



EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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**SUMMARY REPORT OF THE  
STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED  
HELD IN BRUSSELS ON 22 SEPTEMBER 2014 - 23 SEPTEMBER 2014  
(Section Phytopharmaceuticals - Pesticides Residues)**

**CIRCABC Link:** <https://circabc.europa.eu/w/browse/db6d229f-a1d2-4e5e-9972-ca7f04103036>

President: Michael Flueh

25 Member States were present. Bulgaria was absent and represented by the Czech Republic. Portugal was absent and represented by Spain. Malta was absent and not represented.

Qualified majority: 260 votes and 15 Member States in favour

**A.01 News from the European Food Safety Authority (EFSA):**

1. Progress under Article 12. Priorities discussed under point A.02

The European Food safety Authority (EFSA) reported that since the last Committee meeting, ten new Reasoned Opinions on maximum residue level (MRL) reviews under Article 12 of Regulation (EC) No 396/2005 were published.

2. Progress under Article 10

EFSA reported that since the last Committee meeting, ten new Reasoned Opinions on MRL applications under Article 10 of Regulation (EC) No 396/2005 were published. It mentioned the key changes to the evaluation that were presented and discussed at the Pesticides Steering Committee on 19/20 June 2014. The relevant documents are still open for commenting by Member States as the deadline was prolonged until 30 September 2014. EFSA plans to present further details on the changes at the next meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) – section Pesticide Residues.

3. Update on Art. 43 mandates

Not discussed.

#### 4. Data Warehouse Access Policy

The Commission explained that the topic is under discussion in several sections of the Committee. However, formal endorsement will be sought only in the section General Food Law in December 2014.

EFSA presented an update on the data warehouse access rules and a demo version of some features of the new database. The presentation is available on CIRCABC.

A Member State asked for sufficient time to be allowed for consultation with the control authorities who are the data owners.

#### **A.02 Follow up to EFSA Pesticides Steering Committee in June 2014 and other procedural issues:**

##### 1. Priorities under Art. 12 (e.g. pyrethrins, dithiocarbamates, chlorpyrifos, chlorpyrifosmethyl and triclopyr)

The Commission highlighted that the Committee had previously asked EFSA to prioritise the MRL review under Article 12 for dithiocarbamates, cypermethrins and chlorpyrifos, chlorpyrifos-methyl and triclopyr. Given the upcoming renewal procedure (AIR-3) for these active substances and the possibility that amended endpoints are agreed or the approval is restricted or not renewed, the Commission asked the Committee to take a position as to whether these substances can be moved from the intermediate process to the future process as proposed by EFSA. The same question applies for pyrethrins for which prioritisation under Article 12 was only recently requested by a Member State. Moving substances to the future process would delay the MRL review but ensure efficient use of resources. As regards chlorpyrifos, the Commission proposed to rediscuss the issue at the next meeting because the ongoing discussions in the Committee's section on Plant Protection Products – Legislation would need to be taken into account. The Commission invited Member States to send comments by 17 October 2014.

##### 2. Import tolerance requests: procedural issues

The Commission introduced its discussion paper. It invited Member States to send comments by 17 October 2014.

##### 3. Quizalofop (additional point to original agenda - discussed here instead of under agenda item A.26.04)

EFSA received an application under Article 6 to modify the MRLs for propaquizafop in celeriac, parsnip, parsley root, radish, cauliflower, poppy seed, soya bean and mustard seed. It considered that since propaquizafop is an ester variant of quizalofop, it is not consistent to have two different sets of MRLs for these substances. The residue found in plants is quizalofop only. The current MRLs are not consistent with each other. The problem has so far not surfaced, because no applications to set or amend MRLs were received after the harmonisation of MRLs in 2008. EFSA proposed to include propaquizafop in the residue definition of quizalofop, because all

MRLs for propaquizafop are already covered by the existing MRLs for quizalofop, except for poppy seed. At the same time, the column for propaquizafop should be deleted from the Annexes to Regulation (EC) No 396/2005.

