EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

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SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 28 JANUARY 2016 - 29 JANUARY 2016

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/40ac8038-6be1-4a88-8ccf-795c4544432f*

A.01 Summary Report of previous meetings.

No new summary report was uploaded on the web since the last meeting.

A.02 New active substances:

1. New admissible dossiers (to be noted)

i. Admissibility report in case of resubmission of a dossier

The Commission asked Member States to always follow the procedure of Article 8 and perform an admissibility check for active substances which are currently not approved. Such an admissibility check should also be performed in case of submission of a dossier for a substance which was approved in the past and for which the approval ended.

ii. Napropamide-M (point added to original agenda)

The Committee took note of the confirmation of admissibility of the dossier for napropamide-M, provided by the United Kingdom as rapporteur Member State.

2. European Food Safety Authority conclusions

i. *Bacillus amyloliquefaciens* strain MBI 600

Member States were informed that the EFSA Conclusion for this new active substance had been published and that in the next meeting a first proposal would be made and discussion initiated.

3. Commission Draft Review Report and Regulation concerning the (non-) approval of:

i. *Beta-Cypermethrin*

Member States were informed of comments received from Member States since the previous meeting and told that some further internal discussion was taking place on the proposal. One Member State had strong concerns about the risk to non-target arthropods. A new version of the review report and a draft Regulation would be made available in the March 2016 meeting. Member States were asked for comments by 12th February.

ii. *Beauveria bassiana* strain 147

No discussion.

iii. *Beauveria bassiana* strain NPP111B005

No discussion.

iv. *Reynoutria sacchalinensis* extract

No discussion

v. S*accharomyces cerevisiae* strain LAS02

Member States were informed that the EFSA conclusion had been published for this micro-organism active substance. Commission seeks to approve it as a low-risk substance. A draft review report was presented. Member States were invited to provide comments on this document by 15 February 2016.

A.03 Renewal of Approval:

1. 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/0148/2014 Rev. 6) (For information)

No new information under this agenda point.

2. List of studies relied upon for AIR (Annex I Renewal Project) assessments

Member States were reminded that according to the Guidance Documents on List of Studies and on Article 43, the list of studies relied upon for renewal should be made publicly available. Such lists should be sent to the Directorate General for Health and Food Safety (DGSANTE/Unit E4) for uploading in the pesticide database. The lists will be available on the webpage of the related active substance, in the same box as the review report.

The sooner the list is available online, the easier the planning is for authorisation holders and competent authorities.

3. AIR II: State of play

The Commission expects that for a few substances of the AIR II programme, no decision can be published by 30 June 2016.

In line with the requirements of the legislation, the Commission will propose an extension of the approval period for those substances where the review is delayed for reasons outside of control by the applicant.

The Commission intends to submit a draft Regulation for a vote in March.

4. AIR III: State of play

The Commission is aware of substantial delays in the submission of many renewal assessment reports (RAR) for which the deadline expired. The Commission is concerned, as this will inevitably lead to delays in the decision-making process and will most likely trigger an extension of existing approvals for substances of the AIR III programme, in line with the provisions of the legislation concerning procedural delays not under the control of the applicant.

5. AIR IV: State of play

The Commission will adopt a work programme to set priorities for substances with an expiry date which is comprised between 1 January 2019 and 31 December 2021 (AIR IV). The substances are listed in Part B of the Annex to Commission Implementing Regulation (EU) No 686/2012 (as amended). Setting priorities is necessary in view of a large number of substances under AIR IV. Adoption of the programme by the Commission is foreseen in Article 18 of Regulation (EC) No 1107/2009.

- The assessment of active substances which given their properties are low-risk, will be prioritised. Their assessment should not to be delayed or be delayed as little as possible. The objective is that low risk products can be available on the market in compliance with Article 47 of Regulation (EC) No 1107/2009 as soon as possible.

- The assessment of active substances for which given their properties, it is expected that they could meet the cut-off criteria (points 3.6.2 to 3.6.5 and 3.7 of Annex II), will also be prioritised. Their assessment should not to be delayed or be delayed as little as possible.

- The approval period of other substances not covered may be extended.

