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Standing Committee on Plants, Animals, Food and Feed
Section *Phytopharmaceuticals - Legislation*
16 - 17 July 2019

CIRCABC Link: ***https://circabc.europa.eu/w/browse/c46bc996-9f82-4f11-831d-13b6d80994db***

SUMMARY REPORT

A.01 Summary Report of previous meetings.

The Commission informed that the summary report of the last meeting is to be published in the next days.

The Commission also informed that the draft documents presented for opinion or discussion under Sections B and C, respectively, will be made available via the Comitology Register as of the current meeting, with the objective to increase transparency.

A.02 New active substances:

1. ***New admissible dossiers to be noted:***

   The Committee took note of four new admissible dossiers for the following substances: fluindapyr (fungicide, rapporteur Member State is Germany), as well as *Bacillus subtilis* strain RTI477, *Bacillus velezensis* strain RTI301, and *Phthorimaea operculella* granulovirus (PhopGV) (three microorganism strains for which the rapporteur Member State is the Netherlands).

2. ***Exchange of views on new European Food Safety Authority (EFSA) conclusions:***

   a) Napropamid-M (update)

   The Commission informed that it had asked EFSA for clarification based on the comments received from the applicant.

3. ***Draft Review/Renewal Reports for discussion:***

   a) Lavandulyl senecionate

   The Commission summarised that no area of concern was identified in the EFSA conclusion but a data gap concerning the R-isomer related to EFSA's interpretation of the semio-chemical guidelines. Two potential ways forward seem possible: to proceed with an approval as low risk substance or - before any draft for approval - to mandate EFSA to clarify the case of Lavandulyl, in particular with regard to general natural levels expected for arthropod pheromones.

Several Member States indicated their potential support for an approval as low risk active substance, while other Member States asked for mandating EFSA. One Member State did not support the approval of the active substance.

Based on the discussion, the Commission indicated that it would prepare a proposal for draft as low-risk active substance and at the same time mandate EFSA as regards natural levels expected for arthropod pheromones.

The Member States were invited to comment by 6 September 2019.

b) 1,3-Dichloropropene

The Commission summarised the positions expressed by several Member States and considered it necessary to get a clearer overview from all Member States. A tour de table revealed that only 14 Member States would support a non-approval.

The Commission presented as potential alternative a very restricted approval subjected to conditions, based on the comments of the Rapporteur Member State, which would avoid continued recourse to emergency authorisations. Such a potential approach would be subject to some further verification by the Rapporteur Member State and EFSA before it could be pursued. The Commission announced to circulate a document setting out the details of the potential alternative approach shortly after the meeting.

Member States were invited to comment by 6 September 2019.

A.03 Renewal of approval:

1. ***Annex I Renewal Programmes: State of play***

The Commission summarised the state of play for the AIR3 and AIR4 programmes. For the AIR3 programme, a document detailing the status of the on-going renewals, including as well the status of the assessments for endocrine disrupting properties in the framework of Article 11a of the amended Commission Implementing Regulation (EU) Nº 844/2012 had been made available on CIRCABC. Concerning the AIR4 programme, a document with a list of the active substances for which no application has been received or the dossier had been withdrawn, had been made available on CIRCABC also.

2. ***Exchange of view on EFSA conclusions/EFSA scientific reports:***

a) Pyriproxyfen

The Commission summarised the EFSA Conclusion which had recently become available. No critical areas of concern had been identified, however some points could not be finalised by EFSA: validated analytical methods to support most of the available (old) toxicological studies, comparative in vitro metabolism information with possible identification of unique human metabolites, the consumer dietary risk assessment. Also the chronic risk assessment to aquatic invertebrates (metabolite), the risk assessment to sediment-dwelling organisms and the risk assessment for bees could not be fully concluded. EFSA had concluded that pyriproxyfen should not be considered as having endocrine disrupting properties in the light of the new criteria.

The Commission indicated that reasoning to resolve the data gaps seemed possible. Member States were asked to indicate by 6 September 2019 if they would support a renewal with some restrictions and risk mitigation measures.

3. ***Draft Review/Renewal Reports for discussion:***

a) Bromoxynil

The Commission summarised the comments received from Member States since the meeting of the Committee in May, in particular those related to the measures proposed by the applicant to refine the non-dietary exposure assessment and address the risks for workers and for residents.

The Commission explained that the evaluation of the BREAM2 project data (to refine the resident exposure assessment) would need to be carried out and agreed at EU level, rather than by Member States at national level. The ongoing review of the non-dietary guidance document by EFSA would include a review of the project data but a final output was not foreseen for several years.

Member States were asked if they would consider an ad-hoc review of the project data at EU level that could then be used in the case of bromoxynil (and other substances) and – if the outcome would then be favourable for bromoxynil allow a renewal under Article 4.7 (given the proposed classification as R1B), or rather consider that the approval should not be renewed given the risks identified.

Member States were invited to comment by 6 September 2019.

b) Flumioxazin

After the RAC opinion of March 2019, which re-eclassifies flumioxazin from toxic to reproduction Cat 1B to toxic to reproduction Cat 2, the Commission re-examined the possibility to renew the approval of this substance: this might be possible pending an assessment of endocrine disrupting (ED) properties according to the new scientific criteria. The Commission therefore proposed to mandate the EFSA for an update of the ED assessment in line with the new ED criteria and Guidance Document.

Member States were invited to comment by 6 September 2019.

c) Clodinafop

The Commission informed that following discussions in previous meetings and in response to comments received from Member States it would send a mandate to EFSA to further consider several aspects of the assessment: the derivation of the AOEL (an exceptional case given the results seen in certain studies and the need for further technical discussion), refinements to the non-dietary assessment (but excluding new data being taken into account) and an update of the assessment of endocrine disrupting properties (only if the non-dietary exposure assessment is found to be acceptable following a consideration of the first two points).

The Rapporteur Member State had already agreed to carry out the necessary update of the assessment to be sent to EFSA for further review.

Member States were informed that the substance would be removed from the agenda until the first output of the mandate (an updated EFSA Conclusion, expected early 2020) will be available.

d) Fenamiphos

Member States were informed that a draft renewal report for the non-renewal of the approval had been made available and sent to the applicant for comments. The applicant had submitted comments that were available on CIRCABC.

Member States were asked to provide comments on the draft renewal report, taking into consideration the comments of the applicant by 6 September 2019.

e) Cypermethrin

The Commission informed about the comments received from six Member States since the last meeting.

Eleven Member States had commented on the approach proposed (renewal restricted to professional users and subject to the necessary exposure reduction to achieve a safe use for aquatic organisms, off-field arthropods and bees, which will be included in the approval conditions in the Implementing Regulation, giving examples of risk mitigation measure to achieve this reduction of exposure in the renewal report). The majority of the Member States expressed their potential support. Two Member States do not support the renewal. One Member State indicated that while it supports the renewal, it does not agree to specify the objective of the exposure reduction in the Implementing Regulation, but it should be included in the renewal report only. The support of another Member State still depends on the exact wording of the conditions.

The Commission informed that EFSA was consulted on the options to achieve the required exposure reduction so that the risks to aquatic organisms, non-target arthropods and bees become acceptable.

The Member States were invited to comment by 6 September 2019.

f) Beta cyfluthrin

The Commission informed that a draft renewal report for the non-renewal of the approval had been made available. The Commission also informed the Member States about the comments received from the applicants on the draft report.

The Commission summarised the key issues that led to the proposal for non-renewal:

i. Non-dietary human exposure

The applicants' arguments with regard to the setting of the AOEL were not found substantiated. The peer review had established that for the type of effects observed in a repeated inhalation study (Pauluhn 1984) as well as in various other animal studies and considering that the substance represents a pyrethroid, a neurotoxic mode of action is plausible. The neurotoxic mode of action together with behavioural abnormalities and decrease in body weight clearly support that the effect is systemic. The fact that beta-cyfluthrin is classified as fatal if swallowed and fatal if inhaled signals high toxicity by both exposure routes (inhalation and oral). The peer review concluded that since the

AOEL systemic from inhalation is the lowest, this should be used for the non-dietary risk assessment.

ii. Non-target arthropods

The applicants complained that the reliability of the field studies with non-target arthropods had been evaluated based on wrong criteria, and that this and uncorrected errors in the RAR led to an inappropriate outcome of the EFSA Conclusion.

The peer-review meeting report clearly states that experts evaluated the actual documents provided by the applicants, that they discussed the studies and considered the correct criteria during the experts meeting. The RAR as well as EFSA Conclusion describing the available non-target arthropod field studies could be improved but this would not lead to a change in the conclusion of the risk assessment. The overall conclusion was that recovery within one year was not sufficiently demonstrated based on the available data.

