EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 16 JUNE 2016 - 17 JUNE 2016

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/996edfb1-8e0e-4c1a-b574-a62f374e9c49*

A.01 Dimethoate follow up.

The Commission gave an update on the state of play. As a follow up to the outcome of the extra Plants, Animals, Food and Feed (PAFF) Committee on Pesticides Residues of 28 April 2016, a prioritised Maximum Residue Level (MRL) review for dimethoate under Article 43 of Regulation (EC) No 396/2005 has been initiated. Furthermore the Directorate General for Health and Food Safety (DG SANTE) has sent a letter to the French authorities asking them to amend the French national measure in order to make it more proportionate, by restricting the measure to cherries, originating from Third countries or Member States that have authorisations in place for dimethoate on cherries, in which the presence of dimethoate residues has been demonstrated. Such an amendment would avoid discrimination of producers who are able and willing to produce cherries without using dimethoate even if the use on cherries is authorised in their country. France informed the Committee that a response to the Commission's letter was under preparation. The Commission also informed the Committee that on 11 June 2016 France published a list of Member States and Third countries that cannot import cherries into France based on the French national measure.

A.02 Exchange of views of the Committee on a working document on maximum residue levels for chlorate in or on certain products (Article 16) (SANTE/10684/2015 Rev. 0).

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. Comments received from Member States and a presentation from Specialised Nutrition Europe (SNE) on chlorate residues in food for infants and young children were uploaded on the Communication and Information Resource Centre for Administrations, Businesses and Citizens system (CIRCABC).

A.03 Exchange of views of the Committee as regards maximum residue levels for bitertanol, chlormequat and tebufenpyrad (Article 12) (SANTE/10827/2016 Rev. 0).

The Commission presented the proposed Regulation covering the review of these three substances. For bitertanol, prohibited in the EU since 2013, MRLs are proposed to be lowered to the limits of quantification (LOQs), including for the commodities for which there are some Codex maximum residue limits (CXLs) in place, as toxicological data on certain impurities of the active substance are missing. For tebufenpyrad, as the critical GAPs for apples and pears lead to consumer concerns, fall back Good Agricultural Practices (GAPs) were used to derive the MRLs. For chlormequat, CXLs were maintained. For pears and cultivated fungi MRLs were derived from monitoring data to cover unintentional carry over. As different risk management options were proposed for cultivated fungi by EFSA, the Commission proposed to follow the same approach as for mepiquat in cultivated mushrooms (the respective measure was voted in February 2016).

Member States were invited to submit their comments by 30 June 2016.

A.04 Exchange of views of the Committee as regards maximum residue levels for fenpyroximate, triadimenol and triadimefon (Article 12).

The Commission presented two options for MRL setting and for the residue definition for animal origin commodities. EFSA proposed to bring the relevance of the M3 metabolite for animal origin commodities to the attention of the Joint FAO/WHO Expert Meeting on Pesticides Residues (JMPR) via a concern form.

The Commission proposed to set separate residue definitions for triadimenol and triadimefon in line with the EFSA reasoned opinion.

Member States were invited to comment by 19 August 2016 on the options outlined in an Explanatory Note on CIRCABC.

A.05 Exchange of views of the Committee as regards maximum residue levels for hexachlorocyclohexane.

Based on the comments reived from Member States, the Commission proposed to delete the sum residue definition for hexachlorocyclohexane (HCH) and to only keep the separate residue definitions for the alpha, beta and gamma isomer (lindane). EFSA compiled the recent monitoring data for HCH, that will be used for a proposal to delete the sum residue definition and to update the MRLs and Limits of Quantifications (LOQs) for the 3 HCH isomers.

A.06 Substances for which Limits of Quantifications (LOQs) need to be increased in line with the working document on the summing up of LOQs.

A list of substances was discussed for which the MRLs set at the LOQ could be increased for commodities for which no use is authorised, in line with document

SANCO/12574/2014. Comments were received from the EU Reference Laboratories (EU RLs) and several Member States. The Commission clarified that the residue definition should not be changed in this exercise.

A Member State proposed to add captan and folpet to the list and will send the comment in writing. A Member State indicated that, as separate residue definitions have been set for clothiandin and thiamethoxam, these substances could be removed from the list. EFSA proposed that for substances for which at EU level, no toxicological reference values were set (e.g. aldrin, dieldrin and aldicarb) toxicological reference values set by the Joint FAO/WHO Meetings on Pesticides Residues (JMPR) could be considered.

Member States were invited to comment by 19 August 2016.

A.07 Procedures for routine Maximum Residue Level (MRL) setting under Regulation (EC) No 396/2005:

1. Planned revision of SANCO/01981/2008 (now re-named into SANTE/2015/10595) - State of play

The Commission introduced the changes made compared to the previous version of the document (previously named SANCO/01981/2008) outlining the MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009. The Commission plans to formally take note of the document at the Standing Committee in September 2016.

