EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)6245920

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 22 SEPTEMBER 2016 - 23 SEPTEMBER 2016

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/963ff4fe-0abe-4784-8f9c-8cd8a99ddba2*

A.01 Procedures for routine Maximum Residue Levels (MRL) setting under Regulation (EC) No 396/2005 for Note Taking.

The Commission outlined the amendments brought to the document in its Revision 3. During the meeting, the document was further amended to refine the current wording of some paragraphs. The Commission clarified that it is a living document that may be further amended in the future.

The Committee took note of the document SANTE/2015/10595 Rev. 4, which can be consulted on the Commission 's website:

http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm

A.02 Amendments to the Extrapolation Guidance Document for Note Taking.

The Commission presented the Revision 10.2 of the document. Some minor modifications were introduced during the discussion.

The Committee took note of the Revision 10.2 of the document as amended, which can be consulted on the Commission 's website:

http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm

A.03 Glyphosate-residue definition for Article 12 assessment of MRLs for Note Taking, animal health mandate.

The Commission provided an update on the mandate on animal health. The assessment runs in parallel to the Article 12 review of maximum residue levels (MRLs).

The Commission referred to a revised discussion paper on the future residue definition for enforcement of glyphosate and stressed the need for clarity for the European Food Safety Authority (EFSA), on which basis the MRL review should be conducted. Member States exchanged views and indicated their preference. It was agreed to request EFSA to carry out the assessment for two alternative options:

Option 1: for all commodities of plant origin: "sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate".

Option 2: for all commodities of plant origin for which food and feed from glyphosate-tolerant GM crops are authorised: "sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate". For all other commodities of plant origin: "glyphosate".

In view of the existing authorisations for feed from glyphosate-tolerant GM crops, the residue definition for commodities of animal origin is for both options "sum of glyphosate, AMPA and N-acetyl-glyphosate, expressed as glyphosate".

If during the early steps of the MRL review relevant information is identified that suggests a revision of this agreement, EFSA will bring this to the attention of the Committee.

The Commission clarified that the residue definition for risk assessment in commodities of both plant and animal origin remains the same as currently in place and confirmed during the peer review, i.e. "sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate".

A Member State suggested to discuss the inclusion into the residue definition of AMPA and N-acetyl-glyphosate in the expert working group for monitoring. The EU-RLs will be present and the analytical issues will be discussed in that framework.

EFSA highlighted that the MRL review for glyphosate will follow the "future process" and provided details on the steps and timelines under agenda item A.14.01.

A.04 Update on chlorate.

The Commission informed that it is still in the process of internal consultation on how to adequately address the problem of chlorate residues in food, including the possibilities of further discussing the issue in the context of the legislation on drinking water and/or food hygiene.

A.05 Exchange of views of the Committee as regards maximum residue levels for bitertanol, chlormequat and tebufenpyrad (Article 12).

The Commission presented the comments received from Member States and how they were taken into account in the revised version of the Regulation. One Member State proposed a higher value for chlormequat in mushrooms on the basis of an alternative method of calculation, arguing that levels in straw used for mushrooms cultivation could contain higher chlormequat level if the straw is produced using the critical

(Good Agricultural Practice) GAP. The Member State also added that the Committee agreed to select the calculation method on a case by case basis. The Commission answered that consistency in the calculation method already used for the similar case of mepiquat was preferred, and that selection of straw for mushroom cultivation could limit the risk of higher level of chlormequat. The Commission also noted that among the 654 analysed samples, only 6 samples were not covered by the proposed MRL (less than 1%). EFSA pointed out that some of the high values could be outliers originating from misuse and were not necessarily representative of the critical GAP. The initially proposed level of 0.9 mg/kg is therefore maintained.