6. EFSA conclusions

i. *Thifensulfuron*

Following a first discussion in the December meeting, the Commission received some comments from one Member State. A draft review report will be made available on CIRCABC for the next meeting.

ii. *Ethofumesate* (first AIR3 conclusion)

Member States were informed that the EFSA Conclusion for this active substance, which is part of the third stage of the renewal programme, had been published by EFSA and that in the next meeting a first proposal would be presented and discussion initiated.

7. Draft Review Reports for discussion

i. Thiabendazole

No discussion.

ii. Amitrole

Member States fully support the withdrawal of amitrole, since no comments were received on the proposal for non-renewal. Following inter-service consultation, some recitals in the Implementing Regulation were revised to clarify that - irrespectively from approval criteria which are not met - the risk assessment for amitrole is not acceptable. For this reason, the applicant cannot be granted the possibility to submit dossiers both for Article 4.7 and for negligible exposure.

A letter from a Member State was received indicating that national authorizations for plant protection products containing amitrole were removed from the market of that Member State even before a decision on the possible non-renewal of the active substance at EU level is taken. The letter is uploaded on CIRCABC, together with other letters received from the applicant.

The Technical Barrier to Trade (TBT) procedure has just been launched and it will last for 60 days. A vote on the proposal for withdrawal is expected for April 2016 in one of the Plants, Animals, Food and Feed (PAFF) Committees.

iii. Cyhalofop-butyl

No discussion

iv. Triasulfuron

The Commission recalls that, on the basis of the EFSA conclusion, a renewal of the substance is problematic, unless Member States, in their role of risk managers, would agree to set themselves the toxicological reference values and finalise the human exposure assessment. It shows however, that there is insufficient support to consider that option, which, in any case, would set a precedent. As a consequence, the Commission will before the next meeting, draft a formal proposal not to renew the substance. The notifier has already been informed on the outcome of the debates.

Whether a vote in March 2016 can take place will depend on the finalisation of the TBT procedure.

v. Bentazone

No discussion.

vi. Isoproturon

The Commission presented a draft Regulation for non-renewal of the substance. Several Member States had already indicated that they supported the proposal. One Member State was concerned about the loss of the substance for growing cereals. Final positions were requested by 12th February 2016.

vii. Famoxadone

No discussion. A draft review report would be presented at the next meeting.

viii. Glyphosate

The Commission presented a first set of draft documents, highlighting the preliminary character and the ongoing consultation of other Commission services. Several Member States took the floor to ask questions on and suggest revisions of the draft documents, and to make more general yet preliminary comments, as consultation within Member States authorities was not yet finalised. The Commission asked Member States to submit written comments by 12 February 2016.

ix. Picolinafen

Member States were updated on the state of play. Following the publication of the EFSA conclusion, the Commission presented a draft review report and a draft regulation for a non-restricted renewal of the active substance. Member States were invited to provide comments by 15 February 2016.

A.04 Confirmatory data:

i. *Epoxiconazole*

The draft review report presented follows as much as possible the EFSA conclusion. The outstanding point is the long term risk to herbivorous birds, which is close to but still below the trigger of acceptability. It must be examined whether this matter, which is highly dependent on local conditions, could be left at the level of Member State. Also, the inclusion of one metabolite to the residue definition is still under debate. Several Member States have already reacted but the Commission would also appreciate the views by the rapporteur Member State (RMS) Germany.

ii. *Bifenthrin*

No review report has been presented yet. The remaining issue is the potential for recovery/recolonization of non-target arthropods (NTA) in field. It would seem that that recovery, at least of some species, is ambiguous. On the other hand, it has been explained by the notifier that the pertinent studies had been carried out at double the maximum intended rates. The Commission therefore asks Member States whether

there is evidence that applying the normal rates would result in an acceptable risk for NTA.