During the meeting, the Commission outlined a series of pending issues and asked Member States to send comments by 15 July 2016.

2. Updated MRL application form (to be noted)

The Commission outlined the minor changes brought to the document following Member States' comments.

The Committee took note of the new revision of the application form (SANCO/4044/2008 Rev. 10.2).

A.08 Amendments to the Extrapolation Guidance Document (SANCO/7525/VI/95 Rev. 10.2).

The Commission outlined a set of issues that will be included in the second draft of the proposal. In particular, as for the specific issue of the open or closed leaf lettuce varieties, the Committee agreed on the proposal of the Commission to move the variety 'lollo bionda/lollo rossa' into the open leaf group.

EFSA took the occasion of this amendment to propose the introduction of some new elements into the Extrapolation Guidance. The representative from EFSA briefly

illustrated the reason of the proposals, which will be included in the second draft of the Revision 10.2.

The Commission will circulate the second draft of the Revision 10.2 and evaluate whether the EFSA proposals could fit in the revision 10.2 or whether it would be more appropriate to take them up at a later stage.

Member States were invited to send comments by 15 July 2016.

A.09 Planned amendments to Annex 1 to Regulation (EC) No 396/2005 (Regulation (EU) No 752/2014).

The Commission plans to update Annex I with some issues that were brought to its attention since Regulation (EU) 752/2014 came into force on 1 January 2015. The updated Annex should enter into force in early 2017. As regards the introduction of new species/varieties, the Commission clarified that only Part B of the Annex I will be amended while Part A would be maintained in its current structure.

A discussion took place on a footnote (footnote (1) dealing with the application of MRLs to feedingstuffs), for which the question was raised whether it should be maintained, amended or deleted. Several Member States expressed their preference for the footnote to remain in the document. A proposal of re-wording of the footnote has been presented by one Member State which will be considered by the Commission.

The Commission will prepare and circulate a written proposal and Member States will be invited to send comments by 31 August 2016. In the meanwhile, Member States are invited to already communicate to the Commission any new species/varieties that should be included in Annex I Part B.

A.10 Glyphosate-residue definition for Article 12 assessment of MRLs for note taking, animal health mandate.

The Commission informed the Committee on a mandate sent to EFSA to consider the impact of glyphosate residues in feed on animal health. The assessment follows the same timelines as the Article 12 review of the existing MRLs, and EFSA is requested to deliver the two opinions at the same time.

The discussion on the residue definition will be continued at the next meeting of the Committee.

A.11 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 (working document (SANTE/10235/2016) to be noted)

The Commission outlined the amendments brought in the new version following comments sent by Member States.

A Member State asked for clarification on how the availability of analytical standards should be addressed by industry. The Commission explained that the analytical standards should be made commercially available to all laboratories via the internet. It is not sufficient to send the EURLs a few grams of reference material. The EURLs inform the Commission on the commercial availability of standards based on the results of an internet search. If the EURLs are informed directly by industry, this is even better as the EURLs then only need to check the specific distributor of analytical reference standards.

The Committee took note of the document SANTE/10235/2016 Rev 2.

3. Communication with Third Countries

The Note addressed to authorities of non-EU countries, informing them about the ongoing Article 12 review process, was finalised and was uploaded on CIRCABC. Once notified by the WTO/SPS secretariat, the Note will also be published on the SANTE website:

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

Stakeholder associations will be made aware of the Note.

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

The Commission outlined in broad terms an approach for follow up on substances for which the Article 12 review had been completed, but for which relevant endpoints were changed in the renewal exercise afterwards. A three step procedure had been agreed with EFSA but details still need to be discussed. The Commission stressed that in view of the scarce available resources priority should be given to complete the ongoing Article 12 review exercise and to follow up on changed endpoints only on substances where there was evidence of an urgent need to act, e.g. in case of health concerns.

As a first step EFSA has prepared a table containing the relevant substances and the information on changed endpoints during the renewal exercise. As a second step, the Commission will, in collaboration with EFSA, identify those substances for which there may be a need to perform a rough screening for exposure, in particular where toxicological reference values may be exceeded. In cases where the screening highlights a potential health risk, an Article 43 mandate would be prepared by the Commission requesting EFSA to review the Article 12 risk assessment in the light of new information.

Member States were asked to provide comments on the approach by 15 July 2016.

5. Other

The Commission and Member States exchanged their views on the meaning of the terms “produced” contained in the transitional measures of the Commission Regulations modifying the existing MRLs according to which “Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced before” the date of application of the Regulation setting those MRLs.

Possible option under considerations were to interpret the “term” produced either as “ready to be placed on the market”, or “harvested, processed and distributed”, or “treated with plant protection products”. Also the specific cases of "imported" products and post-harvest treatment were discussed.

