EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.001(2015)6352682

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 13 JULY 2015 - 14 JULY 2015

(Section Phytopharmaceuticals - Plant Protection Products - Legislation)

CIRCABC Link: *https://circabc.europa.eu/w/browse/bfc4671e-9a79-4025-9ba8-7a05a7a05730*

A.01 Summary Report of previous meetings.

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

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

A.02 New active substances:

01 New admissible dossiers (to be noted):

i. *Metschnikowia fructicola*
ii. *Fusarium sp. L13*
iii. *Tolpyralate*
iv. *Bacillus subtilis IAB/BS03*

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

02 European Food Safety Authority (EFSA) conclusions

- *Beta-cypermethrin*

The Commission informed Member States that after a delay in taking a decision for this substance (submitted under the provisions of Directive 91/414/EEC), it would begin to progress and that a first proposal would be made available for the October meeting. Some key background points were given and the key points highlighted in the EFSA Conclusion were detailed. The applicant's comments on the EFSA Conclusion were made available ahead of the meeting.

One Member State indicated that they could not support approval of the substance due to the risk to aquatic organisms.

Comments/initial views were requested by 31 August 2015.

03 Commission draft Review Report and Regulation concerning the approval of:

i) Cyantraniliprole

The revised EFSA conclusion was published on 28 June 2015. A draft Review Report has been prepared and presented. Comments were requested by 31 August 2015.

One Member State indicated that they could not support approval of this substance due to leaching of metabolites to the ground water.

One Member State requested a confirmatory data requirement regarding the relevance of groundwater metabolites.

ii) Flumetralin

A revised Review Report and Regulation were made available ahead of the meeting. Member States were reminded about the key points pertaining to the substance and how these were being addressed in the current proposal. The substance fulfils the criteria as persistent (P) and toxic (T) so must be considered a candidate for substitution. Confirmatory data would be set to confirm the specification and the equivalence of the specification with toxicity batches, given that the specification considered was based on pilot scale production.

The intention is to take a vote in the October meeting.

One Member State indicated that they could not support approval of this substance due to leaching of metabolites to the ground water.

Another Member State indicated that they had some concerns about a groundwater metabolite and that they would submit written comments about this.

Final comments were requested by 31 August 2015.

iii) 3-decen-2-one

A reminder of the key issues was provided and Member States were informed that a meeting had taken place between the Commission, the Rapporteur Member State (RMS) and the applicant in June to discuss the problems. Two key issues remain unresolved:

1. Genotoxic potential of the active substance remains unresolved. There were known concerns raised by the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) of EFSA about potential for genotoxicity in 2008, before the dossier was submitted. Still the package submitted did not allow a clear conclusion on genotoxic potential to be concluded.

2. Inclusion in Annex IV of Regulation (EC) No 396/2005 could not be confirmed and the MRL application is therefore un-finalised (also linked to data gaps for the toxicology assessment). Based on this, no authorisations could be granted and the approval criteria are not met.

The RMS and another Member State considered that approval is possible and that confirmatory data could be requested to deal with the genotoxicity issue and the Maximum Residue Level (MRL) problem. Member States were reminded that confirmatory data should not be applied to areas where there are clear data requirements and guidance in place; moreover, the issue of genotoxicity is serious and cannot be dismissed.

Member States were informed that a vote would be planned for the October meeting.

Final comments were requested by 31 August 2015.

iv Rescalure

The Commission presented a draft Review Report and Regulation. Member States can send in comments until 31/8/2015.

v) Flupyradifurone

The Commission presented a draft Review Report and Regulation.

One Member State indicated that they could not support approval of this substance due to leaching of metabolites to the ground water.

Member States can send in comments until 31/8/2015.

vi) Mandestrobin

The Commission presented a draft Review Report and Regulation. MS can send in comments until 31/8/2015.

vii) Tricyclazole

An update on the current position was given by the Commission, including a description of a meeting held between the applicant and the Commission in June and some other correspondence that had been made available to Member States via CIRCABC. A draft Review Report and Regulation were explained in detail. The Member States were informed that the draft Review Report had been circulated to the applicant for comments; these comments would be made available ahead of the October meeting.

A number of Member States expressed the importance of the substance for rice growers in southern Member States and had concerns about the proposal tabled.

