://circabc.europa.eu/w/browse/53907e11-09f6-412b-8ad9-26e8c650f38d*

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.

Two Member States requested 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 updated the table with proposed follow-up actions for several substances that went through the Article 12 confirmatory data process.

The following proposals were made:

i. Bentazone: to be addressed by a draft measure, which needs to be notified through the World Trade Organisation's Sanitary and Phytosanitary Standards system (WTO-SPS). In view of the new feeding study submitted by the applicant, MRLs will be amended for products of animal origin. For potatoes EFSA identified a fall-back Good Agricultural Practice (GAP) requiring an MRL of 1,5 mg/kg. The Commission invited Member States to pay attention to the fact that for leeks no fall-back GAP was identified, thus the MRL will be lowered to the Limit of Quantification (LOQ).

ii. Flutolanil: to be addressed in a routine MRL measure deleting the footnotes requesting confirmatory data. A specific recital will be drafted highlighting that data was not submitted for peppers. Member States have to decide whether authorisations can be still granted at national level.

iii. Imazamox: to be addressed in a routine MRL measure deleting the footnotes requesting confirmatory data. The Commission clarified that there is no need to lower the LOQs to lower values than the ones recommended by the EU Reference Laboratories (EURLs) in the framework of the Article 12 review.

iv. Spinosad: to be put on hold pending the renewal decision. By using the newly established Acute Reference Dose (ARfD), an acute risk to consumers could not be excluded for several products. Pending the outcome of the renewal process, the Commission might ask EFSA to perform a focussed assessment on the existing MRLs.

Member States were invited to submit comments by 5 July 2019.

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

The Commission presented the comments received by the Member States on the follow-up table presented at the Standing Committee meeting on Plants, Animals, Food and Feed, section Phytopharmaceuticals – pesticides residues (SC PAFF) of 21/22 February 2019. For sodium silver thiocyanate and sodium hypochlorite the MRLs will be maintained at the default value of 0.01 mg/kg. Fatty alcohols, 1-decanol and 1-abscissic acid are already proposed to be permanently included in Annex IV of Regulation (EC) No 396/2005 under the draft Regulation for vote under point B.01 of the agenda of this meeting. Potassium thiocyanate is proposed to be removed from Annex IV once an analytical method is available to control the default MRL of 0.01 mg/kg that will then become applicable. The EURL for Single Residue Methods (EU RL SRM) will be requested to develop such a method. On tall oils (crude and pitch), the Commission had received diverging views from Member States and proposed to remove the substances from Annex IV and apply the default value as data are not available to prove the absence of toxicity. The Commission considers that the conditions of the Guidance Document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (SANCO/11188/2013) are not fulfilled. This view was supported by one Member State. Several other delegations requested to maintain the substance in Annex IV due to its natural occurrence despite the uncertainties about its toxicity. The Commission invited the Member States that had not yet taken the floor to comment by 5 July 2019.

A.02 Feedback from Legislation Committee

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

The Commission informed the Committee that the new active substance *Verticillium albo-atrum* (formerly *Verticillium dahliae*) strain WCS850 was under discussion in the SC PAFF, section Phytopharmaceuticals - Legislation.

A.03 Specific substances:

1. **Propoxur**

The Commission informed the Committee that it will mandate EFSA to review the assessment published by Health Canada, as agreed at the meeting of the Committee on 21/22 February 2019.

2. **Tricyclazole/India**

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

measures will be discussed first among Commission services, and as appropriate at the pertinent expert group and the Committee's section on Controls and Import Conditions.

3. **Chlorpropham**

The Commission informed that the approval for chlorpropham had not been renewed and that the non-renewal decision would be published on 18 June 2019[1]. The Rapporteur Member State (RMS) made a presentation on the proposed methodology for the setting of a temporary MRL for chlorpropham in potatoes to address cross-contamination in storage facilities. The RMS had started assessing the available data, but had identified some specific issues for agreement of the Committee beforehand. The RMS also stressed that the manufacturer/producer still needs to generate a written guideline for most efficient cleaning practices. Two residue definitions for risk assessment with two different toxicological profiles are set separately for chlorpropham and 3-chloroaniline with 3-chloroaniline being the main driver for the risk assessment due to its lower ARfD.

A Member State questioned the conclusion that no animal studies were necessary to investigate bioavailability while another Member State thought that such studies would probably not be necessary. The RMS confirmed that it was in favour of limiting animal studies as much as possible. A Member State requested that occurrence data below the LOQ would be assessed using middle bound values alongside upper bound and lower bound values in order not to over- or underestimate exposure. The RMS confirmed that it would present several options.

Member States were invited to submit comments to the RMS and the Commission by 19 July 2019.

4. Carfenthrazone-ethyl

The Commission informed that it would soon take up again the Article 12 review of carfentrazone-ethyl which had been put on hold in 2016 due to expected changes of endpoints in the renewal process. Since the renewal process had been concluded and had confirmed the existing endpoints, the Article 12 review can now resume. Minor modifications of the original draft Regulation are needed to take into account a minor change in the expression of the residue definition of enforcement as well as analytical progress with LOQs and the guidelines on summing up LOQs.

