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 22 MARCH 2017 - 23 MARCH 2017

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/a9b05b29-e99a-437b-b980-9f13c1799e72*

A.01 Summary Report of previous meetings.

Member States were informed that the report from the December 2016 meeting had been published and that the January report was under preparation.

A.02 New active substances:

1. New admissible dossiers to be noted:

i. Lavandulyl senecioate

Lavandulyl senecioate is an attractant, the rapporteur Member State is Italy and the applicant is Suterra Europe Biocontrol. Admissibility was reported to the Commission on 29 December 2016.

ii. Sweet Lupin (seeds), Lupinus albus L., germ., ext.

Sweet Lupin (seeds), Lupinus albus is a biopesticide fungicide. The rapporteur Member State is the Netherlands and the applicant is Converde. Admissibility was reported to the Commission on 20 February 2017.

The Committee took note of these new admissible dossiers.

2. Exchange of view on new European Food Safety Authority (EFSA) conclusion

No specific conclusion identified for discussion.

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

No specific reports identified for discussion.

A.03 Renewal of approval:

1. Annex I Renewal Projects: State of play

AIR III
The Commission informed the Committee that letters had been sent to all rapporteur Member States (RMS) who are in delay in their renewal assessment for substances included in the AIR III programme. The letters are available on CIRCABC. The Commission will receive responses in relation to how Member States intend to remedy the situation. The Commission further informed that the applicant for the active substance imazosulfuron has withdrawn their support for the renewal. The substance will subsequently expire on 31 July 2017. Member States were also informed that the RAR for the active substance benalaxyl has been withdrawn by the RMS in order to re-assess the dossier.

AIR IV
The Commission informed that upon request by EFSA and in agreement with the RMSs, the risk assessment processes will be aligned for the substances quizalofop-p-ethyl, propaquizafop and quizalofop-p-tefuryl in line with Article 18 of Reg. 1107/2009. Consequently, the AIR IV work programme has to be amended and quizalofop-p-tefuryl moved to group 4(1) which means the approval period will be extended by two years. The Commission also informed that a RAC opinion was adopted in June 2016 on quizalofop-p-tefuryl on a harmonised classification as R2 and C2, compared with the previously notified classification R1B.
Member States were informed that the legal act extending approval periods for several AIR IV substances with application deadline in October, November and December 2016 was voted on 17 February.

2. Exchange of view on EFSA conclusions:

i. Thiram
The Commission introduced the EFSA Conclusion and some of the key issues identified, in particular in relation to the risk to birds and mammals and the impact of water treatment processes on harmful residue formation. Member States were asked to consider these and provide early comments and views.

3. Draft Review/Renewal Reports and Regulations for discussion:

i. Maleic hydrazide (No detailed discussion)
Commission seeks to renew the approval of maleic hydrazide under certain conditions. The comments sent by some MS were presented. A proposal will be prepared ensuring transition from the current to the new approval conditions. MS to comment by 21/04/2017.
ii. Mesotrione
(discussion under AP B.07)
iii. Pendimethalin
The Commission informed on comments received by some Member States. – Internal consultation ongoing.
iv. 2,4-DB
The Commission presented a draft regulation proposing renewal of the substance and a revised renewal report. It suggest to refer to the more conservative toxicity endpoints set by EFSA in its Conclusion regarding this substance and sets limits to

relevant impurities ((DCP) – dioxins and furans). It further recommends a series of risk mitigation measures to be implemented by Member States.
Member States were invited to send in comments by 21 April 2017.

v. Carfentrazone-ethyl

The Commission presented a draft regulation proposing renewal of the substance and a revised renewal report. Some Member States are reluctant, considering the leaching of certain metabolites and a possible future classification of the parent. A series of risk mitigation measures are suggested while confirmatory data might be requested for exploring if residues are formed in surface water treated to become drinking water and for investigating the relevance of certain metabolites in groundwater.
Member States were invited to send in comments by 21 April 2017.