Sanitary and Phytosanitary Measures (SPS) notification led to comments from third countries notably raising the issue of chlormequat in grapes, which can comply with the current limits of quantifications (LOQ) value of 0.05* mg/kg but not the new proposed value of 0.01* mg/kg. Given the availability of supporting data, the scheduling of their evaluation by the 2017 Joint FAO/WHO meeting on Pesticides Residues (JMPR) and the absence of public health concern, it was agreed to maintain the 0.05* mg/kg value until July 2019, a delay that would allow for data evaluation, Codex endorsement and regulatory processing.

A.06 Exchange of views of the Committee as regards maximum residue levels for fenpyroximate, triadimenol and triadimefon (Article 12).

The Commission introduced the draft and presented its contents.

Members States were invited to submit comments by 14 October 2016.

A.07 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Article 12

The Commission updated the table concerning Article 12 priorities and gave an overview to the Committee.

2. Handling of confirmatory data

The Commission referred to the Working Document of which the Committee took note at its meeting on 16/17 June 2016, and subsequent clarifications on which PROPFile version to use during the assessment of confirmatory data. They are summarised in a document available on CIRCABC. EFSA reported on the update of the overview table on confirmatory data on the EFSA extranet (DMS) and relevant information received from Member States. EFSA invited Member States to further contribute to the table beyond the earlier deadline. The Commission supported EFSA's call and underlined the importance of having as complete an overview as possible. It encouraged Member States to respond, if not yet done, to EFSA's broadcast e-mail of 12 July 2016.

3. Footnotes for commercial availability of analytical standards which expired in 2015:

Exchange of views of the Committee as regards maximum residue levels for benthiavalicarb, chlorpropham, fenpropidin, pymetrozine and thiobencarb (SANTE/2016/11414 Rev. 0)

The Commission informed that during the Art. 12 review the EU Reference Laboratories (EURLs) identified that for certain substances analytical standards were not commercially available and a footnote was added to the residue definition, stating that these standards should be made commercially available within 1 year after publication of the Regulation. For benthiavalicarb, chlorpropham, fenpropidin, pymetrozine and thiobencarb the footnote expired in 2015, however the concerned standards are still not commercially available. Therefore a proposal will be drafted to reduce the concerned MRLs to the limits of quantification (LOQs) for these substances.

4. Substances for which endpoints were changed in AIR process after completion of Article 12

The Commission summarised the approach proposed at the Committee meeting on 16/17 June 2016, to which it did not receive any objections. A Member State suggested that it would be desirable to have periodic MRL reviews after the completion of the Article 12 review exercise, linked to the renewal of the approval of active substances. The Commission considered that in view of limited resources at national and Community levels an automatism would not be feasible. It suggested that a limited number of substances could be subjected to an MRL review, even in the absence of health concerns or changes in relevant endpoints, based on criteria to be agreed, and pointed to alternative mechanisms to ensure that MRLs comply with the ALARA ("As Low As Reasonably Achievable") principle.

5. Other

The Commission informed that following the discussion at the June Committee meeting (Point A.11.5) on the interpretation of the term "produced" contained in the transitional measures of Commission Regulations, a request for legal interpretation was sent to the Commission's Legal Service. The outcome will be shared with the Member States when available.

A.08 Specific substances:

1. Tricyclazole state of play

The Appeal Committee of 15 September 2016 on the non-approval of tricyclazole concluded with a "no opinion". Therefore the Commission will now adopt the non-approval of the substance in the course of October 2016. As a follow up to this decision also the MRL for rice will need to be lowered to the LOQ. Prior to the drafting of this proposal, the Commission shared some considerations with the Member States on whether or not a transitional measure should be granted for products that were produced before the date of application of the new MRL.

Members States were invited to submit comments by 14 October 2016 on whether it is appropriate to set a transitional measure for rice.

2. Chlorpyriphos

Member States informed about the enforcement action they are taking on chlorpyriphos/raisins. 14 Member States reported that they take a proportionate approach for enforcement action using a temporary action level as an interim solution. This solution takes into account the low consumption of dried raisins and the limited period of time for which such action level would be needed.