A Member State enquired on the impact of EFSA's proposal in light of the Evaluation Report for the MRL review under Article 12 that it made available in December 2012. EFSA replied that the review did not progress because information on a certain variant was still missing from the Evaluation Report.

EFSA clarified that the analysis for propaquizafop is done for propaquizafop-acid, which is quizalofop. This was also the case for all residue trials submitted in support of propaquizafop MRLs.

The Commission invited Member States to send comments by 17 October 2014.

#### 4. Changes of residue definitions for risk assessment under Art. 12 (UK request)

The United Kingdom raised the question, where and how an amended residue definition for risk assessment should be formally agreed, and with which lead-in time it should be implemented. The Commission invited Member States to send comments by 17 October 2014.

#### 5. Involvement of TCs in Art. 12 procedures at early stage (additional point to original agenda)

The Commission raised the issue of an earlier involvement of third countries in the MRL review under Article 12, e.g. to ensure timely data submission to include good agricultural practices outside the European Union (EU). It invited Member States to send comments by 17 October 2014.

### **A.03 Cumulative risk assessment - State of play:**

1. Follow up on ACROPOLIS (Aggregate and Cumulative Risk of Pesticides: an on-line integrated strategy)
2. Data sharing-feedback from MS
3. Electronic WG (priorities proposed in the WD for the eWG)

The Commission informed the Member States on the further developments as regards a possible follow up project to Acropolis from Commission side. Under this project, support from the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) to the e-working group could be foreseen. Also EFSA is currently negotiating with RIVM on a follow up project for the implementation of cumulative exposure assessments and the improvement of the accessibility, transparency and capacity of the tool.

An overview was given of the Member States that gave their consent for the use of their consumption and monitoring data by the e-working group on cumulative risk assessment (CRA) for making test cases to assess the impact of certain parameters on the outcome of the CRA calculations.

In Rev. 2 of the 'Working Document on the risk management aspects related to Cumulative Risk Assessment', comments from the members of the electronic working group were implemented. This document lists and prioritises questions on CRA that need to be answered by risk managers. Member States were asked to share their point of view as regards the answers to these questions by 17 November 2014.

#### **A.04 Update on chlorate.**

The Commission reported on the monitoring guideline that it circulated for the collection of monitoring data by 31 December 2014 and its mandate to EFSA for a Scientific Opinion by 30 April 2015. It further reported on stakeholders' efforts to reduce residue levels and their monitoring data. A stakeholders' presentation is available on CIRCABC. The representative of the EU Reference Laboratories (EURLs) gave an overview of recent monitoring results, indicating a declining trend in the residue levels that are being found.

A Member State delegation proposed that a pragmatic approach for enforcement of chlorate levels in food should be followed as a provisional solution pending the risk assessment by EFSA. Given that the default value of 0.01 mg/kg in Regulation (EC) No 396/2005 does not cover the presence of chlorate due to legal uses of e.g. disinfectants and there are no indications of illegal use of chlorate as a pesticide, enforcement by Member States should not be based on this level but rather on Article 14 of Regulation (EC) No 178/2002 following a risk assessment. No objections were raised by the Member States and the approach was agreed by the Committee as a provisional solution until a permanent risk management can be taken based on the scientific opinion of EFSA and monitoring data.

#### **A.05 Monitoring exercise 2016-2018 and monitoring working document.**

The Commission referred to the expert meeting planned for 10 October 2014.

#### **A.06 State of play - approach for acute exposure assessment IESTI equation (International estimated short-term intake).**

The Commission referred to the responses from Member States received, following the presentation by the representative from the Dutch National Institute for Public Health and the Environment (RIVM) and chair of EFSA PPR (Plant Protection Products and their Residues) at the previous meeting of the Committee and the questions raised. It proposed to continue discussions in an electronic working group. Further information and an invitation to participate will follow by e-mail.

A Member State informed the Committee that its agency is currently assessing the impact of the discussed changes to the IESTI equation for 20 substances. It will share the outcome of the exercise once it is complete.

