EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

ddg2.g.001(2015)1994561

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 26 JANUARY 2015 - 27 JANUARY 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/2e04b70e-4392-49f3-91a9-0d99b25f0422*

A.01 Summary Report of previous meetings.

The Summary Report has been uploaded on the EU Health and Food Safety website:

http://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals/index_en.htm

A.02 Stage 4 of the review programme under Directive 91/414 – "Green Track".

There was no discussion on this point.

A.03 New active substances:

1. New admissible dossiers - no new dossiers

2. European Food Safety Authority (EFSA) conclusions
   i. *Flumetralin*
   ii. *Halauxifen-methyl*
   iii. *3-decene-2-one*
   iv. *Pepino mosaic virus CH2*

There was no discussion on this point.

3. First discussion of a Commission draft review report and Regulation concerning the approval of:

i Cyantraniliprole

The Commission outlined the main issues reported in the relevant EFSA conclusions. One Member State expressed reservations regarding the possible leaching of the active substance into groundwater.

The draft Review Report will be made available via e-mail before 18 February 2015.

ii Terpenoid blend QRD-460 (drafts presented for information only) - (additional point to the agenda)

The Commission outlined the main issues reported in the EFSA conclusion and made Member States aware of the rationale behind the draft Review Report and draft Regulation which were made available ahead of the meeting.

Member States were asked to submit comments in writing by 23rd February 2015.

4. *Chromobacterium subtsugae* PRAA4-1 (MBI-203)

This biological insecticide is not a spore forming bacterium and the cells lose viability on completion of the fermentation process, to the extent that when the formulated product is packaged, living cells are not present in the product.

The issue which data requirements (chemical or microbial) apply to this substance will be discussed in a small Working Group together with Member States and EFSA.

A.04 Renewal of approval:

1. Draft Working Document Renewal Programme (Doc. SANCO/11284/2012 Rev. 15) (For information)

A new revision of the document is still in preparation.

2. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EU) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (SANCO/10148/2014 Rev. 4) (For information)

A new revision of the document is still in preparation.

3. EFSA conclusions:

i. Esfenvalerate
ii. Cyhalofop-butyl
iii. Florasulam

The Commission outlined the main issues reported in the relevant EFSA conclusions.

Member States were asked to submit comments by 23 February 2015.

iv. 2,4-D (additional point to original agenda)

The Commission explained that the EFSA conclusions, as well as comments by the applicants, have been received. Next step is the drafting of a draft revision report. It is emphasised that this substance is not subject to the cut-off criteria (unclassified for mutagenicity, carcinogenicity or reprotoxicity). Restrictions for relevant impurities are likely and the risk to aquatic organisms needs attention. Findings of possible endocrine mediated effects have been reported and need to be carefully examined. In general, exposure for consumers, operators, workers, bystanders and groundwater seems acceptable, on the basis of the supported use rates. The Commission recalls however that authorisations exist for rates that are significantly higher.

Member States were asked to submit comments by 23 February 2015.

v. Metsulfuron-methyl (additional point to original agenda)

The Commission outlined the main issues reported in the relevant EFSA conclusions.

4. Draft Review Reports for discussion:

i. Flupyrsulfuron-methyl (update only, no report for discussion)

A draft Review Report is in preparation.

ii. Thiabendazole

A draft Review Report is in preparation.

iii. Lambda-cyhalothrin

The EFSA conclusions will likely be republished with editorial amendments as regards the issues on endocrine disruption. This will delay the vote on the proposal.

The Commission is aware that the proposal presented at the Committee last October followed a precautionary approach, by presenting a restricted approval to greenhouse. Possibly, a revised proposal will be presented at the next meeting, where the restriction is lifted and new provisions for Member States on aquatic assessment are introduced. The rationale for the new proposal is: 1) The aquatic risk assessment is addressed if a weight of evidence approach considering all evidence available is considered, consistently with the approach followed with gamma-cyhalothrin; 2) Safe uses at national level have been demonstrated; the substance is a candidate for substitution, which would be renewed for maximum 7 years.

iv. Acybenzolar-S-methyl

The EFSA conclusions will likely be republished with editorial amendments as regards the issues on endocrine disruption. This will delay the vote on the proposal.

The proposal will not change substantially from the one presented in October. Comments submitted by a Member State will be considered.

v. Amitrole

A draft Review Report has been prepared. Before any decision on the renewal of amitrole will be taken, EFSA has been requested to update the EFSA conclusion on amitrole with respect to the second interim criterion as regards possible toxic effects on endocrine organs.

vi. Pyridate

The draft Review Report was outlined at the Standing Committee in December 2014. Several Member States and the notifier submitted comments on that revision.

The Commission did not agree with suggestions to set requirements for confirmatory data on the long-term risk for mammals. It outlined the reasons for its position, which relate to both the general approach on confirmatory data and specific considerations on the representative uses for the active substance.