Comments were requested by 31st August 2015.

viii) Benzovindiflupyr

A draft Review Report has been prepared and presented. Comments were requested by 31 August 2015.

04 Chromobacterium subtsugae PRAA4-1 (MBI-203)

The question of which data requirements should be used for this active substance is under discussion in the biopesticodes expert group.

A.03 Renewal of approval:

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

This document provides an overview of the applications submitted pursuant to Regulation (EU) No 844/2012.

Member States can send in comments until 31/8/2015.

02 State of play AIR (Annex I Renewal project)

See point B.04.

03 EFSA conclusions:

i) Iprovalicarb

The Commission informed that the EFSA conclusions, the comments by the Applicants, and recent comments by one Member States have been received and tabled.

It shows that groundwater contamination by one metabolite cannot be excluded in pedological zones with low clay contents. No leaching has been observed in zones with a normal clay content. It needs to be further investigated whether low clay contents is a common issue, in which case a EU-use restriction may be appropriate, or not. Comments by Member States should be received by 31.8.2015.

04 Draft Review Reports for discussion

i) Flupyrsulfuron-methyl
ii) Thiabendazole
iii) Lambda-cyhalothrin
iv) Amitrole

No new information for these points.

v) Flumioxazin

EFSA started the consultation period with Member States 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.

vi) Prosulfuron

Member States were reminded of the proposal tabled at the May meeting in the draft Review Report; since the May meeting a draft renewal Regulation had also been made available. The proposal included a restriction of use to address the risk to groundwater from parent, as identified in the EFSA Conclusion.

One Member State indicated they could not support approval due to the risk of leaching to groundwater.

Two Member States objected to the proposed restriction.

Member States were asked for final comments by 31 August 2015.

vii) Pymetrozine

An update on the state of play was given including a reminder of the various issues currently precluding renewal. The Committee was informed about the submission of some additional information by the applicant at the request of the Commission. The proposal as presented in the review report tabled at the May meeting had not been modified but would be further considered in the light of the additional information received. The Committee was informed of options available to move ahead. The Commission services were discussing internally the next steps which would include the RMS and EFSA.

Two Member States commented on the importance of the substance as part of Integrated Pest Management. A number of Member States indicated support for the approach being taken which would include consideration of negligible exposure and Article 4(7) of Regulation (EC) No 1107/2009.

Member States were asked for comments on the approach outlined as soon as possible.

viii) Metsulfuron-methyl

No new information.

ix) Esfenvalerate

No further comments were received. Interservice consultation on this proposal will be started soon.

One Member State indicated that they could not support the proposal given the risk to aquatic organisms.

x) Pyraflufen-ethyl

No new information.

xi) Cyhalofop-butyl

One comment was received for which the EFSA and the RMS will be consulted. Further comments can be submitted until 31 August 2015.

xii) 2,4-D

The Commission informed that the EFSA conclusions (including its revision), all comments by the Applicants, and several comments by Member States have been received and tabled. A new draft revision report and a first draft regulation, reflecting the state of debates, are also tabled. In general, it shows that none of the Member States are in favour of a rate restriction and that consumer safety, in the case of higher application rates, can be handled at national level, given the low level of (acute and chronic) exposure. Additional data as regards endocrine effects, including ecotoxicity, should be examined and provided as confirmatory information. Other risks are to be evaluated and mitigated in line with the Uniform Principles. In the EU classification system (Regulation (EC) No 1272/2008) 2,4-D is not classified for carcinogenicity, nor is there any proposal in that sense by EFSA nor the rapporteur. However, the class of chlorophenoxy acid herbicides, to which 2,4-D belongs had been classified by the International Agency for Research on Cancer (IARC) some decades ago as "possibly carcinogens to humans" (Group 2B). That classification has recently be confirmed for the individual substance, but the monograph has not yet been made available and consequently it is unclear on which basis IARC comes to such conclusion. As this may take considerable time, it is agreed that the decision-making process should not be delayed for this reason and at next meeting, it is intended to submit an internally agreed proposal for a vote.

xiii) Metalaxyl-M

A draft Review Report has been prepared and presented. Comments are requested by 31 August 2015.

xiv) Triasulfuron

The EFSA conclusion, comments by the Applicants, and a first draft Review report have been tabled. It must be examined whether the information that has now been made available is acceptable as to rule out the genotoxicty of an impurity, which also occurs as a metabolite for other substances of this family of chemicals, and the parent compound itself. EFSA, as well as the Rapporteur, observed flaws in one in vivo test and considered it ought to be replaced by another assay. Although consumer exposure (AOEL, ADI), as set in the renewal dossier, is very low, and no Acute Reference Dose (ARfD) is proposed, EFSA did not define reference toxicity values, and as a consequence, the exposure assessment remained un-finalised. Other issues, such as

the risk to groundwater in vulnerable zone and the risk to aquatic plants might possibly be mitigated at national level, while remaining endocrine issues might be covered by the submission and evaluation of confirmatory information. Comments by Member States are expected by 31.8.2015.