**A.07 Pesticide residues in conventional and genetically modified (GM) crops – proposed approach how to deal with possibly different residue definitions under Reg. (EC) No 396/2005.**

The Commission described the state of play on MRL setting for genetically modified (GM) crops and informed the Committee of its intention to transform the discussion paper into a working document that can be updated at any stage as more experience will be gained in future.

**A.08 Annex IV inclusions:**

1. State of play of Annex IV inclusions

An updated list of possible candidates for Annex IV inclusion was made available.

2. Exchange of views of the Committee on a draft Commission Regulation amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for *Trichoderma polysporum* strain IMI 206039, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strains IMI 206040 and T11, *Trichoderma harzianum* strains T-22 and ITEM 908, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma asperellum* (strain T34), *Trichoderma atroviride* strain I-1237, geraniol, thymol, ferric sulphate (Iron (III) sulphate), ferrous sulphate (Iron (II) sulphate), folic acid in or on certain products (SANCO/11632/2014)

The Commission outlined the rationale for the inclusion of the various substances in Annex IV. It proposed an amendment to a footnote indicating that the Annex IV inclusion is without prejudice to other food legislation. A Member State suggested to broaden the reference to include any other legislation, to ensure that other relevant legislation, e.g. on fertilisers, is also covered by the footnote.

The Commission invited Member States to send any further comments by 17 October 2014.

3. Follow up on discussion of possible inclusion of *Bacillus thuringiensis* species in Annex IV to Regulation (EC) No 396/2005: overview of comments received by MS and next steps

The Commission received information from several Member States and made it available on CIRCABC. A Member State commented that more information on incidences is needed. The Commission asked that it should be specified which kind of further information is still sought. Another Member State is reanalysing the pertinent *Bacillus thuringiensis* strains and will provide information by the end of 2014. A third Member State asked that the mandate to EFSA include the question if enterotoxins can build up to levels that are relevant for human health. The Commission invited Member States to provide possible additional information to serve as background documentation for a possible mandate on the subject to EFSA by 17 October 2014.

#### **A.09 Data protection and Art. 12.**

The Commission was asked to clarify if residue studies evaluated and published in the context of an MRL review under Article 12 still enjoy data protection. It referred to a specific case and the correspondence available on CIRCABC, as well as to a discussion of the topic at the Post-Annex I Group meeting on 16/17 September.

From the outset, the Commission observed that Regulation (EC) No 396/2005 does not contain any rules on data protection. Thus Regulation (EC) No 396/2005 is completely neutral. The fact that data is submitted for an MRL review under Article 12 makes this data neither protected per se, nor “unprotectable”. Under the plant protection product system, data protection is solely granted by the provisions of Regulation (EC) No 1107/2009. The general principle under Article 59 of that Regulation is that data protection applies to data submitted which is “necessary for the authorisation or an amendment of an authorisation in order to allow the use on another crop”. The status (protected/not protected) of data submitted before an MRL review under Article 12 remains unchanged by the review process. The status of data submitted following an MRL review needs to be established following the criteria of Article 59 of Regulation (EC) No 1107/2009.

On the specific case, the Commission still had questions that it will clarify with the involved parties before responding to the correspondence received.

Several Member States supported the Commission’s view. It was highlighted that data may benefit from provisions outside the framework of the plant protection product system (i.e. Article 59), such as national legislation on intellectual property.

Italy highlighted the necessity to characterise a harmonised and agreed approach in relation to the practical application of measures adopted by the Member States and outlined its view of the issue.

#### **A.10 Exchange of views of the Committee as regards maximum residue levels for azoxystrobin, benalaxyl, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products (Art. 12) (SANCO/11973/2014).**

The Commission announced its intention to present a draft on the above mentioned substances.

#### **A.11 Exchange of views of the Committee as regards maximum residue levels for carfentrazone-ethyl, ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone in or on certain products (Art. 12) (SANCO/11739/2013).**

The Commission had circulated a first draft to the Member States via e-mail and referred to the comments received that are available on CIRCABC.

As regards ethofumesate, the Commission highlighted divergent opinions on the inclusion of the parent compound in the residue definition. A Member State pointed

out that the peer review of the risk assessment for that substance in the context of the renewal procedure (AIR-3) is likely to be launched in early 2015.