In the June Committee and following concerns raised by stakeholder organisations and third countries the Commission stated that it was in favour of Member States taking proportionate action in this specific case to facilitate the marketing of raisins for an interim period. This would provide sufficient time to sell-off processed products containing dried grapes that were compliant with the previous (higher) MRL at the time of production.

It was discussed with Member States if the summary of Member States' national enforcement actions could be shared with third parties if requested. Some Member States did not agree. Member States were therefore invited to communicate national measures to national trade organisations directly.

3. Mercury

The Commission informed that the technical discussions on specific maximum levels were now finalised in the Expert Group on industrial and environmental contaminants as also presented in the June Committee meeting on pesticides residues. The Commission will now consult the Commission's Legal Service on the legal construction of the measure prior to launching formally the internal consultation procedures. Member States will be kept informed.

One Member State raised concerns as to the proposed maximum levels for mercury in foods for infants and young children "as sold" given that for pesticides residues in such foods the maximum residue levels are set on the product "as consumed".

4. Amitraz, coumaphos, flumequine, oxytetracycline, permethrin and streptomycin used in Veterinary Medicinal Products

The EFSA Reasoned Opinion on "the setting of MRLs for amitraz, coumaphos, flumequine, oxytetracycline, permethrin and streptomycin in certain products of animal origin" was published in August 2016. The Commission prepared a table outlining the amendments that will be reflected in the Annexes to Regulation (EC) No 396/2005 in order to align pesticides MRLs with MRLs for veterinary medicinal products as much as possible.

For amitraz, flumequine, permethrin and streptomycin, the existing residue limits, which are set in Regulation (EC) No 37/2010 in view of the existing uses in Veterinary Medicinal Products, will be directly transposed in Regulation (EC) No 396/2005. For coumaphos, EFSA recommends setting the MRL for honey.

However, a risk management decision needs to be taken as to whether it is appropriate to set all other MRLs to the default value of 0.01 mg/kg. As regards oxytetracycline, EFSA does not recommend transposing the existing MRLs because a risk could not be excluded.

Members States were invited to submit comments by 14 October 2016.

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

Since last meeting the EFSA published its conclusion on oxathiapiprolin.

A.09 Preparation CCPR 49 (2017) (Codex Committee on Pesticide Residues):

1. Priority list: priority of EU nominated substances

The EU priority list for periodic evaluation was updated on the basis of the comments received by Member States. No objections were raised on the proposed ranking in the Excel table distributed. The list also indicates where concern forms are still needed.

The respective Rapporteur Member States were invited to submit concern forms in the appropriate template by 31 October 2016 for those substances in the list for which concern forms were not yet provided. The concern forms will subsequently be sent by the Commission to JMPR and the chair of the electronic working group on priorities.

Regarding the discussion paper on the "Active substances not scheduled for periodic review 2017-2021 and not listed in Table 2B (periodic review list) for which the last JMPR full toxicity evaluation was more than 15 years ago, including substances that were evaluated less than 15 years ago but for ARfD only", the Commission acknowledged the receipt of comments of two Rapporteur Member States only. No concerns were signalled by those two Member States for their respective substances.

2. Concern form quinclorac

The Commission referred to documents received on this matter, and invited Members States to submit comments by 14 October 2016. A Member State enquired on the need to assess existing EU-MRLs for this substance. The Commission suggested to discuss this in the light of a future decision taken on the reservation/concern form.

3. Other info; e.g. new reporting templates, comments to Codex Circular Letter CL 2016/28-PR (Cereals items)

The Commission informed the Member States that from now onwards the Codex Open Commenting System (OCS) will need to be used for submitting the EU comments on Codex documents. The Commission will introduce the EU comments in the OCS system. In order to facilitate the Commission's work, Member States are asked to already use the OCS commenting format (the template is uploaded on CIRCABC), when they send their comments to the
Commission. In practice for each comment the following information is needed:

- Page and paragraph number
- Added text should be indicated in bold and underline, removed text in strikethrough
- A rationale is needed for each comment
- An indication is needed whether the comment is S (substantive), E (editorial) or T (technical).