05 Next stage of renewal programme:

- *Proposed Rapporteurs and Co-rapporteurs for AIR-4 (Annex I Renewal)*

This document is a revised proposal regarding the appointment of RMS and Co-RMS for the AIR IV active substances.

A.04 Confirmatory data:

i) dithianon

The mandate for the peer review by EFSA was send on 19 June 2015, with a deadline for the evaluation by 31 October 2015.

Haloxyfop-P

The Commission will prepare an amended Regulation as to restrict the application rate and timing, so as to protect groundwater from the leaching of a metabolite, the relevance of which has recently been established. It is intended to submit at the next meeting an internally agreed proposal. Comments, if any, are expected by 31.8.2015.

Pyrethrins

Point deleted (erroneously carried over from the May agenda).

Imazalil (confirmatory data and application to amend the ARfD)

A revised Review Report was presented to the Committee taking into account the outcome of the confirmatory data assessment and the outcome of the assessment to modify the ARfD. Member States were asked to consider this and provide comments by 31 August 2015.

Fluazifop-p

A revised Review Report was presented to the Committee taking into account the outcome of the confirmatory data assessment. Member States were asked to consider this and provide comments by 31 August 2015.

Iron sulphate

A revised Review Report was presented to the Committee taking into account the outcome of the confirmatory data assessment. Member States were asked to consider this and provide comments by 31 August 2015.

Epoxiconazole

All relevant documents are tabled but no revised review report could be finalised due to the need to further examine the dossier. The point is postponed to next meeting.

Bifenthrin

The EFSA report, the reporting tables and the addenda on fate and ecotoxicity prepared by RMS France are tabled. It seems that the fate and behaviour section has been adequately addressed. The off-field risk for non-target arthropods is acceptable provided that an adequate buffer zone is applied. However, it is not clear whether the in-field risk for, at least some species, can be excluded. It is well noted that the tests have been done with an application rate that is the double of the intended GAP and that actual exposure is therefore significantly lower.
It will be further explored how this issue is to be dealt with in future (mandate to EFSA, restriction on uses, risk mitigation at Member State level).

Member States were invited to comment by 31.8.2015.

AOB

No points for discussion.

A.05 Article 21 Reviews:

i) Diflubenzuron

The Commission referred to additional comments from Member States available on CIRCABC and informed the Committee of the revised target date for submission of the EFSA Conclusion. It invited Member States to analyse the EFSA Conclusion, once available, ahead of the next meeting of the Committee, and to send comments in light of that Conclusion and/or on the Margin of Exposure approach.

ii) Chlorpyrifos – state of the dossier

The Commission informed about the ongoing discussion on the review of MRLs of concern. A proposal for vote has been submitted to the June Pesticides Residues section of the Plants, Animals, Food and Feed Committee and it is expected a vote will be finalised in October. This agenda point is linked to points A.10 and A.32. The new toxicological endpoints triggered review of MRLs at EU level, however the new Acceptable Operator Exposure Level (AOEL) would lead to review of authorisations of Plant Protection Products (PPP) and it was recommended to Member States to proceed with the review of authorisations of PPP in order to ensure consistency and mutual recognition.

A.06 Amendment of the conditions of approval.

No new applications.

A.07 Basic substances [no new application]:

01 Pilot projects: state of play

The Commission informed on a recent e-mail from the Netherlands supporting as candidates for next pilot project: onion oil, Urtica dioica, milk and calcium chloride. The Commission recalled the proposal for the pilot project expressed in the last Plants, Animals, Food and Feed (PAFF) meeting and urged Member States interested to take part to prepare draft applications for the candidate substances. At present, only Urtica dioica has been received. When applications will be received the Commission will proceed with organising the experts meeting. It was recommended to send applications as soon as possible to allow the organisation of experts working group to be ready for October.

