EUROPEAN COMMISSION

HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

sante.ddg2.g.5(2016)2061075

SUMMARY REPORT OF THE STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED HELD IN BRUSSELS ON 22 FEBRUARY 2016 - 23 FEBRUARY 2016

(Section Phytopharmaceuticals - Pesticides Residues)

CIRCABC Link: *https://circabc.europa.eu/w/browse/64858c51-f501-44d5-81d5-9e06d95815ea*

A.01 Exchange of views of the Committee as regards maximum residue levels for acrinathrin, bifenthrin, carbetamide, cinidon-ethyl, fenpropimorph, metalaxyl and triflusulfuron in or on certain products (Article 12).

A draft document will be provided by e-mail in March 2016.

A.02 Exchange of views of the Committee on a working document on maximum residue levels for chlorate in or on certain products (Article 16).

The Commission informed that it is currently in the process of consulting the hierarchy on how to adequately address the problem of chlorate residues in food, including the possibilities of further discussing the issue in the context of the legislation on drinking water and/or food hygiene. Any possible legal proposal arising from these discussions would be accompanied by a stakeholder consultation in which the opportunity would be given to stakeholders to comment and submit further data. More data is needed on processed products and on food for infants and young children. In order to allow an efficient evaluation and summary of the data, they should preferably be submitted under the European Food Safety Authority (EFSA) Standard Sample Description (SSD) format. However, data submitted under other formats will also be considered.

The Commission informed the Member States on a paper describing the uptake of chlorate by tomatoes as a result of the use of chlorine disinfectants in the water circulation systems for soilless growing systems. Residues up to 0.25 mg/kg were quantified in tomatoes. It is described that these uses aim at protecting crops from phytosanitary problems. As sodium hypochlorite is approved as a pesticide, it would be interesting to get a view on the authorisations that are in place in the different Member States. In order to decide whether the Article 12 review of sodium hypochlorite should be prioritised, Member States are requested to send information on authorisations for plant protection products (PPP) and biocidal uses of chlorine disinfectants to the Commission and EFSA by 31 March 2016.

A.03 Exchange of views of the Committee as regards maximum residue levels for cymoxanil, fenpyroximate, phosphane and phosphide salts, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolatein and triadimenol in or on certain products (Article 12).

The Commission gave an overview of the proposal and explained its intention to circulate the first draft via e-mail for comments and to present it for vote during the Committee meeting of 16/17 June 2016. The Commission discussed the Codex maximum residue levels (MRLs) and residue definitions for fenpyroximate and triadimenol, and EFSA shared its point of view on these matters. The Member States are asked to comment by 4 March 2016.

A.04 Exchange of views of the Committee as regards maximum residue levels for aclonifen, deltamethrin, fluazinam, methomyl and sulcotrione in or on certain products (Article 12).

The Commission gave an overview of some major points of the proposal and explained its intention to circulate the first draft via e-mail for comments and to present it for vote during the Committee meeting of 16/17 June 2016. It highlighted concerns identified for deltamethrin as described in a letter from the applicant. The Member States were asked to comment by 18 March 2016.

A.05 Exchange of views of the Committee as regards maximum residue levels for hexachlorobenzene in or on certain products (Article 16).

The Commission explained that hexachlorobenzene (HCB) is a fat soluble persistent organic pollutant that is expected to mainly occur in the fat part of meat rather than in the muscle part. As currently the same MRLs are in place for both muscle and fat, it would be appropriate to lower the MRLs for muscle. Furthermore, the Commission drafted a proposal for also lowering other MRLs based on the most recent monitoring data and limits of quantification (LOQs) that were reported to EFSA.

A Member State enquired for the justification of the proposed MRLs for eggs and honey. For eggs the MRL was proposed at the LOQ that can be achieved by the majority of the laboratories. For honey, taking into account findings and analytical capability, indeed a lower MRL of 0.01* mg/kg could be considered. Member States are invited to comment on the proposal by 1 April 2016.

A.06 Substances for which Limits of Quantifications (LOQs) need to be increased in line with the working document on the summing up of LOQs.

The Commission explained that in line with document SANCO/12574/2014 Rev 5, it would be appropriate to increase the MRLs set at the LOQ for certain substances in case no use is authorised. A Member State drafted a first list of substances that would qualify for such a proposal. The Commission commented on this list and requested Member States to further comment by 1 April 2016.

A.07 Procedures for routine Maximum Residue Levels (MRLs) setting under Regulation (EC) No 396/2005 procedures:

1. Planned revision of SANCO/01981/2008 - State of play

The Commission prepared a document outlining the MRL setting procedure in accordance with Articles 6 to 11 of Regulation (EC) No 396/2005 and Article 8 of Regulation (EC) No 1107/2009 (SANTE/10595/2015).