The Commission reminded the Members States that the deadline to submit comments to the Commission on Codex Circular Letter CL 2016/28-PR, on the Cereals group expired. Since no comments were yet received the Commission agreed to extend the deadline until 3 October 2016. Comments should be made using the new template and should be focused only on the crops to be listed in each group/subgroup but not on the grouping system as such on which the discussion was closed in the 2016 CCPR.

A.10 Exchange of views of the Committee as regards maximum residue levels for fluopyram, HCH isomers, profenphos and nicotine.

Regarding fluopyram, the future draft proposal complements the proposal SANTE/11309/2016 Rev. 1 voted under agenda item B.01 by lowering down to the LOQ the MRLs of the commodities for which data were not provided. Based on EFSA advice, a new LOQ value of 0.01*mg/kg is proposed for most of these commodities.

Regarding nicotine and profenofos, recent monitoring data from EFSA and different sectors of the food industry revealed no significant evolution in recent years of the levels in commodities for which temporary MRLs were set. Therefore, monitoring should be continued and it is proposed to extend the existing temporary MRLs.

Regarding HCH isomers, it is proposed to lower all the MRLs to the appropriate LOQs based on monitoring data and in line with Codex maximum residue limits (CXLs) for lindane.

Members States were invited to submit their comments by 14 October 2016.

A.11 Maximum residue levels for substances for which LOQs (limits of quantifications) need to be increased in line with the working document on the summing up of LOQs: Exchange of views of the Committee as regards maximum residue levels for bifenazate, daminozide and tolylfluanid.

The Commission introduced the draft and presented its contents.

A Member State asked whether for bifenazate a consumer risk assessment had been carried out with the increased LOQs. The Commission informed that an initial assessment with the PRIMO model indicated that this was not the case but that confirmation of this would be sought from EFSA.

A Member State enquired on the analytical feasibility of the proposed MRLs. The Commission clarified that the EURLs had confirmed analytical feasibility.

A Member State questioned the need to increase the LOQs given the current analytical possibilities to achieve lower levels. The Commission explained that generally a target LOQ of 0.01 mg/kg per component is proposed in order to not to put unnecessary burden on the enforcement laboratories, except in cases of highly toxic compounds where lower LOQs may be necessary.

Different views were expressed on the currently established MRL at the LOQs for captan and folpet. The Commission explained that the MRLs were set taking into account the agreed approach on the summing up of LOQs and the advice of the EURLs. The Commission will confirm analytical feasibility with the EURLs.

Members States were invited to submit comments on SANTE/11397/2016 Rev. 0 by 14 October 2016.

A.12 Exchange of views of the Committee as regards maximum residues level for achrinathrin, lambda-cyahalothrin, metalaxyl (combined review) and thiabendazole. (Article 12).

The first draft of this proposal will be presented at the next November Committee meeting.

The Commission presented the specific issue of the substance lambda-cyhalothrin and its links to other related substances (gamma-cyhalothrin and cyhalothrin). The Commission referred the results of an enquiry launched among the Member States about their national authorisations on gamma-cyhalothrin. It confirmed the connection between the lambda cyhalothrin, gamma cyhalothrin and cyhalothrin which share common isomers. Therefore the Commission confirmed its intention to consider all three substances together. One Member State commented that it is may be not necessary to involve cyhalothin in this stage.

A document will be prepared by the Commission after the meeting on which Member States will be invited to submit comments.

A.13 Monitoring:

1. Annual Report 2014- conclusions on risk assessment

The item was deferred to the November Committee meeting.

2. Follow up on EFSA recommendations

In the draft 2014 monitoring report on pesticides residues, EFSA made some recommendations on commodities and substances that could be added to the EU multiannual control programme (EU MACP). These suggestions will be discussed in the expert group on pesticides residues monitoring of 21 October 2016.