The Commission services will analyse the contributions of Member States and, after internal consultations, will provide guidance on the interpretation of these transitional measures which, according to Article 49 of Regulation (EC) No 396/2005, can be granted only when there is no risk to consumers.

A.12 News from the European Food Safety Authority:

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

EFSA reported that it had finalised the review of 270 substances so far. Additionally, a statement for 39 substances for which an Article 12 review would not be needed was issued. Those substances can be or have already been included into Annex IV of Regulation (EC) No. 396/2005. A new version of the EFSA PROFILE is being prepared. Member States were invited to comment on the updated PROFILE.

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

EFSA reported that there were nine clock-stops that were not advancing at Member State level for more than one year. The Member States were invited to check whether there are any applications which are no longer relevant and should therefore be withdrawn. The Commission requested a list of these substances from EFSA to have a better overview. EFSA furthermore reported that organisational and structural changes are being done in EFSA currently and that this may result in delays.

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

EFSA reported that it had received the mandate from the Commission on substances that are both being used as pesticides and as veterinary medicinal products. The Commission sent this mandate in view of a possible alignment of MRLs set under different legislative frameworks. The deadline for EFSA is 31 of July 2016.

On omethoate/dimethoate the Commission recently sent a mandate to EFSA under Article 43 of Regulation (EC) No 396/2005 with a deadline of mid-November 2016

for EFSA to complete this task. This assessment will not replace the Article 12 review which will be done only after the renewal procedure and will therefore not assess the existing CXLs.

In the terms of reference the Commission asked EFSA to take account of:

- all Good Agricultural Practices (GAPs) in line with the current MRLs that will be submitted by Member States in response to a call for data made by EFSA.
- residue trial data for the critical GAPs: Member States should only submit data sets in which residues for omethoate and dimethoate are measured separately.
- all relevant metabolism studies for the crop groups for which GAPs are reported, that were submitted under the renewal dossier or by Member States in response to the EFSA call for data. This will allow assessing for which crops the metabolites, for which toxicological data are missing, are not of relevance.

As regards the mandate on foods for infants and young children that the Commission sent to EFSA in November 2015 EFSA reported that the mandate had been split into two parts of which one was of a more general nature and therefore would comprise a wider range of substances than pesticides. The Commission requested that a formal acceptance letter be prepared by EFSA and the approach that EFSA follows (splitting into two parts) clearly outlined together with the timelines for the work. A Member State asked the Commission to share the mandate with the Member States. The Commission agreed to do so.

A.13 Monitoring:

1. Presentation of the EU monitoring report and follow up

EFSA presented the outcome of the monitoring programme carried out in 2014. The report is expected to be adopted in July 2016.

Member States were invited to send comments on the draft report to EFSA by 30 June 2016.

A Member State commented on the fact that for food for infants and young children the majority of the residues were reported at levels below the generally accepted LOQs and it questioned whether these levels were properly validated. It suggested to report separately, the number of findings above the accepted LOQs i.e. the MRLs.

A Member State enquired on how the EFSA recommendations on the design of the EU coordinated multiannual control programme (EU MACP) would be implemented. The Commission explained that the recommendations would be discussed during the Expert Group Meeting on Pesticides Residues Monitoring of 21 October 2016.

2. Working document on pesticides to be considered for inclusion in the national control programmes SANCO/12745/2013 Rev 6(3)

Member States were requested to inform the Commission on the substances to be included in the working document (Annex VI) by 30 June 2016.

3. Expert Group Meeting on Pesticides Residues Monitoring 2016

This expert group meeting will take place on 21 October 2016 in Brussels. During this meeting the EU MACP for 2018-2020 and the working document on pesticides to be considered for inclusion in the national control programmes will be discussed.

Experts who are interested in the working group should inform the Commission by 19 August 2016.

A.14 Specific substances:

1. Mercury

The Commission gave an update on the state of play.

Food consumption advice is available in most Member States on fish, but it seems necessary to raise awareness. The list of fish species is being redrafted in a way that all relevant species are covered in a consistent manner. On other commodities than fish the discussions have led to a sometimes very detailed subdivision of food commodities.

The stakeholder consultation will be launched at the beginning of July 2016. The next Expert Committee on Environmental and Industrial Contaminants is scheduled for 30 June 2016. The proposal will be further discussed in autumn 2016 and is scheduled for vote at the latest in December 2016.

2. Chlorpyriphos

The Commission provided an overview of the reactions of stakeholders for chlorpyrifos since the publication of the EFSA Reasoned Opinion on this substance.

Concerns as regards the marketing of dried raisins and products containing dried raisins (products with long shelf lives) after the application date of the Regulation on 10 August 2016 were brought to the attention of the Commission and to national authorities. Since the EFSA reasoned opinion identified health concerns with fresh grapes, the Regulation did not contain a transitional period for products produced before the application date, which is the normal procedure if health concerns exist. Since monitoring data and consumption figures have been provided on raisins showing that there is no health risk for consumers, the Commission agreed to discuss with the Member States about possibilities for proportionate enforcement action in this specific case.