The intention is to provide clarity on the various steps involved in the procedure for interested stakeholders (Member States, applicants, third countries, etc.) on the timelines and on specific circumstances related to the MRL setting process. Once the document is agreed upon by the Standing Committee, it will be uploaded on the website of the Commission's Directorate-General for Health and Food Safety (DG SANTE).

The Commission invited Member States to send comments by 31 March 2016.

2. Other

Not discussed.

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

1. Priorities under Article 12

The Commission informed that the Excel table setting out priorities for the Article 12 review had been updated and that there were only two open points for discussion: buprofezin and sodium hypochlorite. For buprofezin, discussions in the Committee's section on Plant Protection Products (PPP) Legislation are currently ongoing on possible use restrictions. This follows the confirmatory data assessment that highlighted an issue with the metabolite aniline, a genotoxic metabolite that can be produced during high temperature processing. The Commission suggested waiting for the outcome of discussions in the section on PPP Legislation before deciding on possible prioritisation. The possible prioritisation of sodium hypochlorite was discussed in the context of point A.02 on chlorate. For bitertanol, EFSA informed the Committee that the EFSA Article 12 Reasoned Opinion was finalised. EFSA also clarified that for metam/dazomet, it was concluded in the Committee's meeting of 21/22 September 2015 that it should be handled under the interim procedure but without additional prioritisation.

2. Handling of confirmatory data

The Commission presented a Working Document on the basis of the discussions held at the Committee meeting of 30 November/1 December 2015. It also incorporated some points regarding analytical standards from a separate document, in order to consolidate such information in a single document. The Commission invited Member States to send comments in writing by 31 March 2016, in view of note taking of the document at the Committee meeting of 16/17 June 2016.

Some of the footnotes that were set during the Article 12 review regarding missing analytical standards have expired in the meantime. For benthiavalicarb, chlorpropham, fenpropidin, pymetrozine and thiobencarb the concerned standards have not yet been made commercially available. The Commission will now send the applicants of those substances a letter reminding them of this obligation. If the standards are not available 3 months after that letter was sent, the concerned MRLs will be lowered to the LOQ.

3. Communication with Third Countries

The Commission introduced a draft note to third countries' authorities to inform about the Article 12 reviews and how, and in which stages of the procedure, third countries can actively participate in the process. The note will be notified to the World Trade Organisation (WTO) under the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and published on the DG SANTE website. The Commission invited the Member States to comment on the draft note by 4 March 2016.

4. Other issues

Not discussed.

A.09 News from the European Food Safety Authority (EFSA):

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

For about half of the substances (250 substances) the Article 12 review is finalised. Eight evaluations are currently ongoing. 37 evaluations are still to be done under the interim procedure, 120 under the future procedure. Besides that, EFSA works on about 100 potential candidates for Annex IV inclusion. For some of them, the Article 12 review will not be necessary. The Pesticide Residues Overview File (PROFile) has been revised to include the Organisation for Economic Cooperation and Development (OECD) livestock feeding tables. EFSA works on further exchanges with the European Union Reference Laboratories (EURLs) to give their input early on, i.e. at the stage of the completeness check, by contributing to the evaluation report with validated methods and summaries of data from the EURL data pool.

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

EFSA shared an Excel table that was distributed on the Communication and Information Resource Centre for Administrations, Businesses and Citizens (CIRCABC), showing all 47 reasoned opinions published in 2015. In total 238 MRLs were proposed, in 49 cases the stop-clock mechanism had to be used to invite further clarification/data. The main reason for this high number of clock-stops is that often information on good agricultural practices (GAPs) is not clear. EFSA considers that the information in the application form should be the reference in case of diverging information. If the GAP is changed during the evaluation, that needs to be clearly highlighted. Other reasons for clock-stops are: not enough residue trials, trials not in

line with GAP, deficient information on storage stability, lack of information on the authorisation status of the GAP in the country of origin in case of import tolerances.

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

EFSA informed that work on two mandates is currently ongoing: the mandate on thiabendazole and on the scientific support for preparation of the EU position for the Codex Committee on Pesticide Residues (CCPR).

A.10 Specific substances:

1. Mercury

The Commission representative in charge of the Commission's expert group on industrial and environmental contaminants informed about the state of play of the discussions in this group. A detailed working document with proposals for maximum levels (MLs) for different food groups was shared with the Committee. Main areas of discussion in the contaminants expert group are the MLs for fish, national consumption advice to be given by Member States' competent authorities and to be distributed e.g. through national professional health channels, MLs for wild boar, MLs for mushrooms, in particular of the species "boletus" as well as on tree nuts and oilseeds. Following the discussions at the Committee's meeting on 30 November/1 December 2015, maximum residue levels for foods for infant and young children were also introduced. The proposal is a key deliverable for the year 2016 and is scheduled for vote in the third or fourth quarter of 2016.