As regards fenamidone, the Commission highlighted divergent opinions on the inclusion of the 2-oxo metabolite in the residue definition. The problem is that in certain processed products, such as wine, most if not all residue is present as the 2-oxo metabolite, in contrast to the situation in raw agricultural products, on which MRLs are set.

As regards fluoxastrobin, the Commission underlined that decision making in different sections of the Committee should be consistent and reminded Member States that the issue of confirmatory data on non-rat metabolites had already been conclusively addressed in the Committee's section on Plant Protection Products – Legislation. This is reflected in the Review Report of September 2012.

**A.12 Exchange of views of the Committee as regards maximum residue levels for amidosulfuron, dichlorprop-P, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (Art. 12) (SANCO/11404/2014).**

The Commission announced its intention to present a draft on the above mentioned substances.

**A.13 Exchange of views of the Committee as regards maximum residue levels for captan, flonicamid, flutriafol, folpet, metalaxyl, pirimicarb, prothioconazole, teflubenzuron in or on certain products (Art. 12) (SANCO/11481/2014).**

The Commission announced its intention to present a draft on the above mentioned substances.

**A.14 Exchange of views of the Committee as regards maximum residue levels for 2,4,5-T, barban, binapacryl, bromophos-ethyl, camphechlor (toxaphene), chlorbufam, chloroxuron, chlozolate, DNOC, di-allate, dinoseb, dinoterb, dioxathion, ethylene oxide, fentin acetate, fentin hydroxide, flucycloxuron, flucythrinate, formothion, mecarbam, methacrifos, monolinuron, phenothrin, propham, pyrazophos, quinalphos, resmethrin, tecnazene and vinclozolin in or on certain products (Annex V proposal) (SANCO/10701/2014).**

The Commission introduced the draft and presented its contents. It concerns non-approved substances. The deadline for third countries to comment on the proposal notified to WTO was extended to 2 October 2014. MRLs are proposed at the specific limits of determination (LODs) as recommended by the EU-RLs. Comments from Member States were received and taken into account for the latest revision. The Commission stated its intention to present the draft for the Committee's opinion at the next meeting. It invited Member States to send any further comments by 17 October 2014.

#### **A.15 Notifications under Article 18(4) to Reg. (EC) No 396/2005.**

There were no updates as regards this agenda item.

#### **A.16 Specific substances:**

##### 1. Phenmedipham

In the EFSA Reasoned Opinion on the modification of the existing MRL for phenmedipham in lettuce, a data gap regarding the nature of residues in leafy crops was identified.

Member States and EFSA exchanged views on whether it was appropriate to accept extrapolation of metabolism data from sugar beet leaves to lettuce, as such an extrapolation had previously been accepted from sugar beet leaves to spinach. A Member State considered that even if it could be agreed today that such an extrapolation was no longer acceptable, the previous requirements should apply to the application at hand because it was submitted before the Reasoned Opinion on the MRL review under Article 12 was published and it was decided to no longer accept the extrapolation. EFSA took the view that the earlier decision to accept extrapolation of metabolism data from sugar beet leaves to spinach was taken on the basis of a sufficiently close taxonomical relationship between these two crops, which was not the case for lettuce.

The Commission stated that it currently does not intend to present a proposal to amend the existing MRL for phenmedipham in lettuce.

##### 2. Tebufenozide

In the EFSA Reasoned Opinion on the modification of the existing MRLs for tebufenozide in various crops, lower and in some cases indicative MRLs were derived. The Commission stated that it currently does not intend to present a proposal to amend the existing MRLs on the basis of the Reasoned Opinion and will consider it following the MRL review under Article 12.

##### 3. Bupirimate

EFSA clarified that in its Reasoned Opinion on the modification of the MRLs for bupirimate in several crops, it derived provisional MRLs for some crops because only one metabolism study on melon was submitted, and guidance clearly stated that conversion factors should be derived from residue studies. It hence required residue trials conducted according to the residue definition for risk assessment. The Evaluating Member State underlined that the peer review for the active substance had already delivered a conversion factor of 3 for all fruit crops, which would allow setting permanent MRLs, and that there was no need to wait for the MRL review under Article 12. The Commission asked the Evaluating Member State to submit detailed information in writing until 17 October 2014, to consider if a risk management decision can be taken to set MRLs at next meeting.

