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 12 FEBRUARY 2015 - 13 FEBRUARY 2015

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/bedbf291-64cc-42ce-820e-b1e6a2a537db*

A.01 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).

The Commission will circulate a new revision once it is available.

A.02 Exchange of views of the Committee as regards maximum residue levels for captan, flonicamid, flutriafol, folpet, indolylacetic acid, indolylbutyric acid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (Art. 12).

As regards prothioconazole in cranberries, the Commission received comments from the United States to support an increase of the maximum residue level (MRL) from 0.02* mg/kg to 0.2 mg/kg, instead of the proposed decrease to 0.01* mg/kg. The Commission invited the United States to submit an import tolerance request. This substance/commodity combination will also be discussed at the 2015 Codex Committee on Pesticide Residues (CCPR).

A.03 Exchange of views of the Committee as regards maximum residue levels for abamectin, desmedipham, dichlorprop-P, haloxyfop-P, oryzalin and phenmedipham in or on certain products (Art. 12).

The Commission introduced the draft and presented its contents.

- Abamectin

The European Food Safety Authority (EFSA) identified certain concerns in the consumer risk assessment and proposed in those cases MRLs based on fall-back good agricultural practices (GAPs).

A Member State enquired whether a pending Article 6 application on abamectin would be integrated in the Article 12 proposal. The Commission informed that this would not be the case, it will be dealt with in an Article 10 proposal. However, depending on the progress of the application, when possible, the application dates could be aligned.

A Member State enquired why a GAP for abamectin on apricots was not taken into account by EFSA. EFSA will check this.

A Member State enquired on the limits of quantification (LOQs) that are proposed for abamectin. The Commission explained that since the risk cup for abamectin is nearly full, the lowest possible LOQs proposed by EFSA were taken up in the proposal.

- Haloxyfop-P

EFSA identified certain concerns when including existing Codex MRLs (CXLs) in the consumer risk assessment and therefore recommended not to include the existing CXLs in the European Union (EU) legislation.

- Phenmedipham

EFSA indicated that insufficient data were available to derive MRL proposals and to set a residue definition for swine and ruminant commodities. However, EFSA calculated significant intakes for all groups of livestock. The Commission proposed a general approach for dealing with such cases in the Article 12 reviews.

A.04 Exchange of views of the Committee as regards maximum residue levels for guazatine in or on certain products (Art.12).

In view of the ongoing administrative review under Article 13 of Regulation (EC) No 396/2005 of the EFSA Reasoned Opinion on the modification of the existing MRL for guazatine in citrus fruits, published in August 2014, the Commission did not seek a formal opinion of the Committee on the draft at this meeting. The Commission referred to additional comments received from Member States, Third Countries, and stakeholders that are available on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC). It will circulate a revised draft by e-mail that will include amendments to the recitals to reflect the outcome of the administrative review, and the new Annex I to Regulation (EC) No 396/2005.

A.05 Extrapolation Guidance Document updating.

Point not discussed.

A.06 Rapid Alert System for Food and Feed (RASFF) Standard Operating Procedures and working instructions.

Rapid Alert System for Food and Feed (RASFF) Standard Operating Procedures and working instructions for Note Taking

The Commission informed the Committee that the Rapid Alert System for Food and Feed (RASFF) Standard Operating Procedures (SOPs) were agreed and are available on the Health and Food Safety Directorate-General website. The discussion in this section of the Committee is focused on the RASFF Working Instructions (WI) 2.2 "Guidelines for the calculation of Consumer Intake and Evaluation of the Risk for Pesticide Residues".

Further clarification is needed whether or not to notify non-compliances in the absence of risk, when the consignment originates from a Third Country. That discussion will take place in the relevant section of the Committee and its working group.

The Commission summarised the comments received and referred to CIRCABC for details. It introduced the revised draft WI and explained the amendments. Based on the comments, the key issue is to find an appropriate wording for instructions on when and how to apply the measurement uncertainty.

The Commission reminded the Committee of the detailed discussions in previous years as well as the previous meeting and urged Member States to show flexibility in order to reach an agreement.