A Member State shared some concerns regarding the EFSA recommendation for reviewing the MRL for chlopyrifos on carrots and asked to take into account the refined assessment that was carried out in the 2015 reasoned opinion on certain maximum residue levels (MRLs) of concern for the active substance chlorpyrifos.

EFSA clarifield that the Article 12 review for chlopyriphos is under preparation, in which the trial data supporting the MRLs will be assessed and in which the refined calculations will be updated. The draft reasoned opinion will be circulated for comments in October 2016. The Commission asked to reconsider the recommendation in the monitoring report in view of the on-going MRL review.

As regards the EFSA recommendation to reconsider the default MRLs for phenthoate on the basis of an acute risk calculation with the ADI (Acceptable Daily Intake), the Commission explained that it would be more appropriate to await a review by JMPR to assess whether an ARfD (acute Reference doses) needs to be established for this substance that is not approved in the EU.

3. Expert Group Meeting on Pesticides Residues Monitoring 2016

The expert group meeting on pesticides residues monitoring for 2016 is planned for 21 October 2016. During this meeting the EU MACP for 2018-2020 will be discussed as well as the working document on pesticides to be considered for inclusion in the national control programmes.

A.14 News from the European Food Safety Authority:

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

EFSA outlined the current state of play. 217 substances have been finalised. 11 substances are currently being assessed. Another 29 substances are under the interim procedure (for 8 of them the quality check is being performed).

EFSA made a presentation outlining the future process regarding the Article 12 assessment. It should be implemented in 2017. The new process is already being applied for the glyphosate review and timelines for this review were detailed. Finalisation is expected for July 2017.

Some Member States commented, as regards the timelines, and in particular those for glyphosate, that the timelines would be too tight to submit their data given the multitude of data and the sensitivity of the file. Existing authorisations at Member State level would need to be adapted to the new approval conditions (e.g. ban of the co-formulant POE-tallowamine). EFSA commented that the future process was agreed with Member States in the Pesticides Steering Committee (PSC) in June 2014 and that it will streamline procedures and give the best possible snaphot of authorisations. The Commission explained that timelines for specific cases could be dicussed in case of specific needs, but that overall the agreed process should be followed. If Good Agricultural Practices (GAPs) were submitted still based on

existing authorisations of plant protection products containing POE-tallowamine, this should be clearly highlighted in the GAP tables.

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

EFSA presented recent staff changes in the EFSA pesticides unit. EFSA explained that the use of the stop-the-clock procedure will be limited and bilateral discussion with Member States sought to clarify potential data gaps within 5 working days. The animal model (2015) has been replaced by a new version (2016) on the SANTE and the EFSA DMS webpages. A new template for Article 10 reasoned opinion in line with Article 12 is now used by EFSA. PROFILE version 3.0 now in use already integrates all these changes.

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

As regards the Article 43 mandate on dimethoate, EFSA has collected all data and the completeness check is done. The draft reasoned opinion is expected to be delivered by mid-November 2016.

A.15 Amendments to Annex I to Regulation (EC) No 396/2005 (Regulation (EU) No 752/2014) - state of play.

The Commission informed the Member States that few comments were received on the proposal circulated to Member States before the Committee meeting. The deadline for comments is therefore extended to14 October 2016.

A Member State informed the Committee of a specific case in which a large lot of soybeans and soybean products labelled as "intended for feed" were blocked at import by the respective competent authorities based on levels for paraquat exceeding the current MRL for soybeans. Since paraquat is not authorised in the EU for many years, the incident was explained by better analytical methods achieving lower LOQs. The Commission asked the other Member States whether they had experienced similar problems. While this was not the case for this specific situation, Member States felt that this could happen to any Member State in principle. The discussion between Member States revealed that there are different interpretations of how MRLs should apply. In this context the footnote (1) of Annex I is under discussion and can contribute to clarifying the issue.