Member States are asked to submit comments by 6 February 2015.

vii. Flumioxazin

The Commission informed about the comments received from the applicant.

viii. Sulfosulfuron

The Commission informed about the comments received from the applicant and Member State. The Commission explained the changes in the new version of the review report.

One Member State expressed reservations regarding the possible leaching of the active substance into groundwater.

One Member State asked for a confirmatory data requirement regarding the relevance of certain groundwater metabolites. The Commission explained that, as save uses were demonstrated, under the rules of Regulation (EC) No 1107/2009 no confirmatory data can be set here. However, Member States are free to ask for additional information where this is necessary to assure safe uses under their specific conditions.

Member States were asked to submit comments by 23 February 2015.

ix. Fenhexamid

The Commission provided some brief background on the substance and explained the key points from the EFSA Conclusion. Member States were asked to consider the draft Review Report made available before the meeting (the applicant had already seen a previous version and commented; Member States were informed that the version made available to them contained some minor changes) and provide comments in writing by 23rd February.

x. Prosulfuron

The Commission explained that a draft Review Report had not yet been prepared as the EFSA Conclusion was pending a revision (based on expert discussion to establish the relevance of a common metabolite for sulfonylureas; the expert meeting was due to be held in February 2015). Once the revised EFSA Conclusion was available, a draft review report would be made available to Member States.

xi. Pymetrozine

The Commission provided some brief background on the substance and explained the key points from the EFSA Conclusion. Member States were asked to consider the draft Review Report (which was also with the applicant for comments) and provide comments in writing by 23rd February 2015.

A.05 Confirmatory data:

1. Flurochloridone (updated review report to be noted)

The Committee took note of the review report.

Two Member States did not support the note taking because of: 1) leaching of metabolites to groundwater; 2) the ISO name of fluorochloridone does not correspond precisely to the specification of the technical material used in the assessment.

2. Tall oil pitch

Satisfactory confirmatory data on the toxicological profile of tall oil pitch were not received by the Rapporteur Member State (RMS). The Commission will prepare a proposal for withdrawal of this active substance.

3. 8-Hydroxiquinoline

The Commission provided a brief background of the dossier. Confirmatory data was received in time and evaluated by the RMS resulting in an addendum to the Draft Assessment Report (DAR). No major comments were received by EFSA and MSs in the reporting table. The RMS proposes to maintain the approvals without modifications. The Commission uploaded the revised review report proposing to finalise the process without modifications to the conditions of approval.

Member States were asked to submit comments by 23 February 2015.

4. Etridiazole

Differently from EFSA, the Commission supports the view of the RMS and of another Member State that the confirmatory data submitted by the applicant are acceptable because: 1) considering the weight of evidence available from the in silico/in vitro studies, the plant metabolites are not considered relevant; 2) the data on environmental assessment submitted on edible crops were satisfactory.

A revised review report will be submitted for noting at the next meeting, including provisions for Member States as regards environmental assessment for ornamentals.

One Member State indicated concerns on the concluded non-relevance of one plant metabolite.

Member States were asked to submit comments by 23 February 2015.

5. Dazomet

Dazomet was approved with a request for confirmatory information. The points as regards the potential for groundwater contamination by methyl isothiocyanate (MITC) and the long range atmospheric transport potential of MITC have been addressed. The RMS will provide some further clarifications regarding the residue data on seeds and arthropods used for acute and long term risk assessment for birds and mammals.

6. Diflubenzuron

The Commission reported on the status of the ongoing review of the approval under Article 21 of Regulation (EC) No 1107/2009.

7. Dithianon

a. the storage stability and the nature of residues in processed products,
b. the aquatic and groundwater exposure assessment for phthalic acid,
c. the risk assessment for aquatic organisms with respect to phthalic acid, phthalaldehyde and 1,2 benzenedimethanol.

The applicant sent this information within the deadlines and the RMS Greece evaluated it. According to the RMS, there are no open points and all points are addressed.

Based on the available information, it is concluded that the confirmatory data do not substantially modify the conclusions of the original risk assessment and no further review by EFSA is necessary.

Member States were asked to submit comments by 23 February 2015.

8. Dodine

The Commission provided a brief background of the dossier. Confirmatory data was received in time and evaluated by RMS resulting in an addendum to Draft Assessment Report (DAR). Following the comments received on the reporting table, the RMS proposes to further discuss with experts some open points regarding birds and mammals evaluation. The Commission therefore announced that a specific mandate will be sent to EFSA in order to organise discussion on those open points.

9. Haloxyfop-P (additional point to the agenda)

The Commission explained that confirmatory data have been requested for the groundwater exposure by 3 metabolites. EFSA concludes that one of these (DE-535 pyridinone) must now be considered toxicologically relevant and therefore should not leach above 0.1 µg/l. Metabolite DE-535-phenol remains well below 0.1 µg/l, while DE-535 pyridinol is confirmed to be non-relevant (yet, it may trigger a consumer assessment as it is found above 0.75 µg/l in all scenarios.