vi. Acetamiprid

Changes were made to the renewal report based on the received comments.
Due to an inconsistency in the EFSA conclusion, in the residue section, the conclusion will be amended and republished (*post meeting note: corrected version is online* [1]).
Concerning the MRLs, COM intends to mandate EFSA to review the existing MRLs in light of the new acute reference dose (ARfD). This should be carried out following the note taking of the renewal report. Action will then be taken as soon as possible. After that, a proposal will be prepared that will undergo SPS/WTO consultation. COM also considers some kind of advance information to third countries about the planned review, but the details are still under discussion.
Member States are invited to send in comments or positions on the proposal for renewal and the renewal report by 21/04/2017.

vii. Propyzamide COM informed on comments received by some MS on draft report as uploaded in previous meetings. No change. COM asked any other comment by 21 April 2017.

viii. Bentazone

Commission presented an amended draft proposal for a renewal period of seven years. Commission considers that confusion with candidates for substitution is not possible as bentazone is not proposed to be included in the list of candidates for substitution (Annex E to Regulation (EU) No 540/2011). Regulation (EC) No 1107/2009 allows renewal periods for up to 15 years which includes a renewal period of 7 years. One Member State indicated the need for a shorter deadline for the confirmatory data requirement regarding the potential endocrine activity of bentazone.
Member States were invited to send in comments by 21 April 2017.

ix. Silthiofam

COM informed on a draft renewal report supporting a decision for renewal subject to submission of confirmatory data on relevance of metabolites present in groundwater. Comments received by some Member States and notifier have also been uploaded in CIRCA BC. Member States were asked to comment by 14 April 2017 to be able to proceed with Interservice consultation in time.

x. Isoxaflutole

An update on the state of play was given. Member States were asked for the comments and views on the EFSA Conclusion concerning negligible exposure.

xi. Benzoic acid

It was indicated that a vote on this substance would take place at the MAY PAFF meeting. Comments or positions on the proposal for renewal to be sent by 14/04/2017.

xii. Propoxycarbazone

It was indicated that a vote on this substance would take place at the MAY PAFF meeting. Comments or positions on the proposal for renewal to be sent by 14/04/2017.

xiii. Imazamox

It was indicated that a vote on this substance would take place as soon as the internal procedures are completed. Final comments or positions on the proposal for renewal to be sent by 14/04/2017.

[1] EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 26 pp. doi: 10.2903/j.efsa.2016.4610

A.04 Confirmatory Data:

1. Bifenthrin

The Commission concludes that two problems remained unsolved: the recovery of non-target arthropods in-field and subsisting doubts on the quality of the monitoring study on bioaccumulation/biomagnification. Some MS support the opinion of setting restrictions in rates and number of applications while others could at maximum accept uses in greenhouse.

Member States are invited to reflect on which alternative is the most appropriate and to provide their opinion by 21/04/2017.

2. Thiamethoxam

Discussed under AP C.03.

3. Clothianidin

Discussed under AP C.03.

4. Imidacloprid

Discussed under AP C.03.

5. Tetraconazole

The Commission thanked the RMS IT for the clarification provided and presented a tentative review report. Remaining issues are the triazole derivatives (suggestion to await the ongoing common assessment of these compounds) and non-target arthropods. Member States are invited to comment by 21/04/2017.

6. Cyflumetofen

No news, therefore this point was not discussed.

7. Napropamide

The Commission recalls that the confirmatory information related to the surface water exposure by photolysis metabolites and NOPA, and, more in general, the risk to aquatic plants. It appears that certain refinements that seemed easy to do were only intended to be submitted at national level. On the other hand the RMS UK believes it is possible to mitigate the risk, considering the choice of a very conservative endpoint.

As regards the fate of the metabolite NOPA which was already considered non-relevant, RMS UK considers it is very unlikely this would generate significant risks, neither to aquatic organisms or to consumers.
Member States are invited to comment by 21/04/2017.

8. Malathion
The Commission indicated that it has reason to belief that a mandate to EFSA might not be of much added value. It is also noted that there is quite some variety in the GAPs on which the studies submitted in the context of confirmatory data are based. (some studies relate to strawberries (the original GAP), other to citrus, etc.). It must be further examined whether the consumer risk is not jeopardized. Furthermore, a high risk to birds cannot be excluded. Alternative solutions may be a restriction to greenhouse only or a limitation in number and timing of application, possibly in conjunction with lower rates.
Member States are invited to comment by 21/04/2017.