The Commission believes that a wider discussion is needed and invited the Member States to share their views on the issue, taking into account the fact that there are many commodities that are ingredients for food and feed at the same time and that processed products made from soybeans can go into the feed as well as the food chain. It invited comments on the three options for the wording of footnote (1) as well as more general comments on how to deal with similar situations by 14 October 2016.

A.16 Honey guidance.

A draft guidance documents regarding the setting of MRLs in honey was prepared by France together with an overview of additional data.

Members States were invited to submit comments by 4 November 2016. Further revisions will be coordinated by the Commission with support from France.

A Member State provided feedback on several issues regarding the setting of MRLs in bee matrices (pollen, honey, etc.). Monitoring data showed residues in bee matrices for some substances (e.g. thiacloprid, glyphosate and iprodione). Furthermore residue data are received in zonal authorisation dossiers. It was questioned if extrapolation from pollen to honey could be envisaged. EFSA could be involved to assess whether this is feasible.

The Commission indicated that monitoring data for bee matrices will be requested from EFSA for the years 2013-2015. Further actions depend on this data.

A.17 Screening exercise on t-MRLs in Regulation (EC) No 396/2005 that will be expiring in 2016 and beginning of 2017.

The Commission gave an update on the state of play.

A.18 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

An updated excel table regarding the status of Annex IV inclusions was uploaded on CIRCABC. One Member State provided feedback on the inclusion of denathium benzoate in Annex IV of Regulation (EC) No 396/2005 and could agree with the inclusion based on the current authorised uses. The Commission intends to propose inclusion of denathium benzoate in a next routine proposal.

2. EFSA opinion on Bacillus thuringiensis and follow up

EFSA published on 20 July 2016 the Scientific Opinion on risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs.

Comments received on this opinion from stakeholders and the public were made available on CIRCABC. Feedback of EFSA on these comments was requested by the Commission.

A presentation of the opinion will be given by EFSA at the November Committee meeting and Member States were invited to send comments/questions by 4 November 2016 for further discussion with EFSA.

A.19 Commission working document on risk management aspects related to the assessment of cumulative exposure:

The Commission presented a summary of the chapters under discussion.

Member States gave their agreement to ask EFSA and the contractor RIVM (the Dutch Institute for Public Health (RIVM)) to implement the approach described in chapters 3.5.1.1, 3.5.1.2, 3.5.1.6, 3.5.1.7, 3.5.1.8, 3.5.3.3. and 3.5.3.4 of the working document.

Furthermore Member States gave their agreement to test the options described in Chapters 3.1.2.1, 3.5.3.1, 3.5.3.2 and 3.5.4 of the working document.

Two Member States indicated that they would send further written comments on chapter 3.5.1.7. A Member State asked to add some further explanations to chapter 3.5.1.8 and proposed to rephrase 'non detect' with 'not quantified'. This will be considered in Rev.7.

A Member State commented on the options for dealing with non-quantified residues described in chapter 3.5.3.1. The Commission clarified that further discussions on the described options will take place once calculation examples are available.

As part of the grant agreement between the Commission and RIVM, automatic calculations for all EU diets are now possible in the ACROPOLIS IT tool.

The Commission invited the Member States to comment on the draft output sheet proposed by RIVM by 28 October 2016.

A.20 Notifications under Article 18(4) to Regulation (EC) No 396/2005.

The Committee was informed about an application from the UK (August 2016) for a temporary MRL for chlorantraniliprole in hops according to Article 18(4) following an emergency authorisation under Article 53 of Regulation (EC) No 1107/2009. The Commission had asked EFSA to prioritise this request. The reasoned opinion is expected around mid of October 2016.

A.21 Designation of Member States for maximum residue levels (MRL) applications.

The United Kingdom accepted to act as EMS (Evaluating Member State) for an import tolerance request received for fluensulfone on solanaceae and cucurbits. The Committee took note of this.