A presence below 0.1 µg/l for DE-535 pryridinone might be reached if the Good Agricultural Practices (GAP) is varied (lower rates, change on growth stages, application every three years).

The Commission does not exclude that minor variations in supported GAPs could be accepted but is examining to which extent this is possible.

In any case, it would seem that future uses of the substance would need to be severely restricted.

Member States were asked to submit comments by 23 February 2015.

10. Chlormequat (additional point to the agenda)

For the majority of the requested confirmatory data, it would seem that the situation is adequately elucidated.

However, as regards the risk to birds and mammals, minor changes have occurred to the growth stages for some subcategories of cereals. The amended GAPs have been duly assessed but for principle reasons it may be not advisable to add these to the review report. In any case, it would seem that the outcome would not change and that the risk to mammals is acceptable, even considering only the GAPs that were part of the original assessment dossier.

Member States are asked to submit comments by 23 February 2015.

A.06 Amendment of the conditions of approval.

Bacillus subtilis QST 713 is approved as a fungicide. The bactericidal use against fire blight is erroneously not included in the approval regulation. An amendment to the approval regulation will be prepared.

A.07 Basic substances:

The Commission brought to the attention of the Committee the recent proposal submitted by the Netherlands concerning the establishment of a working group on basic substances with objectives to share best practices and knowledge on candidates substances, plan co-operation in compiling and submitting application-dossiers and share. The current list of candidates could be considered as a starting point. Member States were asked to comment on this proposal. Some Member States expressed their agreement on this approach. The Commission reminded all Member States to express their views and potential availability to cooperate.

Member States were asked to submit comments by 23 February 2015.

1. Pilot projects: state of play

Calcium hydroxide draft review report

The Commission summarised the content of the draft review report which is based on the EFSA technical report on calcium hydroxide and on the additional information submitted by the applicant and uploaded in CIRCABC under the specific folder for the substance.

One Member State expressed its support for the potential approval of the substance as basic.

Member States were asked to submit comments by 23 February 2015.

2. New dossiers received

There was no discussion on this point.

3. EFSA Technical Reports

i. Sodium hydrogen carbonate

There was no discussion on this point.

4. Draft Review Reports for discussion

i. Salix alba

The Commission outlined the main issues identified by EFSA and the comments received from the applicant and Member States. The Commission explained the changes in the new version of the review report.

One Member State asked how the Commission sees the difference between basic substances and botanical active substances when proposing approvals of basic substances. The Commission explained the importance of having an EU evaluation such as an European Medicines Agency (EMA) monograph as traditional medicine. In absence of such an evaluation and indications in the dossier of possible toxicity to humans and non-target organisms, an exposure assessment is considered necessary. In such cases a non-approval might be proposed.

Member States were asked to submit comments by 23 February 2015.

ii. Rheum officinale

The Commission outlined the main issues identified by EFSA and the comments received from the applicant.

The inter service consultation for this proposal will be launched after the meeting.

iii. Vinegar

The Commission outlined the main issues identified by EFSA.

Member States were asked to submit comments by 23 February 2015.

iv. Lecithins

The Commission outlined the main issues identified by EFSA.

One Member State expressed its support for the approval of lecithin with the same purity as food grade.

Member States were asked to submit comments by 23 February 2015.

v. Artemisia vulgaris

The Commission outlined the main issues identified by EFSA.

Member States are asked to submit comments by 23 February 2015.

A.08 Exchange of views and possible taking note of the following Guidance Documents:

1. Draft Guidance Document on the assessment of certain applications for which reference is made to Article 34 of Regulation (EC) No 1107/2009 (SANCO/11371/2014 Rev. 2) (for discussion)

No document was available for discussion. Based on comments received a new revision will be prepared.

2. Draft Guidance Document on renewal, withdrawal and amendment of authorisation under Regulation (EC) No 1107/2009 (SANCO/13170/2010 Rev. 10) (for discussion)

No document was available for discussion. Based on recent discussions a new revision will be prepared. This new revision will only deal with the renewal of authorisations. It is the intention that the chapters related to 'withdrawal and amendment' will be included in the Guidance Document on Zonal Evaluation.

3. Draft Guidance Document on the assessment of negligible exposure of an active substance in a plant protection product under realistic conditions of use (points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009) (SANCO/12096/2014) (for information)

No draft document was presented but the Commission updated on the last developments. A meeting with experts took place the 13 of January, 18 Member States are involved, plus Norway and EFSA. Discussions started in September 2013, based on input provided by MS previously. A total of 5 expert meetings were held so far.

The discussions on the content of the Guidance Document can be considered almost finalised, with one technical point still to be defined. Regarding the general approach, there is no full consensus between Member States, but discussions during the last 1.5 years showed that further discussions will most likely not lead to unanimous support.