9. Fluroxypyr (review report to be noted in conjunction with item B.10)
See AP B.10

10. Quinmerac
The request for confirmatory information is considered addressed; there are some minor open points on residues, but the Commission considers that these are better addressed through the residues procedures. Therefore, the Commission suggested to formally close the procedure on confirmatory information and to immediately launch a review according to article 12 of Regulation (EC) No 396/2005, which seems to be better suited to treat the remaining issues. Member States are asked for their consent on this approach.
The meeting was informed that this issue was already raised in the last SCPAFF section residues and got support.
Member States are requested to provide a feedback coordinated between the approval and residues sections by 7 April.

11. Dithianon
The Commission presented an overview of the different steps in the proceedings of the dossier and the EFSA conclusion on the confirmatory data.
MS are invited to send in comments or positions on a possible withdrawal of approval by 21/04/2017.

12. AOB
No item raised.

A.05 Article 21 Reviews:

i. Thiametoxam, clothianidin, imidacloprid (other uses than seed treatments and granules) (*amended schedule of review*)
See points C1 to C3.

A.06 Amendment of the conditions of approval:

1. New admissible dossiers to be noted:

i. Prosulfuron

The admissibility of this dossier, submitted to the RMS, France, was taken note of.

A.07 Basic substances:

1. Pilot projects: state of play

Talc and quassia are the two pilot basic substances for which a decision is pending. On talc new information concerning risk assessment for groundwater and operators was provided. The Commission is examining need for a mandate to EFSA to update the technical report of 2016.
On quassia the applicant submitted extensive information to address the comments collated in 2013 and currently the Commission has required them to update also the application itself to be able to re-launch the assessment.

2. New dossiers received (only for information):

i. Flavan-gallo tannins
No further discussion.

ii. Equisetum (extension of use)
The documentation for extension of use as fungicide in carrots and strawberries has been uploaded in CIRCABC. The information provided seems sufficient to proceed with the application for extending the use. An amended review report will be made available for the next PAFF meeting.

3. Exchange of view on EFSA Technical Reports
No specific report identified.

4. Draft Review Reports for discussion:

i. Honey from rhododendron (*No detailed discussion; Member States are requested to send in comments after the meeting.*)
Member States are invited to send in comments by 21 April 2017.

ii. Sodium chloride (*No detailed discussion; Member States are requested to send in comments after the meeting.*)
The Commission informed Member States that a draft of the review report and regulation proposing the approval of sodium chloride as a basic substance was uploaded to Circabc. Member States were requested to send in comments by 14 April. Without prejudice to the comments received, the Commission intends to put forward the proposal for a vote in the May meeting.

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

No discussion.

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

Spain sent in 84 notifications, the Czech Republic sent in 22 notifications, all of which relate to products containing glyphosate as an active substance.
Greece detected nitrosamines in some of the pendimethalin-formulations on their market. Greece has revoked the authorisation for the products concerned and made efforts to withdraw these products from the retail chain. As a consequence, Greece will also increase specific controls measures. It seems likely that the contamination is caused by a contamination in the technical material.
As it cannot be excluded that products containing the same technical material are also on the market in other Member States. Member States are asked to check the products on their market and to take appropriate measures, where necessary. Member States are invited to report back about any findings by 28 April.

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

Two notifications have been submitted:
A notification by Germany is considered not relevant, as it is not related to an obligatory mutual recognition.
A notification by Hungary is considered invalid, as it is not covered by the exemptions provided for in article 36(3). In addition, the Commission reminds that the refusal also contradicts the provisions of the guidance document on article 43 concerning the treatment of applications under the zonal system.

