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 08 OCTOBER 2015 - 09 OCTOBER 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/adff7253-0311-4bd1-abac-942361ee5133Blank Link*

A.01 Summary Report of previous meetings.

Member States were informed that the reports from March and May had been published. The report from July was under preparation.

A.02 New active substances:

1. New admissible dossiers (to be noted):

i. *Aluminium potassium sulfate dodecahydrate*
ii. *Beauveria bassiana IMI389521*
iii. *Beauveria bassiana PPRI 5339*
iv. *Chromobacterium subtsugae PRAA4-1 (MBI-203)*

Member States took note of these four new dossiers for new active substances.

2. EFSA conclusions

No new conclusions were received.

3. Commission draft Review Report and Regulation concerning the approval of:

i *Cyantraniliprole*

Comments were received on the first version of the draft review report. Comments received mainly referred to the groundwater risk assessment. The Commission gave a reminder of this key issue and requested for further comments by the 23rd of October 2015.

ii *3-decen-2-one*

A brief update on the state of play was given, including an update that a TBT notification had been launched in mid-September. Member States were informed that a letter has been received by the Commission from the applicant's legal counsel contesting the proposal for non-approval. However, given the concern identified with regards potential genotoxicity of the substance and the lack of definite toxicological reference values and possibility to exclude the need for Maximum Residue Levels (MRLs), the Commission explained that the Regulation did not allow for approval.

A vote is foreseen for the December meeting.

iii *Tricyclazole*

Member States were informed that the inter-service consultation was being completed. Since the July meeting the Commission had received further comments which had been made available to Member States. The Rapporteur Member State (RMS) Italy had asked the Commission to consider approving via Article 4(7), but the Commission explained that this was not appropriate in this case. A number of Member States expressed their concern about loss of tricyclazole. The Commission explained that all information was still being taken into consideration but that the EFSA Conclusion highlighted serious concerns that could not be ignored.

A Technical Barriers to Trade (TBT) notification was due to be launched pending completion of the inter-service consultation. A vote is possible in January 2016.

iv *Benzovindiflupyr*

Comments were received on the first version of the draft review report. The need for setting a confirmatory data requirement regarding possible endocrine disrupting properties will be aligned with other dossiers.

v *Beta-Cypermethrin*

A first draft of the review report was introduced to the Committee. Member States were reminded that this is one of the final few substances where a decision is to be taken in accordance with Directive 91/414/EEC in conjunction with Regulation (EU) No 188/2011. Despite several critical areas of concern being identified, it is possible that mitigation measures and further data to refine assessments would enable safe uses to be identified at Member State level. Confirmatory information requirements can also be set (in accordance with the provisions of Directive 91/414) to further address those areas.

Member States were asked to provide comments by 30th October 2015.

A.03 Renewal of approval:

1. Applications for renewal of approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009 and in accordance with Regulation (EU) No 844/2012 (doc. SANCO/10148/2014 Rev. 5) (For information)

A new version will be sent as soon as possible.

2. State of play AIR (Annex I Renewal Project)

During the last PAFF Pesticides Residues meeting in September, a Regulation was voted concerning the extension of the expiry dates of several AIR II substances. The regulation should be published by the end of November at the latest so that the entry into force is before the end of December 2015. (Post meeting note: The Regulation was published on 21/10/2015:

http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445418230285&uri=OJ:JOL_2015_276_R_0009)

3. EFSA conclusions:

i Iprovalicarb

The Commission explained that metabolite PMPA must be considered a priori relevant, given its limited toxicological database and the classification of the parent. Leaching of that metabolite only occurs however in low-clay containing soils. A renewal seems therefore possible, be it limited to normal clay containing soils, and the submission of confirmatory information to examine any endocrine properties. Possibly, further toxicological evidence on the said metabolite might be requested as well. One Member State already opposed due to the potential of leaching of that metabolite. As there seems to be a wide consensus to proceed in this manner, the Commission will try to prepare the dossier in time for a vote in the December 2015 meeting.