Member States were invited to comment by 12 February 2016.

iii. *Dodine*

The Commission gave an update on the file. The EFSA Conclusion concerning evaluation of confirmatory data had been published in August 2015. The Conclusion indicates critical areas of concern based on the representative uses for long term risk for bird and mammals. The Commission drafted a new revision of the review report in which this is indicated. The Member States were requested to submit comments by 19 February 2016.

iv. *Thiamethoxam*

The Commission gave an update on the file. The request for confirmatory information is linked to the modification of the conditions of the approval provided for in the Commission Implementing Regulation (EU) No 485/2013. The Rapporteur Member States evaluated the data received from the applicant. The commenting table is currently under finalisation. The Commission would like to highlight that not all the data requested were submitted by the applicant and therefore the Commission is reflecting on the next steps following the finalisation of the commenting round.

v. *Sulfuryl fluoride*

The Commission gave an update of the file. Following the publication of the EFSA technical report, the Commission indicated that restrictions and monitoring were necessary. Member States were invited to provide comments on the approach by 15 February 2016.

vi. *Bromuconazole*

A revised review report was made available for Member States to consider. The positions/comments of several Member States were shared with the Committee. The Commission advised that further comments could be submitted by 29th February and that the report would be tabled for noting at the next meeting.

vii. *Oxyfluorfen*

The Commission gave an update on the state of play following a meeting held with the applicant in December 2015. A number of points remained to be investigated. Member States were asked to provide comments and details of certain authorised Plant Protection Products (PPPs) by 29th February 2016. Two Member States had already indicated that they could not support continued approval of the substance given the high risk for aquatic organisms identified in the EFSA Conclusion.

viii. *Tetraconazole*

Still no feedback has been received from the RMS Italy.

ix. *Fluquinconazole*

Nothing to mention. The dossier is currently being examined by EFSA.

x. *Metazachlor*

Nothing to mention. The new commenting round organised by RMS United Kingdom should be ongoing.

xi. *Prochloraz*

A draft review report has been tabled. The main issue is the remaining ambiguities as regards the specification. EFSA suggests that at least an additional Ames test should be done with the minimum level of prochloraz and the maximum level of impurities. The Commission recalls that the regulation already foresees very strict levels for impurities of concern but would not oppose if Member States would be in favour of that option. The commenting Member States agreed on that. One Member State however, raises points of principle as regards the approval itself of this substance and would, in any case, not be in a position to take note of the report. If no other comments by Member States would emerge by 12 February 2016, the Commission intends to propose to take note of the amended review report in March 2016.

xii. *1-NAD*

The situation is identical to the one on 1-NAA but it might be possible to waive a separate chronic bird study for 1-NAD by bridging the results from the one on 1-NAA (see below). The Commission will revise the wording of the report and present it for note-taking in March 2016.

xiii. 1-NAA

A draft review report has been tabled. The remaining question concerns the long term risk for birds which has been extrapolated from acute data. Ideally, that outcome should have been derived from chronic studies and not be waived. It would seem nonetheless that there is a large margin of safety and therefore the Commission proposes to maintain the conditions for approval but requesting the submission of a chronic study at Member State level. The alternative of a residue study measured on foliage-dwelling arthropods is not acceptable. The Commission will revise the wording of the report and, if no other comments from Member States are received by 12 February 2016, present it for note-taking in March 2016.

xiv. Buprofezin

No progress had been made since the previous meeting. The use of the Margin of Exposure methodology had become a divisive issue and as such it was proving impossible to find a solution for crops that are subject to processing. The Commission indicated that further internal discussion would take place and a firmer update and

possible amended proposal provided in March. Member States were asked for any further comments or positions by 12th February 2016.

xv. Myclobutanil (revised review report to be noted)

A revised Review Report was noted. A new residues definition was set for risk assessment to include the triazole derived metabolites (TDMs). This may be further reviewed once the full scale EU assessment of the TDMs has been completed.

xvi. Pyridaben

Member States were given an update on the state of play. The EFSA Conclusion following evaluation of confirmatory data had been published in January 2016. The Conclusion indicates no critical areas of concern based on the representative uses. The Commission will draft a new revision of the review report in which this is indicated.

AOB

None

A.05 Article 21 Reviews:

i. *Diflubenzuron*

The Commission provided a brief update on the state of play.

ii. Chlorpyrifos – state of the dossier

The Commission informed about the adoption of Regulation (EU) No 2016/60 setting new MRLs for several crops. The act is considered as a final step of the review under Article 21. Beyond this, the substance is subject to a complete re-assessment for possible renewal. The RMS has confirmed a complete dossier has been submitted and evaluation is ongoing.