02 New dossiers received

i. Sesame oil
ii. Origanum vulgare L. essential oil
iii. Capsicum spice
iv. Sunflower oil
v. Millefolii herba

Member States were made aware of the new dossiers received for the basic substances listed above.

03 EFSA Technical Reports

No news to report.

04 Draft Review Reports for discussion:

i. *Artemisia absinthium*
ii. *Tanacetum vulgaris*
iii. *Arctium lappa*
iv. *Sodium hydrogen carbonate*
v. *Quassia*

Interservice consultations on the draft proposals for A. absinthium, T. vulgaris, A. lappa and sodium hydrogen carbonate will be started soon. Comments received will be carefully considered before starting these consultations.

A.08 Green substances – garlic extract (revised review report to be noted).

The revised review report has been uploaded on CIRCABC and no further comments were received.

The Committee took note of the revised review report. One Member State objected to note-taking.

A.09 Exchange of views and possible taking note of the following Guidance Documents:

01 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 (SANCO/12096/2014) (for discussion)

The Commission thanked Belgium, Spain, Norway and EFSA for sending comments to the draft made available at the last meeting and invited Member States to further comment by the 24th of July. Sweden clarified they do not intend to send further comments in addition to the ones sent in the context of the expert Working Group (WG).

Stakeholders were consulted via the Advisory Group on the Food Chain and Animal and Plant Health the 25th of June, and were invited to send written comments by the 24th of July. The internal procedures are initiated. The guidance is expected to be published in the Official Journal as a Commission Notice.

02 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 (SANCO/11509/2013 Rev. 5) (to be noted)

No detailed discussion.

03 Draft Guidance document concerning the parallel trade of plant protection products (SANCO/10524/2012 Rev. 5.2) (to be noted)

The Committee took note of the guidance document version 5.2. Two Member States objected to note-taking.

Germany made the following declaration:

The Federal Republic of Germany does not agree to the amendment of document SANCO/10524/2012 (14 July 2015, Rev. 5.2) concerning the parallel trade of parallel traded plant protection products (page 4) due to the following reasons:

1. The amendment contradicts German jurisdiction. According to the court decision 2 A 1056/12 of the Administrative Court of Brunswick from 14 November 2012, confirmed by the Court Decision 10 LA 1/13 of the Higher Administrative Court of Lower Saxony from July 23, 2014, the parallel trade of parallel traded products is not permitted according to Regulation (EC) No 1107/2009.
2. The Court Decision C-108/13 of the European Court of Justice from 6 November 2014 refers exclusively to Directive 91/414/EEC and is not applicable to Regulation (EC) No 1107/2009. This corresponds to the German jurisdiction as the parallel trade of parallel traded products was permitted in

the past under Directive 91/414/EEC according to the court decision 13 K 192/07 from the Administrative Court of Cologne from 7 February 2008.

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

The document is under further discussion in the expert group on biopesticides.

05 Draft Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/3170/2010 Rev. 13) (to be noted)

A few Member States believe that their comments were not sufficiently taken into account. The Commission, however, is keen not to further delay the note-taking and commits to consider again the latest comments received at the occasion of a possible future revision of the document.

The Committee took note of the guidance document. One Member State objected to note-taking.

06 Draft List of Obsolete Guidance Documents (SANTE/11073/2015) (to be noted).

The Committee took note of the document.

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

The United Kingdom submitted 14 notifications concerning products containing chlorpyrifos. The Commission recommended Member States to proceed with review of authorisations in view of new AOEL and new MRLs proposal to be voted in October 2015.

The Committee took note of the notifications submitted by United Kingdom.

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

Belgium submitted two notifications.

The Committee took note of the notifications submitted by Belgium.

A.12 Notifications under Article 53 of Regulation (EC) No 1107/2009 (to be noted).