Member States were asked for comments by 30th October 2015.

ii Thifensulfuron

The Commission informed on availability of comments on EFSA conclusions issued in July 2015 received from the two applicants. A Commission review report on the substance will be finalised in the coming weeks.

In addition, the Commission informed about a paper drafted by a Member State concerning the soil metabolites which are common to substances belonging to the group of sulfonylureas. A comprehensive review must also include the confirmatory information which will be submitted for some of these substances in the near future. The Commission will explore with EFSA how to proceed.

iii Isoproturon

Member States were made aware of the Conclusion of EFSA that was issued in July. Comments from the applicants on this Conclusion had been made available to Member States ahead of the meeting. A draft review report would be prepared for discussion in the December meeting. A brief summary of the critical issues identified was given.

Member States were asked for any early comments by 30th October 2015.

i. *Famoxadone*

The Commission informed the meeting that the EFSA conclusion was published in July 2015. Comments on the conclusion can be send before 30/10/2015

4. Draft Review Reports for discussion:

i Flupyrsulfuron-methyl

Member States were provided with an update on how this file would proceed (along with pymetrozine; see point 4 vi.) given that the proposed classification triggered the interim criteria for being an endocrine disruptor. Given that the applicant did not foresee the classification proposal, and this issue aside, there was a basis to support renewal, the applicant was given an opportunity to provide further information to either demonstrate that the substance could be used with negligible exposure or that the substance met the provisions of Article 4(7) of Regulation 1107/2009. Information had been received and was available to Member States.

The Commission explained their intention to progress the file. An evaluation of the additional information would need to be carried out by the RMS and then peer-reviewed by Member States and EFSA. With regard to Article 4(7), EFSA had already set up a Plant Health Working Group to consider the case of flumioxazin.

Further update on progress would be given in the December meeting.

Member States were asked to provide comments by 30th October 2015.

ii Thiabendazole

The Commission informed the meeting of a change of desk officer for this dossier.

iii Lambda-cyhalothrin

The Commission presented a revised draft review report and legislative proposal which is under inter-service consultation.

Member States were asked to provide comments by 30th October 2015. A vote was planned for December 2015.

iv Amitrole

The Commission informed the meeting of a change of desk officer for this dossier and confirmed the intention to start an inter-service consultation with a proposal for withdrawal of approval of this active substance.

Member States were asked to provide comments by 30th October 2015.

v Flumioxazin

EFSA continues to work on the mandate for scientific assistance as regards data on evidence that the application of flumioxazin is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods. Impacted Member States might be consulted by the EFSA shortly.

vi Pymetrozine

See item 4 i. Flupyrsulfuron-methyl. A separate update for pymetrozine was not given as the status was the same.

vii Metsulfuron-methyl

Member States were informed that a revised review report (revision 1) was now available. A vote was planned for December 2015.

Final comments were asked to be submitted by 23rd October 2015.

viii Pyraflufen-ethyl

The Commission informed the meeting of a change of desk officer for this dossier.

ix Cyhalofop-butyl

Discussion postponed until next meeting.

x Metalaxyl-M

Comments were received from several Member States. These comments are under internal discussion in the Commission. Outcome of this discussion will be presented during the next meeting.

xi Triasulfuron

The Commission informed that the formal situation for this dossier is still a non-renewal, as EFSA did not set any toxicological reference values, nor finalise the human exposure assessment. The reason was the insufficient genotoxicity assessment of the parent and of triazine amine, the common metabolite for this family of compounds, which occurs here also as an impurity. It would seem that during the peer review a number of experts had been in favour of setting provisional reference values but that option has finally not been retained by EFSA. It is theoretically possible that the risk managers re-establish themselves these values, but that is a far reaching and uncommon decision. The Commission would only explore that route if there would be a very wide support by Member States to such an approach.

Member States were asked for any comments by 30th October 2015.

xii Bentazone

A draft Review Report has been prepared and presented.

Comments are requested by 30 October 2015.