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

Mancozeb (Austria)
Imazamox(Austria)
Zinc phosphide (Czech Republic)
Lime sulphur (calcium polysulphid) (Czech Republic
Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Germany)
Fludioxonil, Metalaxyl-M, Thiamethoxam (Estonia)
Beta-Cyfluthrin, Clothianidin (Estonia)
Gibberellic acid (Spain)
Metrafenone (Spain)
(E,Z)-3,8-Tetradecadien-1-yl acetate, (E,Z,Z)-3,8,11-Tetradecatrien-1-yl acetate (Spain)
Metrafenone (Spain)
lambda-Cyhalothrin (Spain)
Aureobasidium pullulans (strains DSM 14940 and DSM 14941) (Spain)
Iprodione (Greece)
Prochloraz, Triticonazole (Italy)

Fludioxonil, Metalaxyl-M, Thiamethoxam (Lithuania)
Beta-Cyfluthrin, Clothianidin (Lithuania)
Sodium silver thiosulphate (Latvia)
Beta-Cyfluthrin, Clothianidin (Latvia)
Fludioxonil, Metalaxyl-M, Thiamethoxam (Latvia)
Gliocladium catenulatum strain J1446 (Portugal)
Paclobutrazol (Portugal)
Boscalid, Pyraclostrobin (Portugal)
1,3-Dichloropropene (Portugal)
Beauveria bassiana strains ATCC 74040 and GHA (Portugal)
Imazamox (Portugal)
Bromoxynil (Sweden)
Pyriproxyfen (Slovenia)
Beauveria bassiana strain BB1 (Slovakia)
Chlorpyrifos (Slovakia)
Tefluthrin (Slovakia)
Chlorpyrifos (Slovakia)
The Committee took note of the notifications submitted by Austria, Czech Republic, Germany, Greece, Italy, Latvia, Lithuania, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

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.

The Commission requested Member States to assure entering all information requested into the Plant Protection Application Management System, as this information is necessary to judge whether any such authorisation was granted according to the provisions of Article 53 of Regulation (EC) No 1107/2009.

In case of doubt, the Commission, in line with the provisions of Article 53(2), will consider asking EFSA to evaluate whether the preconditions for granting an authorisation according to Article 53 are fulfilled.

A.12 News from European Food Safety Authority (EFSA).

EFSA informed about the withdrawal of the Renewal Assessment Report for benalaxyl. A resubmission is planned and the pee review will be relaunched from the public consultation.

Although note-taking was not finalised yet, EFSA strongly recommends Member States to always use of the combined DAR/CLH template. Member States are reassured that ECHA confirmed accepting the template as CLH report.

The Annual Monitoring Report for 2015 has been finalised and will be published in April.

EFSA is unsure about product dossiers containing formulations with more than one active substance. EFSA sees different possible options (e.g. identifying data gaps for the additional active substances in the formulation or perform a mixture assessment) and advice on how such dossiers should be handled.

EFSA reported on the ongoing discussions in the Pesticide Steering Network concerning an action plan for improving the EU peer review.

A.13 News from the Directorate General for Health and Food Safety (SANTE) Directorate F, Health and food audits and analysis (former FVO).

No news under this agenda point.

A.14 Report from working groups:

1. Plant Protection Products Application Management System (PPPAMS)

An update on ongoing activity, including the next planned release, which was foreseen in mid-May, was provided. Member States were also updated on activity related to data collection and on collaboration with EPPO to develop new EPPO codes for plant protection uses.

2. Post Approvals Issues group (PAI)

Belgium reported about the recent activities of the Post Approval Issues Group. The remit of this group, implementation of art. 43 of Regulation (EC) 1107/2009, data protection, zonal assessment of plant protection products and authorisation procedure for low-risk products were discussed amongst other issues. Member States were reminded that they should always send the quarterly updates to the United Kingdom on confirmatory information for which they act as Rapporteur Member States. Upon request of two Member States, the Commission confirmed that the remit of the PAI group will be discussed and endorsed within the Standing Committee. One of these Member States also called for the Commission to plan a discussion at SCoPAFF level where the PAI group cannot sort it out.