5. Copper MRLs

The Commission referred to the publication of the EFSA Conclusion on the peer review of copper compounds and the EFSA Reasoned Opinion on the review of existing MRLs for copper compounds. It recalled that the approval of copper

[1] Post Meeting Note: Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 160, 18.6.2019, p. 11), Link: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1560932540431&uri=CELEX:32019R0989

compounds had recently been renewed. In the MRL review, EFSA had identified a possible chronic risk to consumers and corresponding risk mitigation measures.

The Commission plans to prepare a measure based on the MRL review and invited Member States to provide early input to the preparations, by sharing observation on consumer risk and mitigation measures as well as any general comments by 9 August 2019.

Two Member States recalled the discussion at the Committee meeting of 13/14 June 2018 and highlighted that the ongoing procedure for renewal of authorisations is likely to lead to amendments of authorised GAPs, in view of the new and more restrictive approval conditions. Once the renewal of authorisations is complete, the MRL review may need to be updated, and all possible risk mitigations options examined based on the updated MRL review.

Another Member State reported an increased number of non-compliances in certain products of animal origin and asked that any delays to the follow-up are kept to the minimum.

Member States were invited to submit comments by 9 August 2019.

6. Pesticides residue findings on mushrooms

The Commission had recently addressed occurrences of chlormequat and mepiquat in mushrooms by setting temporary MRLs. In March 2019, the Commission had a meeting with the European Mushroom Growers' Group to better understand the extent to which transfer of residues might occur and also identify those active substances that might pose a problem in the future. The group presented several options on how the issue could be addressed. This could include requirements for the applicant to already consider the use of treated cereal straw as growing medium for mushrooms when submitting data supporting an application for a higher MRL for cereals (similar to the approach currently taken for animal products), the use of certain transfer factors and label restrictions. The Commission asked the Member States and EFSA for their views and possible further suggestions and proposed to address the issue in a systematic and forward looking way instead of taking a reactive approach to already existing problems.

EFSA and a Member State suggested that the applicant should calculate transfer factors to predict the levels found in cultivated mushrooms. EFSA also suggested to differentiate between different species of mushrooms in the framework of the data reporting for the annual monitoring programme, although it was acknowledged that most of the samples are taken from Agaricus species which are the most widely consumed. Another Member State pointed out that in general the level of compliance with MRLs for mushrooms would be high, thus necessitating little attention in Member States' risk based national programmes. That Member State clarified that occurrences of mepiquat and chlormequat had previously not been in the focus of control authorities due to the need to use extra single residue methods.

The Commission will draft a discussion paper providing some background information and outlining the various options to address the issue.

7. Prochloraz

The Commission recalled that prochloraz had initially been included in a previous draft Regulation, but that the vote 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.

The Commission clarified that after having carefully checked the matters of concern, it does not see any reason to amend the proposed values and will prepare a draft Regulation on the basis of the previous draft in view of a vote at the next meeting of the Committee.

8. Dimethoate- follow up to non-renewal decision

The Commission informed the Committee on its intention to draft a measure lowering the MRL for cherries following the non-renewal of dimethoate. The measure is expected to be presented to the Committee in autumn when the 3-month grace period for cherries will have expired. The draft measure will also lower the MRL for omethoate. The MRLs for other crops will be reviewed only at a later stage when the relevant longer grace periods will have expired.

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 made a presentation on the work programme for Article 12, which is currently addressing 39 active substances (38 in the new procedure and 1 in the interim procedure). EFSA reported that the updated reasoned opinion for glyphosate is expected to be published in October.

The Committee discussed substances that could be added to the work plan for MRL reviews in 2019, where substances for launch in October and December 2019 have not yet been designated.

The MRL review for cyproconazole (RMS IE) can be scheduled for December 2019.

MRL reviews for quinoxyfen (RMS UK, co-RMS AT) and spirodiclofen (RMS AT) could be scheduled in 2019 as well, but the (co-)RMS indicated lack of resources due to other ongoing commitments in both peer review and MRL review. The Commission invited Member States to consider their availability to take over the MRL review for one or both substances from the RMS by 25 June 2019.

Orthosulfamuron is not approved and the only remaining MRL will be deleted upon adoption of the draft Regulation presented for an opinion of the Committee under agenda item B.04. As there are no Codex MRLs in place for the substance, EFSA could fulfil its obligation under Article 12 of Regulation (EC) No 396/2005 through inclusion in a statement.

Oxadiazon has the same status as orthosulfamuron except for one MRL established for the group of small berries. The origin of that MRL needs to be verified before deciding on the appropriate way forward. One Member State indicated that the MRL had been put forward by the United Kingdom during the harmonisation of MRLs following the entry into force of Regulation (EC) No 396/2005. The Commission invited the United Kingdom, or any other Member State holding pertinent information, to clarify by 25 June 2019 whether the MRL for oxadiazon in the group of small berries is based on an import tolerance request.

The MRL review for zoxamide should be postponed until end-2021 in view of the pending Category IV data requests in the context of the renewal of authorisations that are relevant for the sections of residues and analytical methods.

Further information from the RMS Hungary is necessary before deciding on the appropriate way forward for *Gliocladium catenulatum* strain J1446 (*Clonostachys rosea* strain J1446).

Member States were invited to send comments addressing the points mentioned above on quinoxyfen, spirodiclofen and oxadiazone by 25 June 2019.