The Commission highlighted that it was in favour of Member States taking proportionate enforcement actions in the case of dried grapes and products containing such dried grapes. The Commission will however not embark on proposing non-statutory enforcement levels that would contradict legislation and would set an

unwanted precedent. Since enforcement action is the sole competence of Member States, the Commission however considers the available calculations provided by some Member States as useful examples and tools for other Member States to consider such proportionate enforcement action at national level and sees itself in the role of facilitator of an exchange of views between Member States in this respect.

There was broad support by the Member States on applying a more proportionate enforcement approach in this specific case. Several Member States confirmed that they would be in favour of applying such proportionate action for a certain time span and that they were grateful for the Commission to take the issue up. One Member State remarked that other products than dried raisins may also be concerned.

Several delegations supported the level of 0.2 mg/kg for dried raisins as proposed by one Member State as a sort of action level for dried raisins, however two Member States indicated reservations. Some would have preferred the Commission to suggest such a level instead of leaving it up to the Member States to decide. The Commission emphasised again that it would not recommend levels that are not in line with Regulation (EC) No. 396/2005 and that Member States would remain flexible to take their own decision. The Member States had different views on the time span for which such proportionate action should be taken, ranging from the end of 2016 to the end of 2017. This decision will also left up to the discretion of the Member States who know their market situation best. The Commission requested the Member States to inform the Commission in writing about the approach taken and to also actively communicate with stakeholder organisations at national level. In the discussion with Member States the following additional issues were noted by the Commission that would require some follow up:

- the need for a discussion on processed products in general
- the update of the EFSA PRIMO model

3. Quizalofop/Propaquizafop

A reasoned opinion on the setting of MRLs for propaquizafop was recently published. In that framework, EFSA proposes the two following options to be considered by risk managers:

1. to set specific MRLs for propaquizafop for the crops under consideration;
2. to delete the MRLs for propaquizafop from the EU legislation and to report all MRLs for all quizalofop ester variants in the EU legislation as ‘quizalofop’.

In view of the diverging views received by the Member States on the two options received and the fact that further investigation/consultation is needed on the appropriate LOQs, it was agreed to stick to the normal procedures and not to propose a change of residue definition within the context of this proposal, but to do this in the Article 12 review at a later stage (Option 1).

4. Gamma and lambda cyhalothrin

Lambda- and gamma-cyhalothrin are approved under Regulation (EC) No 1107/2009 since 2015 and 1016, respectively, whereas the active substance “cyhalothrin” is not

approved. MRLs are set in the Annexes to Regulation (EC) No 396/2005 for lambda-cyhalothrin. For gamma cyhalothrin the default MRL of 0.01 mg/kg applies. Gamma-cyhalothrin is twice as toxic as lambda-cyhalothrin. The current residue definition of lambda cyhalothrin includes gamma cyhalothrin, therefore the two substances are inter-linked. Enforecment problems have been signalled by Member States that arise from the fact that both substances are linked, but the default value applies for gamma-cyhalothrin.

The Commission asked Member States, the Rapporteur Member State (RMS) in particular, to clarify how currently national authorities are dealing in practice with these substances (during authorisation but also enforcement) to fully understand the issue.

In parallel, the Commission already consulted the European Reference Laboratories to gather information on the analytical methods currently available to discriminate the various isomers for enforcement purposes. As the revised reasoned opinion for the review of lambda-cyhalothrin was recently published and will need to be addressed in the near future, this may be an occasion to look at the residue definitions for both compounds again.

5. Procymidone, iprodione and vinclozolin residue definitions

The Commission intends to find a consistent approach for the residue definitions, which are currently set for vinclozolin, procymidone and iprodione in products of animal origin. As analytical methods for the parent compound in animal products were confirmed by the EU RLs to be available, the parent could be set for all three compounds, as it is already the case for plant products.

However, in view of the fact that analytical data are currently being requested for iprodione under the provisions of Regulation (EU) 2015/400 as confirmatory data, it would be appropriate to wait until the information has been received before taking action (i.e. 14 March 2017).

6. Spirotetramat

A reasoned opinion on the modification of the existing MRLs for spirotetramat in various crops was published on 29 March 2016. EFSA recommends changing the residue definition for both plant and animal origin commodities. This implies that most of the MRLs already in place need to be reviewed.

The Committee agreed that it was more appropriate to deal with this reasoned opinion in a future Article 12 proposal.