5. Next stage of renewal programme:

- Proposed Rapporteurs and Co-rapporteurs for AIR-4

See point B 12.00

A.04 Confirmatory data:

i *Imazalil* (confirmatory data and application to amend the ARfD) (amended review report to take note)

Member States took note of the reviewed review report.

ii *Fluazifop-p* (amended review report to take note)

Member States took note of the reviewed review report. One Member State could not support the revision due to the risk of leaching of the substance to groundwater.

iii *Iron sulphate* (amended review report to take note)

Member States took note of the reviewed review report.

iv *Epoxiconazole*

The Commission informed that it is awaiting further feedback from the RMS Germany.

v *Bifenthrin*

The Commission informed that the issue of the non-target arthropods is still under consideration. Meanwhile the notifier has submitted the requested monitoring study as regards bioaccumulation which will be dealt with under the procedure foreseen for confirmatory data and reviewed by RMS France.

vi *Buprofezin*

Member States were given an update on the state of play. The EFSA Conclusion following evaluation of confirmatory data had been published in July. The Conclusion did not indicate any critical areas of concern based on the representative uses, but did indicate that exposure to aniline from processed commodities should be considered a priority. The use on lettuce was considered acceptable, as was the use on tomato when using the Margin of Exposure (MoE) approach. The use on citrus could not be concluded due to data gaps. A revised review report was explained by the Commission. Member States were asked to consider this and submit comments by

30th October 2015. Some Member States had already submitted comments with regards to the MoE approach. The applicant had submitted comments on the EFSA Conclusion which were made available to Member States via CIRCABC.

A further discussion would be held in December following receipt of Member State comments.

vii *Dodine*

No new developments. Discussion postponed.

viii *Pyridaben*

No new developments. Discussion postponed.

ix *Myclobutanil*

A revised review report was presented to the Committee based on the evaluation and peer review of the confirmatory data submitted by the applicant. The requirements had been addressed. As part of the evaluation a revised residue definition was proposed to provisionally include the triazole metabolites to align with more recent conclusions for triazole substances (until an EU wide assessment had been completed). Member States were asked to consider the need for a revised definition for monitoring. The RMS, Belgium, indicated that they had now revised their view that the monitoring definition should be changed. Another Member State agreed. The Commission also indicated that they did not consider it necessary to revise the monitoring definition currently.

Member States were asked to provide comments by 30th October 2015.

x Withdrawal of approval of *Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate*

As the applicant did not submit the confirmatory information, the approval will be withdrawn. The inter-service consultation is ongoing; the Commission intends to present the act for vote in the December meeting.

xi Withdrawal of approval of *Z-13-hexadecen-11-yn-1-yl acetate*

As the applicant did not submit the confirmatory information, the approval will be withdrawn. The inter-service consultation is ongoing; the Commission intends to present the act for vote in the December meeting.

xii *Thiamethoxam*

No new developments. Discussion postponed.

Point added to the original agenda:

xii *Metam*

The Commission informed on the conclusions of the assessment of confirmatory data on long range transport and potential groundwater contamination from methylisothiocyanate. Following the EFSA technical report, there was no unacceptable risk for the environment and no need to change the conditions of approval. An amended review report including this information will be submitted to the meeting in December for taking note.

A.05 Article 21 Reviews:

i *Diflubenzuron*

The Commission referred to comments from Member States available on CIRCABC, regarding the Margin of Exposure approach to the EFSA Conclusion, and to the applicant's comments on the EFSA Conclusion. The Commission is currently analysing those documents.

ii *Chlorpyrifos* – state of the dossier

No new developments. Discussion postponed.

A.06 Amendment of the conditions of approval.

No new developments. Discussion postponed.

A.07 Basic substances:

1. Pilot projects: state of play

The Commission solicited Member States to submit the applications which were identified as the basis for the experts group to be organised, to identify constructive approaches to propose for the elaboration of applications with the cooperation of EFSA.