The subsequent discussion confirmed the different views held by Member States on the application of the measurement uncertainty. An ad-hoc working group was established to further clarify the concerns and find acceptable language for the draft WI. Seven EU Member States, one country that is member of both the European Free Trade Association (EFTA) and the RASFF, and the Commission participated in the working group. Discussions in the working group were very constructive and resulted in a revised draft WI (Rev. 2) that was presented to the Committee.

While no further amendments were requested in the Committee, several Member States indicated the need to consult their analytical experts before formally agreeing to Rev. 2 of the WI. The Commission asked Member States to send written feedback by 15 April 2015. It clarified that this was not an invitation of additional comments for improvement of the text but that feedback should be limited to whether Rev. 2 is acceptable.

A.07 Procedures for routine MRL setting under Regulation (EC) No 396/2005 procedures:

1. Update from the European Food Safety Authority (EFSA) on documents presented at the 2014 Pesticides Steering Committee

EFSA referred to documents discussed at the Pesticide Steering Committee (PSC) in June 2014 that were made available for further commenting, concerning i.a. the overlap of old and new data requirements. It asked Member States if those documents can be agreed. Several Member States indicated the need for additional time to further examine the documents as well as for a discussion on the calculators, and highlighted discrepancies between templates for Conclusions and for Reasoned Opinions. It was agreed that comments would be received by the end of March 2015.

2. Updated MRL application form for note taking

The Commision presented a revised application form (revision 9). No comments were received from Member States during the meeting.

Post-meeting note: Since no written comments after the meeting were received either, the MRL application form revision 9 is considered as noted by Member States.

3. Planned revision/update of SANCO/01981/2008

The Commission identified the need to revise the document and will prepare a proposal for discussion at the Committee meeting in June 2015.

A.08 Article 12 of Regulation (EC) No 396/2005 procedures:

1. Priorities under Art. 12

The Commission referred to the updated priority table, as discussed at the Committee meeting on 24/25 November 2014, and taking into account discussions at the PSC in June 2014. For four substances, EFSA required the submission of additional information from the rapporteur Member State (RMS).

As regards imidacloprid, the RMS will submit such information only in spring 2015 due to the complex evaluation. EFSA confirmed that the substance can stay in the schedule for the interim procedure.

As regards dithianon, such information was submitted, and the substance can stay in the schedule for the interim procedure.

As regards imazalil, the RMS informed that it plans to submit such information within one month.

As regards prochloraz, the RMS awaits information from the notifier.

No additional substances were proposed for prioritisation.

2. Follow up on Art. 12 confirmatory data

A Member State enquired on the procedures for follow-up on data submitted subsequent to an Article 12 review. The Commission explained that this depended on the circumstance of the submission.

If data that was identified as missing by EFSA in the MRL review is submitted as an integral part or alongside an MRL application (Article 6), then the evaluating Member State (EMS) and EFSA will follow the usual procedures for the evaluation of the application. To ensure that the data gap overview table is maintained up-to-date, it is helpful if the EMS highlights to EFSA that the data address a data gap identified under Article 12 (ideally the applicant would highlight this at the point of submission).

If data that was identified as missing by EFSA in the MRL review is submitted outside the context of an MRL application, it further depends on the type of data. Where the data gap concerns few additional residue trials to confirm an MRL, the RMS should evaluate and report to both EFSA and the Standing Committee. The Committee could then endorse without the need to involve EFSA. Where the data gap concerns information that is more generally applicable (e.g. metabolism studies), the RMS should submit its evaluation to EFSA. The Commission will discuss with EFSA bilaterally the possibility to have a single standing mandate for this task.

3. Other issues

Point not discussed.