Cyantraniliprole (Belgium)
Pepino mosaic virus strain CH2, isolate 1906 (Belgium)
Azoxystrobin/Cyproconazole (Bulgaria)
Trifloxystrobin/Cyproconazole (Bulgaria)
Bordeaux mixture (Bulgaria)
Copper hydroxide (Bulgaria)
Thiamethoxam (Bulgaria)

Picoxystrobin/Cyproconazole (Bulgaria)
Fipronil (Bulgaria)
Pyraclostrobin (Bulgaria)
Azadirachtin (Czech Republic)
Spirotetramat (Czech Republic)
Thiamethoxam (Czech Republic)
Aureobasidium pullulans (Germany)
Azadirachtin (Germany)
Halosulfuron-methyl (Germany)
Propyzamide (Denmark)
Rimsulfuron (Denmark)
Dazomet (Denmark)
Propanil (Spain)
Straight Chain Lepidopteran Pheromones (Spain)
Chlorpyrifos-methyl (Spain)
Dimethoate (Spain)
Emamectin Benzoate (Spain)
Mancozeb/Pyraclostrobin (Spain)
Oxamyl (Spain)
Spirotetramat (Spain)
Flonicamid (Spain)
Spinosad (Spain)
Spirodiclofen (Spain)
Thiophanate-methyl (Spain)
Chlorantraniliprole (Finland)
Quinoclamine (Finland)
Abamectin (Greece)
Alpha-cypermethrin (Greece)
Etofenprox (Greece)
Fludioxonil (Greece)
Fluopyram (Greece)
Fosetyl (Greece)
MCPA (Greece)
Paraffin oil (Greece)
Propanil (Greece)
Pyrimethanil (Greece)
Quinclorac (Greece)
Spirotetramat (Greece)
Sulphur (Greece)
Tricyclazole (Greece)
Penoxsulam (Hungary)
Abamectin (Ireland)
Asulam (Ireland)
Fluopyram (Ireland)
Bacillus thuringiesis var kurstaki ABTS-351 (Lithuania)
Metazachlor/Clomazone (Sweden)
Metazachlor/Quinmerac (Sweden)
Phenmedipham (Sweden)
Spinosad (Sweden)
Azoxystrobin/Cyproconazole (Slovakia)

Boscalid/Pyraclostrobin (Slovakia)
Cyprodinil/Fludioxonil (Slovakia)
Emamectin (Slovakia)
Thiram (Slovakia)
Copper hydroxide (Slovakia)
Methoxyfenozide (Slovakia)
Potassium hydrogen carbonate (Slovakia)
Spinosad (Slovakia)
Spirodiclofen (Slovakia)
Spirotetramat (Slovakia)

The Committee took note of the notifications submitted by Belgium, Bulgaria, Czech Republic, Germany, Denmark, Spain, Finland, Greece, Hungary, Ireland, Lithuania, Sweden and Slovakia.

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

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

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

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

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

01 NAP (National Action Plans) Report

The report is under internal consultation, it is expected to be submitted under the Luxembourg Presidency. In parallel also the FVO analysis on NAPs will be published on the Directorate General for Health and Food Safety (SANTE) webpage.

02 State of play

Requests for the advanced implementation of the provisions of the Sustainable Use Directive (SUD) and in particular on Integrated Pest Management (IPM) have been raised again recently by some stakeholders during a conference organised in the EU Parliament "Redefining IPM". The Commission took part restating the importance of

implementation of IPM which is well defined in the SUD which provides detailed description of IPM general principles. Further information is available here:

http://ebcd.org/event/redefining-integrated-pest-management/

Member States are reminded that the next SUD meeting is planned for 2 October 2015.

A first Better Training for Safer Food (BTSF) workshop on inspection of machinery equipment was held last week in Barcelona. Member States can nominate for participation either public officers or other professional qualified experts having a role in equipment inspection coordination.

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

Postponed.

A.15 Report from working groups:

01 Plant Protection Products (PPP) Application Management System (PPPAMS) (Authorisation database)

The Committee was informed that an ad hoc Working Group for Implementation of PPPAMS had been established comprising of seven Member States and Industry. The group will discuss issues related to the functionality and implementation of the PPPAMS to ensure a smooth road to implementation.

Member States were reminded of the two exercises that were ongoing to migrate data from national databases into the PPPAMS and the importance of the second step (migration of data) was emphasised given that this information would be necessary to inform the ongoing Impact Assessment on endocrine disruptors.

Member States were informed that the Commission had met with the European Crop Protection Association (ECPA) in June and would meet with the International Biocontrol Manufacturers Association (IBMA) and the European Crop Care Association (ECCA) in July to discuss their role in the PPPAMS.

Member States were encouraged to run pilot projects with applicants for new applications.