A.06 Amendment of the conditions of approval.

No news.

A.07 Basic substances:

1. Pilot projects: state of play

The applications announced that Netherlands have not submitted so far. Hence the candidates for the pilot project were reshuffled.

2. New dossiers received:

i. Landes pine tar

ii. Nettle
iii. Honey from Rhododendron (point added to original agenda)
iv. Comfrey steeping (point added to original agenda)

The Commission informed Member States that four new dossiers have been submitted. A more detailed introduction and discussion will follow at a later stage.

3. EFSA Technical Reports

None to report.

4. Draft Review Reports for discussion:

i. DAP
ii. Sweet whey

Member States were asked to provide any final comments on these two substances.

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

1. Draft Technical Guidance Document (GD) on the interpretation of points 3.6.3 to 3.6.5 of Annex II of Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use (SANCO/12096/2014) (update/discussion)

The Commission thanked Member States for the comments received on the draft presented at the last meeting and informed that the progress on this GD is put on hold due to prioritisation of other areas.

2. Draft Guidance Document on Semiochemical Active Substances used in Plant Protection Products (SANCO/12815/2014 Rev. 4.1)

Member States were informed that the draft GD was finalised by the WG on Biopesticides. They were invited to provide comments by the 15/2/16.

3. Guidance Document for Applicants on Preparing Dossiers for the Approval or Renewal of Approval of a Micro-Organism Including Viruses According to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (clarification).

Member States were reminded that Rev. 1 of this GD had been withdrawn. The Commission drafted Rev. 2 of the Guidance Document in order to clarify the numbering of the dossier.

4. The Commission Communications on the List of Test Methods and GDs for Active Substance or Plant Protection Products (PPP) dossiers (for information).

Member States were informed that the Commission will update its Communications on the Test Methods. They were invited to provide feedback on new tests internationally validated to the Commission by 31 March 2016.

A.09 Notifications under Article 44(4) of Regulation (EC) No 1107/2009 (to be noted).

No notifications received.

A.10 Notifications under Article 36(3) of Regulation (EC) No 1107/2009 (to be noted).

No notifications received.

A.11 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Asulam (Belgium)
Bromadiolone (Croatia)
Chlorpropham (Finland)
Asulam (France)
Indoxacarb (France)
Copper compounds (France)
Carbon dioxide (France)
Pepino mosaic virus strain CH2 isolate 1906 (France)
8-Hydroxyquinoline (Germany)
Zinc phosphide (Slovakia)
1,3-Dichloropropene/ Chloropicrin (Spain)
Spirodiclofen (Spain)
Abamectin (Spain)
Pymetrozine (Spain)
Trifloxystrobin (Spain)
Boscalid/Pyraclostrobin (Spain)
Chlorantraniliprole (Spain)
Spinosad (Spain)
Diquat (Spain)
Fluxapyroxad (Spain)
Imazamox/Metazachlor (Spain)
Spirotetramat (Spain)

The Committee took note of the notifications submitted by Belgium, Croatia, Finland, France, Germany, Slovakia, and Spain.

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.12 Sustainable Use Directive (Directive 2009/128/EC):

1. NAP (National Action Plans) Report
2. State of play

The Commission informed on the delay with respect to submission of the report to Parliament and Council and aims to proceed in the coming months. Minutes of last meeting of the Sustainable use Directive (SUD) working group held in December 2015 are available in CIRCABC.

A workshop on Integrated Pest Management (IPM) demonstration farms is going to be organised in Germany in cooperation with C-IPM Eranet platform on 24 and 25 May 2016.

A.13 News from European Food Safety Authority (EFSA).

Glyphosate: EFSA informed on the responses to comments and the planned meeting with the International Agency on Research on Cancer (IARC) in February, 2016. Most experts have submitted the annual declaration of interest (ADOI) and EFSA stressed the convenience of having the ADOI of all experts involved in glyphosate, and also asked Member States to inform EFSA in case they have a national system publishing the declarations of interest for the experts involved in the assessment of pesticides.