A.09 Specific substances:

1. Lambda –cyhalothrin

The Commission will mandate EFSA to take into account new data from the import tolerance request and revised toxicological reference values, once they are agreed in the Committee's section on Plant Protection Products (PPP) - Legislation. With the proposed toxicological reference values, 14 MRLs would no longer be considered safe. For seven of those fall-back GAPs are available, but not for the other seven MRLs. EFSA will give time during the Member State consultation to submit additional data for more fall-back GAPs

2. Thiabendazole

The Commission will mandate EFSA to take into account revised toxicological reference values as proposed in the EFSA Conclusion, once they are agreed in the Committee's section on PPP - Legislation. The evaluation of newly submitted data might be included in this mandate

3. Copper compounds

The Commission referred to an extract from the Article 12 Evaluation Report (ER) by France that was uploaded on CIRCABC for previous meeting of the Committee. The full ER is available on the EFSA Extranet. Experts on animal nutrition from Member States and the Commission will be consulted and a discussion is planned in the next Expert group on feedingstuffs in the near future. The Commission asked Member States to ensure internal coordination between the different experts, France to reflect

the outcome of that discussion in its ER, and EFSA not to start work yet on the Article 12 review to allow for another discussion in the Standing Committee. EFSA indicated that it planned to start working on the dossier in the second half of 2015. The Commission has not yet received any additional data, however data is expected to be submitted to EFSA. Also data from 2013 monitoring report will be considered, once they become available.

On wild game, the Commission received data so far only from one Member State, and encouraged the other Member States to also provide such data. A Member State referred to its Article 6 application on MRL setting for wild game and doubted that other Member States will deliver relevant data. It stressed that EFSA's assessment of the application is complete and that the chronic risk assessment is not impacted by MRL setting for wild game. The Member State asked that its application is processed further. The Commission emphasised that given the chronic risk of copper and the fact that the copper Article 12 assessment will be dealt with by EFSA very soon, it does not intend to anticipate the issue of wild game, but will include it in the Article 12 review to ensure that there will be a full overview on the substance

4. Mercury compounds

The Commission referred to revision 4 of its discussion paper. It received comments from several Member States. The paper presents two main options: setting maximum levels (MLs) under the legislation on contaminants (Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs), or setting MRLs under Regulation (EC) No 396/2005. The Commission indicated that the available database contains sufficient data for most commodities to derive MLs, even for those commodities with few samples (e.g. cocoa beans). It plans to present a proposal to the next Expert group on environmental and industrial contaminants under the Committee's section on Toxicological Safety of the Food Chain, but regularly report on the state of discussions in the section on Pesticide Residues.

Several Member States indicated their preference for option 1a as presented in revision 4 of the discussion paper.

One Member State raised concerns: (a) on the Minamata Convention as it is not yet binding, and hence it cannot be excluded that PPP and biocide products containing mercury are still produced and used, which is important for commodities imported from Third Countries; (b) on the legal situation, as the default MRL in Regulation (EC) No 396/2005 cannot be ignored, as it is a fall-back in the legal system.

The Commission reported that its Legal Service confirmed that option 1a is possible from a legal perspective. It pointed out that mercury is a very specific case, in that it is already regulated under Commission Regulation (EC) No 1881/2006, addressing levels from environmental sources. The Legal Service pointed to problems with conflicting levels set in different pieces of legislation. The Commission also pointed out that the main sources of mercury are mining activities, coal, cement, ferrous and non-ferrous metal production, etc. (see e.g. United Nations Environment Programme 2013 report). If mercury-containing PPP were still used elsewhere in the world, this would be picked up in the data analysis as in that case the levels are expected to be much higher.

The Commission invited Member States to send comments by 28 February 2015.

5. Oxadixyl

Commission Regulation (EU) No 592/2012 set temporary MRLs, pending submission of confirmatory information on plant metabolism and soil degradation by 31 December 2014. The requested data were not submitted. As oxadixyl is a non-approved active substance, this situation is likely to remain unchanged. A Member State informed the Commission that residues of oxadixyl are still detected in some products and submitted data supporting possible higher MRLs than the default for some commodities while also showing that in some cases higher than the default MRLs are no longer needed. In view of adopting a harmonised approach, the Commission invited Member States to share their monitoring data by 30 March 2015, especially those Member States with previous uses of oxadixyl.

6. Anthraquinone

The Commission referred to the recent amendment of MRLs following the Article 12 review. Stakeholders reported problems for tea, herbal infusions and spices, and wondered if processing (e.g. smoking and drying) could lead to formation of anthraquinone. The Commission considers that no such formation should occur if good practice is followed during processing. Otherwise it is the responsibility of stakeholders to demonstrate that problems persist in spite of the application of best practices. Stakeholders have studies ongoing and the results will be shared with the Commission and Member States once available.