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

The following conclusions for new active substances were published by EFSA since last meeting of this Standing Comittee and are now under discussion in the Standing Committee – PAFF – Legislation:

- Cyclaniliprole

- Bacillus amyloliquefaciens FZB 24

A.15 Feedback and follow up to Codex Committee for Pesticides Residues (CCPR) 48 (2016):

1. Overview on main conclusions on the agenda items

The Commission thanked the Member States for their active participation and support in CCPR 2016 and outlined the progress made on specific issues such as the revision of the classification for food and feed, the guidance on performance criteria for methods of analysis, the Codex schedule of priority lists, the proposed draft MRLs and EU reservations and the discussion on the future work on the IESTI equation. The Commission emphasised that participation of more Member States' experts at the next CCPR meeting 2017 would be very welcome as it would help sharing the high workload, in particular in view of the sensitive files that will have to be dealt with in future (new work was agreed on the IESTI equation).

2. Work organisation for the preparation of coordinated positions for CCPR 49 (2017)

At the request of some Member States, a discussion took place on how to best coordinate between Member States and the Commission in view of preparing coordinated positions for the preparation of CCPR 2017 and beyond, in order to avoid overlaps and duplication of work. The Commission also suggested coordination at an early stage of input into electronic working groups whilst acknowledging that each Member State that wishes to participate in an electronic working group is appointed as a member of its own and as such has the full rights to contribute. The Commission confirmed that for preparing coordinated positions for the discussion with Member States in the preparatory Council Working Parties (CWPs), the Commission would always submit a first draft for Member States to comment on, also on items that are falling under mixed competence. As regards the discussions on specific substances Rapporteur Member States should play a key role in scrutinising the draft EU coordinated comments. The Commission, in collaboration with EFSA, will also look into ways to improve cooperation with JMPR. On the suggestion of the Commission to also coordinate as much as possible the input into electronic working groups at an early stage, two Member States commented that they would like to retain some flexibility to comment on their own. The Commission concluded that a discussion on whether a coordinated position could be prepared at an early stage would need to be agreed with Member States case by case, also taking into account practicalities such as the sometimes short deadlines.

The Commission informed that at the request of the chair of the electronic working group on priorities, it is currently preparing a table with suggestions for prioritisation of the active substances that were previously proposed by the EU and now included in the draft schedules for periodic review in 2018-2021. The table will be shared with Member States for comments before forwarding to the electronic working group.

3. Preparations for Codex Alimentarius Commission (CAC) 2016

The Committee advised to recommend that the EU lifts its reservations to the adoption of the following MRLs at the 39th session of the Codex Alimentarius Commission (CAC):

- 106 ethephon in figs
- 256 fluxapyroxad in banana and oranges, sweet, sour
- 263 cyantraniliprole in cotton seed, rape seed and sunflower seed

The Commission noted that in the 2016 CCPR Report, it is erroneously stated that the EU introduced a general reservation for MRLs for 160 propiconazole. The Commission has therefore left this substance out of the draft EU position for the CAC (because no specific reservations apply, either).

All other EU reservations introduced at CCPR 2016, where they concern draft MRLs forwarded by CCPR to CAC for adoption, should be maintained at the CAC meeting.

The Commission clarified the procedures for submitting concern forms, of which two different types exist, both applying for cases of concerns for public health. The concern form presented in Annex A to section IV of the Risk Analysis Principles (chapter 5.5.1. of the Procedural Manual) is for concerns on the advancement of an MRL or the evaluation of a pesticide and is typically used to stop the advancement of an MRL by CCPR requesting JMPR for a new evaluation. The form is sent to both the Codex and the JMPR secretariats. The concern form in Annex B (chapter 5.5.2. of the Procedural Manual) is to express a public health concern on a previously evaluated pesticide for prioritisation and is sent to the JMPR secretariat and the chair(s) of the electronic working group on priorities. The Commission clarified that it is grateful for the respective Rapporteur Member States to fill in the details of such concern forms, but that the formal sending must then be done by the EU.

The Committee agreed that concern forms should be submitted for 130 diflubenzuron (Form Annex B) and for 287 quinclorac (Form Annex A), but not for 146 lambda-cyhalothrin. The relevant RMS have prepared or will prepare the forms, which will then be submitted via the EU Codex contact point.

The Commission prepared a 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 paper highlighted some issues that would need to be further investigated:

- some active substances that would be due for periodic review (falling clearly under the 15 year rule) are not yet flagged (listed)
- some active substances that are not yet subject to periodic review (not yet falling under the 15-year rule) have been evaluated in the last 15 years for ARfD only, or ADI and ARfD only.

Rapporteur Member States are asked to identify substances of concern, to fill concern forms (Annex B) for these substances, if appropriate, and to send the draft concern forms to the Commission by 31 July 2016.

A.16 Screening exercise on t-MRLs in Regulation (EC) No 396/2005 that will be expiring in 2016.

The Commission outlined the state of play.