The applicant found that beta-cyfluthrin has got unfair treatment compared to lambda-cyhalothrin in case of the evaluation of the NTA.

iii. Use of EFSA model

High-risk to residents were concluded by EFSA model, but not by the Martin model in place at the time of application.

The Commission also informed that so far six Member States, had indicated their support for non-renewal.

The Member States were invited to comment by 6 September on the draft renewal report as well as the applicants' comments on the draft renewal report, in particular as regards the transparent reporting of the risk assessment during the peer review and the consistency of the approach with respect to the renewal of lambda-cyfluthrin in case of non-target arthropod risk, and the use of EFSA model for the risk assessment for residents.

g) *Pseudomonas chlororaphis* MA 342

The Commission recalled that it proposed non-renewal of approval. The Commission summarised the comments submitted by the Member States as regards the updated position paper of the Rapporteur Member State (RMS). One Member State supported the RMS, and two Member States expressed the opinion that even if the new data were taken into account, they would not address all the data gaps identified in the EFSA Conclusion.

The Commission informed about its intention of sending a mandate to EFSA requesting a weight of evidence assessment on the translocation potential by *Pseudomonas chlororaphis* MA342 in plants and on the risk to humans from its use in seed treatment.

Member States were invited to comment by 6 September 2019.

h) Bifenazate

The Commission recalled that it proposed non-renewal of approval.

The Commission gave an update on the positions of Member States received since the meeting in May. The majority of the commenting Member States were of the opinion that the ecotoxicological concerns identified by EFSA should be dealt with at zonal evaluation level and would support the renewal of approval, at least for the outdoor uses. Nevertheless, they did not provide any calculations to demonstrate that the refinement of the assessment of risk to birds and mammals is indeed possible. One Member State had submitted calculations for a refined risk assessment for birds and mammals for crops and focal species relevant in one of the zones, and for the lower dose of the dose-range proposed by the applicant. The conclusion of these calculations was that for none of the uses mitigating measures allowing safe use could be demonstrated in the risk assessment for birds and mammals for bifenazate.

Member States were invited to comment by 6 September 2019.

i) Clopyralid

No news to discuss.

j) Cyazofamid

The Commission informed that the applicant sent substantial comments, which had been made available on CIRCA BC.

Member States were invited to clearly indicate their views by 6 September 2019, in particular under consideration of the comments from the applicant and with respect to a support for a renewal or non-renewal of approval.

k) Famoxadone

No news to discuss. Member States were invited to comment by 6 September 2019 on the draft renewal report in view of non-renewal of the approval.

l) Foramsulfuron

The Commission summarised the comments received so far from Member States and presented a revised draft renewal report. Member States were invited to comment by 6 September 2019, in particular whether they could agree with the renewal of the approval of the active substance.

m) Etoxazole

The Commission informed that it was reflecting on the possibility of a restricted renewal to non-edible crops in greenhouses.

n) Fosethyl

The Commission summarised the comments submitted by the Member States since the meeting in May.

One Member State did not agree to consider the risk assessment with regard to aluminium as illustrative, as indicated by EFSA in the conclusion. Another Member State confirmed that the interpretation with regard to aluminium did not contradict the discussion in the experts meeting nor the EFSA conclusion.

One Member State send comments on the draft renewal report. Two Member States indicated support for the renewal of approval.

The Commission informed that it will now proceed with mandating EFSA for an update of the assessment as regards endocrine disrupting properties in line with the new criteria.

o) Assessment of ED potential in accordance with Commission Regulation (EU) No 2018/605, according to Commission Regulation (EU) No 2018/1659 amending Commission Implementing Regulation (EU) No 844/2012

This point was covered under A.03.1.

A.04 Confirmatory Information:

1. ***General update (no news)***

No news to discuss.

2. ***Spiroxamine (review report to take note)***

The point was postponed.

3. ***Fluopicolide (review report to take note)***

The Commission informed that confirmatory data as regards the relevance of the metabolite M15 for groundwater had been requested and the assessment was finalised. Based on the comments on the preferred way forward received from several Member States, a draft revised review report was presented, leaving the application rate refinement for the consideration of Member States when performing the exposure assessment for plant protection products containing the substance at national level. The Commission invited Member States to comment by 6 September 2019.

4. ***Dithianon (short update)***

The Commission informed it is considering to mandate EFSA to review the assessment made by the Rapporteur Member State based on the new submitted data and to revise its conclusions (dated 2015), with the aim to clarify the data gaps on residues and to solve the acute intake concern.

5. ***Triazole derived metabolites (TDMs) (short update)***

The Commission recalled that no specific concerns had been identified for consumers due to exposure to triazole derived metabolites in the assessment.

However, a number of data gaps and outstanding issues have been identified pertaining to specific substances. Since the gaps differ by active substance and use, it is considered most practical to enable these to be filled either at renewal of approval or during authorisation procedures.

In order to close the confirmatory information process and provide clarity for applicants and Member States at renewal, the Commission proposed to update review reports for each relevant active substance in order to finalise the process. These updates will make clear that the findings in the EFSA Conclusion (July 2018) should be taken into account during renewal or during assessment of plant protection products, as appropriate. Member States were asked to indicate by 6 September 2019 if they could not support such an approach.

6. ***Sulfoxaflor***

   The Commission gave an update on the positions of Member States received since the meeting in May. Three Member States indicated being able to support a restriction to greenhouses. Six Member States informed about the national authorisations in place and, if applicable, associated risk mitigation measures to reduce the risk to bees. Two Member States indicated being able to support field uses after flowering with risk mitigation measures in place.

   The Commission asked the Co-Rapporteur Member State and EFSA for some further clarifications regarding the EFSA conclusion. The Commission informed that a draft will only be prepared upon receipt of these requested clarifications.

7. ***Fenpyrazamine***

   Given that the confirmatory data had been addressed, the Commission proposed to amend the approval and the review report accordingly, by including a maximum concentration for hydrazine as relevant impurity, which reflects the change in production from pilot to commercial scale.

8. ***Isofetamid***

   No discussion took place.

9. ***Benzovindiflupyr***

   Confirmatory data had been required to confirm the technical specification of the active substance as manufactured (on commercial scale) including the relevance of impurities and the compliance of the batches with which the (eco)toxicology studies were conducted with the confirmed technical specification. This compliance had been demonstrated. With regard to mammalian toxicology, the confirmatory data requirements had been partially addressed; a potential for clastogenicity cannot be excluded for one impurity but the evidence for clastogenicity is weak. The Commission proposed to amend the approval and the review report accordingly including a maximum concentration for this relevant impurity.

10. ***Geraniol***

    No discussion took place.

11. ***Eugenol***

    No discussion took place.

12. ***Thymol***

    No discussion took place.

13. ***Clove oil***

    No discussion took place.

14. ***Gamma-cyhalothrin***

    The Technical Report of EFSA of gamma-cyhalothrin was not conclusive with regard to the metabolites PBA, PBA (OH) and a peer-review will need to be requested to EFSA. The long –term risk to wild mammals was also not solved.

    However, there is also an on-going evaluation on confirmatory information as regards the same metabolites of lambda-cyhalothrin. Therefore, the Commission proposed to wait for the finalisation of the evaluation of lambda-cyhalothrin before

mandating EFSA to provide for a harmonised assessment on those metabolites, covering both gamma- and lamba-cyhalothrin. In the same mandate, EFSA will be asked to verify whether a restricted GAP as proposed by the Rapporteur Member State would provide for safe use in case of the wild mammals.

Member States were invited to comment on this proposed approach by 6 September 2019.

A.05 Article 21 Reviews:

No news to discuss.

A.06 Amendment of the conditions of approval:

1. ***New admissible dossiers to be noted:***

   No news to discuss.

2. ***Exchange of view on EFSA conclusions:***

   a) Azadirachtin

   The Commission explained that the EFSA conclusion covers two assessments: confirmatory data from the initial approval and changes to the conditions of approval to extend the use as acaricide for ornamentals. The Commission summarised the issues that could not be finalised indicating that the consumer risk assessment could not be completed due to some remaining uncertainties because the active substance contains several components. As this issue is common to botanicals, the Commission will reflect on the approach to be taken in the light of similar cases.

   The Commission indicated that in the context of the renewal of azadirachtin, it is expected to differentiate between three different active substances, one for each source or origin. At this stage, the Commission considers that the extension of use as acaricide for ornamentals in permanent green house would be acceptable.

   Member States were invited to comment by 6 September 2019.

3. ***Draft Review/Renewal Reports for discussion:***

   No news to discuss.