EFSA informed on the publication of the Technical Report of the Ecotoxicology general meeting in December 2015 and on the Mammalian Toxicology general meeting which took place 12-15 January 2016: technical report will be prepared and published in the coming weeks. Some Member States expressed concerns on the discussions held in those meetings on risk management issues. EFSA clarified that the meetings are part of the peer-review process and the discussions shall be limited to the risk assessment problems and methodologies.

Article 4(7): EFSA will request extension of the existing deadline by another 3 months in order to discuss the Member States' comments on the methodology. Several Member States expressed concerns about the process. EFSA clarified the procedural issues (EFSA working group under Plant Health), and confirmed that the Member States' comments will be considered. A meeting of the working group with the

Member States experts was considered essential by some Member States and EFSA will consider this proposal.

Neonics mandate: EFSA reiterated that input from Member States has been requested on Good Agricultural Practices (GAPs) for clothianidin, thiametoxam and imidacloprid and monitoring reports; requested deadline for providing info to EFSA: 29 January 2016.

Draft assessment report template on harmonised classification (DAR-CLH template): EFSA informed on the on-going commenting round with Member States and that ECHA launched in parallel commenting with the Risk Assessment Committee (RAC) and CARACAL. Deadline for providing comments to EFSA: 12 February 2016.

First AIR III conclusion (ethofumesate) finalised, 5 more are expected by end February. EFSA indicated to collect information from the different sections on the new data requirements for which there are no agreed test guidelines in order to harmonise the risk assessments.

Dates next Pesticide Steering network: 14 (pm) and 15 (full day) June 2016. Main issue: reviewing the contribution of Member States' experts to the EFSA peer-review. The United Kingdom and the Commission expressed concerns as in their view, EFSA is not sufficiently considering the views from the Member States' experts and the Commission. EFSA clarified the different roles of the RMS experts and the other Member States' experts, and requested examples where the views of the non-RMS experts had not been considered in the EFSA assessments or the EFSA conclusion did not reflect the majority view of the non-RMS experts participating at the meeting. Regarding the RMS, EFSA reiterated that when the RMS has a different view on a relevant issue this should always be mentioned in the Conclusion; minority views reporting during the expert meetings are also mentioned.

A.14 Report from working groups:

1. PPP Application Management System (Authorisation database)

A short update on the ongoing activities was provided by the Commission. A meeting of the Implementation Steering Group took place on the 14th December 2015. Member States were testing the new version of the PPPAMS and reporting back to the Commission. The 'go live' date for the revised system was foreseen for early March.

A workshop for industry was being run in March.

The data migration exercise was ongoing and progress was being made. The data was feeding into the impact assessment on Endocrine Disruptors.

Training for Member States would be considered once the new version of PPPAMS was operational.

2. Low risk: presentation of working document for proposal to review criteria

Following the presentation in the last Standing Committee meeting the Commission received comments from two Member States.

In addition, one of the stakeholders who is represented in the expert group submitted a substantial amount of comments long after the deadline for the expert group. The Commission will consider these comments but at the same time will make sure that the further planning will not be delayed by this. The Commission also informed that following the presentation of the working document to support possible amendment of criteria for low risk in December, comments have been received by Denmark and Sweden. In addition, the NGO PAN who is part of the experts group; has only now sent some further comments to the working document. These comments arrived with a delay of almost two months, they will be circulated to the experts working group before finalisation of the document as it was planned to proceed with the proposal for the criteria to be adopted in time for renewal programme.

3. Expert group on Article 43

The Member States were invited to provide comments on a clarification document drafted by the expert group on Article 43. This clarification paper identifies area where the GD on renewal of authorisations (rev. 14) should be updated.

4. Post Approvals Issues group (PAI) (no news)

There was no meeting since the last Standing Committee meeting.

5. Seed treatment

The Commission informed Member States that the latest inputs have been received by the end of 2015. Now the draft GD document is complete from a technical point of view. The Working Group will reconvene in March to finalise the document.