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

In 2019, EFSA finalised 20 Reasoned Opinions and is currently assessing 27 applications. EFSA stressed that there is a total of 52 applications, which are still under the clock-stop procedure in spite of the efforts made to reduce the number. Information is still needed from several Member States who will now be contacted by EFSA bilaterally. Under this agenda point EFSA also reported on the development of a new more user friendly GAP table in Excel format.

EFSA requested comments from the Member States on possible options to deal with GAPs reported in previous Article 10 assessments but then later not reported in the GAP overview file that serves as basis for the Article 12 review process.

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

EFSA has recently published the statement on the dietary risk assessment for the proposed temporary MRL for chlormequat in oyster mushrooms.

CCPR:

The Committee discussed the designation of Member States to substances without RMS for the purpose of Codex preparations. The Commission invited the co-RMS Belgium to confirm its availability to take over mesotrione from the RMS United Kingdom after Brexit, and all Member States to consider their availability to take on methoprene, and provide feedback to the Commission by 25 June 2019.

Member States were invited to send comments on mesotrione and methoprene by 25 June 2019.

The Commission informed that it will also prepare the mandate to EFSA for the assessment of substances that will be covered by the two 2019 meetings of the Joint FAO/WHO Meeting on Pesticides residues (JMPR).

4. **Strategy for risk assessment of triazole fungicides**

A discussion took place on how to handle triazole derivative metabolites (TDM) in the framework of Article 6 applications and the Article 12 review process. The Committee agreed to set an application date of 1 September 2019 for the new strategy:

- For applications received by a Member State under Article 6 or within the context of the renewal process (date of receipt of application by a Member State)
- For Article 12 reviews (date of data call-in by EFSA).

Furthermore EFSA proposes a monitoring programme for TDMs and a comprehensive TDM risk assessment for which a way forward was outlined. The

strategy paper from EFSA will be updated in the light of the comments received from Member States. As regards monitoring, a discussion will take place in the next expert group on monitoring that the Commission plans to hold in autumn 2019.

5. **PRIMo rev. 3.1**

   The presentation of the PRIMo model revision 3.1. was postponed due to lack of time.

6. **Cumulative RA – further steps by EFSA and COM**

   EFSA presented the current developments for the pilot project of assessing the cumulative risk for the chronic and acute effects of pesticide residues on the thyroid and the nervous system, respectively, and announced the publication by mid-September 2019 of 2 batches of 4 documents. For each of the two organs concerned, the thyroid and the nervous system, EFSA will publish 4 reports:

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

   EFSA provided a brief overview of the methodology that was followed, explaining that the project is based on the monitoring results from 2014, 2015 and 2016 for 10 population groups and 30 commodities by using both the EFSA-developed SAS© software and the EuroMix MCRA software. EFSA clarified that the methodology is based on the assumptions that were agreed with the Member States in the meeting of the SC PAFF – section Phytopharmaceuticals – Pesticides Residues, in September 2018, provided a brief overview of the methodology followed for the uncertainty analysis and presented the outcome. EFSA explained that the results are mainly driven by:

   - single substance/commodity combinations and not by co-exposures,
   - missing processing factors (PFs) and
   - non-compliant samples (samples exceeding MRL).

   The Commission thanked EFSA for the huge amount of work on this important project and welcomed the explanations on risk drivers which clearly show that high exposures can be effectively addressed by risk managers and that some of the issues identified had already been addressed.

7. **Presentation of annual monitoring report**

   EFSA made a presentation on the main findings of the draft annual monitoring report 2017 for which publication is planned for end of June 2019 and which shows that overall the residue situation is well under control.

   In light of the plan to report cumulative exposure in the context of the monitoring exercise as from the reporting year 2020 onwards, EFSA requested Member States to voluntarily report qualitatively findings above the limit of detection, but below

the LOQ. The sample description (SSD) format will be adapted accordingly. Member States had different views on this approach. Furthermore, EFSA presented a modified approach for the timing and reporting of data as from the reporting year 2019 onwards (start of data collection in 2020), including new visualisation tools and output, as well as a different consultation strategy. One Member State already indicated that it would have difficulties with the timelines. Member States were asked to comment by 5 July 2019.

A Member State requested that the residue definition for risk assessment would be more appropriate to be used in the context of exposure assessment instead of – as current practice – the residue definition for enforcement. EFSA replied that conversion factors were not always available to do this. On request of a Member State it furthermore explained that the project to compile risk assessment endpoints was currently put on hold due to lack of resources. EFSA clarified that any quantified analyte should be reported separately and as a sum to give EFSA the biggest possible flexibility in carrying out exposure assessments. For example for aldicarb also findings of sulfoxide and its sulfone should be reported.

A.05 Foods for infants and young children.

The Commission informed that work is on-going on this topic and that further details would be provided in the next meeting of the Committee. A presentation of the EU RL SRM on the analytical project for foods for infants and young children had been uploaded on CIRCA BC.

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

The Commission referred to the comments received from Member States and a non-EU country, and presented a revised draft document. While two Member States supported the approach and wording of the presented document, a non-EU country and another Member State suggested alternative wording. The Commission will examine whether the proposed alternative wording will improve the document without shifting the balance proposed in the document regarding proportionate action.

A.07 Project on data collection dithiocarbamates.