A.07 Basic substances:

The Commission gave a summary on the state of the applications for basic substances. In the last 2 months the Commission has processed 18 applications. Most of them were sent back to the applicants because they were not complete. Two applications are probably out of scope of Article 23 (basic substances) and the applicants were asked for clarifications. There are 6 applications that are still pending, 3 of them are on hold because there are some legal questions that need to be clarified.

The Commission indicated the need for reflection on some general aspects as regards interpretation of the provisions of Article 23 and the whole concept of the basic substances.

1. ***New dossiers received (for information)***

   - Lecithin (extension)

     The Commission informed about a new application received for extension of use of lecithin.

2. ***Exchange of views on EFSA Technical Reports***

   - Propolis extract

     Based on the EFSA Technical Report, the information seems to be insufficient to conclude that the approval criteria for basic substances are satisfied. The Commission summarised the comments submitted by an applicant to the EFSA Technical Report. There was a delay in the process due to a change of contact details of applicant, which had not been communicated to the Commission. The applicant had also provided two letters of support for an approval of propolis for the use in organic production of bananas.

     The comments of the Member States received since the meeting in May were in favour of non-approval as a basic substance. Member States were invited to comment by 6 September 2019.

3. ***Draft Review Reports for discussion:***

   - Milk

     Postponed.

A.08 Guidance Documents:

1. ***EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)***

   The status of the review of the Bee Guidance Document by EFSA was discussed under agenda point A. 15.

   The Commission informed that the implementation plan for the Bee Guidance Document is expected to be adopted as a Commission Implementing Decision in accordance with Article 77 of Regulation (EC) No 1107/2009, subject to advisory procedure, rather than as a non-binding Commission Notice. The Commission also reminded that the amendment of the uniform principles (see agenda point B.07) is a pre-condition for the application of the part of the Guidance related to acute toxicity to honeybees. Therefore, a vote on the Commission Implementing Decision will only be possible when the scrutiny period for the draft Regulation subject to vote under agenda point B.07 will be over.

2. ***Working Document on emergency authorisations according to Article 53 (discussion)***

   The Commission updated on the state of play. The comments of Member States had been compiled into a Reporting Table and reacted to, as appropriate. The draft document had been revised considering these comments. Both of these documents had been made available via CIRCABC.

   Many comments related to the need to make adjustments to improve clarity. One Member State had also commented on the need to better differentiate the information

to be provided by applicants and Member States - some changes and restructuring were made but further comments on that question would be welcomed.

The Commission also highlighted a number of general points raised by the Member States in their comments including the scope of a single authorisation, the evidence base for assessments and decisions, the use of mitigation measures and the granting of emergency authorisations for seed treatments. The document had been updated to clarify these areas.

The Commission also asked Member States for their views on whether the maximum area permitted under an emergency authorisation could be added for all authorisations issued in order to also allow the refinement of the relevant Harmonised Risk Indicator in the future. It was noted that some Member States already include a maximum area as a limitation when granting an emergency authorisation. However, some Member States indicated that an indication of area could be problematic for some uses. Member States were asked to reflect further on this point and to submit comments.

Member States were also invited to provide comments on the revised draft document. It was indicated that following the further updating of the document a consultation of stakeholders would be arranged.

3. ***Data requirements and list of agreed test methods - Update of the Communications 2013/C 95/01 and 2013/C 95/02***

   No news to discuss.

4. ***Draft Guidance document on the approval and low-risk criteria linked to antimicrobial resistance (state of play)***

   The Commission presented the current draft prepared by the Biopesticides Working Group. Member States were invited to comment by 6 September 2019, in particular on two open points: (1) should the acquired anti-microbial resistance be proven by both genotypic and phenotypic testing or could a positive result obtained with genotypic testing be enough to conclude on acquired resistance and hence leading to not approving the micro-organism at all; (2) shall the phenotypic testing be limited to WHO critically important antimicrobials or should the testing be extended to antimicrobials listed by Member States as critical, which would be in addition to those identified by WHO. Member States were invited to comment by 6 September 2019.

5. ***Draft Guidance document on the risk assessment of metabolites produced by micro-organisms (state of play)***

   The Commission presented the current state of play of this guidance document. The Biopesticides Working Group will continue to discuss in particular the way forward for cases where a metabolite of potential concern has been identified (full chemical part A dossier vs end-points of concern identified in previous steps). To support the finalisation of this guidance document, Member States were invited to comment by 6 September 2019 on the decision tree elaborated by the Biopesticides Working Group.

6. ***Guidance on the impact of water treatment processes on the nature of residues in drinking water (state of play)***

   The Commission recalled that Regulation (EC) No 1107/2009 introduced a requirement in Article 4(3)(b) that products should not have any immediate or delayed harmful effects on human health '… *directly or through drinking water (taking into account substances resulting from water treatment) …'*. However, no specific guidance exists

to address the issue and EFSA concludes for some active substance dossiers that the issue cannot be finalised and that, as a consequence, the overall consumer risk assessment remains open. Consequently, a requirement for applicants to provide confirmatory information 2 years from the date of publication of a pertinent guidance document is set.

Several Member States had previously expressed willingness to develop relevant guidance and the UK also produced a position paper on the subject. However, since there had been no concrete development, DG SANTE intended to mandate EFSA and ECHA to develop a joint guidance on the topic (since the requirement to address by-products from water treatment processes also exists for biocidal substances and available guidance is not yet fully complete).

The Commission informed that a mandate was under preparation and would be sent to the two agencies in the near future.

7. ***Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev. 11)***

   The Commission informed that the current version had recently been updated to include the improvements to the process identified at the Dublin 'Zonal Evaluation and Mutual Recognition' Workshop in 2015. The updated version also now included a new section on low-risk products. It is considered vital to improve the operation of the zonal evaluation and mutual recognition processes. Member States were invited to submit comments by 20 September 2019 A separate commenting period for stakeholders (applicants) will run in parallel, in order to involve all concerned parties.

8. ***Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004– rev 9)***

   The Commission informed that the current version had recently been updated in the framework of the Post Approval Issues Working Group, according to the experience gained, to cover the new needs derived from the renewals of active substances. Member States were invited to submit comments by 20 September 2019. A separate commenting period for stakeholders (applicants) will run in parallel, in order to involve all concerned parties.

9. ***Guidance document on Data Matching for applications for authorisation of PPPs according to Article 33/43***

   The Commission informed that the document had been developed in the framework of the Post Approval Issues Working Group. As this is a new Guidance document, its content will be internally discussed before a commenting period will be launched.

A.09 Defining Specific Protection Goals for environmental risk assessment:

The Commission informed about the attendance and results of the workshop held with Member States experts on 21 June 2019, and indicated that the next workshop will take place with stakeholders (on 25 September 2019) followed by a joint workshop for Member States and stakeholders early 2020. The Commission invited the Standing Committee members who participated on 21 June 2019 to also attend the joint workshop with stakeholders to ensure continuity, as well as to be involved in the organisation of further steps of the process to define specific protection goals. Member States were invited to indicate their views by 6 September 2019.

A.10 Commission Regulation (EU) No 547/2011 and risk mitigation:

1. ***Feedback about notification of additional phrases by Member State (no news)***

   No news to discuss.

2. ***Risk Mitigation / list of risk reduction measures (proposed way forward***)

   The Commission informed about the updated version of the draft document outlining the EU list of risk mitigation measures, which incorporated the comments received from Member States.

   In order to settle the main principles and start discussing the technicalities of the measures and their potential uses, the Commission invited Member States to volunteer for the organisation of a kick-off event/workshop.

   Member States were invited to comment on the revised draft outline by 30 September 2019 and to communicate their suggestions as regards the event as soon as possible.

A.11 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted):

No notifications received.

A.12 Notifications under Article 36(3) of Regulation (EC) No 1107/2009:

1. New notifications (to be noted)

Two notifications had been received, both corresponding to rejection of mutual recognition applications. One was noted, concerning a product containing azoxystrobin; for the other one, concerning a product containing a mixture of copper and cymoxanil, the Member States involved agreed to open bilateral discussions. Additionally, postponed from the previous meeting, the notification concerning the rejection of the mutual recognition for a cyantraniliprole-based product, and after bilateral discussions between the two Member States concerned, was noted.

2. Differences in application of Article 36(3) amongst Member States

Postponed.

A.13 New authorisations granted under Article 53 of Regulation (EC) No 1107/2009:

1. ***New notifications (to be noted)***

   The Committee took note of 63 notifications received in the period from 10 May until 5 July 2019, as detailed below. Member States were reminded of the need to fully justify emergency authorisations, in particular detailing the rationale for granting it and mitigation measures imposed to limit and control the use.