6. Sustainable plant protection temporary experts group (point added to original agenda):.

As a follow up to the proposal made by the Dutch presidency in the Agri-Council meeting of October 2015, a temporary expert group has been organised to identify concrete short-term and long-term actions to increase the availability of low risk plant protection products and speed up the application of IPM in Member States . The outcome of this expert group should be presented to the Agri-Council in June 2016 and should consist of an overview of actions, timeline, actors and the leading organisation for their implementation. Next meeting will be held on 22 February a draft mandate for the group has been uploaded in CIRCABC for the delegates to consider. Currently 18 Member States and Norway are part of the group.

A.15 OECD

No news.

A.16 Bees:

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

The Commission informed that the process is currently running. EFSA is performing the risk assessment and as long as this exercise is not finalised, the Commission does not plan to modify the conditions of approval on the 3 active substances.

One Member State requested clarification on the reason behind the request of the Commission in the terms of reference of the mandate to take into account the EFSA GD on the risk assessment of plant protection products on bees while this document is not yet endorsed by the Committee. The Commission explained that this specific review is carried out in the framework of Article 21 of Regulation (EC) No 1107/2009. The Commission clarified that the process under Article 21 is different from that of Articles 7 to 13 of Regulation (EC) No 1107/2009. In the frame of a review under Article 21 the approval of an active substance is assessed in the light of new scientific information.

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

No news under this agenda point.

3. Uniform principles – Amendment to the Regulation (EC) No 546/2011 as regards the trigger values for bees to take into account the new scientific development.

No news under this agenda point.

4. Follow-up - EU Conference "Field studies and Monitoring Activities carried out at National level on the effect of Pesticides on Bees and other Pollinators" (MAPoB) 9-11September 2015, Bonn

The Commission requested Member States to provide comments on the possible follow up of the meeting. The Commission indicated that it had only received comments from 2 Member States. Additional comments are welcome up to 12 February 2016.

5. AOB

None.

A.17 Court cases:

On-going cases:

The Commission provided information on C-673/13 and C-442/14: the hearings for these cases which relate to confidentiality and the interpretation of Aarhus Regulation are scheduled on 4 February 2015.

New cases:

The Commission informed the Committee about two new cases:

- T-732/15 ICA v. Commission: in this case the company is seeking to annul the Regulation (EU) 2015/1910 setting maximum residue levels for guazatine
- T-746/15 BIOFA v. Commission: in this case the company is seeking to annul the Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate

A.18 Endocrine disruptors:

- Impact assessment

The Commission indicated that it is duly taking note of the Court judgement of 16 December 2015 and that it has every intention to comply with its legal obligations. However, the impact assessment remains a useful and essential tool to guide its future decision on the criteria. The decision to launch an impact assessment in 2013 was justified for several reasons: in particular, the scientific complexity of the issue and the fact that this will be pioneer work, since there is no precedent of legislation in this area in the world.

The preparation of the impact assessment is well advanced and in response to the judgement of the Court, the Commission is accelerating the process as much as feasible, in order to put forward the draft legal acts establishing the criteria for endocrine disruptors as soon as possible.

A.19 Minor Uses:

- State of play

A paper with an update about the activities of the Coordination Facility was uploaded on CIRCABC. The coordinator will be invited to present a more detailed update about the activities of the facility in another Standing Committee meeting (May is preliminarily envisaged).

A.20 Interpretation Issues:

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

No news.

A.21 Classifications under Regulation (EC) No 1272/2008:

1. Status of harmonised classifications

No update.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States and amendment of the format of DAR (Draft Assessment Report) and RAR (Risk Assessment Report)

- The Commission urges Member States to prepare submissions for the classification of substances for all substances which are not "low-risk" substances (CHL dossiers). This is a very important step for the evaluation of substance approvals and renewals. It is foreseen under Article 37 of Regulation (EC) No 1272/2008.

- The Commission informed Member States that ECHA has confirmed that it will accept submissions of CLH dossiers from MS on the basis of Article 37 of Regulation (EC) No 1272/2008 not only to propose a new classification for a substance but also to confirm an existing harmonised classification or to confirm the absence of classification.

  Some MS indicated that this would improve the procedure for the approval or renewal of active substances under Regulation (EC) No 1107/2009.

- EFSA had offered during the Pesticide Steering Network meeting to prepare, in cooperation with ECHA and MS, a draft amendment for the DAR guidance in order to incorporate the CLH dossier format.