Germany referred to its earlier reservations on the fact that the default levels would be removed by this proposal wherever the Regulation setting MLs for contaminants in food would not propose any specific level. It wondered why in this case the column for mercury was kept in the Regulation (EC) No 396/2005 and whether the default level of 0.01 mg/kg was still applicable to foods for infants and young children. The Commission replied that the proposed approach had been discussed in detail with its Legal Service and been found appropriate and that for foods for infants and young children a maximum level of 0.01 mg/kg would be specifically set in the contaminants legislation to avoid any legal ambiguity.

2. Acetamiprid

At the meeting of the Committee's section on PPP Legislation of 28/29 January 2016, it was formally agreed not to endorse the toxicological reference values that were derived by EFSA in the framework of the Scientific Opinion on the developmental neurotoxicity potential of acetamiprid and imidacloprid. The situation will be reviewed when renewing the approval of the active substance, taking into account all available data submitted in that framework.

3. Cyantraniliprole

A reasoned opinion on the setting of MRLs in various crops was recently published. The Commission intends to present a draft act regarding those MRLs once the active substance is approved under Regulation (EC) No 1107/2009.

4. 3-decen-2-one

The active substance was recently non-approved by Commission Implementing Regulation (EU) 2016/138. In its Conclusion, EFSA did not recommend including the substance in Annex IV to Regulation (EC) No 396/2005. The Commission intends to prepare a proposal setting MRLs at higher levels than the default value with a view to addressing natural occurrences of the substance.

5. Tricyclazole

The Committee was informed that a draft act proposing non-approval under Regulation (EC) No 1107/2009 is planned to be presented for an opinion at the Committee's section on PPP Legislation. If the proposal receives a favourable opinion, it will have an impact on the current MRL on rice, which was set to accommodate an import tolerance request.

6. Fluopyram

Temporary MRLs were set by Regulation (EU) No 1004/2013, pending data submission on rotational crops. Several applications were submitted addressing a set of those crops. For efficiency purposes, EFSA will assess the various applications in the framework of a single reasoned opinion.

7. Chlorpropham

The Commission received a letter from Freshfel, highlighting problems with cross-contamination in various commodities after the lowering of LOQs in 2014. The Commission elaborated on the situation while also taking into account written and oral comments of Member States from last meeting.

One Member State requested postponement of the application of the lowered LOQs.

Some Member States indicated that the decision to lower LOQs should not just be based on analytical capabilities but should also consider problems that may occur.

One Member State stated that volatility is a problem of certain substances and that concerns with cross-contamination can be addressed via conditions on authorisation, and by optimising formulations. Possible problems will first occur on certain crops (e.g. parsley, cabbage).

The Commission does not see a necessity to amend the LOQs for chlorpropham as the problem should be contained with Good Agricultural Practices in order to avoid cross-contamination.

8. New active substances currently under discussion in the Legislation Committee

The Commission announced two new substances for which the discussion started in the Committee's section on PPP Legislation: Saccharomyces cerevisiae strain LAS02 and Bacillus amyloliquefaciens strain MBI 600.

The Commission informed the meeting of ongoing discussions with EFSA on a procedure to follow-up on changed residue definitions and toxicological reference values for substances after (Annex I Renewal Project) AIR II and AIR III review. The Commission will present this procedure in the next meeting.

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

See agenda item A.12.04.

A.12 Codex Committee for Pesticides Residues (CCPR):

1. State of play on ongoing work in the electronic Working Group (eWG) on the Classification of Foods and Animal Feeds and Priorities

The Commission informed about the state of play of ongoing Codex activities. On the classification of foods and animal feed, a coordinated reply was sent to the eWG in January 2016. Once a new document from the eWG becomes available, a draft co-ordinated position will be prepared by the Commission for discussion with Member States in the Council Working Party on 14 March 2016.

On priorities, general comments, the Commission outlined the draft comments prepared in view of the discussions at the Council Working Party on 14 March 2016. It underlined that the shift towards periodic reviews proposed by the eWG on Priorities was a step in the right direction but did not go far enough. One Member State suggested taking a stricter approach on substances that remain unsupported for several years, and delete/withdraw those substances and the corresponding Codex MRLs. The Commission asked Member States to provide written comments by 4 March 2016.