   The Commission also referred to the ongoing update of the guidance document (see agenda item A.08.2) and the need to ensure a baseline to further harmonise the notifications.

MS	Active substances	Function
BE	Mancozeb	fungicide
BE	Pelargonic acid (CAS 112-05-0)	herbicide
BE	Carfentrazone-ethyl	herbicide
CZ	Ethandinitril	insecticide
DE	Cyantraniliprole	insecticide
DE	Plant oils/ Rape seed oil Pyrethrins	insecticide
DE	Plant oils/ Rape seed oil Pyrethrins	insecticide
DE	Cydia pomonella Granulovirus (CpGV)	insecticide
DE	Mancozeb	fungicide
FI	Quizalofop-P-ethyl	herbicide
FR	Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348	insecticide
FR	Azoxystrobin	fungicide
FR	Cyantraniliprole	insecticide
FR	Tefluthrin	insecticide
FR	Spirotetramat	insecticide
FR	Trifloxystrobin	fungicide
FR	(Z)-11-Hexadecenal (Z)-13-Octadecenal	attractant
FR	Pyrethrins	insecticide
FR	Cyprodinil Fludioxonil	fungicide
FR	1-Naphthylacetic acid (1-NAA)	plant growth regulator
FR	Spinosad	insecticide
FR	(Z)-11-Hexadecenal (Z)-13-Octadecenal (Z)-9-Hexadecenal	attractant
FR	Copper oxychloride	fungicide
FR	Acetic acid	attractant
FR	Copper oxychloride	fungicide
FR	Spinosad	insecticide
FR	Azadirachtin (Margosa extract)	insecticide
FR	Cyantraniliprole	insecticide
FR	Cyantraniliprole	insecticide
FR	(E,Z)-3,8-Tetradecadien-1-yl acetate (E,Z,Z)-3,8,11-Tetradecatrien-1-yl acetate	attractant
GR	Abamectin (aka avermectin)	insecticide
GR	Abamectin (aka avermectin)	insecticide
GR	Abamectin (aka avermectin)	acaricide
GR	Abamectin (aka avermectin)	insecticide
GR	Abamectin (aka avermectin)	insecticide
GR	Abamectin (aka avermectin)	acaricide
GR	Spirotetramat	insecticide
GR	Cyantraniliprole	insecticide
GR	Flupyradifurone	insecticide
GR	1,3-Dichloropropene	nematicide
GR	1,3-Dichloropropene	nematicide
GR	Boscalid (formerly nicobifen) Pyraclostrobin	fungicide
GR	Boscalid (formerly nicobifen) Pyraclostrobin	fungicide
GR	Terbacil	herbicide
IT	Dimethyl disulphide	herbicide
LT	Ethametsulfuron	herbicide

LV	Kieselgur (diatomaceous earth)	acaricide insecticide
LV	Thiacloprid	insecticide
PL	Beta-Cyfluthrin Clothianidin	insecticide
PL	Fludioxonil Metalaxyl-M Thiamethoxam	insecticide
SI	Maleic hydrazide	plant growth regulator
SI	2,4-D Florasulam	herbicide
SK	Azadirachtin (Margosa extract)	insecticide
SK	Azadirachtin (Margosa extract)	insecticide
SK	Spinosad	insecticide
SK	Fluazinam	fungicide
SK	Flonicamid (IKI-220)	insecticide
SK	Spirodiclofen	insecticide
SK	Cyprodinil Fludioxonil	fungicide
SK	Zinc phosphide	rodenticide
UK	Acequinocyl	insecticide
UK	Spinosad	insecticide
UK	Cyantraniliprole	insecticide

2. ***1,3-Dichloropropene***

   The Commission informed about the note from one Member State concerning a request for a mandate to EFSA concerning the risks to consumers from commodities treated with 1,3-D in the context of emergency uses authorisations.

   The Standing Committee for Plants, Animals, Food and Feed, section Phytopharmaceuticals – Pesticide Residues was similarly informed at its last meeting in June and a specific question was addressed to Member States concerning possible national Maximum Residue Levels in relation to emergency uses granted for 1,3-dichlorpropene.

A.14 Plant Protection Products Application Management System (PPPAMS).

The Commission updated Member States on two aspects related to the further development of PPPPAMS:

1. *Development of the public database in which emergency authorisation notifications will be published.*

   It was announced that work is well underway and that it is expected that the relevant part of the database would be ready to go live in October (exact date to be confirmed).

   As announced previously, notifications will be made publicly available once published in PPPAMS to increase transparency. The database will enable users to search by key details (Member State, active substance, and crop) and to open the detailed notification as a linked pdf document.

   The Commission recalled the need to ensure that the information is correctly entered by Member States and that the justifications are completed fully. Again, the

update to the guidance document on emergency authorisations discussed under agenda item A.08.2 should help to address needs of applicants and Member States.

2. *Further development of the system to enable all applications types and to allow for full implementation. The work will also include a review of the GAP information to ensure all product/use types are covered.*

   The Commission announced that work will begin after summer to complete the analysis on different procedure types and to include these in the system, also enabling the possibility of including existing authorisations when new applications are made.

   The Commission informed Member States that further details will follow and a dedicated presentation will be given at the relevant time point. As part of this further work, the GAP fields in the system will be reviewed, also in light of ongoing work of EFSA to create a single GAP template covering all processes (approvals, authorisations and MRLs). Member States will be consulted on all changes.

A.15 News from European Food Safety Authority (EFSA).

EFSA informed of the following activities:

- Publication on 5 July 2019 of the outline for the review of the bee guidance document that describes the procedure that will be followed for the project including stakeholder interactions.
- The report of the ecotoxicology general expert meeting that took place in October 2018 has been published.
- A mammalian toxicology general expert meeting will be held in October 2019.
- EFSA has initiated work on producing a good agricultural practice (GAP) table in EXCEL format, which will aim to facilitate applications for approval, authorisation and MRLs and their assessment. This format will be presented for Member State commenting at the Committee's section legislation and section residues at the next meetings in September / October 2019.
- The next steps for the guidance document on soil exposure (PEC in soil) and the associated calculation tools; a discussion at this Committee on an implementation timetable is envisaged for this autumn.
- An overview of the main outcomes of EFSA expert meetings discussing individual active substances among Member State risk assessors that took place over the period May to July was provided.

A.16 Improving the efficiency of the process of a.s. approval:

– **Update on on-going activities including feedback of Member States**

– **Transparency of decision making**

The Commission referred to the on-going activities aiming at improving the efficiency of the process of active substances approvals or renewals, in particular the on-going discussions with EFSA to improve the format and wording of the EFSA Conclusions in order to be more fit for purpose for regulatory decision making, a unified GAP-table document currently under preparation by EFSA, and the possibility to mandate EFSA on particular issues related to active substance

dossiers which were controversial or not resolved during the peer review. The Commission also reminded Member States of the importance of resolving all open issues during the peer review.

To increase transparency in the decision-making process, the Commission explained that documents presented under agenda sections B and C of the meetings of this Committee will in future be published in the Comitology Register, this having started with the current meeting. The Commission also referred to the proposal for an amendment to the Comitology Regulation that had been under consideration by Council and Parliament for quite some time, and reminded Member States that they could, if so desired, always make a protocol declaration on their voting positions or publish their voting position on their national websites.

A.17 News from Health and Food Audits and Analysis (SANTE, Directorate F, former FVO).

No news to discuss.

A.18 News from Sustainable Use Directive (Directive 2009/128/EC).

The Commission reminded Member States of the transposition deadline (5 September 2019) for Directive 2019/782 establishing harmonised risk indicators and the legal deadline to publish the HRI I and II indicators for 2011-2017 by 30 August 2019.

The Commission will provide all Member States with their individual HRI I and II calculations as performed by ESTAT by 31 July 2019 – Member States can accept these calculations or perform their own calculations.

The Commission requested Member States to provide a link to the websites where they will publish their HRIs by 31 July 2019 to allow the Commission to publish these links by 30 August 2019. The Commission plans to publish the EU-28 HRI I and II, and the links provided by Member State, by 30 August 2019 on the SUD web-portal.

In response to a letter from the Commission on 8 April 2019, 20 Member State had made amendments to the data held by the Commission on emergency authorisations. 547 new notifications had been made relating for the period 2011-2017. The data had been made available on CIRCABC in the meeting folder.

The EU-28 HRI I and II indicators for 2011-2017 were presented. These show a 19% decrease in risk in HRI I for 2011-2017 and a 50% increase in HRI II over the same period.