##### 4. Tau-fluvalinate



In the EFSA Reasoned Opinion on the modification of the existing MRLs for tau-fluvalinate in various crops, a data gap regarding the toxicity of the metabolite 3-phenoxybenzaldehyde and its magnitude in processed (sterilized) commodities was identified. The applicant argued that the data gap only applies to tomatoes and not to pome fruit, peaches and apricot. The Evaluating Member State agreed with that reasoning, on the basis of existing guidance and a processing study evaluated in the framework of the approval of the active substance tau-fluvalinate. The Commission stated that it intends to present a proposal to amend the existing MRLs in pome fruit, peaches and apricot on the basis of the Reasoned Opinion.

**A.17 Screening exercise on t-MRLs in Regulation (EC) No. 396/2005 that will be expiring in 2013/2014.**

The Commission did not receive new information on the temporary MRLs (t-MRLs) for spinetoram in cherries. An MRL at the LOD of 0.05\* mg/kg will be applicable after 31 December 2014, as foreseen in Commission Regulation (EU) No 473/2012.

The Commission pointed out that for oxadixyl confirmatory data on plant metabolism and soil degradation are required to be submitted to EFSA and the Commission by 31 December 2014. There is no automatic decline of the MRLs on this date, however, re-assessment of the data may lead to modifications of the MRLs.

**A.18 Designation of MS for MRL applications.**

There were no updates as regards this agenda item.

**A.19 Extrapolation Guidance Document updating – Presentation of the draft (SANCO/7525/VI/95 - Rev. 10).**

The Commission reported that it is still in the process of analysing the comments received. A new version will be circulated at a later stage. It underlined that the scope of the current project is to update the tables in the extrapolation guidance document; it is not foreseen to revise basic rules. The Commission will invite Member States by e-mail to submit comments on the Organisation for Economic Co-operation and Development (OECD) Draft Guidance Document on Crop Field Trials - Draft September 2014 by 17 October 2014, with a view to submitting coordinated comments.

**A.20 Update on foods intended for infants and young children – delegated acts under Reg. (EU) No 609/2013.**

The Commission gave an update regarding the ongoing work on draft delegated acts to replace the current Commission Directives 2006/125/EC and 2006/141/EC.

#### **A.21 RASFF SOPS and working instructions.**

The Commission gave an update regarding the ongoing work on draft Rapid Alert System for Food and Feed (RASFF) Standard Operating Procedures (SOPs) and working instructions. It plans to discuss open points in the working instructions 2.2 (Guidelines for the calculation of consumer intake and evaluation of the risk for pesticide residues) in more detail at the next meeting of the Committee. Member States stressed the importance of achieving a harmonised approach on the topics covered by the working instructions and raised questions on the use of national consumption data vs. the current Pesticide Residues Intake model (PRIMo model) Rev. 2.

#### **A.22 ECPA position paper on fish metabolism/fish feeding studies.**

The Commission received a position paper from the European Crop Protection Association (ECPA) and comments from Norway and made both available on CIRCABC. It invited Member States to send any further comments by 31 October 2014. A Member State suggested that the Commission clarify that new requirements will only apply once guidance has been established. Another Member State indicated that it is working on a paper on the level of residues, and on general shortcomings in the system and the appropriate choice of fish species.

#### **A.23 German project on compilation of processing factors.**

Germany introduced the project that is based on the existing compilation of information on processing factors of the Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR). The planned evaluation of those data according to quality criteria is scheduled to begin in late autumn 2014. BfR developed guidance on quality criteria and asks for the input of other Member States. Germany hence invited Member States to send comments to BfR by 24 October 2014. The Commission thanked Germany for the initiative and asked whether information on processing factors available at EFSA and/or published in Reasoned Opinions would be taken into account. A Member State pointed out that frequently a range of processing factors for a substance/commodity combination exists and asked that the entire range or at least the maximum value be considered.