The Commission explained the general approach taken, which is shared by most of the Member States. It should be noted that any substance approved under these articles referring to "negligible exposure" will be a candidate for substitution.

The Commission explained that where there is scope for interpretation in the legislation, a risk approach is taken because of 1) the legislation refers to the term 'exposure', which supports this approach (hazard + exposure = risk) and 2) The Commission/European Union is bound by international agreements according to which decisions should be taken based on risk. In conclusion, where possible, in interpreting the text one should favour a risk approach with a stricter than usual protection goal. Supporting this approach, the Commission is consistent with its previous line during the negotiation of the legislation (as put in evidence for example in answers to parliamentary questions). Further, the legal service of the Commission supports the approach.

The Commission informed that the format of the Guidance Document is not yet decided, due to changes of procedure associated with the new Commission.

One Member State thanked for the clarifications. Questions regarding timing could not be answered in detail due to the changes of procedures mentioned above, which still need to be clarified.

4. EFSA Guidance Document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (implementing document SANCO/12184/2014) (to be noted)

The Commission informed about new text in the implementing page of the Guidance Document, providing a link between the definition of "greenhouse" in Regulation (EC) No 1107/2009 and the Guidance Document. The new text was on CIRCABC since 2 weeks before the meeting. Five Member States expressed concerns about the new text, providing explanations of how differently they interpret and apply the term "greenhouse" at national level. For this reason, they would not support the interpretation proposed by the Commission in the implementing page of the Guidance Document. Another Member State informed that, as already expressed in previous meetings, they would not support the note taking of the Guidance Document because it is not ready for implementation. One Member State asked for clarification about the note taking procedure in general.

The Commission decided to take note of the Guidance Document as presented at the meeting in December 2014, i.e. with no new text linking the definition of "greenhouse" in Regulation (EC) No 1107/2009 and the Guidance Document.

The Committee took note of the Guidance Document . Three Member States could not support the note taking because: 1) models are not yet ready; 2) lack of clarity on mutual recognition; 3) the Guidance Document poses problems in the Member States.

The Commission (supported by comments from one Member State during the meeting) pointed out that the link between the definition of "greenhouse" in Regulation (EC) No 1107/2009 and the Guidance Document is still missing and will need to be addressed somehow within the shortest delay. The Commission will consider whether to address it via the published "Questions & Answers document" or via more formal and likely more lengthy procedures.

5. EFSA Guidance Document on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874 (for discussion)

The Commission thanked Member States for the feedback sent after the last meeting regarding the Guidance Document and the letters received from stakeholders. General consensus is to take note of the Guidance Document as soon as possible, with an adequate implementation date for notifiers. Taking note in May with implementation date of 1 January 2016 is proposed.

At the Standing Committee on Plants, Animals, Food and Feed (PAFF) in March and before taking note of the Guidance Document, it is foreseen to estimate the impact the new Guidance Document and the calculator will have on the risk assessment. Calculation outputs with the new calculator, to be sent in advance to the Commission by Member States, are welcome for this discussion. One Member State suggested to also invite notifiers to provide information about their experience with the calculator. The estimation of potential impacts should not further delay the implementation date of the Guidance Document.

The Commission thanked one Member State for its offer to draft terms of reference for the development of the AAOEL (acute acceptable operator exposure level). This document will be discussed between Member States either at the Pesticide Steering Network (EFSA) or the PAFF Committee. How to organise the development will be decided at a later point in time.

6. Draft Annexes of the Guidance Document on the presentation and evaluation of dossiers according to Annex III of Directive 91/414/EEC in the format of a (draft) Registration Report - (Doc. SANCO/6895/2009) (for information)

This point is to remind Member States of the deadline for commenting by 1 February 2015. Following the receipt of any comments received the documents will be finalized.

7. AOB

It was indicated that possibly some additional comments will be submitted as regards two documents which were noted in the PAFF meeting of 12 December 2014. This applies to the Template for the list of endpoints SANCO/12483/2014 Rev. 1 (in particular with regard to the part on micro-organisms) and the *Guidance Document for applicants on preparing dossiers for the approval or renewal of approval of microorganisms including viruses according to Regulation (EU) No 283/2013* and Regulation (EU) No 284/2013 (SANCO/ 12545/2014 Rev. 0). This is to avoid that the numbering in these documents will deviate from the agreed OECD-numbering.

A.09 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted)

Asulam (BE)
Ethylene (BE)
Propyzamide (DK)
Ipsdienol/cis-Verbenol (DK)
Clothianidin/beta-Cyfluthrin (FI)
Thiamethoxan/Metalaxyl-M/Fludioxonil (FI)
Fosetyl (FR)
Metalaxyl-M (FR)
Quinclorac (PT)
Pyrethrins (PT)
Copper hydroxide (PT)
Azadirachtin (PT)
Piriproxyfen (PT)
Flonicamid (PT)
Tricyclazole (PT)
Ethoxyquin (PT)
Thiophanate-methyl (PT)
Chlorantraniliprole (SE)
Cyprodinil/Fludioxonil (SE)
Ipconazole/Imazalil (SE)
Mandipropamid (SE)
Quinoclamine (SE)
Zinc-phosphide (SK)

The Committee took note of the notifications submitted by Belgium, Denmark, France, Portugal, Sweden and Slovakia.