The Commission informed that work is on-going on this topic and further details would be provided at the next meeting of the Committee. A presentation of the EU RL SRM on the data collection project for dithiocarbamates had been uploaded on CIRCA BC.

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

The Commission reminded the Committee that temporary MRLs had been set for benzalkonium chloride (BAC) and didecyldimethylammonium chloride (DDAC) by Regulation (EU) No 1119/2014 on the basis of the available monitoring data and the reasoned opinion of EFSA (2014). Those temporary MRLs should be reviewed to evaluate new data and information that will become available by 31 December 2019. For this purpose, the Commission will ask EFSA to extract the available monitoring data.

Member States were invited to submit comments on the current use of BAC and DDAC as biocidal products and on levels found in recent samples by 9 August 2019

in view of further discussion whether the level should be maintained for the time being.

A.09 International Matters:

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

   The OECD Residue Chemistry Expert Group is currently developing case studies to compare the various approaches taken by the JMPR, the United States Environmental Protection Agency, the Australian Pesticides and Veterinary Medicines Authority, the European Crop Protection Association and EFSA when establishing residue definitions.

2. **Codex Alimentarius/JMPR issues- feedback from CCPR and future work organisation**

   The Commission thanked Member States and EFSA for their preparation of and active participation in Codex related activities, i.e. electronic Working Groups (eWGs), Council Working Parties and the Codex Committee on Pesticide Residues (CCPR).

   It reported the key outcomes of the 2019 CCPR.

   It explained that the origin of the proposed draft Codex MRL for chlorfenapyr in fruiting vegetables, cucurbits is unclear, and referred to the ongoing preparations of the EU position for the upcoming meeting of the Codex Alimentarius Commission.

   In line with last year's practice, a Member State was attributed to each of the various eWGs established by the CCPR, to follow the discussions and give feedback to the Committee, without in any way preventing the active participation of other Member States. The following attributions were agreed:

   - eWG on revision of the classification: the Netherlands
   - eWG on review of the IESTI equation: France
   - eWG on the revision of guidance on mass spectrometry: Spain
   - eWG on JMPR participation in international reviews: Austria
   - eWG on substances with low public health concern: France
   - eWG on the management of unsupported compounds: awaiting confirmation
   - eWG on the national registrations database: Germany
   - eWG on priorities: Germany

   The Commission informed Member States that it had asked the General Secretariat of the Council to examine the possibility of a third Council Working Party in early 2020, in view of the expected increase in workload due to the extraordinary meeting of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) that took place in May 2019.

   The Commission encouraged Member States to stay actively involved in Codex related activities throughout the year.

A Member State stressed the need for the development of an EU position regarding the classification of certain processed products. The Member State will share a draft with the other Member States via the Commission's distribution list and request comments.

2.1 **Concern form for chlorpropham**

The Commission circulated a final version of the concern form, which addresses the various comments sent by Member States.

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

A Member State had granted an emergency use for flonicamid on carrots in accordance with Article 53 of Regulation (EC) No 1107/2009. An MRL of 0.3 mg/kg is required to address the use. The Member State submitted a notification under Article 18(4) of Regulation (EC) No 396/2005 with a view of setting a temporary MRL whilst informing Member States of the emergency use.

The Committee took note of the notification.

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

The Netherlands reported receipt of an import tolerance request for afidopyropen, which is a substance for which no application for approval had ever been submitted under Regulation (EC) No 1107/2009. The Committee agreed that this Member State acts as RMS for this substance.

Germany had received an MRL application for difenoconazole in cereals. The Committee agreed that Germany evaluates the application instead of the RMS Croatia.

Belgium had received import tolerance requests for methoxyfenozide in tea and pineapple and spinosad in tea. The Committee agreed that Belgium evaluates the applications instead of the RMS United Kingdom or co-RMS Netherlands.

A.12 Next substances for new Article 12 review: metam, dazomet, hexythiazox and clethodim in or on certain products.

The discussion was postponed due to lack of time. The Commission drew the attention of Member States to the preparatory documents uploaded on CIRCABC and asked them to comment by 5 July 2019.

A.13 Next substances for new Article 12 review: chromafenozide, fluometuron, pencycuron, sedaxane, tau-fluvalinate and triazoxide in or on certain products.

The discussion was postponed due to lack of time. The Commission drew the attention of Member States to the preparatory documents uploaded on CIRCABC and asked them to comment by 5 July 2019.

A.14 State of play of evaluation of Reg. (EC) No 396/2005 and Reg. (EC) No 1107/2009.

The Commission gave an update on the state of play. The Staff Working Document and the Report to Council and Parliament are still under internal consultation. The submissions of those documents to the European Parliament and Council is tentatively scheduled for July 2019.

A.15 Revision of GD SANCO/3029/99 rev. 4 und SANCO/825/00 rev. 8.1

The Member State in charge of the preparation of the updated guidelines informed that it was still waiting for a contribution from another Member States and that therefore no document for discussion was yet available. The presentation of the draft guidelines will likely be scheduled for the meeting of the Committee in September 2019.

A.16 SANTE extrapolation guidelines.