#### **A.24 State of play biocides.**

The Commission reported on the possible re-assignment of responsibilities between Directorates-General when the new Commission will be in place.

#### **A.25 News from EU-Reference Laboratories.**

The EU-RLs presented an update on the work on single residue methods, in particular on phosphonates, chlorate and triazole derivate metabolites. The presentation is available on CIRCABC.

## A.26 AOB:

### 1. State of play Art. 15(5)

The Commission reported on the on-going discussion in the Working Group on Commission Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin (15(5) WG) as regards a link with the coordinated control programme under Regulation (EC) No 396/2005. An explanatory footnote was proposed to clarify that only substances but not commodities should be aligned with the coordinated control programme. The Commission clarified that the wording of the footnote as currently proposed is only an example. The actual list of substances included therein will be discussed in the 15(5) WG. Member States pointed to possible difficulties due to the divergent scope of the coordinated control programme (focused on consumer exposure) and Commission Regulation (EC) No 669/2009 (risk-based), and commented on cost recovery and on release for free circulation. The Commission invited Member States to send comments by 03 October 2014. Further discussions in the 15(5) WG will take place on 10 October 2014.

### 2. TTIP

The Commission provided an update on the state of negotiations of the Transatlantic Trade and Investment Partnership (TTIP). In this context, the Commission made reference to ongoing work in multilateral, international fora, in which it and the Member States are engaged.

### 3. News on Annex I (publication, revision by linguistic experts and corrigenda)

The Commission informed the Committee of the publication of the revised Annex I to Regulation (EC) No 396/2005 on 15 July 2014, as Commission Regulation (EU) No 752/2014. It received several comments following linguistic checks. A list is available on CIRCABC. Moreover, corrections to the layout are needed even in the English language version. A Member State raised a question on the footnote regarding products or parts of the product used exclusively as ingredients for animal feed, and considered that clarification is needed as regards the application of Regulation (EC) No 396/2005 for feed.

### 4. Approach for MRL application propaquizafop

Discussed under agenda item A.02.

### 5. Guidance document on implementation of Reg. 178/2002 – request from NL

The Netherlands had sent comments with respect to the classification of non-complying products, which are available on CIRCABC. It summarised the issue and asked whether the Committee supported its view that food that does not meet the requirements of Regulation (EC) No 396/2005 (i.e. it is not compliant with an MRL) can be deemed "unfit for consumption" and thus "unsafe" in the context of Article 14 of the General Food Law (Regulation (EC) No 178/2002) with the consequence of follow up action according to Article 19 of the General Food Law. In this case the Netherlands requested an update of the guidance document on the implementation of

Regulation (EC) No 178/2002 that states that a breach of MRL without health risk renders the food neither "injurious to health" nor "unfit for human consumption". Another Member State did not agree with the Netherlands' view, as Member States can take action on the basis of the MRL non-compliance, and need not make reference to the General Food Law. The Commission stated that according to the guidance document on the implementation of the general Food Law and in particular its Article 19 should be interpreted in a proportionate way, i.e. the Article should only be applicable if there is a health risk, but not in cases of non-compliances without health risk. It invited other Member States to send information on their approach and any comments.

#### 6. New Commission – changes for the Directorate-General for Health and Consumers (DG SANCO).

The Commission informed the Committee of the Commissioner-designate and possible changes to the organisation of DG SANCO.

#### 7. MRL database – language versions

In view of the complexity of the EU Pesticide database – MRL part and recurrent technical issues, the Commission is currently reflecting on possible simplifications, including a reduction of the extent to which the MRL database is available in multiple languages. It pointed out that the active substance part of the database has always been available in English only. The Commission will gather Member States' views by e-mail or survey.

#### 8. Codex Preparation

The Commission informed Member States of the planned dates for two Council Working Party meetings to prepare a coordinated position for the Codex Committee on Pesticide Residues (CCPR) 2015 meeting: 10 March 2015 and 25 March 2015.

### **B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, chromafenozide, cyazofamid, dicamba, difenoconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products.**

The Commission introduced the draft and presented its contents.