2. New dossiers received:

i. Capsicum spice
ii. Sunflower oil
iii. Satureja montana oil
iv. Millefolii herba
v. Talc
vi. Citrus pulp

The Commission introduced the dossiers received. A detailed discussion will follow at a later stage.

3. EFSA (European Food Safety Authority) Technical Reports

The Member States were informed that EFSA issued the technical report for Diammonium sulphate.

4. Draft Review Reports for discussion

Currently no draft review reports for discussion available.

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

i Draft Technical Guidance Document on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 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 (doc. SANCO/12096/2014) (for discussion)

The Commission presented an updated version of the draft Guidance Document (GD), which addressed the comments received from Member States before Summer 2015 and the comments received from stakeholder via the stakeholder consultation the 25 of June 2015 (all stakeholder comments received are publicly available via:

http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/working_groups_2015_en.htm).

The discussion on the draft GD could be summarised as 7 Member States supporting the GD and 8 Member States not supporting the current draft GD because of either procedural or content aspects, or because they need further internal consultation. Member States, in particular the 13 Member States which did not expressed their views, were invited to provide written comments by 31st of October. The Commission suggested also considering during the respective internal discussions at national level, the information provided in previous Committee meetings.

ii Draft Guidance Document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (doc. SANCO/11509/2013 Rev. 5) (to be noted)

The PAFF Committee took note of the revised guidance document SANCO/11509/2013 Rev. 5.2. One Member State abstained.

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

Discussion postponed.

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

No notifications under Article 44(4) were sent by Member States.

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

Vibrance Gold (Germany, reference Member State Czech Republic)

The Committee took note of the notification submitted by Germany.

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

Clothianidin (Bulgaria)
Alpha-cypermethrin (Croatia)
Azadirachtin (Croatia)
Chlorothalonil (Croatia)
Imazalil/2-phenylphenol (Croatia)
Potassium hydrogen carbonate (Croatia)
1,3-Dichloropropene (Cyprus)
Sulfoxaflor (Cyprus)
Cis-verbenol/Ipsdienol (Denmark)
Pyrethrins (Denmark)
Abamectin (Denmark)
Clothianidin (Denmark)
Tebuconazole (Estonia)
Asulam (France)
Potassium bicarbonate (France)
Boscalid / Pyraclostrobin (France)
Chlorpyrifos-methyl (France)
Cyantraniliprole (France)
Fosetyl-Aluminium (France)
Aluminium silicate (France)
Metobromuron (France)
Milbemectin (France)
Pendimethalin (France)
Phenmedipham (France)
Phosmet (France)
Picoxystrobin (France)
Pyrethrins (France)
Spinetoram (France)
Spinosad (France)
Spirotetramat (France)
Tefluthrin (France)
Trifloxystrobin / Fluopyram (France)
Beauveria brongniartii (Germany)
Fenoxycarb (Germany)
Lambda-cyhalothrin (Germany)
Metobromuron (Germany)
Pyrethrins (Germany)
Zinc phosphide (Germany)
Straight Chain Lepidopteran Pheromones (Greece)
S-abscisic acid (Greece)

1,3-Dichloropropene (Greece)
Chloropicrin (Greece)
Abamectin (Greece)
Pyraclostrobin (Greece)
Chlorantraniliprole (Greece)
Ethylene (Greece)
8-methyl-2-decanol propanoate (Hungary)
Maleic hydrazide (Hungary)
Pyrethrins/Rape seed oil (Hungary)
Spiromesifen (Hungary)
Sodium silver thiosulphate (Latvia)
1,3-Dichloropropene (Malta)
Spinosad (the Netherlands)
Pepino mosaic virus mild isolates (the Netherlands)
Cyazofamid (the Netherlands)
Clofentezine (the Netherlands)
Aluminium phosphide (the Netherlands)
Formetanate (the Netherlands)
Lambda-Cyhalothrin (Poland)
Chloropicrin (Portugal)
Propanil (Portugal)
Iprodione (Portugal)
Oxadiazon (Portugal)
Spinosad (Portugal)
Fludioxonil (Portugal)
Pyrethrins (Portugal)
Tricyclazole (Portugal)
Pyriproxyfen (Portugal)
Spinetoram (Portugal)
Spirotetramat (Portugal)
Azadirachtin (Portugal)
1,3-Dichloropropene (Portugal)
Clothianidin/ Beta-Cyfluthrin (Romania)
Imidacloprid (Romania)
Zinc phosphide (Slovakia)
Spinosad (Slovakia)
Bifenazate (Slovenia)
Spirodiclofen (Slovenia)
Fluopicolide/Propamocarb (Spain)
Bentazone (Spain)
1,3-Dichloropropene/Chloropicrin (Spain)
Chlorothalonil (Spain)
Cyflufenamid (Spain)
Cypermethrin (Spain)
Dichlorvos (Spain)
Ethephon (Spain)
Ethylene (Spain)
Fludioxonil (Spain)
Fluopyram (Spain)
Gibberellic acid (Spain)