1. **Draft revision of guidance document SANCO 7525/VI/95**

   The Commission presented the main points of discussion for the future revision of the guidance document on trials comparability and crop extrapolations. The revision aims at addressing Member States concerns on parts of the text and discrepancies between the guidance document and other guidelines (OECD, Codex, EFSA) as well as with EU Regulations.

   Several Member States welcomed the initiative to revise the text of this guidance document, as only the annexes had been recently updated, and stressed that most of the issues they had noted were being addressed in the draft revision. A Member State underlined that they had been facing issues regarding the number of trials because of discrepancies in the guidance, leading to products being authorised in some Member States and not in others. Member States added that they would look at the proposed draft revision in detail and send comments.

   EFSA encouraged to start thinking about the development and inclusion of tools to implement the provisions of the guidance document and support the applicant in finding what the requirements for a given situation are (i.e. automatic filling of excel files).

   Member States were invited to submit comments by 3 July 2019.

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

   The two Member States working on a discussion paper for seed treatments – number of trials- summarised the comments they had received. They welcomed that most of their proposals appeared in the draft revised guidance document. In addition, they stressed that it was sometimes difficult to get three trials for major crops in the case of seeds treatment, and asked whether the interpretation could be extended to representative groups, as Regulation (EU) No 283/2013 does not mention “major crops” but commodities “significant in diet”.

   On the terms “major crop” and “significant in diet” another Member State mentioned that an OECD definition existed for “significant in diet” that includes production, consumption and economic impact, and that crops used as feed should also be considered in this case. The Member State further considered that major crops by being significant in diet would consequently also have to be produced in sufficient quantities and that therefore “significant in diet” would in most cases also be identical with “major crop”.

A.17 Approach for import tolerances for substances falling under the cut-off criteria.

The Commission referred to the discussion at the meeting of the Committee on 18/19 September 2018. Following internal discussion within the Commission in the light of Member States' comments, the approach to import tolerance requests for active substances meeting the human health-based cut-off criteria of Regulation (EC) No 1107/2009 was confirmed as presented at the meeting of the Committee on 13/14 June 2018.

The Commission drew Member States' attention to written comments of the European Crop Protection Association, raising various concerns and asking the Commission to reconsider its approach.

A Member State questioned the applicability of Article 17 of Regulation (EC) No 396/2005 to lower MRLs that were not established based on uses previously authorised in EU Member States. It requested further detail on the position of the Commission's Legal Service.

Another Member State stated its support for setting import tolerances on the basis of a risk assessment. It stressed the need for timely communication to industry and non-EU countries, e.g. through the WTO-TBT Committee. It suggested considering longer timelines between initiation of work on MRLs for substances meeting the cut-off criteria and the date of application of the revised MRLs, to allow interested parties more time to either submit the necessary import tolerance requests or change their agricultural practice.

Several Member States reiterated these points.

Another Member State recalled its position against the acceptance of import tolerance requests for substances meeting the cut-off criteria.

The Commission pointed to the standard wording used in its WTO-TBT notifications in relation to non-approval decisions on pesticide active substances, specifying that "separate action will likely be taken on MRLs and a separate notification will be made in accordance with SPS procedures".

Member States stressed the importance of keeping track of those MRLs which are set to address an import tolerance request and believe a database would be useful for the purpose.

A.18 Other Information points.

- *Follow up on the resolution from the European Parliament on the draft Regulation SANTE/11195/2018*

  The Commission recalled that this was the first time that a draft MRL measure had been rejected by the European Parliament during the scrutiny period. It expressed its concern about this precedent which undermines risk management action that is based on sound science. After careful reflection, the Commission now considers preparing new proposals in the form of two separate draft Regulations – one for all the other substances and one for clothianidin - as required by comitology rules.

  The Commission reminded the Member States that setting MRLs is a collective risk management action and called for stronger support from the Member States when a draft objection is tabled in the European Parliament. Several Member

States expressed their strong concern about the Parliament's way of acting. Some Member States requested more detailed information from the Commission in cases where a draft objection is tabled in the Parliament, which the Commission agreed to do. A Member State wondered whether a formal statement could be made by the Committee and recorded in the Minutes to support the Commission. The Commission was of the view that this was already implicitly the case through the Member States' support by voting in favour (in the example at hand a favourable opinion by unanimity had been delivered in November 2018) and reminded Member States that they exercise their own right of scrutiny in the Council. It seemed thus more appropriate that Member States act via their Permanent Representations during the scrutiny period.

- *Glufosinate ammonium*

  The Commission recalled the regulatory history of the active substance glufosinate, whose approval expired on 31 July 2018 following withdrawal of an application for renewal of approval. EFSA published a review of the existing MRLs for glufosinate according to Article 12 of Regulation (EC) No 396/2005 in 2015.

- *Question from Post Approval Issues (PAI) group on honey*

  It was clarified that, in general, issues brought up by the PAI group or the Inter Zonal Steering Group (IZSG) should always be discussed in the relevant section of the SC PAFF which would report back to the requestor. Parallel discussions in different groups should be avoided as they lead to confusion.

  The Guidance Document (GD) on residues in honey will be applicable as from 1 January 2020 (see specific details as agreed in the meeting of the SC PAFF – Section Phytopharmaceuticals – Pesticides Residues on 18/19 September 2018). As from that date it will also apply to new product authorisations or re-authorisations. The IZSG is concerned that for many product authorisations, a (new) MRL in honey may have to be set and that the MRL setting process may last longer than the product authorisation process, which would be delayed in consequence.