The draft had already received a favourable opinion in the Committee on 13 June 2014. However, an incorrect document was uploaded on CIRCABC at the time. Thus, a re-voting of the draft became necessary.

Sweden stated that in the inclusion Directive of tebuconazole under Council Directive 91/414/EEC, specific provisions are set stating that the potential endocrine disrupting properties of the substance must be further investigated.

**Vote taken:** Favourable opinion.

**B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, benfuracarb, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazapyr, malathion, picoxystrobin, spirotetramat, tepraloxym and trifloxystrobin in or on certain products (Art. 10).**

The Commission introduced the draft and presented its contents.

Several MRL applications were submitted under Article 6(1) of Regulation (EC) No 396/2005:

- **1,4-dimethylnaphthalene** for the use on potatoes;
- **esfenvalerate** for the use on peppers, broccoli and lettuce;
- **ethephon** for the use on table grapes and olives;
- **fenhexamid** for the use on blueberries, cranberries, gooseberries and azarole;
- **malathion** for the use on citrus fruit, strawberries and lettuce;
- **picoxystrobin** for the use on sugar beet;
- **spirotetramat** for the use on olives for oil production;
- **tepraloxym** for the use on Jerusalem artichokes and radishes;
- **trifloxystrobin** for the use on cane fruit.

Several import tolerance applications to modify MRLs were submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005:

- **fenamidone** for the use on root and tuber vegetables of code number 0213000, bulb vegetables, tomatoes, peppers, Chilli peppers, aubergines, broccoli, Chinese cabbage, lettuce and other salad plants, spinach and similar (leaves), herbs, cardoons, celery, fennel and rhubarb;
- **imazapyr** for the use on soya bean, lentils, sunflower seed, rape seed, mustard seed;
- **malathion** for the use on apple, pears and plums.

As regards ethephon, a Member State raised the issue that residues below the proposed MRL for table grapes may already lead to significant exceedances of the acute reference dose (ARfD). While it is aware that discussions on a revision of the IESTI equation are still ongoing, the Member State felt that in this case the exceedance is of a magnitude that cannot be ignored. Other Member States supported this notion and proposed a lower MRL (e.g. the current Codex MRL of 1 mg/kg) instead of 1.5 mg/kg, justifying the deviation from standard procedure with expert judgement. Another Member State was not in favour of the proposed amendment, as it would not be consistent, and several other cases should then be considered in the same manner. One Member State pointed to information from retailers on the frequent detection of products with residues below the MRL but exceeding the ARfD. In this context, the Member State asked for PRIMo Rev. 3 to be released by EFSA and agreed in the Committee as soon as possible. The Commission postponed the

amendment of the current MRL for ethephon in table grapes, to allow for further discussion; however, it kept the proposed new MRL for ethephon in olives.

As regards fenhexamid, a Member State asked why the extrapolation from currants to cranberries, blueberries and gooseberries was not accepted by EFSA although the application rate was within 25%. EFSA clarified that the extrapolation was indeed acceptable and the Reasoned Opinion needed to be revised in this respect. The Commission included the extrapolation in its draft.

As regards carbofuran, the representative of the EU-RLs presented validation data of the analytical methods and LODs for carbofuran and other components of the residue definition. Carbosulfan and benfuracarb degrade to carbofuran under acidic conditions. Furathiocarb is more stable under acidic conditions, but degrades in alkaline conditions. If LODs for a complex residue definition comprising all degradation products are summed up, the resulting MRL will not be low enough to be sufficiently protective. The EU-RLs proposed a new residue definition: “Carbofuran (sum of carbofuran (including any carbofuran generated from carbosulfan, benfuracarb or furathiocarb) and 3-OH carbofuran expressed as carbofuran)”, which the Commission took over in its proposal. The Commission confirmed that the default MRL of 0.01 mg/kg will continue to apply to the individual components carbosulfan, benfuracarb and furathiocarb. It further confirmed that for animal commodities, 3-OH carbofuran alone is a sufficient residue definition and as such part of the draft. As the EU-RLs confirmed that 0.001 mg/kg is an achievable LOD for high water and high acid matrices, the Commission amended its proposal accordingly, in spite of concerns of one Member State on the achievability of such a low level.