3. Sustainable plant protection experts group Dutch proposal (no meeting since December)

The Commission informed the Member States of the upcoming meeting of the working group on 4-5 April. The Commission also informed the Member States of the resolution on low-risk plant protection products of biological origin that was adopted by the European Parliament in February. The resolution calls upon the Commission

and Member States to take several actions to increase the availability of such products.
As a related point, the Commission asked MS to send in information about their nominated experts for the Working Group on low-risk substances.
4. Drift Risk Assessment Workshop (DRAW). Improving Representation, Management and Mitigation of Spray Drift for Plant Protection Products in Arable Crops (8-9 February 2017).
The Commission informed about this SETAC-workshop which took place in February. Follow up actions are planned, which include generation of new field data on drift, and analysis / modelling based on existing data on drift. The workshop has interest for risk assessment but also risk management, as they are activities which are follow up of the MagPie workshops. A 3rd workshop is planned and Commission will maintain this Committee informed.
5. Working group on Biopesticides
The Commission reported about the recent activities of the Biopesticide Working Group. The experts discussed about secondary metabolites of micro-organisms. They exchanged views of the renewal of the strains of Bacillus thuringiensis and finalised the template for micro-organisms' assessment reports.
6. Working group on Seed Treatments
The Commission reported about the recent discussions in the Working group on Seed Treatment. Progress was made in the sections for risk assessment in the draft guidance. Some minor issues should be finalised before the draft guidance goes for a round of comments, involving the Member States, EFSA and third parties.
7. Working Group on implementation of Ruling in C-442/14
A first meeting of the WG took place on 13.03.2017. The objective was to discuss the status of studies submitted under data requirements in Reg. 283/2013 (points 5 to 8) and Reg. 284/2013 (points 6 to 10) and under data requirements for micro-organisms. It was concluded that not all studies listed in those sections can be considered as information on emissions in the environment. As NL authorities had performed a first assessment of the data requirements in the light of this ruling, the WG decided to use this work as a basis for the discussion. A new meeting should take place before the summer break. The objective is to establish a guidance document for MS, EFSA and the Commission.

A.15 OECD.

The Commission informed the Standing Committee about an on-going process to declassify a document related to the Global Harmonised Submission Transport Standards. The Member States were also informed of the discussion led by Canada on sharing early information related to pesticides amongst Member Countries to the OECD.

A.16 Bees:

1. AOB

Belgium explained certain parts of the new Guidance Document for bee risk assessment are applied for national authorisations in order to assess those studies for

which currently no Guidance Document exists. This approach should ensure harmonisation in decision making. Belgium explains their approach on their national website and intends to discuss this approach in the zonal Steering Committee.
Commission expressed concern for increased confusion, also for industry, and emphasized that the available processes to implement Guidance Documents should be used.
One Member State indicated the need for a Working Group to discuss this approach. This was endorsed by several Member States.

The Commission invited Member States to send comments by 5 May 2017.

A.17 Court cases.

No news on court cases.

A.18 Endocrine disruptors.

The Commission informed that as a follow up of the PAFF meeting the 28 of February, internal reflections are on-going regarding how to further proceed. As a consequence of the technical discussions in the expert meeting under the Biocides Regulation which took place the 28 of February after the PAFF meeting, an additional meeting will take place the 7 of April focusing only on the draft criteria for biocides. The work on the joint EFSA/ECHA guidance document is progressing well. EFSA announced that the first consultation on the draft guidance document is planned for April.

One Member State asked when the implementing act, announced by the Commission in previous meetings, would be available and insisted in having it tabled before voting on the criteria, as this implementing act is key for the implementation and therefore may define the position of this Member State.

Another Member State asked if o 7 April a revised version of the draft criteria will be discussed; the Commission clarified that it would be the version as revised on 28 February during the meetings. Further, this Member State asked if the Commission intended to proceed with the adoption of the delegated act in a first step; the Commission clarified that no decision on the next step is taken so far.

A.19 Minor Uses.

An update was provided by the coordinator of the European Minor Uses Coordination Facility touching upon the following points:

- The first newsletter of the MUCF has been released and can be found on the minor uses website (https://www.minoruses.eu/).
- Feedback Stakeholder Advisory Forum: The stakeholders welcomed the establishment of the MUCF and were satisfied with the progress made to date. Overall the forum stakeholders were very positive about the work achieved by

the MUCF, and agreed that this newly established structure should continue. Strong engagement and commitment from Member States' governments and EU Commission is expected.