On priorities, specific substances, the Commission outlined the draft comments prepared in view of the discussions at the Council Working Party on 14 March 2016. It underlined that all the compounds suggested by the EU were now listed in the schedule for 2021, but that a discussion was needed whether there is a need to advance specific substances to an earlier schedule on the basis of the criteria for prioritisation discussed at the Committee meeting of 30 November/1 December 2015. In order to facilitate such discussion, the comprehensive Excel table containing detailed information on relevant substances was updated. The Commission proposed amitraz as a possible candidate for earlier scheduling and asked the respective Rapporteur Member States for the substances kresoxim-methyl, oxamyl, clethodim and fenpyroximate for more detailed information on those substances, currently scheduled for 2017. The Commission asked Member States to provide written comments by 4 March 2016.

2. Work organisation for the preparation of CCPR

The Commission informed the Committee that only one substance (quinclorac) remains that is not approved in the EU and for which there is no Rapporteur Member State (RMS). France volunteered to pay particular attention to this substance during the Council Working Parties and the CCPR.

Following two sub-points added to original agenda:

3. General section of JMPR Report

Comments on the general section (section 2) of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Report have already been provided by EFSA. The Commission invited the Member States to submit further written comments on section 2 by 4 March 2016 with a view to preparing a draft coordinated position for the Council Working Party on 14 March 2016.

4. IESTI equation

Comments on the general section (section 2) of the JMPR Report, including on the International Estimate of Short-Term Intake (IESTI) equation, have already been provided by EFSA. The Commission invited the Member States to submit further written comments by 4 March 2016 with a view to preparing a draft coordinated position for the Council Working Party on 14 March 2016. A working group of several Member States and Australia looked into the impact of the amendments to the IESTI equation proposed by the workshop in Geneva in September 2015. The outcome of that analysis may already be available for the 2016 CCPR meeting. Moreover, a side event at CCPR 2016 on the IESTI equation is in preparation.

A.13 Screening exercise on t-MRLs in Regulation (EC) No. 396/2005 that will be expiring in 2016.

The Commission gave an update on the state of play and informed that further discussions will take place on nicotine and profenphos in herbs for which there is a deadline of 19 October 2016 for data submission. EFSA will be requested to extract monitoring data for the relevant substance/commodity combinations.

A.14 Inclusions in Annex IV of Regulation (EC) No 396/2005:

1. State of play of Annex IV inclusions

The Commission made an updated Excel table of the substances proposed for inclusion in Annex IV to Regulation (EC) No 396/2005 available on CIRCABC. It explained its intention to circulate a new proposal via e-mail for comments and to present it for vote during the Committee meeting of 16/17 June 2016. This new proposal will include the substances diammonium phosphate and whey if approved as basic substances in the Committee's section on PPP Legislation of 9 March 2016. The Commission explained some details regarding the no residue situation for whey as it contains the allergen lactose.

2. Follow up on discussion of possible inclusion of Bacillus thuringiensis species: update on the state of play.

An EFSA working group met in January 2016 during which industry was given the opportunity to answer questions from the panel members. Work is still ongoing. The next meeting of the working group is planned for March 2016. Publication of an opinion is expected by the end of June 2016.

A.15 Update on foods intended for infants and young children.

Two delegated acts were published very recently, Commission Delegated Regulation (EU) 2016/127 on infant formula and follow-on formula, as well as Commission Delegated Regulation (EU) 2016/128 on food for special medical purposes. The draft delegated act on processed cereal based foods and foods for infants and young children was rejected by the European Parliament due to concerns over food composition requirements. A new EFSA evaluation on food composition is envisaged.

A.16 Follow up from the Post Approval Issues Working Group (PAI).

The Commission explained the way of working of the Post Approvals Issues Working Group (PAI WG). The PAI WG holds regular meetings of which from now onwards regular feedback will be provided both to the Committee's sections on PPP Legislation and Pesticide Residues. A Member State questioned the appropriateness of putting certain items on the agenda of the PAI WG. The Commission clarified that the PAI WG has a purely consultative role and that currently the mandate of this group was further defined. The Commission sees the role of the PAI WG in providing input on matters for which the Member States have the responsibility, e.g. defining best practices or enhance harmonisation where no EU rules or guidance exist. The Commission also clarified that the applicability of the OECD feedingstuff tables was not put into question as the Committee agreed to the use of these procedures in September 2015, and it was decided to use them from 1 October 2015 onwards.

A.17 Cumulative risk assessment: outcome of second physical meeting CRA working group.