  One delegation expressed already their view that some pragmatism would be needed in order to limit the number of situations on which an MRL in honey would be needed, as it was the spirit when adopting the mentioned GD. Another delegation shared their experience with pre-submission meetings with companies, seeking advice on the need to perform tests and studies for product authorisation purposes..

  The Commission considered that a better overview of the situation would be first needed and will ask EFSA to extract recent national monitoring data on honey from the database. It emphasised that the GD was drafted with a view to keep the data requirements to a minimum, and that it would in principle support a pragmatic approach.

  Member States were invited to submit comments by 1 August 2019.

- *Letter from France on 1,3-Dichloropropene*

  The Commission asked Member States to report on whether MRLs were set at national level in relation to emergency uses granted for 1,3-dichlorpropene and reminded that in such case an Article 18(4) application should have been

submitted. This would help to consider whether EFSA shall be mandated for a specific dietary consumer risk assessment resulting from the exposure to food commodities deriving from crops grown on fumigated soils or substrates, as suggested by one Member States.

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 1-decanol, 2,4-D, ABE-IT 56, cyprodinil, dimethenamid, fatty alcohols, florpyrauxifen-benzyl, fludioxonil, fluopyram, mepiquat, pendimethalin, picolinafen, pyraflufen-ethyl, pyridaben, S-abscisic acid and trifloxystrobin 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):

- cyprodinil for the use on Florence fennels;
- dimethenamid-P for the use on several products;
- fludioxonil for the use on Florence fennels;
- fluopyram for broccoli;
- mepiquat for the use on cultivated fungi;
- pendimethalin for the use on several products;
- picolinafen for the use on barley, oats, rye and wheat;
- pyraflufen-ethyl for the use on several products;
- pyridaben for the use on tomatoes and aubergines;
- trifloxystrobin for the use on broccoli.

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

- 2,4-D for the use on soyabeans (Canada and the United States)

For 2,4-D, dimethenamid, pendimethalin, picolinafen and pyraflufen-ethyl, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005.

As regards mepiquat, mushroom growers submitted recent monitoring data specifically on oyster mushrooms showing that residues occur in those products at higher levels than the current temporary MRL set for cultivated fungi. Those residues result from a cross-contamination of cultivated fungi with straw lawfully treated with mepiquat. The MRL for oyster mushrooms is proposed to be set at the level corresponding to the 95th percentile of the total of occurrence data while maintaining the existing MRL for other cultivated fungi.

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

The draft measure proposes to include ABE-IT 56, 1-decanol, fatty alcohols and S-abscisic acid in Annex IV to Regulation (EC) No 396/2005 on a permanent basis.

During the meeting, a Member State enquired on the possibility to restore the MRL for celeries, which was previously set for fluopyram to cover occurrences in rotational crops. The Commission indicated that the procedure outlined under Article 16(1) of Regulation (EC) No 396/2005 should be followed. Based on the urgency, all individual actors involved could make an effort to speed-up the process while addressing the various steps foreseen by the procedure. Another Member State indicated that an application to set permanent MRLs will be submitted in parallel to address a new use on those crops.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for imazalil in or on certain products

The Commission introduced the draft measure and presented its content.

The Commission drew Member States' attention to the comments received from Member States, EFSA, the applicant, stakeholder associations and non-EU countries including those received following the notification under the WTO-SPS agreement. While all comments were available to Member States, the Commission presented a summary of the key points raised.

Several Member States expressed their preference for setting an MRL for imazalil in bananas at 2 mg/kg in alignment to the Codex MRL currently in place. While agreeing with EFSA that using the median peeling factor carried an unacceptably high uncertainty in this particular case and that it was therefore not appropriate to use in the exposure assessment the highest residue in whole fruit multiplied by the peeling factor, they considered that the highest residue level in pulp as reported in the 1977 Report of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should have been used, instead of the highest residue level in whole fruit without further refinement. They further considered that an MRL on that basis would be sufficiently protective for consumers. Two Member States reported on national authorisations (granted in one case, pending in the other case) for less critical good agricultural practices (GAPs) but acknowledged that the corresponding information had not been submitted for the MRL review, as the authorisations were not yet in place at the time.

Several other Member States expressed their support for lowering the MRL for bananas to 0.01 mg/kg.

EFSA recalled the key points of the risk assessment for this complex dossier with evaluations under different legal provisions, and that they can only assess information that is available to them. EFSA had considered the option to use the highest residue in pulp but eventually decided against. It explained that the data available in the 1977 JMPR Report were very limited and no details were reported on the trials. Moreover, differences between the GAPs assessed by JMPR and authorised in the EU introduced additional uncertainty. EFSA also pointed to the issue on the toxicity of metabolites for post-harvest uses.

The Commission stated that it had weighed the arguments presented and on balance decided to maintain its draft as notified under the WTO-SPS agreement and presented

to the Committee. It also indicated that it was nonetheless seeking a solution that enjoyed wide support from Member States. It noted that the widest support was in favour of the draft as presented.

One Member State voted against and three Member States abstained because they disagreed with the lowering of the MRL in bananas due to the lack of consumer risk. One abstention was additionally motivated by concerns on the wording used for transitional measures.