02 Low risk

For the meeting in June, a draft document had been prepared including a proposal for an amendment of the current low-risk criteria. This "Working Document for the Purpose of a Possible Amendment of the Current Low-Risk Criteria" was discussed in detail. The group agreed to focus on possible amendments for Annex II.5 to Regulation (EC) No 1107/2009 and leave amendments of the enacting terms up to the future revision of the Regulation.

As a next step, it was agreed to carry out a simple 'impact check' in order to see how many amongst the approved active substances actually might qualify as low-risk.

It is anticipated that a first proposal for an amendment of the criteria is not expected to be available earlier than for the December PAFF Committee meeting.

03 Zonal Workshop

The Commission thanked Ireland for organising the workshop which covered very important issues for the regulatory framework. The presentations and discussions reflected a number of problems encountered by Member States and also confirmed by the FVO audits of Member States authorities.

It appears that, in case of many Member States, neither the co-operation between Member States, nor the level of implementation of the harmonised legal framework works as desired. Some national authorities keep on insisting on national assessment schemes and ignore the harmonised EU endpoints, unnecessarily burdening mutual recognition of authorisations.

The Commission recognises that more intensive collaboration between Member States of the same zone is important and welcome. However, this should not lead to an additional layer to be inserted between national and EU level, but zonal requirements shall replace national requirements with a view to maximise compatability with similar requirements of the other zones.

The Commission is also concerned about the delays occurring in all levels of the process and for different types of decisions. The legal deadlines for authorisation and mutual recognition are regularly exceeded and in a number of cases the re-registration of existing authorisations following approval, was not done in time. This impacts also those Member States who would wish to profit from the benefits of mutual recognition.

The Commission also wonders whether there are links between the fact that some Member States do not implement the harmonised system, insisting on national provisions and delays accumulating in these countries.

The Commission urges Member States to correctly apply the legislation and its deadlines, to refrain from repeating risk assessments at national level where assessments on higher level exist and not to misuse the provisions of Article 36(3) in that respect.

04 Post Approvals Issues group (PAI)

Postponed.

A.16 16 OECD [no news]

A.17 Bees:

01 Review of Neonicotinoids – state of play and next steps

The specific open call for data prepared by EFSA is running until 30 September 2015. Following that, the Commission will prepare a specific mandate to ask EFSA to perform a review of the risk assessment for bees. The Commission informed that it had received several requests on the timeline of the process from several stakeholders. The timeline is not yet defined and will depend also on the amount of data collected in the open call.

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

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

The ECPA again reiterated its comments on this subject. A letter received on this topic is available in CIRCABC.

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

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

04 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, Germany

The final programme is under finalisation. Eleven Member State authorities communicated to the Commission the experts to be invited for the Conference. The Commission welcomed the nomination from other Member States. The Commission will send out the official invitations soon and confirmed that 2 experts per Member States could be reimbursed. Moreover, the Commission clarified that in addition, experts invited as speakers could be reimbursed as well.

AOB

EFSA gave a short update on the "state of play" of the ongoing peer review of risk assessment for bees for the three neonicotinoid insecticides (clothianidin, thiamethoxam and imidacloprid) considering all the uses other than seed treatments and granules. A round of consultation on the draft EFSA conclusions is ongoing. EFSA plans to adopt the Conclusions before end of July (planned deadline). The publication is foreseen in August after the standard procedure of consultation for confidential information. EFSA applied the new risk assessment scheme for bees and the EFSA guidance document to assess all the authorised uses available in Member States. EFSA thanked Member States' collaboration in this exercise. Moreover, EFSA applied in practice for the first time, the EFSA guidance on bees. From this experience, EFSA indicated that the Guidance Document, despite all the criticisms, is applicable also in this very complicated case (where all uses have been evaluated).

A.18 Court cases:

- Case T- 578/13:

The company requested annulment of a letter of the Commission to EFSA concerning the confidentiality claims. The court rejected the request. In its Judgment of 3 June 2015, the General Court declared: "Therefore, it is apparent from both the wording and scheme of Article 7(2) of Regulation (EC) No 188/2011, that that Article authorises EFSA to determine, in its own right, requests for confidentiality". In conclusion, in Regulation (EU) No 188/2011 and Regulation (EC) No 1107/2009, EFSA is entrusted with the task of deciding, in its own right, on requests for confidentiality.

- Case T-296/15:

Point added to original agenda.