A.10 News from the European Food Safety Authority (EFSA):

EFSA informed Member States about a request for access to documents on all data, including raw data, received by EFSA from Member States for chemical and microbiological monitoring, for all years. EFSA will contact Member States to formally inform them due to the ownership of the data.

1. Progress under Article 12 of Regulation (EC) No 396/2005

See also agenda item A.08.

Until and including 2014, EFSA finalised the Article 12 review for 185 substances. For 2015, it envisages the publication of MRL reviews on another 42 substances.

2. Progress under Article 10 of Regulation (EC) No 396/2005

In 2014, EFSA published 45 Reasoned Opinions under Article 10. In addition, some MRL applications were included in the procedures for the renewal of the approval of active substances. In total, EFSA provide recommendations on the setting of ca. 250 MRL.

As regards spirotetramat, many EU MRLs were taken over from CXLs, however the residue definitions are different between Codex and the EU. EFSA suggested seizing the opportunity of a pending MRL application to correct the affected values and bring them in line with the EU residue definition.

Several Member States and the Commission expressed agreement with EFSA's proposal, provided it is transparently presented.

3. Update on Article 43 mandates of Regulation (EC) No 396/2005

Point not discussed.

A.11 State of play- approach for acute exposure assessment IESTI equation (International estimated short-term intake).

A Member State carried out an impact assessment of the discussed changes to the International estimated short-term intake (IESTI) equation, which is available on CIRCABC. It focused on available Article 12 Reasoned Opinions where the MRL proposals are based on the Organisation for Economic Co-operation and Development (OECD) calculator, and for which acute reference doses (ARfDs) are available; this limited the assessment to 20 substances. Only few MRLs were identified where the results with respect to ARfD exceedance differed between the current and the revised IESTI equations. In general, applying the revised IESTI equations led to a higher level of protection for commodities with a variability factor of 3 and 5, and to a slightly lower level of protection for commodities with a variability factor of 7, while providing a more transparent approach for MRL setting and risk assessment. The assessment also notes that less than 1% of market samples analysed pertains to commodities with a variability factor of 7. Overall, the impact of the proposed revision is rather low in terms of identification of ARfD exceedances. The Commission invited Member States to send comments by 15 April 2015.

A.12 Approach for summing up limits of quantifications (LOQs) for substances with complex residue definitions.

In Rev. 0 of this paper it was explained that for MRL setting in case a use is reported LOQs are summed up by EFSA in accordance to OECD Guidance. To be consistent the same approach needs to be followed for MRLs at LOQ if there is no use reported. There seems to be general agreement on this point.

In order to achieve consistency between the MRL setting and the enforcement policy it was proposed to also sum up LOQs for reporting the LOQ value of the analytical result. Several comments were received that this approach would in certain cases, lead to problems for reporting and enforcement of residues of individual metabolites. Therefore, after discussion with EFSA in Rev. 1 a compromise solution was proposed which resolves this problem but still includes summing up of LOQs both for MRL setting and reporting. The Commission explained that the proposed approach would lead to consistency between the MRL setting and the enforcement policy. Furthermore it is supported by EFSA and would be in line with the approach that is currently followed by EFSA for the exposure assessment.

Some Member States could support this proposal. However several Member States could not agree on the way in some cases the analysis result for the full residue definition is proposed to be calculated. A Member State indicated that in case of changes in the way the results need to be reported, a sufficient transitional period should be foreseen.

The Commission indicated that a way to avoid problems for reporting and enforcement would be not to report a sum LOQ for the sum result and to report on a mandatory basis, all individual components that are measured separately together with their individual LOQ. Instead of reporting an LOQ for the sum result of the measured residues, then a simple reference could be made to the individual LOQs that are reported. A few Member States indicated they would be in favour of such detailed reporting for all analysed components. For EFSA such an approach would bring along additional work on data processing. As no agreement could be reached the Commission will discuss with EFSA on possible alternative proposals.