  EFSA specified that it called for comments of Member States on the new DAR format with deadline on 12 February 2016.

A.22 Glyphosate:

• State of the dossier

See agenda item A.03.07.08.

A.23 Exchange of information from the section Pesticide Residues of the PAFF Committee: possible impact on authorisations (no new meeting has taken place since December 2015)

No news.

A.24 New greenhouse operator exposure model.

The Commission thanked Germany for their proposal to coordinate the project to develop an exposure model for greenhouse and suggested to forward the document to EFSA for consideration of inclusion into the Operator Exposure Guidance Document.

A.25 Way ahead on identification of inacceptable co-formulants (Article 27).

Member States were informed that the WG will meet on the 11/02/2016.

A.26 Tefluthrin - Article 56 submission by Syngenta (DE).

Postponed.

A.27 Phosphonic acid (inorganic metabolite) - Assessment of relevance (DE).

Postponed.

A.28 Acetamiprid (new toxicological reference values) (to be noted) (DE).

The Committee formally agreed not to consider the toxicological values that were derived by EFSA in the framework of the Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid. The situation will be reviewed when renewing the approval of the active substance, taking into account all available data submitted in that framework.

A.29 Straight Chain Lepidopteran Pheromones (SCLP): new compound amended Review Report (SANCO/2633/08 Rev. 9) (take note).

The Committee took note of Rev. 9.

A.30 Question concerning acute Acceptable Operator Exposure Levels (AOEL) (DK)

The Commission clarified that the acute risk assessment of operators and workers could be already carried out based on the EFSA OPEX GD, using AOEL which is more conservative than the AAOEL. Risk mitigation possibilities exist for these population groups which could be considered in the assessment. For bystanders and residents this assessment cannot be fully considered, as mentioned in SANTE-10832-2015 taken note at this Committee.

Belgium clarified that in the central zone similar discussions as in the northern zone (raised by Denmark) are expected. France mentioned that developing a methodology to derive an AAOEL is becoming urgent, and that at national level they are already considering acute exposure assessments to residents.

It was discussed if the Terms of Reference for deriving an AAOEL, taken note previously at this PAFF, could be already implemented on a case by case basis to derive AAOEL by Member States and EFSA during the peer review. This would allow being able to cover the assessment of acute effects, to gain experience, and to decide if at a later point a more detailed guidance would be needed. MS were requested to provide comments on this proposal, if any, by February 2016.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance

pinoxaden, 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. SANCO/11794/2013 Rev. 3).

The draft document was presented for vote. Two Member States voted against because of the risk of metabolites leaching to groundwater. Three other Member States abstained because they would prefer an extension of the provisional authorisation until an ECHA opinion on the possible classification of pinoxaden is available.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance acibenzolar-S-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 Review Report Doc. SANTE/12284/2015 Rev. 1).

The Commission intends to present the draft for a vote on 23 February to the PAFF section on Pesticides Residues.

Three Member States commented that the current confirmatory data should also require information on the potential endocrine mode of action of acibenzolar-S-methyl. The comment will be taken into account in a revised proposal. A MS also requested consideration of additional confirmatory information on analytical methods for the metabolite SYN546642 in water and soil.

Vote postponed

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of the active substance tricyclazole, 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 (Draft Review Report SANTE/11866/2015 Rev. 0).

Vote postponed

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

A presentation was foreseen but had to be cancelled. The presentation will be given at the meeting in March 2016.

M.02 New scientific publications.

No new publications to be discussed under this point.

M.03 AOB

- Guidance Document DegT50 (SANCO/12117/2014 - final, 12 December 2014) – Clarification on implementation (Germany).

Germany is reporting back from its enquiry on possible difficulties to implement the Guidance Document by the formerly agreed date (i.e. 1.5.2015). The response was limited (7 Member States). Most of the Member States did not react, while, at least one Member State declared it did not face any specific problems, nor did the companies that submitted their dossiers for authorisation. The Commission will reflect further after examination of concrete examples before reconsidering the current time lines or trying to align the approaches of Member States.

M.04 Date of the next meeting.

The next meeting was confirmed for 7-8 March 2016.