A.22 Information on ongoing work on endocrine disruptors.

The Commission gave an update on the state of play.

On 15 June 2016, the Commission presented two draft legal acts containing hasard based criteria to identify endocrine disruptors: one draft delegated act under the Biocidal Products Regulation and one draft Commission Regulation under the Plant Protection Products Regulation (regulatory procedure with scrutiny).

The criteria presented are the same for plant protection products and biocidal products and are based on the WHO definition of an endocrine disruptor. In addition, they specify how the WHO definition should be used to identify endocrine disruptors: using all available scientific evidence, applying weight of evidence approach, etc. The Commission also proposes amending point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 to take into account current technical and scientific knowledge based on a mandate provided for in the same Regulation.

Discussions with Member States took place on 22 June and 21 September 2016. The discussions were focused on the main concerns identified: the scope of the WHO definition, the need for additional categories or consideration of potency, the level of evidence considered, the implementation date, and the proposed amendment to point 3.6.5 of Regulation (EC) No 1107/2009.

The Commission informed Member States on the consultations processes held over the summer: the feedback mechanism to consult general public and the WTO notifications. The draft act under the Plant Protection Products Regulation was notified both to TBT and SPS. Detailed information on these consultations is available via CIRCABC. Following the request of third countries, an information session on endocrine disruptors will be organised on 26 October 2016 in Geneva, in the margins of the WTO SPS Committee.

One Member State asked to submit a written position of the view of the Commission's Legal service on the mandate of the Commission to propose the amendment to point 3.6.5. The Commission needs to verify if this can be shared, but referred to the summary records of the respective Committee meetings where a summary will be provided in any case.

Member States were invited to submit comments by 30 September 2016 on the draft criteria.

A.23 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

The draft roadmap was approved by DG SANTE and still needs to be adopted by the Commission. The final roadmap will be published, to receive feedback during a period of 4 weeks, on the following website:

http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm

A.24 Official Food and Feed Control Regulation – areas where delegated/implementing acts will be needed.

Official Food and Feed Control Regulation – areas where delegated/implementing acts will be needed

The Commission informed that the Council and the European Parliament reached a political agreement on the new Official Controls Regulation (OCR) in June 2016. Now that the negotiations are finalised, DG SANTE will have to implement the new Regulation and will have to follow up on several empowerments for delegated or implementing acts. A detailed summary of the impact of the new OCR on Reg. (EC) No 396/2005 was uploaded on CIRCABC.

A Member State indicated that it supports the Commission's proposal to replace certain repealed provisions from Regulation (EC) No 396/2005 by an implementing act. It could be considered whether additional amendments are needed.

A.25 Update on the state of play of MRL setting for biocides.

The Commission informed that a meeting with Member States' experts on biocides would go ahead simultaneously with the Pesticides Residues Committee meeting, so that the outcome could only be shared with Member States after the meeting.

A.26 Guidance document extraction efficiency.

The item was deferred to the November Committee meeting.

A.27 Guidance document processing factors.

The item was deferred to the November Committee meeting.

A.28 AOB:

The chair added some items under this agenda point.

- Number of residue trials from non-EU countries (United Kingdom request)

The UK received an enquiry on the topic and asked for the view of the Committee.

Members States are invited to submit comments by 14 October 2016.

- Follow up on the Post Annex 1 (PAI) meeting June 2016

A question on chronic exposure assessment at product authorisation stage was referred to the Committee on Pesticides Residues by the Post Approval Issues (PAI) group of Member States. Three options for dealing with chronic exposure assessment were presented. The Commission invited Member States for their comments by 31 October 2016. Four Member States took the floor and gave their preliminary feedback. Since diverging views were expressed the Commission emphasised that feedback from as many as possible delegations would be needed in order to get a complete picture on current practices.

Members States were invited to submit comments by 31 October 2016.