The Guidance for calculating the HRI was presented and Member State were informed that it was planned to note this guidance at the meeting of the Committee section residues on 26-27 September 2019. Member States were invited to send comments by end of July.

A.19 Minor Uses:

The draft guidance document on minor uses according to Regulation (EC) No 1107/2009 was briefly presented. It provides more clarity regarding the rules for authorisation of PPP for minor uses and contributes to further harmonisation between Member States. Member States were invited to comment on the draft (rev. 6.3) by 1 October 2019 by using the provided commenting table.

The EU Minor Uses Database (EUMUDA) contains a list of the minor uses needs and priorities of all EU Member States, Norway and Switzerland. The current information is based on a survey conducted in 2018. It is critical that the information in EUMUDA stays updated, as this is the starting point to solve minor uses issues at European level, and, therefore, the Minor Use Coordination Facility (MUCF) had carried out the 'Survey 2019 on minor uses needs and priorities'. Based on the replies from Member States it is envisaged that the updated list of minor uses needs and priorities will be available in EUMUDA in autumn 2019.

In June 2019, MUCF had sent a request to all Member States for financial contributions for 2020 to support its work. These letters had been addressed to National Minor Uses Contact Points and Heads of National Plant Protection Organisations as Member States may consider paying alongside their EPPO contribution.

A.20 Progress Report on Low Risk Active Substances (update).

The Commission mentioned that the Progress Report on the Implementation Plan to increase the Availability of low risk Plant Protection Products and accelerate Implementation of Integrated Pest Management (IPM) in Member States was presented by Commissioner Andriukaitis to the AGRIFISH Council on 15 July 2019.

The progress report indicated that Member States should do more for the prioritisation of low risk active substance review and the authorisation of low risk PPP by meeting the (shorter) timelines provided for in the EU legislation. On IPM, Member States are encouraged to increase information sharing and trainings of farmers on alternative approaches or techniques, such as non-chemical alternatives to pesticides. The Commission briefly presented the feedback from Member States during the Council meeting (10 Member States intervened) and how the Commission would address it.

One Member State stressed that some indication as to the potential for a product to be low risk would be welcome, for instance a list of co-formulants considered as low risk would be helpful. The Commission indicated that it will reflect on possible ways forward.

A.21 Court cases.

Following the requests by Member States, the Commission informed the Committee on the General Court's decision of 7 March 2019 in case T-329/17 (Hautala and others vs EFSA) and its delimitation to the General Court's decision in T-545/11 RENV of 21 November 2018, both involving the interpretation of information relating to emissions into the environment under the Aarhus Regulation (Regulation (EC) No 1367/2006). While the analysis among Commission services was not yet completed, it should be noted that it is not always possible to extract a general interpretative principle from a single or a limited number of cases, especially where the underlying facts are different. The Commission therefore pointed at the different facts underlying the cases, one pertaining to information on the product formula and impurities contained in the rapporteur Member State's assessment report for the first EU wide approval of the active substance glyphosate, the other pertaining to access to studies on the carcinogenic potential of the substance in the context of the renewal of approval process, i.e. on a question that was core to the decision-making. A specific case-by-case analysis should be carried out for access to document requests, taking account of the regulatory and contextual elements of each application. The Commission invited Member States to share their analyses, if any are available.

Further, on Case C-445/18 – Vaselife International and Chrysal International the Commission informed that the Advocate-General had issued his opinion for this preliminary reference case, concerning the interpretation of Article 52 of Regulation (EC) No 1107/2009 on parallel trade.

A.22 Ombudsman cases.

The Commission informed about recent or on-going ombudsman cases:

- The Ombudsman had closed the inquire following complaint 687/2018/TE lodged by Pesticide Action Network (PAN) Europe on the application of Article 17 of Regulation 1107/2009 by concluding that no maladministration by the Commission has taken place. The Ombudsman noted that, under Article 17 of the Regulation, the Commission is obliged to extend the approval of active substances if it does not complete a reassessment in time provided the manufacturer of the product did not cause the delay. She also found that the most significant delays in the reassessment of active substances used in pesticides are not due to the Commission, as they occur during the scientific assessment stage, which is conducted by a designated rapporteur Member State authority and then peer-reviewed by the other Member States and EFSA. However, she encouraged the Commission to support those involved in the risk assessment in any possible way and to identify why the six-month deadline for producing a draft Regulation after adoption of the EFSA Conclusion are not respected in 25% of cases and to take the necessary measures to address this. The Commission will react with further observations.

- The Federation of European Rice Millers had submitted to the Ombudsman a complaint for failure to establish transitional measures in the context of the deletion of the Maximum Residue Level of buprofezin in rice. The Federation of European Rice Millers had raised its concerns in two letters addressed to the Commission on 9 February 2018 and 17 July 2018, to which the Commission had not yet replied – although it had shared the letters with Member States and discussed the content in the Committee – section residues. The Ombudsman had closed the case but requested the Commission to formally reply to the complainant, which had been done.

- In case 2142/2018/TE a French non-profit organisation POLLINIS had lodged a complaint concerning the Commission's refusal to grant access to documents containing the positions of EU Member States on the 2013 EFSA guidance submitted to the Standing Committee under comitology rules. The Commission had refused access on the ground that these documents contain positions of individual Member States and in line with the comitology rules these are considered confidential.

  In May 2019, the Ombudsman found that the Commission's refusal to grant public access to the positions of Member States on the draft bee guidance constituted maladministration on the basis of the following: the documents at issue should, in view of the context in which they were drawn-up and in view of their purpose, benefit from the wider access granted to "legislative documents" under the EU law on public access to documents; the documents in question contain environmental information, as defined in the Aarhus Regulation; the disclosure of Member States positions on the draft bee guidance document is not contrary to the Comitology Regulation as Article 10(2) (stating that summary records of meetings shall not mention the individual position of the members in the committee's discussion) and

Article 13(2) (stating that the Committee's discussions shall be confidential) of the Standard Rules of Procedure for are not founded on the Comitology Regulation. The exception invoked by the Commission to refuse public access to the requested documents must therefore be applied more restrictively. Moreover, she found that the Commission had not demonstrated that disclosure of the documents in question would seriously affect, prolong or complicate the proper conduct of the decision-making. The Ombudsman had asked the Commission to respond to her findings by 10 August 2019.

- An European Ombudsman's inquiry into complaints 1570/2018/JN and 1973/2018/JN lodged by Pesticide Action Network (PAN) Europe concerning the European Commission's approval of active substances for plant protection products (pesticides) is on-going, in particular as regards confirmatory data requirements in a sample of active substances selected by the Ombudsman for discussion (flazasulfuron, isofetamid and benzovindiflupyr).

A.23 New Transparency rules: General Food Law amendment.

The Commission informed on the progress as regards the adoption of the legislative proposal on the transparency and sustainability of the EU risk assessment in the food chain. This proposal would amend the General Food Law and - as regards transparency – eight other related sectorial legislative acts including Regulation 1107/2009. The Council and the Parliament had reached agreement on the proposal in February 2019, the vote took place in the Parliament in April 2019 and the Council adopted it in June 2013.

The new rules are expected to be published in the Official Journal at the beginning of September 2019 and they will enter enter into application in early 2021. Follow-up work concerning the pesticide sector includes an amendment to Implementing Regulation No 844/2012 by the end of 2020 and significant implementation preparations by EFSA and the Commission.

A.24 Endocrine Disruptors:

The Commisison informed that the second Better Training for Safer Food (BTSF) Workshop on endocrine disruptors will be held in Brussels on 27-28 November 2019. Participation is open to experts from Member States who did not follow the 1st workshop on the same issue.

A.25 Clarifications & questions related to specific active substance:

1. ***Maleic hydrazide***

   The Commission summarised the comments received from Member States since the meeting in May. The commenting Member States shared the view of the Commission, and believed that the applicants should apply for amendment of the conditions for approval, and the new studies should be assessed and peer-reviewed. Member States were invited to comment by 6 September 2019. If no new comments were to be received, the point will be considered closed.

2. ***Chlorotalonil monitoring data***

   One Member State informed in the meeting in May about the finding of the potentially genotoxic metabolite chlorothalonil-amidosulfonic acid in the drinking water of one region in their territory. That Member State informed that findings

drop to below 0.01 µg/L after the installation of carbon filters in drinking water plants.

During the meeting in May, Member States were asked to inform about their situation. Three Member States had replied directly to the Member State concerned.

Member States were invited to provide final comments by 6 September 2019.

3. ***Candidates for substitution***

The discussion was postponed.

A.26 Interpretation issues:

1. ***2,4 D / 2,4 D EHE***

The Commission recalled that, in the original approval, the acid form and the ester were both referenced in the dossier and the endpoints were listed for the two forms, based on the data contained in the application dossier.