A.13 Codex Committee for Pesticides Residues (CCPR) 2015 – state of play of preparations.

EFSA and the Commission reported on the status of the preparations and the planned steps for the coming weeks. The Commission underlined that all Member States are invited to send comments on the draft position for all substances, but that it counts in particular on the RMS to closely scrutinise the draft position for those substances for which they are rapporteur. It also announced a possible change in date of the first Council Working Party from 10 to 11 March 2015, pending confirmation from the General Secretariat of the Council.

The Commission enquired if the Netherlands plan to continue to chair the electronic working group on crop grouping. The Netherlands replied that in the absence of the key expert for this topic, the United States as current co-Chair will have to assume greater responsibility.

A.14 Screening exercise on t-MRLs in Regulation (EC) No. 396/2005 that will be expiring in 2013/2014.

The Commission outlined the latest updates of the screening table.

A.15 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

The Commission informed the Committee that no substances have been added to the table

2. Exchange of views of the Committee as regards inclusion into Annex IV to Regulation (EC) No 396/2005 of capric acid, Paraffin oil/(CAS 64742-46-7), Paraffin

oil/(CAS 72623-86-0), Paraffin oil/(CAS 8042-47-5), Paraffin oil/(CAS 97862-82-3), lime sulphur and urea (SANTE/00108/2015)

The Commission introduced the draft and presented its contents. The Commission invited Member States to send comments by 13 March 2015.

3. Follow up on discussion of possible inclusion of Bacillus thuringiensis species in Annex IV to Regulation (EC) No 396/2005: next steps.

The Commission drafted a mandate to EFSA, on which it received written comments from one Member State. Two Member States provided feedback on the scope of the mandate. The Commission invited them to submit this feedback in writing, and all Member States to send any additional comments by 13 March 2015.

A.16 Update of the Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005.

The Commission presented an updated version based on experiences gained from discussions of proposals to include substances in Annex IV during the past year, as well as comments received from the OECD BioPesticides Steering Group on Rev. 0.

The Commission invited Member States to send comments on Rev. 1 by 15 April 2015.

A.17 Footnotes for substances in Regulation (EC) No. 669/2009.

The Commission informed the Member States that a new version of Annex I to Commission Regulation (EC) No 669/2009 will be presented for vote in the Committee's section on Controls and Import Conditions on 06 March 2015. In this new Annex I, the pesticides to be analysed in a specific commodity are not all listed anymore. Instead a footnote has been added that in any case all pesticides that are listed in the EU coordinated multiannual control programme and that can be analysed with multi-residue methods should be analysed. Additional substances that should be analysed with a single residue method or substances that are not taken up in the multiannual control programme, are listed for each commodity with a specific footnote. This approach will ensure that a wide scope of substances will be monitored in commodities subject to an increased level of official controls.

A.18 Update on foods intended for infants and young children.

The Commission informed Member States of progress on the work for the delegated acts to be established under the new legislative framework, which must be adopted by 15 July 2015. Existing MRLs from the old legislative framework will be transferred to the delegated acts. In a second step, EFSA will assess (with a longer timeline) whether the approach by which these MRLs were derived is still the most appropriate to protect consumers, i.e. infants and young children. For this step, the Commission will prepare a mandate to EFSA. A Member State asked if it was possible to submit

comments on draft mandate. The Commission agreed but needs to define the procedure internally.

A.19 Cumulative risk assessment – Feedback from first physical working group.

The Commission informed the Member States on a grant agreement it concluded with the Dutch National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM) for a follow-up project on Acropolis during 2015-2016 and gave a short description of the project. Also EFSA concluded a framework partnership agreement with RIVM for improvement of the accessibility, transparency and capacity of the tool. Furthermore RIVM will perform cumulative exposure assessments for acute effects on the nervous system and chronic effects on the thyroid.

The Commission reported from the working group meeting that took place on 23 January 2015 in Brussels. The presentations and minutes of the meeting have been circulated via CIRCABC.

In the course of 2015, additional examples will be provided and data on other cumulative assessment groups will become available in the Acropolis tool.

The Member States are asked to send their additional points of view regarding the questions in the working document by 31 March 2015.