One Member State voted against the draft because it had initial concerns on the chronic risk assessment for malathion. While those concerns had been addressed at the time of the vote, it was too late to change the mandate.

**Vote taken:** Favourable opinion.

**B.03 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for guazatine in or on certain products (Art. 12).**

The Commission introduced the draft and presented its contents. It had been originally included in the draft SANCO/11738/2013 that was voted at the Committee’s meeting on 13 June 2014. However, at the time the Commission had withdrawn the substance from the draft, based on requests from the Evaluating Member State, the Republic of South Africa and stakeholder associations, to allow for completion of the then ongoing evaluation of an import tolerance request on citrus.

EFSA concluded in its recently published Reasoned Opinion on the import tolerance request that the data are not sufficient to demonstrate that residues are safe. It outlined the main concerns. The Evaluating Member State stated that they do not dispute the EFSA’s conclusion.

The Commission drew Member States' attention to letters received from the applicant, the Republic of South Africa and stakeholder associations, which are available on CIRCABC.

### **Vote postponed**

**B.04 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-naphthoxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in or on certain products. (Art. 12).**

The Commission introduced the draft and presented its contents.

As regards chloropicrin, a Member State pointed to the ARfD exceedance for milk and oranges highlighted by EFSA, with the proposed MRLs at the LOD of 0.01\* mg/kg. The Commission explained that the draft is based on the LOD that was considered feasible by the EU-RLs.

**Vote taken:** Favourable opinion.

**B.05 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,3-dichloropropene, bifenox, dimethenamid-P, prohexadione, tolylfluanid and trifluralin in or on certain products (Article 12).**

The Commission introduced the draft and presented its contents.

**Vote taken:** Favourable opinion.

**B.06 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products (Article 12).**

- Update on metalaxyl
- Update on lambda-cyhalothrin

The Commission introduced the draft and presented its contents.

It withdrew metalaxyl and lambda-cyhalothrin from the draft.

As regards propargite, the Evaluating Member State referred to its evaluation sent to the Commission on 31 July 2014. On genotoxicity, the available information was considered overall to be sufficient to draw a favourable conclusion. One Member

State voiced its concern that a precedent could be set regarding genotoxicity. Member States agreed to the Commission draft to set all MRLs at LOQs, applying the multiplication factors for specific groups of crops with matrices that are difficult to analyse.

As regards metazachlor, a general discussion took place on the question of adding up LODs for constituent substances of complex residue definitions. The Commission suggested differentiating between use situations that do not lead to detectable residues, and no-use situations. In the former case, the Commission proposed to sum up the LODs, in line with EFSA's recommendations on those MRLs. In the latter case, for which no EFSA recommendation exists, the Commission proposed to set as MRL the highest LOD among the constituent substances of the residue definition, to strengthen enforcement against non-authorised uses. The implications for the assessment of monitoring data were also discussed, with EFSA using the upper bound. If MRLs were set on the basis of summed-up LODs even for no-use situations, the problem of overestimating consumer exposure would be exacerbated. Several Member States commented on the draft. The Commission suggested that the expert monitoring platform on 10 October 2014 discuss the issue, and invited Member States, EFSA and EU-RLs to send comments by 17 October 2014. On the draft to be voted (as regards MRLs for metazachlor), the Commission put forward 0.06\* mg/kg (LODs summed up) for cases specifically mentioned in the EFSA Reasoned Opinion (i.e. use situations that do not lead to detectable residues) and 0.02\* mg/kg (LODs not summed) for all other cases.

As regards paraffin oil, a Member State was informed by the food industry that it is used in food manufacturing, which may lead to residues above the LODs.

**Vote taken:** Favourable opinion.

**B.07 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for lactic acid, *Lecanicillium muscarium* strain Ve6, chitosan hydrochloride and *Equisetum arvense* L. in or on certain products.**

The Commission introduced the draft and presented its contents.

**Vote taken:** Favourable opinion.