On the contrary, the renewal Regulation only refers to the acid form of 2,4-D as the application for renewal had only specifically refered to the acid form, i.e. the applicants had only included information relevant for the acid form in the supplementary dossiers. The rationale for this choice of the applicants is unknown to the Commision.

Based on this situation, it is not possible that Member States authorise plant protection products containing the ester form, based on a so-called bridging dossier prepared by one Member State. Instead, an application under Article 7 of Regulation (EC) No 1107/2009 should be submitted, containing the necessary information for approving the ester form. Interested applicants should thus submit a new application. An evaluation might be straight forward if the information builds on the already established bridging dossier. Once the EFSA conclusion is ready it would be possible to amend, if found appropriate, the approval to also list the ester form.

No Member State voiced any dissenting view during the meeting.

2. ***Scope of Regulation (EC) No 1107/2009:***

a. Follow-up in situ generation (update)

No news to discuss.

b. CVAS Disinfectant product based on propan-2-ol

The Commission informed that a new version of the border case table was posted on CIRCA-BC to confirm the proposal for interpretation of the recent cases submitted to this Standing Committee (biofumigation, colouring agents in seed treatment).

Member States were invited to comment on two new border cases: kaolin as sunscreen (proposed not PPP) and propan-2-ol, a disinfectant for gardening equipments (proposed not PPP). Member States were invited to provide comments on these new cases by 6 September 2019.

A.27 Classification under Regulation (EC) No 1272/2008:

1. ***Status of notifications for harmonised classification (summary table for info)***

An updated table was made available on CIRCABC. The commenting period is still open for dimoxystrobin (until 30/8/2019), isoflucypram (until 26/07/2019) and quinoclamine (until 16/08/2019).

2. ***General update***

   No news to discuss.

A.28 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

The Commission informed that political validation of the report is still ongoing and that, due to the summer recess, the report is not expected to be published before end of September.

A.29 Report from Working Groups, in particular:

1. ***Working group on Biopesticides***

   The Commission informed about the ongoing discussion concerning the two guidance documents on Antimicrobial Resistance and Metabolites of Concern (see point A.8.) and about the revision of the data requirements and uniform principles, which will continue in the coming months.

2. ***Working Group on Seed Treatments***

   The Commission informed that a draft Seed Treatment Guidance Document had been prepared through intense discussions over the last years by a working group of experts from 12 Member States, chaired by Belgium. Stakeholders had been consulted on the current version of the draft document (#16) via the Advisory Forum of DG Health and Food Safety from September – November 2018.

   As the scope of the Draft Guidance is very broad, the Commission suggested, after consultation of the working group and EFSA, who agreed, to split the document and to mandate EFSA to finalise the exposure part of the Draft Guidance as its falls under the remit of EFSA. A mandate to EFSA is under preparation.

   The Working Group and the Commission will continue working on the remaining parts of the draft guidance, which are more related to legal and risk management issues.

3. ***Post Approval Issues***

   The Commission informed about recent developments in the Post Approval Issue (PAI) Group, which had its last meeting on 6 and 7 June 2019:

   a) A new chair was elected.

   b) Update of the overview table on confirmatory data.

   c) Planning of a new structure of CIRCABC to simplify the search for documents. An update of the working document on naming conventions will follow.

   d) Call for the importance of communicating the list of studies relied upon during the renewal process. The studies in the list should be matched later on during the process of product authorisation.

e) Debate in the interzonal Steering Committee on the necessary consensus within the three zones on a Guidance Document as regards environmental risk assessment for protected crops.

A.30 OECD and EPPO:

a) General update

b) Debriefing of OECD Meetings in June 2019

The Commission informed about the activities held at OECD during June: (1) workshop on Bioinformatics, (2) Expert Group on Biopesticides, (3) Risk Reduction Seminar on mechanical, digital technologies, (4) Working Group on Pesticides. Reports of the meeting(s) will be published on CIRCA-BC.

A.31 Exchange of information from the Pesticide Residues section of the Committee: possible impact on authorisations.

The Commission informed that the Committee – section pesticides residues met on 13 and 14 June 2019 and that draft Regulations introducing the following changes had received favourable opinions:

Substance	Type of change	Agenda item (meeting June 2019)	SANTE doc number
Imazalil	Lowering of MRLs and amendment of the residue definition.	B 02	SANTE/11207/2018
Cyflufenamid	Lowering of MRLs and amendment of the residue definition.	B 03	SANTE/11337/2018
Fenbuconazole	Lowering of MRLs and amendment of the residue definition.	B 03	SANTE/11337/2018
Fluquinconazole	Lowering of MRLs.	B 03	SANTE/11337/2018
Tembotrione	Lowering of MRLs.	B 03	SANTE/11337/2018
Amitrole	Lowering of MRLs.	B 04	SANTE/10909/2018
Fipronil	Lowering of MRLs.	B 04	SANTE/10909/2018
Flupyrsulfuron-methyl	Lowering of MRLs.	B 04	SANTE/10909/2018
Imazosulfuron	Lowering of MRLs.	B 04	SANTE/10909/2018
Isoproturon	Lowering of MRLs.	B 04	SANTE/10909/2018
Orthosulfamuron	Lowering of MRLs.	B 04	SANTE/10909/2018
Triasulfuron	Lowering of MRLs.	B 04	SANTE/10909/2018

A.32 Scientific publications and information submitted by stakeholders.

The Commission informed about the letters from stakeholder associations sent for the purpose of the discussions at this meeting.

A.33 Date of next meeting(s).

The next meeting is scheduled for 21 and 22 of October 2019, subject to confirmation.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance *Bacillus subtilis* strain IAB/BS03, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report SANTE/10318/2019 rev 1).

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiophanate-methyl, 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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11254/2018 Rev.3).

The Discussion was postponed as clarifications from EFSA are awaited on details of the performed risk assessment and the peer review.

Vote postponed.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision concerning the renewal of the approval of the active substance *Verticillium albo-atrum* WCS850 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 (Draft Renewal Report SANTE/10198/2019).

The Commission informed that the draft was to approve the active substance as low risk, and referred to an editorial error on the title in the agenda of the meeting but not in the text of the draft Regulation shared for the meeting.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance alpha-cypermethrin, as a candidate for substitution, 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 (Draft Renewal Report SANTE/11525/2018).

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of approval of the active substance methiocarb, 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 Commission Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/11710/2018).

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-p, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron, amending the Annex to Implementing Regulation (EU) No 540/2011

France made the following statement:

For B06, we voted against, for the same reasons as constantly raised for several years. We consider that substances of concern, especially those substances meeting a cut-off criterion, should not be prolonged. Several of them are included in the act submitted to the vote, therefore we could not support it. For the future, we propose either to commit at an early stage to conclude the procedure at the current deadline as it is the case for chlorpyriphos, either to submit the prolongation in a separate act.

The Netherlands made the following statement:

The Netherlands does not agree with the extension of the approval period of difeconazole because of the risks regarding fungal resistance.

Nevertheless, because we are faced with a package of substances, we will vote in favour of the entire package.

In addition, we ask the Commission to consider to provide us with the possibility of an individual vote on substances when it is requested by Member States.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards bees principles for evaluation and authorisation of plant protection products.

The Commission reminded that, after the non-acceptance of the bee Guidance Document by most Member States for almost 6 years, it had proposed in a spirit of compromise a staged implementation with the parts related to acute toxicity for honeybees being implemented quickly, and the parts related to chronic risk at a later stage together with the parts related to the risk to bumblebees and solitary bees, following a review by EFSA of the guidance document. Member States had already agreed that the Commission should mandate EFSA to review the guidance document, in particular because since 2013 new scientific evidence has emerged. The Commission

had sent the mandate to EFSA in March and the review process has already started (see agenda point A.15).

The Commission reminded that the proposed amendment of the uniform principles is a pre-condition for the application of the part of the Guidance related to acute toxicity to honeybees. The draft Regulation was submitted to the feedback mechanism (public consultation) from 13 June to 11 July 2019.

The Commission gave a summary of the feedback received from stakeholders:

In total 4735 comments had been received of which 15 with an attachment. Citizens in 21 Member States had sent comments, in different proportion (Top 3: France (82%), Belgium (11.8%) and UK (1.4%)). There were also a few comments from outside the EU (e.g. Switzerland). A total of 97% of the comments came from citizens. The other comments were mainly from administrations or organisations. One comment from the NGO SumOfUs contained 8854 comments from their members in various countries.