A Member State enquired if other Member States could join future meetings of the working group. The Commission confirmed that any Member State interested in joining the working group can do so by sending an e-mail with the contact data of its experts.

A.20 Notifications under Article 18(4) to Reg. (EC) No 396/2005 .

There were no updates as regards this agenda item.

A.21 Designation of Member States for maximum residue levels (MRL) applications.

There were no updates as regards this agenda item.

A.22 Updates of the EU MRL Database.

The Commission presented the functionalities linked to the new version of the EU Pesticides Database.

A.23 AOB

1. Chlorpropham

A Member State informed the Committee on their findings of low levels of residues of this substance in potatoes from previous use in storage facilities. This problem was also noted for onions, but in that case the source is different.

2. Question from Germany as regards the application of MRLs to oil produced from sunflower cake

Germany referred to the question available on CIRCABC regarding the MRLs applicable to sunflower cake (which is a processed product with shells), while the part of the product to which the MRLs apply is the whole product after removal of shells. It considered that Article 20 of Regulation (EC) No 396/2005 cannot be used in this situation, and that Article 15 of Regulation (EC) No 178/2002 is applicable. It further pointed out that this problem may be due to a discrepancy as compared to the directives on maximum levels for pesticide residues, which may have been inadvertently introduced when Annex I to Regulation (EC) No 396/2005 was first established in 2008.

Germany and the Commission agreed to follow up on this question.

3. Routine MRL applications for aluminium phosphide and magnesium phosphide on tree nuts and coffee beans

The United Kingdom considered that there is no need to draft an Evaluation Report, as the above mentioned applications could be addressed by a previous assessment carried out by EFSA (Scientific Report (2008) 182, 1-78).

However, EFSA is of the opinion that the fumigation practices have not been sufficiently defined to allow MRL setting, in particular with regard to the withholding periods, which were not clearly described in the intended GAP.

Discussions were also held regarding the fact that the substances are also in the process of being assessed in the framework of biocides. Moreover, it was pointed out that when carrying out the Article 12 review, all relevant metal phosphides should be covered.

The Commission will further investigate on how to address the issue.

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 difenoconazole, fluopicolide, fluopyram, isopyrazam and pendimethalin 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:

difenoconazole for the use on lettuces, lamb's lettuce, scarole, rocket and basil;

fluopicolide for the use on garlic and shallots;

fluopyram for the use on apricots, peaches, plums, cane fruit, other small fruits and berries of code number 0154000, other root and tuber vegetables of code number 0213000, aubergines, scarole, spinaches, witloof, beans (without pods), peas (with pods), linseed, poppy seed, mustard seed, gold of pleasure, herbal infusions (dried roots), hops, spices (roots or rhizome), chicory roots;

isopyrazam for the use on tomatoes, aubergines and cucurbits;

pendimethalin for the use on carrots, celeriac, horseradish, parsnips, parsley root, salsify, swedes, turnips, root and rhizome spices, chicory roots.

As regards the use of fluopyram on apricots and chicory roots, the submitted data were not sufficient to set new MRLs. The use of difenoconazole on lettuce and rocket does not require a modification of the existing MRLs. As regards the use of pendimethalin on root and rhizome spices, the evaluating Member State confirmed that there are no authorised uses on those crops. The existing MRLs should therefore remain unchanged.

As regards fluopicolide, EFSA assessed an application with a view to setting an MRL for onions resulting from EU uses and gave a reasoned opinion on the proposed MRL. In accordance with the existing EU guidelines on extrapolation of MRLs, it is appropriate to set that MRL value of 0.3 mg/kg for garlic and shallots.

As regards fluopyram, the applicant clarified that the GAP on peaches refers to both Northern and Southern EU. Moreover, it provided further information outlining the experimental designs and the GAP on cane fruit. In view of this, the Committee agreed to set MRLs at the level of 1.5 mg/kg for peaches and 3 mg/kg for cane fruit. The Commission clarified that the reasoned opinion does not need to be amended to reflect the risk management decision. Moreover, it clarified that for fluopyram and pendimethalin the proportionality principle was applied as agreed in previous meetings of the Standing Committee and at Codex level.