Lambda-cyhalothrin (Spain)
Methomyl (Spain)
Metrafenone (Spain)
Natural seed extract of Camellia (Spain)
Spodoptera exigua nuclear polyhedrosis virus (Spain)
Oxadiazon (Spain)
Phosmet/Spinosad (Spain)
Pymetrozine (Spain)
Pyraclostrobin (Spain)
Spinosad (Spain)
Tau-Fluvalinate (Spain)
Thiabendazole (Spain)
Thiacloprid (Spain)
Thidiazuron (Spain)
Tricyclazole (Spain)
Spirotetramat (Sweden)
Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52 (Sweden)
Thiophanate-methyl (Sweden)
Paraffin oil/(CAS 8042-47-5) (Sweden)
Fatty acids C7-C18 and C18 unsaturated potassium salts (CAS 67701-09-1) (Sweden)
Boscalid/Pyraclostrobin (Sweden)
Cyprodinil/Fludioxonil (Sweden)
Fludioxonil/Metalaxyl-M/Thiamethoxam (the United Kingdom)
Beta-Cyfluthrin/Clothianidin (the United Kingdom)
Acetamiprid (the United Kingdom)
Cyantraniliprole (the United Kingdom)
Spinosad (the United Kingdom)
Thiacloprid (the United Kingdom)
Diquat (the United Kingdom)

The Committee took note of the notifications submitted by Bulgaria, Croatia, Cyprus, Denmark, Estonia, France, Germany, Greece, Hungary, Latvia, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

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):

i NAP (National Action Plans) Report:

The Commission informed that the internal consultation was ongoing. It is expected the report to be submitted during the Dutch Presidency in the first half of 2016.

ii. State of play

The Commission informed on the next meeting of the experts group which is confirmed for the 7 December, invitation will be sent out soon.

The Netherlands informed the PAFF delegates of a proposal to be discussed in the forthcoming Agri-Council on the possible organisation of a temporary expert group focussed on low risk, to identify solutions to speed up the implementation of Integrated Pest Management and provide ways to facilitate availability of low risk products.

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

EFSA was not present at the meeting and therefore no updates were provided.

A.14 Report from working groups:

i Plant Protection Products (PPP) Application Management System (Authorisation database) – including presentation from Commission on data migration exercise

An update of the recent activities with development and the data migration exercise was provided. Unit A4 from DG SANTE provided a short presentation outlining the data migration exercise and provided feedback and action points for Member States. Member States would be contacted in the near future with a request to check the data matching exercise. Further updates would be given in subsequent meetings.

ii Low risk : presentation working document for proposal to review criteria

The Committee recalled that a draft working document for potential review of low risk criteria had been made available for the PAFF experts during the July meeting. However, having received only one comment from one Member State, the Commission solicits the delegates to inform relevant experts to send comments in view of the next meeting of the Low risk experts group planned for the 6th of November which will have the main objective of finalising the document itself. Comments should be sent by 26 October at latest.

iii Zonal Workshop

No feedback was received from Member State's side following the intervention of the Commission in the July meeting. There was no further discussion under this point, but the Commission reiterated its commitment to follow up on problems and deficiencies of the zonal system as identified during the workshop.

iv Post Approvals Issues group (PAI)

The discussion under this point was postponed.

v Biopesticides

The group met on 30 September, but with a shorter schedule than initially foreseen. The discussions on dead and non-viable microorganisms, on assessment report templates and on strain issues were continued. The Commission explained tha the group work will continue as foreseen as soon as the vacant position of the chair can be filled again.