Two comments came from Member States authorities. The Swedish Chemicals Agency commented that they would have preferred not to delay the implementation of the chronic risk assessment at the EU level as this is a data requirement. However, given that a revision of the guidance document is foreseen in the near future, Sweden can support the proposed amendment for bees. The German Environment Agency (Umweltbundesamt) acknowledged the need to revise the uniform principles for evaluation and authorisation of plant protection products for honeybees in order to account for the new state of science in risk assessment defined with the new EFSA bee Guidance Document and furthermore underlined the need for EFSA to have sufficient resources to achieve the review of the Bee Guidance Document within the time frame set.

Several environmental NGOs submitted comments:

- Pollinis believed that the draft should also include amendments related to chronic toxicity and larvae toxicity tests. Pollinis underlined that citizens should know the position of Member States and referred to their complaint to the Ombudsman in this regard (see agenda point A. 22 of this meeting).
- Pesticide Action Network (PAN) Europe opposed the draft Regulation, as they believe it is not in line with Regulation (EU) No 1107/2009, which requires a high level of protection of human health, animal health and the environment. They consider the draft furthermore not in line with the Commission Pollinator Initiative. PAN Europe thus asks to re-open discussions with Member States in order to rapidly implement the parts of the Bee Guidance Document concerning acute and chronic toxicity for honeybees and bumblebees.
- SumOfUs considered that the proposed Regulation needs to include additional trigger values for chronic and larvae toxicity to honeybees. In light of the pollinator crisis, there is also need to set trigger values for pesticides' toxicity to wild bees. Bumblebees and solitary bees must be protected.
- Friends of the Earth, Bee Life, France Nature Environment, Landmatters Co-operative (UK), AREC (Greece), and Asociación Bee Garden (Spain) asked for the full implementation of the EFSA Bee GD.

No comments had been received from applicants via the feedback mechanism, however the European Crop Protection Association (ECPA) had submitted an overview of the new data industry has available to support the review of the Bee GD.

The UK National Farmers Union supported the way forward proposed by the Commission as a vital part of the risk assessment process, in terms of providing a clear, predictable and consistent regulatory framework. They also underlined the importance of pollinators with pesticides being just one of the threats and that the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) was not able to rank the threats to pollinators. The Commission should ensure that EFSA has enough resources for the review of the Bee GD.

The Commission summarised the content of comments from citizens and provides its response to some of them as follows:

- More than 3800 citizens responded on the basis of three comments in French prepared by Pollinis. There were other smaller campaigns in French and English as well. These comments asked for a full implementation of the Bee GD and criticised the lobbying power of the chemical industry.
- The demand for full implementation of the Bee GD and criticism on the lobbying power of the chemical industry recurred in most of the other comments. Some especially mentioned other bee species such as solitary bees.
- Several comments demanded that tests should be done by laboratories that are independent from the agro chemical industry. The Commission considers this point covered by the amendment to the General Food Law (See point A.23).
- Several comments referred to the tests requested in the EFSA Guidance Document. The Commission reminded that Regulations (EU) No 283 and 284/2013 include requirements for tests to assess acute and chronic toxicity to bees. The dossiers for approval of active substances must therefore, already today, contain data on chronic toxicity to bees, enabling to assess the potential long-term risks to bees. These Regulations are not amended with the draft Regulation proposed for vote. Therefore, the assessment of chronic risks for bees will remain as protective as today while the level of protection from the acute risks to bees will be improved given the amendment to the decision-making criteria for the acute risks to honeybees for the different exposure routes.
- Several comments requested to have a Regulation, which would make it possible to control/prohibit products that have a major impact on bees.
- Several comments requested a full ban of all pesticides or those pesticides killing bees. In addition, glyphosate/Roundup was mentioned as examples and sulfoxaflor/thiacloprid. The Commission underlined that the draft for vote today will not reverse the restrictions on neonicotinoids.
- Other comments mentioned the need for the precautionary principle to be used. The Commission explained that this principle is embedded in Regulation (EU) No 1107/2009 and as such is always taken into account during decision-making for pesticides.
- The need to assess the cocktail effect of pesticides was mentioned.
- One citizen was also concerned that the proposed Regulation had no retroactive effect. The Commission reminded that all approvals are reviewed periodically and,

if necessary and appropriate, Article 21 of Regulation (EC) No 1107/2009 permits to act if needed at any time.

- One citizen indicated that not enough species are tested for the environmental risk assessment for pesticides. The Commission explained that related discussions are ongoing and referred to agenda point A.09.
- One citizen suggested it should be proven that something is not harmful instead of proving it being harmful. The Commission recalled that Regulation (EC) No 1107/2009 is already based on that principle.
- Many citizens wished that the EU takes very serious measures to reverse the decline in bees. The Commission referred to the 2018 EU Pollinator action plan, which contains actions of a wider scope, acknowledging that pesticides are one contributing factor among others to the pressure on pollinators. One of the actions in the pollinator action plan is to endorse the Bee Guidance Document.

In summary, most comments asked to implement also those parts of the EFSA Bee Guidance Document regarding the chronic risk to bees and the risk to bumble bees and solitary bees. However, given the insufficient support from Member States to implement a bigger part of the EFSA Bee Guidance Document, the Commission considered it not possible to amend the draft Regulation to accommodate these requests.

The Commission then introduced the last changes to the draft Regulation in Article 1, which it proposed based on comments from one Member State and one citizen to improve the clarity of the table in Article 1.

Many Member States expressed support for the draft Regulation, while three indicated that they would vote against or abstain. Five Member States indicated their preference for adopting a more ambitious change to the uniform principles but indicated that they could support the current draft in a spirit of compromise in order to move forward and given that the review of the Bee Guidance Document was ongoing.

On request of one Member State, the Commission confirmed its intention to adopt an implementation plan for the different parts of the Bee GD via a Commission Decision, which will be submitted to the Standing Committee at a forthcoming meeting (see also agenda point A.08.1). The Commission reminded that, after a favourable opinion of the Committee on the draft Regulation presented at this meeting, it will be submitted for scrutiny to the Council and the Parliament for a period of three months. Adoption will only be possible if no objection is raised, and this is a pre-condition for the Commission to schedule the vote on the draft Implementing Decision setting out a schedule for the implementation of the Bee GD.

The Netherlands made the following statement:

As indicated in earlier meetings, the Netherlands intends to agree with the current guidance document and implementation plan. In addition, we urge the Commission and the Member States to implement the B-part of the implementation-plan as soon as possible, but by the end of 2019 at the latest.

We will repeat this statement when the guidance document is to be voted upon in the SCoPAFF meeting.

France made the following statement:

France votes against the amendment of Commission Regulation (EU) No 546/2011 implementing as regards bees principles for evaluation and authorization of plant

protection products, considering that the proposed amendments are far below the needs and expectations in order to provide effective protection for bees and pollinators. France supported the initial Commission proposal of July 2018 establishing trigger values for acute oral and contact toxicity, chronic oral toxicity and larval toxicity, and asked the Commission to submit this proposal to the vote.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Romania for the placing on the market of plant protection product MODESTO 480 FS, containing the active substance clothianidin, and plant protection product NUPRID AL 600 FS, containing the active substance imidacloprid, for use on *Brassica napus* to combat the pests *Phyllotreta* spp. and/or *Psylliodes* spp. in accordance with Article 53 (1) of Regulation (EC) No 1107/2009

Agenda points B.08 and B.09 were discussed together.

The Commission explained the final changes to the legal drafting during the interservices consultation, mainly to insert clarity regarding the connection between the pest/crop combinations evaluated by EFSA and the actual emergency authorisations given in 2017 by Romania and Lithuania, and emphasised that the essence of the drafts was not changed. References to commercial names had been deleted from the drafts.

One Member State indicated not having national authorisations in place for alternative products with the same efficacy and indicated that the surfaces sown with neonicotinoid-treated seeds had decreased in recent years, these being used only in areas with high pest infestation. Furthermore, pest pressure increased due to climate change.

Another Member State asked for more time to check the documents as the final versions had only been made available on 15 July 2019. This Member State indicated that the available alternative for one Member State is thiacloprid for which the Commission is currently proposing a non-renewal.

A further Member State could not support the proposed Decisions as they did not guarantee the restriction of use of the active substances in general given that only specific plant protection product uses are prohibited. This Member State furthermore considered that a derogation should still be possible in cases where there are no alternatives.

Another Member State repeated its question why emergency authorisations on neonicotinoids were targeted and not the emergency authorisations for products containing other active substances, and questioned the involvement of EFSA in what this Member State considered a purely national issue.

Several Member States could not support the drafts as they considered derogations under Article 53 a sole responsibility of Member States and in their views only local experts can judge if the contested derogations are justified or not. One Member State referred to the subsidiarity principle in that regard.