- Information on an application for glyphosate MRLs in corn Cromwell/borage seed

The Commission clarified that for the time being no new MRLs for glyphosate following routine MRL applications will be implemented before a decision on the renewal of the active substance has been taken.

A Member States shared its concerns about this decision with the other Member States as decisions should be made based on scientific considerations, rather than on political ones. It considers this issue an unwanted precedent.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, Trichoderma atroviride strain SC1 and zoxamide in or on certain products (Article 10).

The Commission introduced the draft and presented its contents.

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

- azoxystrobin for the use on rhubarb, linseeds, safflower seeds and borage seeds;
- cyantraniliprole for the use on table grapes, strawberries, beans (without pods), peas (without pods), globe artichokes, herbal infusions from roots, root and rhizome spices;
- cyflufenamid for the use on stone fruits and globe artichokes;
- cyproconazole for the use on pulses, barley and oat;
- dithiocarbamates for the use of mancozeb on persimmons;
- fluazifop-P for the use on pumpkin seeds;
- fluopyram for the use on apricots, peppers, "spinaches and similar leaves", witloof, "herbs and edible flowers", peas (with pods), lentils, other legume vegetables of code 0260990, sesame seeds, sunflower seeds, pumpkin seeds, safflower seeds, borage seeds, hemp seeds, castor beans, barley, buckwheat, oat and sugar beet;
- metalaxyl for the use on grapefruits, oranges, strawberries, Brussels sprouts and "spinaches and similar leaves";
- prohexadione for the use on strawberries;
- propaquizafop for the use on celeriacs, parsnips, parsley roots, radishes, cauliflowers, head cabbages, "lettuces and salad plants", poppy seeds, soyabeans, mustard seeds;
- pyrimethanil for the use on leek;

- zoxamide for the use on "lettuces and salad plants", "spinaches and similar leaves" and "herbs and edible flowers".

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

- diethofencarb for the use on bananas;
- haloxyfop-P for the use on soyabeans.

As regards the use of azoxystrobin on rhubarb, the use of fluopyram on sugar beet and the use of propaquizafop on "lettuces and salad plants", EFSA concluded that the submitted data were not sufficient to set new MRLs.

As regards fluazifop-P, several MRLs were modified by Commission Regulation (EU) 2016/1015. That Regulation lowered the MRL for pumpkin seeds to the relevant limit of determination as of 19 January 2017. In the interest of legal certainty, it is appropriate for the MRL, provided for by this draft proposal, to apply from the same date.

As regards cyantraniliprole, isofetamid and Trichoderma atroviride strain SC1, EFSA submitted conclusions on the peer review of the pesticide risk assessment of those active substances.

As regards Trichoderma atroviride strain SC1, EFSA concluded that as regards the dietary risk assessment for consumers some information was not available and further consideration by risk managers was required. The Standing Committee on Plants, Animals, Food and Feed noted at its meeting on 19 May 2016 that the substance concerned does not produce relevant metabolites of significant toxicity or at levels leading to an exposure higher than negligible. Consequently, the Commission proposed to include the substance in Annex IV to Regulation (EC) No 396/2005.

A Member State abstained because they do not consider Trichoderma atroviride strain SC1 as being a low-risk active substance. In view of such, they believe that the substance should not be included in Annex IV.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph and triflusulfuron in or on certain products (Article 12).

As regards bifenthrin, the Commission informed the Member States about data on herbal infusions that it had received demonstrating that the proposed levels could be difficult to achieve. The Comission proposed to maintain the existing temporary MRL and monitor the situation for a further three years. A footnote was introduced for this purpose.

One Member State highlighted that lowering the MRL for fenpropimorph/beetroot could have a major economic impact. A restriction, applicable to feed at national level could be considered instead. The Commission pointed out that the issue was extensively discussed in June PAFF and agreed that a distinction between food and feed was not possible and not consistent with earlier proposals..

The Commission also clarified the residue definition for triflusulfuron responding to a question from a Member State.

Vote taken: Favourable opinion.