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

"The Netherlands do not support the lowering of the MRL for imazalil in banana and the lack of transitional measures in this regard. As Rapporteur Member State, the Netherlands is of the opinion that there is a sufficient safety margin to exclude a risk for consumers and set an MRL at 2 mg/kg. The Netherlands are however of the opinion that for reasons of food safety it is necessary to lower the MRLs for imazalil in various other products. Therefore, the Netherlands have decided to agree to this draft."

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

"First of all we would like to highlight that the consumers´ safety is of utmost importance in Spain, and for this reason in general we welcome the works of the Commission on the active substance imazalil since it provides updated guarantees about these uses reducing those limits that are detected by EFSA as not to be safe for consumers.

However, the delegation of Spain voted against the proposal because we disagree on the new MRL of 0.01 mg/kg imazalil for bananas. We consider that enough supporting documentation has been provided - registered use and residue trials in ES, among others- to maintain the MRL of 2 mg/kg. The assessment of the Rapporteur Member State RMS (NL) adding more information on the residues of imazalil on pulp (edible part) also supported this position. It is important that the legislation of the EU is harmonized as much as possible with international food safety standards as those set by the Codex Alimentarius Commission (CXL imazalil in bananas 2 mg/kg).

Finally we believe that the final position of the Commission has not been consistent with the approach given to other post-harvest uses in food commodities, even when the scenario was very similar to the banana crops. We would have appreciated a bigger effort to reach a broader consensus since during the discussion it was clearly seen that there was a lack of agreement for several delegations on the draft".

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyflufenamid, fenbuconazole, fluquinconazole, and tembotrione in or on certain products (Art. 12)

The Commission provided an overview of the comments received for this proposal. A discussion took place regarding the MRL for the category "Others", in general. One Member State supported that in case there are MRLs for all crops included within a group, then the highest MRL among them should be attributed to "Other" crops as

consumer exposure is likely to be low. Another Member State argued that the lowest MRL should be given on the basis of the "As Low Reasonably Achievable" (ALARA) principle. EFSA commented that if there is no GAP available for the "Others" category then an MRL should not be assigned, but the LOQ should be considered.

For the pesticide/crop combinations: cyflufenamid/stone fruits "Others", fenbuconazole/citrus fruits "Others" and fenbuconazole/citrus fruits "Others" the lowest MRLs among the crops of the respective groups were finally agreed in order to advance the draft Regulation. However, Member States requested to come back to the discussion with a view to agreeing on some common principles for future cases. The Commission prepared a final Revision 3 of the draft Regulation.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) No …/… amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amitrole, fipronil, flufenoxuron, flupyrsulfuron-methyl, imazosulfuron, isoproturon, orthosulfamuron and triasulfuron in or on certain products

The draft Regulation addresses seven substances that had been either not approved, not renewed or their approval had expired. All MRLs are proposed to be lowered to the LOQ and the substances to be transferred to Annex V to Regulation (EC) No 396/2005. It is proposed to grant transitional measures for all existing MRLs, as they had recently been assessed by EFSA either in the framework of the Article 12 review or in separate assessment and found to be safe for consumers.

The Commission explained that flufenoxuron was withdrawn from the proposal because the Article 12 review procedure had already been launched and while it was confirmed that there were no longer any European uses, information on several Brazilian GAPs had been submitted in this context, which would need to be checked more closely in the Article 12 review process. No reaction was submitted in reply to the WTO-SPS notification by any third country.

Vote taken: Favourable opinion.

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

The Commission informed that following the Working Group meeting of Experts on chlorate held in Brussels on 13 May 2019, it had prepared a revised draft Regulation addressing the experts' concerns regarding the setting of chlorate MRLs on processed food products by means of a specific footnote, the wording of which was however not accepted later by the Commission's Legal service in an informal consultation on the grounds that it would not ensure a sufficiently high level of consumer protection for processed products in line with Regulation (EC) No 396/2005.

Further discussion took place and a variety of possible alternative options were discussed, including modifications of the proposed footnote to address the concerns.

A Member State expressed its concerns on the absence of transitional measures for products already on the market before the application date. The Commission

reminded that this draft Regulation does not lower MRLs but raises them, so that no transitional measures need to be set.

In terms of proposed MRLs, a Member State reminded that during the Working Group some extrapolations had been agreed, which were not yet reflected in the revision. The Commission agreed to include them apart from the extrapolation from broccoli to cauliflower which had been extensively discussed in the working group and rejected.

The Commission referred the Member States to the detailed minutes of the WG uploaded on CIRCA BC.

Member States were invited to submit comments by 21 June 2019.

C.02 Exchange of views of the Committee as regards maximum residue levels for sintofen, myclobutanil and napropamide.

The Commission presented the draft Regulation. A Member State requested clarification on LOQ values below the default. The Commission clarified that the analytically achievable levels were presented in the documentation, but not yet the proposed MRLs. It confirmed that levels below 0.01 mg/kg would in general only be proposed in cases of toxicological concern.

Member States were invited to submit comments by 12 July 2019.