Eight Member States indicated being able to support the drafts. Two of these understood the view of others that granting emergency authorisations is a Member State responsibility but could nevertheless support the draft Decisions as the Commission had correctly followed the legal procedures foreseen in Regulation (EU) No 1107/2009.

Vote postponed.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Decision on the non-repetition of emergency authorisations by Lithuania for the placing on the market of plant protection product "CRUISER OSR" containing the active substance thiamethoxam for use on spring rape to combat the plant pests *Phyllotreta* spp. and/or *Psylloides* spp. in accordance with Article 53(1) of Regulation (EC) No 1107/2009

Vote postponed (see point B.08).

C.01 Exchange of views of the Committee on a draft Commission Regulation (EU) modifying Annex III of Regulation (EC) 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

The Commission informed that several comments had been received from Member States on the draft Regulation. A summary of the received comments and how they were addressed by the Commission had been made available on CIRCABC.

Several Member States raised questions about the listing of the following five non-acceptable co-formulants [Aluminium silicate (Kaolin), Cristobalite (SiO2), Quartz sand, Silicium dioxide, Trydimite (SiO2) – listed with the remark that they would be classified as Carc. Cat. 1A if the content in crystalline silica is > 0.1 % w/w), wondering about the availability of test methods for enforcement and pointing to the fact that the draft for harmonised classification of crystalline silica as carcinogenic had been withdrawn. One Member State noted a discrepancy to its original draft for listing some of the substances with a different condition, i.e. if the content in crystalline silica of particle size < 50 mm is > 0.1 % w/w. The Commisison indicated that it would reconsider the listing of the substances.

One Member State repeated its earlier proposal that also substances classified as Carc. Cat. 2 should be listed. Another Member State would prefer to list (by cross-reference to the CLP Regulation) all substances classified as CMR Cat. 1A or 1B. The Commission repeated the earlier explanation that according to its legal analysis, all substances needed to be identified by name and that only substances found to be unacceptable co-formulants in all products in all Member States could be listed, while Member States could of course refuse authorisations for products containing other co-formulants if they found them unacceptable under their conditions. The Commission also reminded Member States that it will soon present a draft Implementing Regulation setting our criteria and a procedure for nominating further substance to be included in Annex III. The list contained in the current draft Regulation will only be a starting point.

Member States were invited to comment by 2 August 2019.

C.02 Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 844/2012 as regards the harmonised classification of active substances. (SANTE/10722/2017

The Commission informed that the draft Regulation was currently undergoing interservice consultation. The draft Regulation would formalise the amendments already presented to this Committee in its meetings in January and March 2019, and

also presented to the Competent Authorities for REACH and CLP at their meeting in March 2019.

The Commission recalled the main elements, namely the submission of a dossier for harmonised classification and labelling (CLH) to the European Chemicals Agency by the Rapporteur Member State (RMS) in accordance with Article 37 of Regulation (EC) No 1272/2008 for at least the hazard categories listed in Annex II point 5.1.1 of Regulation (EC) No 1107/2009 relevant for the classification as "low risk" as default, and less onerous approaches where either a dossier was already pending before ECHA or where an opinion of the Committee for Risk Assessment of ECHA had already been adopted, covering at least the "low risk" hazard categories and provided that no new information was available warranting a reconsideration of the proposed classification (for pending dossiers) or adopted RAC opinion.

The Commission recalled that the time available to the RMS would be extended by one month (i.e. 13 months would be available for the RMS to prepare the CLH dossier), and the time available to EFSA prolonged by 2 months to allow for a dossier check. On the other side, the applicant would have 3 months less to prepare the supplementary dossiers following the application for renewal than currently.

The draft includes a short transitional period of three months following the entry into force of the amending Regulation, to allow applicants to take account of this shortened time for preparation of the supplementary dossiers.

One Member State suggested that the time available to the RMS should be 15 months. The Commission explained that the tight schedules provided for under Regulation (EC) No 1107/2009, in particular the Regulation's overall 3-year limit for the entire renewal process did not allow for this.

Member States were requested to comment by 6 September 2019.

C.03 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the renewal of approval of the active substance metalaxyl-M, 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 (Draft Review Report SANTE/11112/2019 Rev.0).

The Commission informed that the applicant had been invited to comment on the draft review report, which had also been made available to Member States.

Member States were invited to provide comments as soon as possible in order to facilitate the next steps. Since some restrictions were proposed (seeds to be sown in greenhouses and maximum levels of impurities) a WTO TBT notification would be necessary, therefore, a vote could not be scheduled before the meeting of the Committee in December 2019.

C.04 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance thiacloprid, 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 Implementing Regulation (EU) No 540/2011 (Draft Renewal Report SANTE/10450/2019).

The Commission informed that the inter-service consultation was still ongoing and recalled that a WTO TBT notification needs to be launched. Member States were invited to comment by 9 August 2019, in order to be able to vote at the next meeting of the Committee in October.

C.05 Exchange of views of the Committee on a draft Commission Commission Implementing Regulation concerning the approval of L-cysteine as a basic substance, 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 (Draft Review Report SANTE/11056/2019 Rev.0).

The Commission presented the draft review report and the draft approval Regulation. The Commission summarised the comments received from the Member States. Four Member State were generally in favour of approval of L-cysteine as a basic substance. Two Member State had raised the point of classification of L-cysteine as a substance of concern and proposed non-approval or approval restricted to professional users. The Commission indicated that further reflection is needed as other classified substances had already been approved as basic substances and invited Member States to comment by 6 September 2019.

C.06 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Castanea* and *Schinopsis* tannins as a basic substance, 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 (Draft Review Report SANTE/11444/2019 Rev.0).

The Commission presented its draft review report and the comments received from Member States.

The Commission informed that recently the applicant inquired about the possibility to withdraw the application. The Commission is awaiting confirmation of this withdrawal. If confirmed, this procedure will be considered as closed and no act will be prepared.

C.07 Exchange of views of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Vitis vinefera* cane tannins as a basic substance, 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 (Draft Review Report SANTE/11448/2019 Rev.0).

The Commission presented the draft review report. Three Member States had sent comments indicating their support for non-approval. No comments had been received

from the applicant. The Commission will now proceed with the interservice consultation.

M.01 Miscellaneous

- The Commission updated Member States on the state of play concerning chlorpyrifos and chlorpyrifos-methyl, recalling that:
  - the approvals of chlorpyrifos and chlorpyrifos-methyl expire on 31 January 2020 and that the peer review process in the context of the renewal procedure was still ongoing for both substances;
  - significant delays had been incurred during the renewal process due to the amount of data submitted, in particular during the stop the clock procedure;
  - Expert discussion in the area of mammalian toxicology had been held in the first week of April. A second discussion on chlorpyrifos-methyl was scheduled for early September;
  - The Rapporteur Member State was still working on updates to the ecotoxicology assessment and EFSA had tentatively scheduled an expert discussion for October/November 2019;
  - there was significant attention on these substances from the general public and the media.

The Commission informed that it was aware that experts in the peer review meeting had concluded that there were concerns for human health. Due to the delays in completing the remainder of the assessment, the Commission mandated EFSA to provide statements by 31 July on the currently available outcomes on human health for both substances, indicating whether the approval criteria laid down in Article 4 of Regulation (EC) No 1107/2009 are fulfilled as regards human health.

The Commission will consider the statements of EFSA and if it is clear that the approval criteria are not fulfilled, it will move forward with proposals for non-renewal of approval, based only on the outcome of the human health assessment.

Consequently, draft review reports and Regulations might be tabled for the next meeting in October.

- The Commission informed that on 4 July 2019 the applicant for the approval of extract from rhododendron as a basic substance had withdrawn his application. The Commission therefore considered this procedure as closed and no legal act will be prepared.
- The Commission informed that one Member States had communicated that they applied a voluntary comparative risk assessment according to Art. 50 (2) of Regulation (EC) No 1107/2009.
- The Commission informed that the workshop "Product Chemistry of Plant Protection Products" will take place in Brussels on 19-20 November 2019. The workshop is jointly organised by the Commission and Germany. The Commission will cover travel expenses for one representative per Member State.

  The Commission requested Member States to nominate expert(s) by sending the contact details to: EU_Workshop_PC_206@bvl.bund.de at the latest by 13 September 2019.

A formal personal invitation will then be sent by the Commission a few weeks before the event. Suggestions to the draft agenda, which had been made available on CIRCABC, are also welcome (to the same e-mail address).

- One Member State informed about an epidemiological study linking chlorpyriphos with ADHD and indicated it would provide further information for the next Standing Committee meeting.