The Commission recalled that under the provisions of Article 53, Member States concerned shall immediately inform the Commission and the other Member States of the measures taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

In addition, the Commission pointed out that even if a Maximum Residue Level (MRL) set under Regulation (EC) No 396/2005 cannot be met and a national MRL is set, a consumer risk assessment needs to be carried out and forwarded to the Commission, the European Food Safety Authority and Member States.

Member States were reminded that they shall put in place the necessary risk mitigation measures to ensure acceptable uses for human and animal health and the environment.

Furthermore, the Commission pointed out that for minor uses Member States should make use, whenever possible, of the provisions laid down in Article 51 of Regulation (EC) No 1107/2009. Member States should also take into account efficacious alternatives which are available among bio-pesticides and bio-control agents to promote low input techniques as required by Directive 2009/128/EC.

A.10 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted)

Gandalf (UK):

The Committee took note of the notification submitted by UK.

A.11 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (to be noted)

Luna Experience (UK):

The Committee took note of the notification submitted by UK.

A.12 Notifications under Article 56 of Regulation (EC) No 1107/2009 (to be noted)

There are no notifications under article 56 of Regulation (EC) No 1107/2009.

A.13 Sustainable Use Directive (Directive 2009/128/EC):

State of play:

The Committee gave an update on projects ongoing under the Better Training Safer Food programme, soliciting participation from Member States on the coming first workshop on train the trainers for the sustainable use of pesticides.

The Food and Veterinay Office (FVO) analyses of National Action Plans (NAPs) is currently almost finalised taking into account the comments received after September meeting from MS, it will be published as soon as possible on the Directorate General for Health and Food Safety (DG SANTE) webpage.

The draft Commission report to Parliament and Council will be subject soon to Interservice Consultation.

Next meeting of the Member States' experts group is planned for 13 March 2015, invitations will be sent out soon.

A.14 News from European Food Safety Authority (EFSA)

EFSA informed on the adoption of the Plant Protection Products and their Residues (PPR) Panel opinion on Non-Target arthropods in December, and to be published soon. Based on the alternatives offered in the Panel opinions, EFSA is preparing a document for discussion by the Commission and Member States at the PAFF Committee on protection goals for Non-Targets plants and arthropods, the timeline has not been decided yet.

EFSA informed on the discussions at the Pesticides Steering Network (PSN). A priority list for guidance update/development was presented and the draft Terms of Reference have been distributed for comments with a deadline of 31 January. The next meeting is planned for 10 February, the PSN will finalise the discussion on priorities for guidance update/development. In addition EFSA and European Chemicals Agenda (ECHA) are considering presentations for clarifying the differences and similitudes regarding substance identification (technical specifications) under Regulation (EC) No 1107/2009 and under the Classification, Labelling and Packaging (CLP) Regulation.

Other topics:

Cyantraniliprole: EFSA is investigating a possible error regarding the risk for non-target arthropods, and will republish the conclusion if needed

Chromobacterium subtsugae PRAA4-1 (MBI-203): EFSA considers that the substance is an UVCB chemical, not a microorganism, and the information requirements for chemical active substances should be considered by the Rapporteur Member State (RMS). This topic will be further followed up with the Commission and the RMS.

Endocrine disruption: EFSA confirmed that several conclusions will be republished with editorial clarifications on the application of the interim criteria. The changes are purely editorial and will not affect the EFSA conclusions. Regarding the interpretation of the second interim criterion, EFSA will wait until a clarification on the conditions assessing “may” is provided by the European Commission.

Classification and labelling (C&L) in the EFSA conclusions: EFSA highlighted the cooperation with ECHA; the possibility for diverging opinions in the scientific assessment (including C&L) is continuously monitored and divergences, if any, will be clarified according to the legal requirements. EFSA also clarified the difference between the substance identity in both process, that may affect the classification, as EFSA proposal is based on the active substance under Regulation (EC) No 1107/2009 (according to the technical specifications for the approval), while the harmonised classification follows the CLP substance ID principles.

A.15 Report from working groups:

i. Authorisation database - no discussion on this point.
ii. Low risk

The Commission provided feedback of the meeting of 17th December 2014. The initial separation of 'low risk criteria' in 'chemicals' and 'micro-organisms' will be kept. If criteria for those groups have been defined it will be considered if further differentiation is necessary (e.g. viruses, botanicals, semiochemicals).

The next meeting will be scheduled when a first draft of the amended criteria and 'Guidance Document on Low Risk' are available.