As regards fluopyram, temporary MRLs were set for rotational crops with a deadline set on 19 October 2015 for the applicant to submit further data. An extensive application was submitted within the deadline and only recently the reasoned opinion was published. The Commission intends to draft a proposal where the MRLs for the supported uses will be maintained or increased, whereas the MRLs for the uses no longer supported will drop to the LOQ.

As regards nicotine and profenophos, the Commission had a meeting with stakeholder organisations in May 2016 and received updates on the findings of the substances in the relevant crops. The stakeholder organisations recently submitted monitoring data covering the period from 2011 to 2015. The relevant tables were uploaded on CIRCABC.

A.17 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

An updated Excel table regarding Annex IV inclusions was made available on CIRCABC.

2. Exchange of views as regards inclusion into Annex IV of Trichoderma atroviride SC1

The Commission invited Member States to send comments on the inclusion into Annex IV of Trichoderma atroviride SC1 and denathonium benzoate (bitrex) by 15 July 2016.

3. EFSA opinion on Bacillus thuringiensis and follow up

The Commission announced the adoption of the Scientific Opinion on risks for public health related to the presence of Bacillus cereus and other Bacillus spp. including Bacillus thuringiensis in foodstuffs that took place on 12 June 2016 by the EFSA BIOHAZ Panel. The Commission summarised some main points. Publication of this opinion is expected by mid July 2016 and therefore there is no draft copy available which could be shared. A detailed discussion of this Scientific Opinion will be scheduled for the next meeting of this Standing Committee.

A.18 Update on foods intended for infants and young children.

Specific legislations on certain dietetic foods intended for infant and young children include provisions on pesticides, which consist o a list of prohibited active substances

for the production of raw materials used entering into their composition and specific MRLs. Application of these provisions has revealed some difficulties, due to different residue definitions in these legislations and in the general MRLs legislation and analytical difficulties linked to very low MRLs. These specific legislations are now under review. A first delegated act covering infant formulae and follow-on formulae was already adopted (Commission delegated Regulation (EU) No 2016/127). So far, the existing provisions on pesticides are maintained, but a mandate to EFSA was sent in November 2015 that would inform a possible later revision of these provisions (see point A.12.3.).

A.19 Follow up from Post Annex I (PAI) meeting.

The issue was not discussed.

A.20 Commission working document on risk management aspects related to the assessment of cumulative exposure SANTE/10216/2015 Rev. 6.

During the second physical working group meeting on cumulative risk assessment of 22 January 2016 a discussion took place on the open questions that are listed in working document SANTE/10216/2015. The outcome of the discussions has now been summarised in Rev. 6 of this document. EFSA already sent comments that were uploaded on CIRCABC.

Member States were invited to submit comments by 19 August 2016.

A.21 Notifications under Article 18(4) to Regulation (EC) No 396/2005.

No notifications were received.

A.22 Designation of Member States for maximum residue levels (MRL) applications.

No issues were raised.

A.23 Information on ongoing work on endocrine disruptors.

The Commission updated the Member States on the ongoing work on endocrine disruptors and informed about the planned meeting with Member States on 22 June 2016 in which a draft delegated act under the Biocidal Products Regulation (Reg. 528/2012) and a draft implementing act under Regulation 1107/2009 setting the criteria for endocrine disruptors will be discussed for the first time with the Member States. The meeting will be organised as a back-to-back meeting of biocides experts and experts on PPPs. A Member State commented that it has some reservations as regards the approach proposed by the Commission.

A.24 Planned evaluations of Regulation (EC) No 396/2005 and Regulation (EC) No 1107/2009 – State of play.

The Commission informed that the roadmap was still waiting for the DG SANTE approval and therefore no new developments could be reported.

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

The issue was not discussed.

A.26 Exchange of views of the Committee as regards maximum residue levels for acrinathrin, bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph, metalaxyl and triflusulfuron (Article 12) (SANTE/11418/2015 Rev. 1)

The Commission presented the proposal and asked Member States to agree on some general 'lines to take' as regards specific situations.

Acrinathrin: the Commission asked whether Member States agree on lowering MRLs of all the crops for which GAPs not complying with the existing use restrictions of the substance were presented by Member States. The uses restrictions are in place since 2013.

The Member States agreed to this principle. However one representative noted that for some crops an Article 10 request has been recently presented to EFSA and another one asked more time to check whether a fall back GAPs had been provided.

Fenpropimorph: the EFSA Reasoned Opinion highlights two issues for consideration by risk managers on MRLs for bananas and animal products.

As regards bananas, in revision 0 of the document the Commission proposed to lower the MRL to 0.01* mg/kg, as it is impossible to guarantee that all imported bananas are bagged prior to the treatment. However, a fall-back GAP leading to an MRL of 0.6 mg/kg was recommended by EFSA and could be proposed. It was agreed that the level of 0.6 mg/kg will be proposed in revision 1 of the proposal.