A.15 OECD

No new developments.

A.16 Bees:

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

The call for data, regarding the risk to bees from the uses of imidacloprid, clothianidin and thiametoxam applied as a seed treatment or granules, was closed on 30 September 2015. The Commission is currently drafting a mandate for EFSA to evaluate the data received.

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

The decision-making on the way forward within the Commission services is on-going. Several Member States expressed their concerns regarding the legal uncertainty of using this Guidance Document and asked for confirmation as to which Guidance Document needs to be used. The Commission indicated that the currently adopted GD should be used. Only in the case of a review under Article 21 of Regulation (EU) 1107/2009, the use of the new GD can be defended.

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

The decision-making on the way forward within the Commission services is on-going.

iv. EFSA Conclusions on the peer review of the pesticide risk assessment for bees for the active substances clothianidin, imidacloprid and thiametoxam considering all uses other than seed treatments and granules.

The Commission gave a short overview of these conclusions. The Commission awaits first the comments from the applicants and Member States before further internal discussions.

Member States were invited to send comments by 30 October 2015.

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

The Commission gave a short summary of this workshop held in September in Germany and thanked the German authorities for the excellent organisation. Minutes of the conference are currently drafted. A few Member States already expressed some thoughts on this workshop. A technical discussion on the outcome of this conference will follow when the minutes are available.

vi. Notification of 22 July 2015 by Germany of a measure taken under Article 71 of Regulation (EC) No 1107/2007 concerning the placing on the market and use of winter cereal seeds treated with the active substances clothianidin, imidacloprid or thiamethoxam in Germany.

One Member State considered that Germany had not followed the procedure foreseen in Article 71, as the notification should have been done before the adoption of the measure at national level. Germany should have acted only after it was decided that a measure would not be taken at EU level. The same Member State considered that the Commission should have submitted to the Committee a measure, according to Article 71(2).

The Commission indicated that according to Article 71(1) the matter was submitted to the Committee in September 2015.

Germany is requested to provide the data on the basis of which the national measure was taken to all Member States, to the Commission and EFSA.

In addition, the Commission confirmed that it will ask EFSA to assess this data in the frame of the review of the 3 substances clothianidin, imidacloprid and thiametoxam for which a call for data has been launched by EFSA.

Following the evaluation of the data, and depending on the results of the evaluation, the Commission may propose a measure according to Article 71(2) requesting Germany to amend or withdraw its national measure.

vii. AOB

No additional developments. No discussion.

A.17 Court cases:

Judgment of the General Court of 10/9/2015 - Case T-446/10 DOW v. Commission – Dismissal of the request to annul Commission Directive 2010/355/EU (second non-inclusion of trifluralin).

The Commission informed about Case T-446/10 which has been judged in favour of the Commission by the General Court. This was the fifth case launched by industry against the non-approval of this substance. From a technical point, the Court focussed especially on the Long Range Transport issue on which it agreed with the Commission that the resubmission dossier failed to address this matter properly. Evidently, also this judgement is still open to appeal.

This judgment is publicly available on the webpage:

http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30ddeb8e7ba1e31e44cda7a89c77b0546763.e34KaxiLc3qMb40Rch0SaxuRbxb0?text=&docid=167266&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=94923

New cases:

- T-296/15 IQV v. Commission (metalaxyl)
- T-310/15 European union copper task force v. Commission (copper compounds)

Two actions for annulment against the Commission Implementing Regulation (EU) 2015/408 establishing a list of candidates for substitution.

The Commission informed about these two new court cases.