A.16 Bees

1. Review of Neonicotinoids – state of play and next steps

The Commission announced that no further steps took place since the last discussion in the Standing Committee of December. It is confirmed that the Commission will send a request to EFSA to organise an open call for data. Additional steps cannot be clarified when no clarity is made on the tool to be used by the Commission to "recommend" Member States to partially apply the BEE guidance document and implementation plan.

2. EFSA Guidance Document on the risk assessment of plant protection products on bees –and implementation plan (SANCO/10606/2014) state of play

The Commission announced that no further steps took place since the last discussion in the Standing Committee of December. The Directorate General for Health and Food Safety (DG SANTE) is investigating with other services of the Commission which tool is available to "recommend" harmonised use at Member State level of the bee guidance document and implementation plan. The process is slower than expected due to some recent changes in the internal rules on planning and new initiatives.

3. Uniform principles – Amendment to the Regulation (EU) No 546/2011 as regards the trigger value for honeybees to align to the EFSA Guidance Document.

Commission is initiating the procedure to amend Uniform Principle exclusively as regards the trigger values for honeybees.

AOB

- Conference on National monitoring activities.

The Commission was requested on several occasions by different Member States to organise a Conference to share this information on national monitoring activities.

The German authorities offered to host the conference in July 2015 in Berlin. The exact date will be defined at a later stage. The Commission will investigate the possibility to reimburse to the participation of one or two governmental experts by Member States (to be confirmed).

The European Food Safety Authority (EFSA) will be invited to give a presentation on their expectations on monitoring and the differences between monitoring and field studies.

The Commission will circulate a separate email inviting Member States for nominating experts.

A.17 Court cases

C-405/12 (and C-404/12) – Judgement in the Appeal to judgment in the case T-338/0 -COM v. Stichting natuur en Milieu & Pesticide Action Network (PAN) - Internal review under Aarhus Regulation.

There were two judgments on the Aarhus Regulation [Case C-402/12 P (Joined Cases C-401/12 P, C-402/12 P, C-403/12 P) and Case C-404/12 et C-405/12].

The Court judged that the legality of Article 10(1) of Regulation (EC) No 1367/2006 on internal review requests could not be assessed on the basis of Article 9(3) of the Aarhus Convention.

C-108/13 – Judgement in the preliminary ruling in Mac GmbH – Parallel trade of parallel traded plant protection products.

The court judged that a national law cannot prohibit double parallel trade as such. (See section 42 of the Judgment)

The Commission clarified that as a consequence to the judgment, Regulation (EC) No 1107/2009 should not be interpreted as prohibiting parallel trade of parallel trade. Parallel trade applications for parallel traded products can be examined by Member States under the rules of the Treaty (Articles 34 TFEU and 36 TFEU). Some Member States asked for clarification on the impact of the judgment for the implementation of Regulation (EC) No 1107/2009.

C-442/14 – Request for a preliminary ruling – Request for access to studies – Questions related to the definition of "emissions into the environment" under Aarhus Regulation.

Netherlands court presented questions to the Court of Justice related to the definition of "emissions into the environment" under Directive 2003/4/EC on public access to environmental information. Questions related to studies submitted for an application for authorisation and whether they should be considered as information on "emissions into the environment". Judgement is pending.

T-521/14 - Action for failure to act - Sweden v. COM – adoption of the scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 on biocidal products.

In July 2014 Sweden requested that the General Court establishes if the European Commission, in failing to adopt delegated acts specifying scientific criteria for the

determination of endocrine-disrupting properties, has infringed Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

T-729/14 – Action for annulment – Pesticides Action Network (PAN) v. COM - Request to set MRLs for the active substance imidacloprid to protect bee health.

PAN made an application to change MRLs for the active substance imidacloprid at levels to protect bee health. PAN has asked the Court for the annulment of the Commission's letter informing PAN that its application was out of the scope of Regulation (EC) No 396/2005 whose objective is to ensure consumers' protection.

A.18 Endocrine disruptors:

1. State of play

The Commission updated on the progress of the impact assessment on criteria for defining endocrine disruptors.

The studies linked to the impact assessment have started via an administrative agreement with the Joint Research Center (JRC) and are on track. The first and second studies will assess which chemicals may be identified as endocrine disruptors under each of the various options for the criteria outlined in the roadmap.

Additional studies will be started after the second study is finalised. They will assess the potential impacts on health, environmental, trade, agriculture, and socio-economy in general, when each option for the criteria would be implemented into the relevant sectorial legislation. These studies are expected to be finalised in 2016.

The public consultation closed on 16th January and the Commission thanked those who submitted contributions, including several Member States. The European Commission received more than 27,000 responses, both via the on-line survey and by email. From the total responses received, over 25,000 were submitted via external websites which provided pre-written responses. The responses received will be published on 2nd February on the SANTE website following standard rules.