The company Industrias Quimicas del Valles is seeking the annulment of Regulation (EU) 2015/408 setting the list of candidates for substitution and in particular the inclusion in the list of Metalaxyl.

A.19 Endocrine disruptors:

01 Impact assessment

The Commission updated on the last activities. The Conference of 1 June 2015 has attracted a high interest and the respective presentations and web streaming are available via http://ec.europa.eu/health/endocrine_disruptors/stakeholders_dialogue/index_en.htm.

The report on the public consultation is intended to be published before the summer break on the same website.

The studies are progressing well. An event focused on the on-going 1st study is planned for autumn 2015, but details still need to be defined.

The Commission highlighted the need of data on PPP authorisations for the second set of studies to be performed for the impact assessment, and reminded that Member States were asked via a letter to provide relevant information in the context of the activities performed under A15.01. These data will be crucial to proceed with the impact assessment.

02 Interim criteria

The Commission informed that it was decided not to develop further guidance on the interpretation of the 2nd interim criterion, but to leave interpretation on a case by case basis and to base it on expert knowledge.

A.20 Minor Uses:

- State of play

The Commission informed that the recruitment procedure for the EU Minor Uses coordinator is nearly finalised. Job interviews will take place on 16th June and a decision will be taken as soon as possible.

A.21 Interpretation issues:

01 Scope of Regulation (EC) No 1107/2009

i) Ozone (Question from Hungary)

Concerning the *in situ* generation of ozone, the Commission refers to a position paper provided to Member States in 2013 and the amendment of the conditions for inclusion of ethylene in 2014, touching upon a similar issue.

02 Questions and answers

At the previous meeting two additional questions and one amendment to an existing question were presented. Comments were received from one Member State which will be taken into account. The Questions and Answers will be updated accordingly.

A.22 Status of harmonised classifications under Regulation (EC) No 1272/2008:

Postponed.

A.23 Glyphosate:

- State of the dossier

EFSA and the Commission outlined the next steps in the procedure and the impact of the expected publication of the IARC Monograph. The rapporteur Member State Germany reported on the establishment of a WHO ad-hoc working group on glyphosate to address scientific divergences between WHO organisations, and a new publication on detections of glyphosate residues in breast milk and urine.

A.24 Information from the section Pesticide Residues of the Committee: possible impact on authorisations.

The Commission plans to regularly inform this section of the Committee of relevant decisions taken in the Pesticide Residues section.

A.25 Interzonal workshop on 'harmonisation of risk assessment in section toxicology'.

A brief overview of the workshop was provided and the Commission thanked Austria for their organisation of this event which was attended by the Commission, Member States, Industry and EFSA. A report would be made available via the AGES website after the summer along with the presentations. The report would also be made available to Member States via CIRCABC for their convenience.

Member States were asked to consider whether they could host a follow-up event in 2016.

A.26 Metam - new information submitted.

Not discussed. Point erroneously carried over from the May agenda.

A.27 EFSA Guidance document on protected crops. Follow-up discussion with Member States on feasibility of current application date (1/05/2015) for product authorization.

Follow-up discussion with Member States on feasibility of current application date (1/05/2015) for product authorization.

One Member State asked for clarification on the application of the guidance document and notably the question whether the application date is valid for product and active substance applications. The Member State would appreciate if the application date would only be valid for active substances and should be postponed for product applications.

The Commission referred to a similar discussion several months ago and reminded Member States that the application date for this guidance document was already postponed once for the same reason.

The Commission clarifies that it is common practice that the application date of a guidance document is always valid for all applications introduced after the application date, regardless whether substance or product applications.

The Commission insists that realistic implementation deadlines must be chosen from the outset and later changes should be avoided as far as possible.

A.28 New greenhouse operator exposure model.

Postponed.

A.29 Follow-up activities EFSA Exposure Guidance (AAOEL mandate) (Acute Acceptable Operator Exposure Levels).

Commission thanked the United Kingdom for the updated draft mandate and Member States for sending comments to a previous draft. Comments to the revised version are welcome by 31 of August, 2015. After agreement on the draft mandate at the next PAFF meeting, it is intended to send a mandate to EFSA to proceed on this issue.

A.30 Zonal authorisations, mutual recognition and renewals authorisations: Conclusions from the workshop in Dublin and Food and Veterinary Office (FVO) audit List of PPP contact points for OLAF (European Anti-Fraud Office).