- The funding of the Coordination Facility is guaranteed by the European Commission, France, Germany and The Netherlands for the first three years until April 2018. As discussed in the Minor Uses Stakeholder Advisory Forum the Coordination Facility will now approach all 28 EU Member States for a voluntary assessed contribution.
- From 28-30 March 2017, a series of meetings of the Minor Uses Expert Group meetings will be organised. Two plenary sessions will be held: feedback questionnaire "overview Minor Uses work in Member States" on how the minor uses work is organised in the different Member States and a plenary session on the REFIT of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. This will be followed by discussions in Breakout Groups to gather input for the REFIT process.

A.20 Interpretation issues:

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

i. Colour spray
Postponed
ii. Plant strenghteners (request by LT)
Postponed.

2. Questions and answers

i. Article 47(3): Low-risk product authorisation timelines
The Commission presented an addition to the Q&A document on the timelines for low-risk product authorisation. The document clarifies that Article 47(3) implies that for an application for authorisation of a low-risk product the zonal Rapporteur Member State shall decide within 120 days of receiving it whether the requirements for authorisation are met. An additional period of a maximum of 6 months applies where the Member State needs additional information. The Commission further emphasised the importance of this accelerated procedure for low-risk products.

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

1. Status of harmonised classifications
An updated table was made available on CIRCABC.

2. Preparation of Harmonised Classification and Labelling dossiers (CLH dossiers) by Member States

3. Report from the Working Group (WG) on Assessment Reports (AR template) (merging CLH and xAR templates)
The Commission informed the Member States about the on-going discussion (both internally and with EFSA and ECHA) on the alignment of the procedures for risk

assessment and classification of active substances. Regulation (EC) 844/2012 will be amended to request Rapporteur Member States for the renewal of actives substances to submit a proposal for a harmonised classification. The discussion is not finalised regarding the details and the different scenarios but the Commission and EFSA reassured the Standing Committee that they aimed at designing a balanced pragmatic procedure.

A.22 Glyphosate:

- State of the dossier

The Commission updated the Committee on the ongoing assessments and key developments. The Commission reminded the Committee about a European Citizens' Initiative and informed that this had been formally registered by the Commission on 25 January 2017.
With regards to the two scientific articles made available on CIRCABC at the previous meeting, the Commission informed the Committee that the Rapporteur Member State (RMS) had considered these articles for relevance and had provided two statements which had been made available to Member States on CIRCABC before the meeting. The RMS concluded that these articles do not call into question the results of the risk assessment for glyphosate carried out as part of the procedure for the renewal of approval.

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

The Commission informed about proposals voted in the PAFF Committee Residues of 16/17 February 2017 with possible impact on authorisations:

- Lindane, achrinathrin, metalaxyl, thiabendazole and dimethoate: changes to the residue definition and lowering of MRLs
- Fluopyram and tricyclazole: lowering of MRLs

A.24 Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005).

The Commission informed Member States that the Terms of Reference for the external study will be launched in the coming days and the study is expected to begin in early June. The views of MS Competent Authorities will be important for the evaluation and the contractor will consult MS CA in several ways regarding the risk assessment, risk management and authorisation processes. The Commission is hopeful that the evaluation will identify best practices as well as weaknesses in the system.

A.25 Exposure of florists to plant protection products from cut flowers (Belgium).

An article was published in the French press in February 2017 regarding the presence of pesticide residues in cut flowers. The article pointed out that on average 14

substances are found on roses. Some residues found are high (up to 97 mg/kg) and some substances found are rather acutely toxic. Furthermore the article indicated that a majority of florists is not aware of the presence of pesticides and hence no precautionary measures are taken such as wearing gloves.
Belgium has had a meeting with cut flower producers who indicated the problem is with import of flowers. Belgium also met florist organisations to raise awareness.
France clarified that the issue includes exposure to substances which are banned or not approved within the EU. Currently a study is performed to assess the real transfer of residues to be able to perform a quantitative risk assessment.
EFSA informed that a model for dermal exposure is available. Belgium indicated not to have used this yet as first more info is needed on the acceptability of exposure.
The Commission invited Member States to send written comments by 5 May 2017 and indicated this point will be followed up.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as regards the criteria for the approval of low risk active substances.