M.01 History of residue definitions – update from the Commission on an IT Project

The item was added to the agenda on request of a Member State who requested to have more information on the history of the residue definition for enforcement for active substances in the pesticides database, similar to the presentation of the history of MRL values. The Commission informed that a project for development of such a feature of the pesticides database was ongoing and that very recently good progress had been made. The Commission proposed to make a presentation of the new features at the meeting of the Committee in September.

M.02 Anthraquinone

The item was added to the agenda on request of a Member State who asked for the advice of other Member States on enforcement action for anthraquinone in tea (from China). It also asked for a discussion whether the existing MRL for tea (at 0.02 mg/kg) should be lowered to 0.01 mg/kg in view of the result of a national risk assessment it recently made. The following points were raised during the discussion:

- Potential sources of contamination (smoking and drying processes, environmental or natural occurrence, paper used in tea bags) remains to be elucidated. An audit of DG SANTE's audit and inspection service is planned for October 2019 to China and will help getting some clarity on this issue.
- The anthraquinone transfer rate from tea to water during infusion could be expected to be low, due to the liposoluble characteristics of this substance. However, clear evidence on that is currently not available.
- Toxicological threshold values were not established for this substance, a risk assessment is therefore not possible.

- The substance was recently classified by the European Chemicals Agency (ECHA) as carcinogenic category 1B.
- The EU RLs had advised on an analytical achievable level of 0.02 mg/kg at the time the Article 12 review was carried out. The Commission will confirm whether in the meantime lower levels are analytically achievable for routine control laboratories.
- Reducing current anthraquinone MRLs in tea (established at 0.02 mg/kg) will have an impact on trade. It was mentioned that some operators already stopped selling smoked tea as precautionary measure.

M.03 Folpet (phtalimide), Fosetyl (phosphonic acid)

The item was added to the agenda on request of a Member State who described its current enforcement policy for folpet and fosetyl-Al, and asked other Member States for information about their enforcement practices.

On folpet the Member State recalled that the metabolite phthalimid can also stem from other sources, e.g. as an artefact of the analytical methodology. If its presence is detected there is no unambiguous link to the use of folpet as pesticide. The Member State therefore takes enforcement action only if the parent compound folpet is also detected.

The Rapporteur Member State updated the Committee that the peer review process had started and that the proposed residue definition for enforcement would likely be proposed as folpet only which would solve the problem.

On fosetyl, a Member State pointed to the need to use conversion factors because the residue definition for enforcement covers several residues of approved active substances that are however all expressed as fosetyl. Food products treated with agricultural inputs not placed on the market as plant protection products must still comply with the established MRLs. Label recommendations and/or restrictions may be appropriate to prevent non-compliances.

Another Member State stressed that farmers should not use products containing fosetyl-Al and products containing phosphonates on the same crop. It pointed to phosphonate present in fertilisers as a potential source of problems, but considered that this will be addressed through the provisions of the new fertilising products Regulation that is expected to become applicable in 2022. That Regulation will prohibit the intentional addition of phosphonates to fertilising products and set out a maximum limit for unintentional presence of phosphonates in fertilising products. It will also explicitly state the obligation to respect MRLs established in accordance with Regulation (EC) No 396/2005.

M.04 MRL for soybeans

The item was added to the agenda on request of a Member State, but not discussed due to lack of time. The Member state wished to draw the attention of the other Member States to the forthcoming re-classification of soy beans from code number 0300010 (pulses/beans) to code number 0401070 (oilseeds) as from 1 January 2020 in Annex 1 of Regulation (EC) No 396/2005. This re-classification will have an impact on existing authorisations which would need to be amended in order to avoid non compliances as from 1 January 2020.

M.05 ***Bacillus thuringiensis (Bt)***

The item was added to the agenda on request of the RMS for Bt. Bt is a microorganism that is currently in the peer review process. The RMS reported that a study carried out by the French risk assessment body, ANSES, would soon be published which raises serious concerns about the potential contribution of Bt based pesticides to foodborne outbreaks (FBO).

The study had been carried out following the EFSA 2016 opinion of the Biohazard Panel on the "risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs". In the EFSA opinion a clear conclusion on public health risks with regard to Bt had not been possible as EFSA concluded that "Bacillus cereus (Bc) and B. thuringiensis (Bt) strains are usually not discriminated in clinical diagnostics or food microbiology".

In the new ANSES study 1263 Bc strains (undiscriminated Bc/Bt) isolated from 250 foodborne outbreaks (FBO) that had occurred in France between 2007 and 2017 had been re-analysed and characterised using phenotypic and genotypic (including Whole Genome Sequencing) methods. Bt strains were isolated in 53 out of 250 Bacillus cereus-associated FBOs (21%). In many cases, these strains were isolated from raw food commodities (50% of Bt isolations) and in particular from tomatoes (40% of Bt isolations), hence strengthening the hypothesis of a potential agricultural origin of the Bt isolates. The phenotypic and genotypic analysis also revealed that, in the case of 44 FBO (18%), Bt isolates were genetically close to commercial Bt products from subspecies aizawai and kurstaki, with which they shared virulence markers, such as enterotoxins Nhe, Hbl and CytK2.

Given this genetic proximity and in absence of contradictory evidence, ANSES concluded that it cannot be ruled out that commercial Bt strains would possess the same pathogenic potential than FBO-associated strains.

The Commission thanked the RMS for this important information and asked the RMS to make it available for the peer review process of Bt.