2. Interpretation of the second interim criterion (to be published in the Questions & Answers document)

The Commission thanked Member States for the comments received from various Member States. Discussion on content and format are still on-going. As regards the content, the Committee discussed about the term "toxic effects in endocrine organs" which may be interpreted more or less restrictively from "organs secreting hormones" to "all organs possibly producing/regulating or affected by hormones". The Commission indicated that the legislator did not likely intend "all organs" otherwise it would not have specified "endocrine organs".

As regards the procedures to adopt the interpretation of the 2nd interim criterion, consistency with the approach under the sector of Biocides may be addressed involving ECHA and EFSA in the discussion. Moreover, recent indications from the new Commission suggest that a formal process including approval from the College may be needed.

The Commission informed the Committee about ongoing discussions with EFSA as regards the way issues on endocrine disruption are addressed in the EFSA Conclusions on single active substances. EFSA editorial amendments on a few conclusions may be published soon to clarify whether or not the interim criteria are met, in cases where potential endocrine disruption is concluded.

A.19 19 Minor Uses:

- State of play

It was announced that currently the proposal received is under evaluation. When acceptable the Steering Group can start the procedure to recruit the staff of the Coordination facility for minor uses.

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009
2. Questions and answers

There are no updates as regards this point.

A.21 Status of harmonised classifications under Regulation (EC) No 1272/2008.

The Commission updated the table reporting public consultations on the proposed harmonised classifications and labelling launched by ECHA. The document was uploaded on CIRCABC.

A.22 Glyphosate:

1. State of the dossier

The Rapporteur Member State (RMS) Germany reported on the progress of the assessment of additional data submitted by the notifier. It expects to finalise the evaluation by end of January or beginning of February 2015. EFSA indicated that the expert meetings on glyphosate will take place as scheduled, starting from end of February 2015, subject to timely reception of the RMS assessment.

2. Court case T 545-2011

There are no updates as regards this point.

A.23 Chlorpyrifos - state of the dossier.

The substance had been approved in 2005 on the basis of sole supported use vine grape at the application rate of 245 g/ha per year. The Commission resumed the main conclusions of the toxicological review performed under Article 21 of Regulation (EC) No 1107/2009 which was launched in 2012 and finalised in 2014, indicating necessity to reduce the toxicological reference values and to review all existing Maximum Residue Levels. The majority of Member States agreed on the new toxicological reference values and on the need to prioritise the MRL review.

A clear concern was identified for table grapes at application rate higher than 245 g/ha. Initially, the Commission proposed a restriction of the approval to wine grape at maximum application rate of 245 g/ha. Following comments from several Member States which have granted authorisations, including minor uses, for other uses at the same or even lower application rates, the Commission reconsidered its proposal. A new proposal was presented which sticks with a maximum application rate of 245 g/ha, but which is no longer restricted to the use in wine grapes.

Some Member States reiterated their disagreement with the proposal to set restrictions at EU level considering subsidiarity should apply given still a safe use at EU level is confirmed. Other Member States welcomed the new proposal considered more proportionate to the outcomes.

A.24 Chlorpyrifos-methyl – state of the dossier.

The Commission resumed the RMS conclusions of the assessment of new study to confirm the Acute toxicological reference dose for C-methyl. A draft amended review report has been made available to Member States.

Member States were requested to submit comments by 23 February 2015.

A.25 EFSA Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid.

Following comments and data submitted by the applicants of acetamiprid and imidacloprid on the EFSA Scientific Opinion, EFSA has published a rebuttal where the conclusions drawn in the Opinion are confirmed.

The Commission received several comments from Member States both at the time of publication of the Opinion in February 2014 and now that EFSA confirmed their conclusions.

Most comments from Member States consider that uncertainty in the data does not justify lowering the toxicological endpoints for the two active substances. A few Member States suggest that the information available should be assessed by Member States' experts before proposing any action. On the other hand, the EFSA Panel

indicates that the uncertainty in the data justify taking a precautionary approach, as the developmental neurotoxicity potential of the two substances cannot be excluded on the basis of the information available.

The Commission suggests that rather than asking further assessment by Member States experts of the information available, an appropriate integrated testing strategy on developmental neurotoxicity is developed. This would be in line with the conclusions of the EFSA Scientific Opinion. The in vivo test available (OECD TG 426) is on one hand not sensitive enough as screening/prioritization tool, on the other hand should not be requested for all substances. The integrated testing strategy may be triggered via an EU working group or, even preferentially, directly at OECD level.

Member States were asked to submit comments by 23 February 2015.

A.26 Data requirements and acceptance of waivers/implementation of doc. SANCO/10181/2013.

The Commission referred to the European Crop Producers Association (ECPA) letter from December 2013 (uploaded again on CIRCABC), the comments of one Member State (also on CIRCABC) and discussion at the Pesticides Residues PAFF Committee in relation to fish metabolism studies.