The Netherlands made the following declaration:
"In the light of strengthening sustainability goals, and the importance therein to approve EU criteria for low risk substances, the Netherlands have voted in favour of the proposal of the European Commission for criteria for low risk substances, however:
The Netherlands have on several occasions during the discussions on these criteria brought forward an issue on the part of the environmental criteria, specifically the risk to the aquatic environment. We advocated adding category 2 (chronic) to the criteria for aquatic life. The Netherlands believe this to be an important point and it gives reason for concern, that we like to state for the record. This concern should be addressed through an evaluation of the criteria within 2 years, after using the criteria in the assessment process. Findings, as a result of the evaluation, should be addressed - if necessary - through amending the criteria."

The Commission committed to organising a working group with national experts to elaborate a guidance document for the harmonised implementation of criteria. Nominations for experts were requested by end of April.

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 flazasulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Renewal Report SANTE/10153/2017 Rev. 1)

The draft regulation was presented for vote. Two Member States could not support the renewal of approval due to the metabolites leaching into groundwater. Two Member States abstained because they would have preferred some data gaps to be addressed by a request for confirmatory data at EU level.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the low-risk active substance Bacillus amyloliquefaciens strain FZB24, 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. (Draft Review Report SANTE/12037/2016 Rev. 1)

The draft regulation was presented for vote. One Member State abstained because they do no support the low-risk status of the substance.

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 Beauveria bassiana strain NPP111B005, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/10398/2016 Rev. 1)

The draft regulation was presented for vote. One Member State abstained because it asks for a supplementary fee in order to provide comments during the peer review, which the applicant refused to pay. In consequence, the MS does not support the approval of the substance.

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 *Beauveria bassiana* strain 147, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/10424/2016 Rev. 1)

The draft regulation was presented for vote. One Member State abstained because it asks a supplementary fee to provide comments during the peer review, which the applicant refused to pay. In consequence, the MS does not support the approval of the 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 mesosulfuron in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (Draft Renewal Report SANTE/11827/2016 Rev. 2)

The draft Regulation was presented for a vote. One MS announced to abstain because of the potential risk to groundwater from leaching of metabolites.

Vote taken: Favourable opinion.

B.07 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance mesotrione in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Renewal Report SANTE/11654/2016 Rev. 1)

The draft Regulation was presented for vote. Two Member States voted against: one because it considers that due to long term risk to mammals there was not demonstrated a safe use of the substance and the other because it considers that the substance is falling under 2nd interim criteria for ED.

Vote taken: Favourable opinion.

B.08 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance cyhalofop-butyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011 . (Draft Review Report SANTE/10879/2015 Rev. 2)

The draft Regulation was presented for vote.

Vote taken: Favourable opinion.

B.09 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance picoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. (Draft Renewal Report SANTE/11601/2016 Rev. 1)

Discussion on the proposal took place with Member States.

Vote postponed

B.10 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 fluroxypyr. (Draft Review Report SANCO/11019/2011 Rev. 5)

The draft regulation was presented for vote alongside an amended Review Report. Two Member States raised a point about the need to ensure new agreed endpoints and used in the assessment of plant protection products. This was noted and it was also agreed that the development of the database for List of Endpoints by EFSA would ensure that regular updates can be easily recorded and retrieved in the future.

Vote taken: Favourable opinion.

B.11 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation withdrawing the approval of the active substance methyl nonyl ketone, 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.

The draft regulation was presented for vote. No comments have been raised during the TBT procedure, nor by the Member States.

Vote taken: Favourable opinion.

B.12 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, *Ampelomyces quisqualis* strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, cyhalofop butyl, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, *Gliocladium catenulatum* strain: j1446, imazamox, isoxaflutole, laminarin, mesotrione, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin

The draft Regulation was presented for vote. Two Member States voted against because they considered that some of the substances should not be granted an extension as it may be expected that they will not to be renewed at the end of the assessment process.