As regards animal products, the EFSA Reasoned Opinion states that MRLs are safe only if livestock is not fed with sugar/fodder beet leaves. Therefore in Revision 0 the Commission proposed to lower all animal products MRLs to 0.01* mg/kg. It was agreed to go for an alternative option in Rev. 1 by which the MRL of sugar beet leaves would be lowered to 0.01 mg/kg* instead, so to ensure that residues in the animal products would be at safe level.

Metalaxyl: recently an Article 10 opinion was published by EFSA. The conclusion will be taken into account in the revision 1 of the proposal.

The Commission will prepare the Revision 1 of the proposal and will circulate it. Member States will be asked to comment on it in the usual three weeks' time period.

A.27 AOB

- Thiabendazole:

A recent assessment of thiabendazole under Article 43 was carried out by EFSA and the reasoned opinion will soon be published. The Commission will then consider how to best follow up on this opinion.

- Notification under Article 44(4) of Regulation (EC) No. 1107/2009:

A question from a Member State was raised on whether a notification under Article 44(4) of Regulation 1107/2009 was needed when a Member State withdraws authorisations following an Article 12 review. The Commission clarified that the issue had already been brought up in the May Legislation Committee but no feedback from Member States was received. The Commission will refer this question back to the Legislation Committee.

- Application of MRLs to feedingstuffs:

A Member State requested the Commission to clarify which MRLs should be applied to specific feed products. The issue was covered under item A.09.

- SPS Workshop in Geneva:

A Member State requested information on whether the Commission would participate in the WTO/SPS workshop in Geneva in October 2016. The Commission confirmed its plans to be present.

- Guidance document on honey:

A Member State asked for the planed time schedule to discuss the guidance document for MRL setting in honey. France, who agreed to draft this guidance document, will present a draft for discussion in the September 2016 Standing Committee.

- Thiacloprid in honey:

The Commission informed the Committee that a motion for a resolution on the draft Regulation re-instating the MRL for thiacloprid in honey (voted in April 2016 and currently under scrutiny by Parliament and Council) was for discussion in the COM ENVI Committee on 21 June 2016. The Commission invited Member States to submit relevant information on the topic that may have been received at national level by Monday 20 June 2016.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, ametoctradin, azoxystrobin, cyfluthrin, difluoroacetic acid, dimethomorph, fenpyrazamine, flonicamid, fluazinam, fludioxonil, flupyradifurone, flutriafol, fluxapyroxad, metconazole, proquinazid, prothioconazole, pyriproxyfen, spirodiclofen, trifloxystrobin 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:

- Acetamiprid for the use on table olives, tomatoes, gherkins, beans (with pods), peas (with pods), pulses (dry), rapeseeds, olives for oil production and wheat;
- Ametoctradin for the use on spring onions;
- Azoxystrobin for the use on table and wine grapes;
- Cyfluthrin for the use of beta-cyfluthrin on barley, oat, rye and wheat;
- Dimethomorph for the use on flowering brassica and "spinach and similar leaves";
- Flonicamid for the use on "herbs and edible flowers";
- Fludioxonil for the use on "lettuce and salad plants", "spinach and similar leaves", "herbs and edible flowers" and peas (without pods);
- Difluoroacetic acid and flupyradifurone for the use of flupyradifurone on strawberries, blackberries and raspberries;
- Proquinazid for the use on apples and pears;
- Prothioconazole for the use on sunflower seeds;
- Pyriproxyfen for the use on bananas;
- Spirodiclofen for the use on cranberries and gooseberries;
- Trifloxystrobin for the use on celeriacs.

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

- Dimethomorph for the use on papaya;
- Fenpyrazamine for the use on cane fruits and blueberries;
- Fluazinam for the use on blueberries, flutriafol on strawberries;
- Fluxapyroxad for the use on almonds, Brazil nuts, chestnuts, hazelnuts, macadamia, pecans, pine nut kernels, walnuts, cherries, grapes, strawberries, blueberries, mangoes, "other root and tuber vegetables" of code 0213000, cucurbits, broccoli, Chinese cabbages, mustard greens, cardoons, celeries, Florence fennel, rhubarbs, rice and sugar cane and metconazole on blueberries, potatoes, "tropical and tuber vegetables", pulses and sunflower seeds.

As regards flupyradifurone, EFSA submitted a conclusion on the peer review of the pesticide risk assessment of the active substance. According to the relevant good agricultural practice, the MRL for difluoroacetic acid in lettuce needs to be set at 0.09 mg/kg to adequately address the use of flupyradifurone on that product.

As regards the use of fluxapyroxad in root and tuber vegetables other than radishes, EFSA concluded that the submitted data were not sufficient to set new MRLs. A Member State believes that the trials conducted on radishes were comparable to the ones performed on carrots and should have been considered in support of setting a common MRL for the whole group of root and tuber vegetables. The Commission took note of the concern, which will be discussed and addressed in the framework of SANCO 7525/VI/95 Rev. 10.2.