The point raised by ECPA is that some RMS are requesting studies on data requirements for which currently there is no agreed methodology and they consider a dossier incomplete if these data are not provided. The Commission explained that this is not consistent with the Guidance Document SANCO/10181/2013, which was taken note of by Member States. It is also leading to inconsistency between Member States.

The Commission invited Member States to follow the procedures agreed when taking note of Guidance Document SANCO/10181/2013 in order to harmonise the procedures, i.e. to accept as a general line the waiving for cases where no test guidelines are available. In particular cases, ad-hoc studies could be requested, as it is always the case in justified situations. The Commission does not see an immediate need to amend the Guidance Document. However, the Commission referred to the general policy of reducing animal testing and asked Member States to consider this when asking for additional studies on vertebrates.

The Commission clarified that the new data requirements structure, i.e. Regulation and Communications, was chosen to be able to update the Communications regularly. This is still the intention and the Commission invited Member States to raise the attention of the Commission and PAFF Committee if new international and validated methods would be available for adding to the Communications.

One Member State observed that it is confusing to publish staff working documents on the SANTE website, which are not taken note of by the PAFF Committee. Another Member State mentioned that the wording "waiving" may lead to confusion.

A.27 Follow-up workshop "Harmonisation in Toxicology".

The Commission will circulate a separate email inviting Member States for nominating risk assessors for the workshop to be held in Vienna, 23 and 24 of June (local organizer Austria).

(One expert per Member State possibly might be reimbursed – to be confirmed).

A.28 Imidacloprid revised review report for discussion.

The Commission provided a brief background of the dossier. At least two separate open procedures are ongoing for this dossier, namely: 1) confirmatory data; and 2) review according to Article 21 of Regulation (EC) No 1107/2009.

1. As regards confirmatory data, the data were submitted in time by the applicant and evaluated by RMS resulting in an addendum to Draft Assessment Report (DAR). Following the comments received in the reporting table some open points requested further evaluation by experts. Therefore the Commission mandated EFSA and an EFSA conclusion on the peer review of confirmatory data was published. Based on the EFSA conclusions, the Commission proposes to maintain the conditions of the approval of the active substance.

2. The review according to Article 21 of Regulation (EC) No 1107/2009 was initiated following a request from the RMS. The request resulted from the assessment by a Member State of a new scientific publication suggesting risk for the aquatic organisms. The Commission mandated EFSA to re-evaluate the risk assessment for aquatic organisms. EFSA published its conclusions. The Commission is of the opinion that on the basis of the current outcome and considering the restrictions to the use of plant protection products containing imidacloprid as laid down in Regulation (EU) No 485/2013 and the addendum to the review report (document SANCO/10590/2013 Rev. 2 of 15 March 2013), the conclusions of the original risk assessment on the aquatic organisms are not substantially modified and do not result, at this stage, in the need to further modify the conditions of approval of the active substance imidacloprid.

The Commission uploaded the revised review report (modified in chapter 7 for confirmatory data and in chapter 1 for the review of the risk assessment for aquatic organisms) proposing to finalise the process without modifications to the conditions of approval. Comments are requested by 23 February 2015.

A.29 Note taking procedures.

There was no discussion on this point.

A.30 Study on the trade of illegal and counterfeit pesticides in the EU – presentation of the draft final report by the Food Chain Evaluation Consortium (FCEC).

The consultant FCEC made a presentation on the results of the study on the trade of illegal and counterfeit pesticides in the EU. One Member State commented on the role of the companies in the fights against illegal trade, and particular trade of counterfeit Plant Protection Products (PPP)s. The presentation will be uploaded in CIRCABC.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance COS-OGA, 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 Doc. SANTE/00036/2015 Rev. 0)

The Regulation approves COS-OGA as a low risk active substance. Two Member States can support a low risk approval only if the use of the substance is restricted to greenhouses. The Commission does not follow this request, as the substance is a mixture of two naturally occurring substances (pectin and chitosan), which are constituents of plant cells and occur ubiquitous in the environment.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance cerevisane, 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 doc. SANTE/00033/2015 Rev. 0)

The Regulation approves cerevisane as a low risk active substance. One Member State is not willing to approve any substance as low risk for the time being.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation on Implementing Regulation Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (Doc. SANTE/12589/2013 Rev. 3) (Legal Base: Article 78(2) of Regulation (EC) No 1107/2009) (Opinion of the Committee via the examination procedure)

The Commission prepared a Regulation to establish the list for candidates for substitution.

Some Member State expressed concerns because of the expected workload on national level for comparative assessment, as well as because this list will reduce the available tools for farmers as regards plant protection.

Vote taken: Favourable opinion.

M.01 News from the Food and Veterinary Office (FVO).

No news from the FVO to be reported under this point.

M.02 New scientific publications.

M.03 AOB

The points under AOB were addressed under agenda points A.6 and A.8.7 respectively.