Vote taken: Favourable opinion.

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 diflubenzuron. (Draft Review Report SANCO/831/08 Rev. 6)

The draft regulation was presented for vote. Several Member States request that the decision should be postponed until after the renewal process. The Commission clarified that due to the nature of the concerns it is not appropriate to wait for the end

of the renewal process. One Member State voted against, several abstained because of this issue.

Vote taken: Favourable opinion.

B.14 Exchange of views and possible opinion of the Committee on a draft Commission Implementing regulation concerning the non-approval of the active substance orthosulfamuron, 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/11756/2016 Rev. 0)

The draft Regulation was presented for vote. The draft Regulation was presented for vote.

Vote taken: Favourable opinion.

B.15 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the low-risk active substance *Coniothyrium minitans* strain CON/M/91-08 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Implementing Regulation (EU) No 540/2011. (Draft Review Report SANTE/10155/2017 Rev. 1)

The draft regulation was presented for vote. One Member State abstained because of no support for a proposed low-risk status of the substance.

Vote taken: Favourable opinion.

C.01 Exchange of views 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 clothianidin.

The discussion under section C started with point C.03. The Commission emphasized at the beginning of the discussions that the draft texts presented under this point did not undergo a formal Inter-Service Consultation yet, and therefore shall not be taken as the final position of the Commission.
The Commission explained that the agenda points C.01 – C.03 have been put on the agenda in order to allow a timely discussion of the way ahead with the active substances clothianidin, imidacloprid and thiamethoxam, following the EFSA conclusions received in 2016. Due to the importance of the issues, the Commission wants to avoid undue delays in the decision-making.

Applicants submitted confirmatory data for clothianidin. A review by EFSA was performed and additional risks to bees were identified, specifically to outdoor uses.
The updated version of the addendum of the Review Report covers the two evaluations carried out by EFSA in 2016 (EFSA conclusion on foliar uses under article 21 and EFSA conclusion on confirmatory data for all uses).

Based on the additional risks to bees identified by EFSA, it is proposed to restrict the uses of clothianidin to permanent greenhouses for crops with a full lifecycle in the greenhouse.
It is foreseen to include the restriction of seeds treated with plant protection products containing clothianidin, as was the case in 2013. The seeds may not be placed on the market or used, with the exception of seeds that will be used in permanent greenhouses.
The provisions for clothianidin, imidacloprid and thiamethoxam have been aligned as far as possible.
In addition, it is proposed to align the specific provisions for the approval with the restriction of use to permanent greenhouses.
Member States are asked to provide written comments by 21 April 2017.

C.02 Exchange of views 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 imidacloprid.

The Commission outlined that the timelines and the outcome of the assessment of imidacloprid are very similar to clothianidin and therefore the same type of measures (restriction to use in permanent greenhouses for crops with a full lifecycle in the greenhouse) are envisaged.
Member States are asked to provide written comments by 21 April 2017.

C.03 Exchange of views 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 thiamethoxam.

The Commission explained the background regarding the requested confirmatory data on bees for the substance thiametoxam and in particular the fact that the confirmatory information presented for thiamethoxam did not allow EFSA to carry out a further risk assessment.
The Commission proposed to further restrict the uses of thiametoxam to the full life cycle of a crop in a permanent greenhouse and to align the conditions of approval with the restriction to permanent greenhouses.
It was explained that the updated addendum to the review report addresses simultaneously the conclusion by the EFSA on foliar applications as well as the request for confirmatory data.
The draft measures are consistent with those foreseen for clothianidin and imidacloprid.
Member States are asked to provide written comments by 21 April 2017.

M.01 New Scientific publications and information submitted by stakeholders.

No new information.

M.02 AOB

1. Antibiotics – Yearly reporting by Member States

The Commission reminded Member States to report about any authorisation of antibiotics in plant protection products granted in 2016. Such report should contain detailed information about the use, need and any effort for a phase-out.

M.03 Date of next meeting.

The date of the next meeting was confirmed as 17-18 May 2017.