The pleas in law and main arguments of the applicant of case T-296/15 are publicly available at the webpage:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOC_2015_254_R_0022

The pleas in law and main arguments of the applicant of case T-310/15 are publicly available at the webpage:

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOC_2015_294_R_0089

A.18 Endocrine disruptors:

- Impact assessment

The Commission informed that the impact assessment is progressing well and highlighted the technical event organised for the 6 November 2015,which focuses on the JRC methodology (1st study). The event is open for on-line registration and will be web-streamed.

The Commission thanked Member States for the information provided on plant protection products, uses, pests, crops, via the on-going process linked to the Plant Protection Products (PPP) Authorisation Database (see point A 14.01). This information is essential for the 2nd part of the impact assessment.

The report on the public consultation was published in July 2015.

A.19 Minor Uses:

A short presentation was provided by the EU Minor Use Coordinator to explain ongoing activities by the EU Minor Use Coordination Facility.

A.20 Interpretation issues:

1. Scope of Regulation (EC) No 1107/2009

   i. clayed charcoal:

The Commission presented the method of action of clayed charcoal and requested comments if this method of action falls within the scope o f regulation (EU) 1107/2009 by 30 October 2015.

2. Questions and answers

No updates of the document available.

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

1. Status of harmonised classifications

Discussion postponed.

2. Implementation of the criteria in Annex II point 3.6.2 to 3.6.5 of Regulation (EC) No 1107/2009

Discussion postponed.

A.22 Glyphosate:

- State of the dossier

The Commission reported on the state of play of the EFSA peer review for glyphosate and of the draft measure regarding an extension of the current approval by 6 months. It asked Member States to send comments on the EFSA Conclusions, once available, by 20 November 2015, to already allow for a first informed discussion at the Committee meeting in December.

The Commission referred to several studies pertaining to glyphosate on CIRCABC.

A.23 Information from the Pesticide Residues section of the Committee: possible impact on authorisations.

The Commission prepared a table containing information on draft measures recently voted during the Pesticide Residues section of the Committee that may have an impact on authorisations. The table is available on CIRCABC.

A.24 Changes of toxicological endpoints and consequent review of authorisations.

No new developments. No discussion.

A.25 Metam - new information submitted.

No new developments. No discussion.

A.26 New greenhouse operator exposure model.

Postponed until the next meeting.

A.27 Follow-up activities EFSA Exposure Guidance (Acute Acceptable Operator Exposure Level (AAOEL) (mandate).

There were no further comments by Member States on the thought starter paper prepared by the United Kingdom. Consequently, the Commission suggested proceeding with a mandate to EFSA to develop the AAOEL, and to provide the agreed thought starter as the terms of reference.

A.28 Straight Chain Lepidopteran Pheromones (SCLP): new compound amended Review Report (doc. SANCO/2633/2008 Rev. 8) (take note)

The Committee took note of the Rev. 8 of the review report which include the new SCLP compound : n-tetradecylacetate.

A.29 Additional point to the original agenda:

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

The Commission took note of the remark by Germany that the implementation of this GD might be difficult or, at least, done in a disharmonised manner. Germany also lists a series of possible options. The Commission explained the importance of remaining as close as possible to the implementation date given for the GD Groundwater II and of which the DegT50 is a fundamental parameter. The Commission agreed to reconsider the matter and to find more harmonised solutions, but would first like to collect some concrete examples. Germany kindly offered to coordinate this matter.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance flumetralin, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANTE/10672/2015 Rev. 2).

One Member State could not support the approval because of the possible leaching of metabolite CGA 152604 to groundwater.

Two Member States abstained because of the possible leaching of metabolite CGA 152064 to groundwater.

One Member State abstained because they wanted a confirmatory requirement to address the relevance of metabolite CGA 152604.

One Member State abstained because flumetralin is a candidate for substitution and therefore they believed potential risks are identified. Furthermore, the Member State believed that the endocrine disrupting effects were not clear and that confirmatory information should be set to address this.