As regards proquinazid, EFSA recommended increasing the existing MRLs for liver and kidney in sheep and goat in order to accommodate for the intended uses of that active substance on apples and pears. As no residues of proquinazid are found in ruminant products, it is appropriate to limit the enforcement residue definition to the relevant metabolite only (IN-MU210). The Commission clarified that the residue definition for animal commodities will be further discussed in the framework of the Article 12 review of the substance.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission 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 3-decen-2-one, acibenzolar-S-methyl and hexachlorobenzene in or on certain products.

The Commission outlined the proposal and its contents.

3-decen-2-one was recently non-approved by Commission Implementing Regulation (EU) 2016/138. In its Conclusion, EFSA did not recommend including the substance in Annex IV to Regulation (EC) No 396/2005. Therefore the Commission proposed to set all MRLs at the relevant LOQs. The European Union reference laboratories were consulted in the process.

For acibenzolar-S-methyl, EFSA submitted a conclusion on the peer review of the pesticide risk assessment of the active substance. In that framework, it recommended increasing the MRL for the group of pome fruits to 0.2 mg/kg. Based on the new toxicological reference values, it recommended lowering the existing MRL for tomatoes to 0.3 mg/kg. The Commission clarified to Member States that no fall-back GAP exists leading to an MRL proposal higher than the proposed value.

For hexachlorobenzene, all existing authorisations for plant protection products containing that active substance have been revoked. The Commission explained that hexachlorobenzene (HCB) is a fat soluble persistent organic pollutant that is expected to mainly occur in the fat part of meat rather than in the muscle part. As currently the same MRLs are in place for both muscle and fat, it would be appropriate to lower the MRLs for muscle. Furthermore, the Commission drafted a proposal for also lowering other MRLs based on the most recent monitoring data and LOQs that were reported to EFSA.

Recent monitoring data show that residues occur on pumpkin seeds at a level higher than the LOQ. Residues of hexachlorobenzene are resulting from environmental contamination in soil, due to the use of this persistent compound in the past. The existing MRL of 0.05 mg/kg for pumpkin seeds adequately addresses the occurrence of hexachlorobenzene in that product.

One Member State abstained because it believes that the MRL proposal for 3-decen-2-one is not robust enough.

Vote taken: Favourable opinion.

B.03 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 aclonifen, deltamethrin, fluazinam, methomyl, sulcotrione and thiodicarb in or on certain products (Article 12).

The Commission presented the latest changes to the proposal. Comments were received through WTO, from stakeholders and Member States on the proposed MRL for deltamethrin in wheat. Based on a fall-back GAP from the EFSA Reasoned Opinion on deltamethrin and using processing factors, an MRL of 1 mg/kg for deltamethrin in wheat was proposed in Rev. 2 of the proposal.

Further comments were received from the US on the MRL for fluazinam and methomyl on blueberries. These comments cannot be taken into account for this proposal but an application for an import tolerance can be made under Article 6 of Regulation (EC) No 396/2005.

A Member State regretted that the OECD calculator was not always taken into account. The Commission explained that this should only happen in very exceptional cases and must be substantiated by EFSA with valid arguments.

A Member State made a comment on data which was submitted during the AIR 4 renawal process. The Commission referred to the discussion under agenda point A 11.4.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cymoxanil, phosphane and phosphide salts, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in in or on certain products (Article 12).

The Commission introduced the draft and presented its contents.

Comments were received from the United States on the MRL proposals for raspberries and hops. The Commission explained that since in these cases the data supporting these MRLs had not been submitted to EFSA prior to the drafting of the reasoned opinion, they could not be taken into account. However, if the concerned MRLs are considered necessary, an application for an import tolerance can be made under Article 6 of Regulation (EC) No 396/2005.

A Member States commented on the setting of MRLs at different LOQs within the same commodity group. The Commission explained that this is consistent with the approach taken in previous proposals, where lower LOQs were set in the same group

for commodities for which no use is authorised, allowing for a better enforcement of illegal uses.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards carvone, diammonium phosphate, *Saccharomyces cerevisiae* strain LAS02 and whey.

The Commission presented the proposal.

EFSA recommended the inclusion of D-carvone and not L-carvone in the conclusions and therefore requested adaption of recital 2. This was taken into account in revision 3 of the proposal.

One Member State expressed concern that future authorisations for carvone might lead to a situation in which the pesticide exposure exceeds the natural background level and the ADI might be exceeded. It was decided to include a footnote to highlight the issue in Rev. 3 of the proposal.

One Member State expressed concerns as regards the prosed footnote for carvone as it is not consistent with other substances and might lead to confusion. This Member State abstained because it believes the current proposal is not the appropriate framework to set provisions related to the national authorisation process.

Vote taken: Favourable opinion.