Vote taken: Favourable opinion.

B.02 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II and III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, dimoxystrobin, fluroxypyr, methoxyfenozide, metrafenone, oxadiargyl and tribenuron in or on certain products (Art. 12)

The Commission introduced the draft and presented its contents. No further comments were received.

Vote taken: Favourable opinion.

B.03 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (Art. 12)

The Commission introduced the draft and informed the Committee of the changes made to Rev 0.

As regards trifloxystrobin, a Member State indicated that it has a GAP in place for olives for oil production, which was not reflected in the GAP table in the reasoned opinion. EFSA acknowledged the need of republishing the opinion with an amended GAP table but indicated that this would not have an impact on the final conclusions regarding the MRL for olives for oil production. As no residue trials matching the GAP for olives for oil production are available to EFSA, EFSA is not able to derive an MRL for this commodity. The Commission confirmed that in such cases the MRL is proposed to be reduced to the LOQ. Even if these data were made available now, it would not be possible to take them into account at such a late stage. However they can be submitted in an application under Article 6 of Regulation (EC) No 396/2005.

As regards kresoxim-methyl, the Commission explained why a metabolite different from the one proposed by EFSA was included in the proposed residue definition.

As regards thiacloprid, a Member State pointed to ARfD exceedances for various commodities using the IESTI equation with the MRL and its own consumption data. The concerned consumption data are not taken up in the EFSA Pesticide Residue Intake Model (PRIMo) Rev. 2. The Member State asked for the planned timing for update of the PRIMo to include the latest consumption data. The Commission clarified that, awaiting the outcome of the discussions on the review of the IESTI equation, the current agreed approach is to calculate the acute risk by introducing the highest residue in the IESTI equation. EFSA supported the Commission's view and reported that work is ongoing on PRIMo Rev. 3. EFSA intends to inform Member States at the Committee meeting in June 2015 on concrete timelines for the implementation of this new version of the PRIMo.

A Member State voted against the proposal as it considers that the current MRL for olives for oil production could be maintained because it does not present a health risk to consumers and because it could be defended on the basis of an extrapolation from the residue trial results for table olives.

Vote taken: Favourable opinion.

B.04 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 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 and sucrose in or on certain products

The Commission introduced the draft and presented its contents.

A Member State did not agree with the Commission's view that it can be excluded that the Trichoderma strains, included in the proposal, present a risk for consumers, based on the EFSA conclusions on the peer review of these active substances, and regarded it too early to take a decision on inclusion in Annex IV to Regulation (EC) No 396/2005.

A Member State indicated that footnote 2 should also apply to feed additives and should apply to all substances included in Annex IV.

The Commission explained that the proposed wording of footnote 2 already includes feed additives, through reference to the feed legislation, even if feed additives are not specifically mentioned. The application of footnote 2 to all substances included in Annex IV can be taken up with next proposal on Annex IV.

Two Member States consulted their experts in their respective authorities and/or representatives in the Committee's section on PPP - Legislation and are now in a position to support the Commission's proposal.

A Member State voted against the proposal as currently no definitive toxicological risk assessment is available and it considers it too early to include the Trichoderma strains in Annex IV.

Vote taken: Favourable opinion.

B.05 Exchange of views and possible opinion of the Committee on a draft Commission Implementing Regulation concerning a coordinated multiannual control programme of the Union for 2016, 2017 and 2018 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

The Commission introduced the draft and presented its contents.

A Member State referred to its written comment that for some substances the residue definition for processed commodities differs from the one for raw commodities. The Commission is aware of this problem, however, before Annex VI will be established, there is no legal basis for including such residue definitions in the EU coordinated multiannual control programme.

A Member State requested support from the EU Reference Laboratories regarding single residue methods for two substances. Furthermore it requested an update on the development of improved analytical methods for the dithiocarbamates in commodities with a high CS2 background. Such method should be made available as soon as possible so that the concerned pesticide-commodity combinations can be taken up

again as soon as possible in the multiannual control program. The Commission will consult the EU Reference Laboratories on both items.

Vote taken: Favourable opinion.