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 prosulfuron, 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 Review Report doc. SANTE/10681/2015 Rev. 1).

This point was withdrawn from the Agenda.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance rescalure, 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/11644/2015 Rev. 1).

The draft document was presented for vote. No particular comments were raised.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance mandestrobin, 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/11647/2015 Rev. 1).

One Member State could not support the approval because of the leaching of metabolites to groundwater.

One Member State abstained because of the leaching of metabolites to groundwater.

One Member could not support the approval because the technical specification has to be evaluated before the decision of approval, otherwise member states do not have the possibility to keep the deadlines for product authorisations.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance flupyradifurone, 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/11649/2015 Rev. 1).

One Member State could not support the approval because of the leaching of metabolites to groundwater.

Two Member States abstained because of the leaching of metabolites to groundwater.

One Member State could not support the approval because the technical specification has to be evaluated before the decision of approval, otherwise Member States do not have the possibility to keep the deadlines for product authorisations.

One Member State abstained because of the chronic risk to aquatic invertebrates.

One Member State abstained because of the risk to non-target arthropods, bees and the leaching of metabolites to groundwater. This Member State also requested confirmatory data on the endocrine mediated mode of action of the active substance.

Vote taken: Favourable opinion.

B.06 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance esfenvalerate, 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 Review Report doc. SANTE/10362/2015 Rev. 1).

Two member States could not support the proposal because of the risk to aquatic organisms. Two member States could not support the proposal because of the risk to groundwater.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the active substance 2,4-D, 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/11961/2014 Rev. 3).

Two Member States abstained because they were of the opinion that the specification should be further evaluated at EU level as confirmatory information in order to harmonise the work and to avoid difficulties in mutual recognition. One Member State abstained as it requested more solid commitments from the Commission in the field of endocrine disruption.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Artemisia absinthium* 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 (Draft Review Report doc. SANTE/10313/2015 Rev. 0).

Two Member States abstained because they consider that the plant protection toolbox for organic agriculture as well as the tools for the implementation of Directive 2009/128/EC should be developed as much as possible and consider basic substances as such tools. One Member State was in favour of the proposal but agreed that basic substances form an alternative solution for organic farming.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Tanacetum vulgaris*, 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 (Draft Review Report doc. SANTE/10369/2015 Rev. 1).

Two Member States abstained because they consider that the plant protection toolbox for organic agriculture as well as the tools for the implementation of Directive 2009/128/EC should be developed as much as possible and consider basic substances

as such tools. One Member State was in favour of the proposal but agreed that basic substances form an alternative solution for organic farming.

Vote taken: Favourable opinion.

B.10 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-approval of *Arctium lappa*, 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 (Draft Review Report doc. SANTE/10663/2015 Rev. 0).

Two Member States abstained because they consider that the plant protection toolbox for organic agriculture as well as the tools for the implementation of Directive 2009/128/EC should be developed as much as possible and consider basic substances as such tools. One Member State was in favour of the proposal but agreed that basic substances form an alternative solution for organic farming.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance sodium hydrogen carbonate, 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 Implementing Regulation (EU) No 540/2011 (Draft Review Report doc. SANTE/10667/2015 Rev. 1).

The draft document was presented by the Commission. No particular comments were raised.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.

Vote postponed at the request of the Committee due to extended discussions.

B.13 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 conditions of approval of the active substance haloxyfop-P (Draft Review Report doc. SANTE/12648/2010 Rev. 2).

One Member State voted against due to the leaching to groundwater. Another Member State abstained as it disagreed with the principle of setting restrictions at EU level while this matter could better be left to the national authorities.

Vote taken: Favourable opinion.

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

No update was provided under this point.

M.02 New scientific publications.

The United Kingdom presented their considerations concerning a recent INSERM (Institut National de la Santé et de la Recherche Médical) study on pyrethroid insecticide exposure and cognitive developmental disabilities.

M.03 AOB

No points raised.

M.04 Date of the next meeting.

The next meeting will take place on 10-11 December 2015.