The Commission thanked Ireland for organising the workshop covering extremely important issues for our regulatory framework. The presentations and discussions reflected the problems encountered today. And these are confirmed by the FVO audits of Member States' authorities.

The Commission underlined the issues:

First there is an insufficient co-operation between Member States and insufficient implementation of the harmonised framework. After nearly 25 years, the conclusion is that we are still too far from EU harmonisation.

Second, the implementation of the regulation by Member States is not satisfactory. This is also confirmed by the FVO audits of Member States authorities.

There are serious slippage with EU legal deadlines for authorisation and re-authorisations. There are important delays in the authorisations under the zonal system. The Commission is aware that in many cases, the zonal assessment performed by the zonal rapporteur is not accepted by some Member States, which leads to major delays in the process. Also as some Member States with fewer resources rely on mutual recognition, delays in authorisation in other Member States, makes mutual recognition impossible.

Member States should move away from “national” requirements and apply the uniform principles.

Approval conditions should be complied with in authorisations.

The mechanisms that are available to reduce the administrative burden for Member States and producers are not implemented by national authorities, in particular the zonal system and mutual recognition of authorisations.

The Commission urges Member States to complete (re-)authorisations and conform with EU approvals which they endorse in the Standing Committees.

Member States should rely on each other/trust each other. Harmonisation should be achieved by now. National assessment should no longer exist. The lack of harmonisation and trust is not sustainable. It is a threat to the authorisation system in the EU.

Finally, breach of the EU deadlines is not acceptable. They constitute clear breaches of EU legislation.

A.31 List of PPP contact points for OLAF (European Anti-Fraud Office).

Point added to the original agenda.

The Commission placed on CIRCABC a list of contact points which were provided to OLAF for enquiries on counterfeit of pesticides. The Member States were invited to verify the contact point for their country and advise the Commission if they wished to change. A new column will be included in the larger list for this purpose.

A.32 Changes of toxicological endpoints and consequent review of authorisations.

Point added to the original agenda.

The Committee placed on CIRCABC an e-mail from the United Kingdom referring to the necessity to have a consistent procedural approach on review of authorisations following amendments of toxicological endpoints. The relevant provisions of Regulation (EC) No 1107/2009 do not set a common deadline and this could result in not harmonised evaluations among Member States. The Committee restated the need to prioritise MRLs review to grant harmonised endorsement and recommended Member States to punctually assess whether authorisations comply with new endpoints even if they did not lead to amendment of approval conditions.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation renewing the approval of the active substance florasulam 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/10542/2015 Rev. 1).

The Commission proposed to renew the approval of florasulam.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation approving the basic substance fructose 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. SANCO/12680/2014 Rev. 1)

The Commission presented the document to the Committee.

Vote taken: Favourable opinion.

B.03 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance Bacillus subtilis strain QST 713.

The Commission presented the document to the Committee.

Vote taken: Favourable opinion.

B.04 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation amending Commission Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,4-D, Acibenzolar-s-methyl, Amitrole, Bentazone, Cyhalofop butyl, Diquat, Esfenvalerate, Famoxadone, Flumioxazine, Flupyrsulfuron-methyl, Glyphosate, Iprovalicarb, Isoproturon, Lambda-Cyhalothrin, Metalaxyl-M, Metsulfuron methyl, Picolinafen, Prosulfuron, Pymetrozine, Pyraflufen-ethyl, Thiabendazole, Thifensulfuron-methyl, Triasulfuron.

Vote taken: Favourable opinion.

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

No update or discussion.

M.02 New Scientific Publications.

Nothing to report.

M.03 AOB

The Commission made the Committee aware of a study which accompanied a recently submitted written question of the European Parliament. The study has been uploaded on CIRCABC.

It was carried out by the University of Rennes and concerns a cohort epidemiological study. Despite reporting some limitations, the conclusions underlined that "low levels of childhood exposure to deltamethrin as DBCA its principal metabolite and pyretrodis insecticides in general as reflected by levels of 3-PBA metabolite, may negatively affect neurocognitive development by 6 years of age".

Member States and EFSA are asked to consider the study and in particular the United Kingdom as RMS for deltamethrin, to provide their views to the Commission.

M.04 Date of the next meeting.

8-9 October 2015 (subject to confirmation).