The Commission gave an update on the joint EFSA-RIVM (Rijksinstituut voor Volksgezondheid en Milieu, the Dutch National Institute for Public Health and the Environment) - Commission communication action on cumulative risk assessment (CRA) that took place on 27 January 2016 and on the second physical working group meeting on CRA of 22 January 2016. The outcome of the discussions in the working group will be summarised in Rev. 6 of the working document on risk management aspects related to the assessment of cumulative exposure, that will be presented during the Committee meeting of 16/17 June 2016. Additional comments on the answers to the questions in this document can be sent by 4 April 2016.

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

Austria notified an administrative ordinance, dated 12 February 2016, in which a national temporary MRL for thiacloprid in honey of 0.2 mg/kg is set until a revised EU MRL becomes applicable. See also agenda item A.24.4.

A.19 Designation of Member States for maximum residue levels (MRL) applications.

France received an application for an amendment of MRL(s) for chlorantraniliprole, however the RMS is Ireland. As the evaluation has already started, France is prepared to continue with that evaluation. Ireland agreed to this, and no objections were raised from other Member States.

A.20 Information on ongoing work on endocrine disruptors and substances falling under the other cut-off criteria.

The Commission provided an update on the state of play on endocrine disruptors (ED). The process is now at its final stage: the supportive work for the impact assessment is nearly finalised, the screening of ca. 600 chemicals against four options outlined in the roadmap is finalised and the impacts assessed for different areas. The Commission mentioned the court ruling on the case filed by Sweden against the Commission: the Commission took note of the court judgement, intends to comply with the judgement but will finalise the impact assessment to allow for an informed decision-making not just by the Commission, but also by all other actors, including Member States and the European Parliament. The Commission will present the criteria before the summer 2016 for PPP in a Commission Regulation and for biocides in a delegated act. It intends to present the same criteria for both PPP and biocides. The Commission stressed that both in the PPP and biocides areas, interim criteria for ED are in place and applicable.

A.21 Planned evaluations of Regulation (EC) No. 396/2005 and Regulation (EC) No. 1107/2009 – State of play.

Once agreed within the Commission, the final roadmap will be made available for public feedback for four weeks. The official public consultation will follow at a later stage.

The next milestone in the evaluation process is drafting the terms of reference, which will need to be discussed and agreed by the relevant services of the Commission.

A.22 Update on the state of play of MRL setting for biocides.

The Commission introduced the latest version of its proposal and recapped the proposed approach. This approach takes account of the resources available to both Member States and industry, of the need to strike a balance between these resources and the possible risk, and of the limited evidence that residues of biocidal products actually present a problem.

One Member State asked when the data on residues and analytical method would have to be presented.

The Commission responded that this was information to be submitted at the stage of product authorisation, as the approval of the active substance is based on a single representative use.

A Member State welcomed the clarification added in the document that the applicant would be expected to submit an analytical method on food or feed commodities, in which residues can be expected. It also indicated that it might send further comments as the time to study the document was limited.

The Commission explained that its intention was to finalise the discussion with competent authorities for the implementation of Regulation (EU) No 528/2012 on 16/17 March 2016, and invited further comments to be submitted through the competent authorities for biocides.

A.23 Rapid Alert System for Food and Feed Standard Operating Procedures (RASFF) (SOPs)

The Commission informed the Committee that the Rapid Alert System for Food and Feed (RASFF) Working Instructions (WI) 2.2 "Guidelines for the calculation of Consumer Intake and Evaluation of the Risk for Pesticide Residues" were recently published on the SANTE website, with only minor amendments to the text agreed by the Committee on 12/13 February 2015.

A.24 AOB

At the request of the chair, a number of points were added to the agenda under agenda item A.24.

1. Residue definitions for vinclozolin, procymidone, iprodione

The Commission intends to align as much as possible the residue definitions, which are currently set for vinclozolin, procymidone and iprodione in products of animal origin. A paper was uploaded on CIRCABC outlining the various options. For this purpose, a proposal needs to be drafted, which will be presented at a future meeting of the Committee.

The Commission invited Member States to send comments by 31 March 2016.

2. Glyphosate-residue definition for Article 12 assessment of MRLs

The Commission referred to the discussion at the Committee meeting of 30 November/1 December 2015, and the comments received from Member States, EFSA and EU-RLs. On the basis of those comments, the Commission presented a revised proposal. In the subsequent discussion, Member States and EFSA highlighted the need to balance a comprehensive monitoring with the availability of multi-residue methods and with the comparability of residue defintions between the EU and Codex Alimentarius. The Commission will follow up with further consultations, firstly with the EU-RLs and then Member States.

3. Update application form for confirmatory data

A need was identified to include a field for the assessment of confirmatory data in the MRL application form when discussing the Working Document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs (see agenda item A.08.02). The Commission presented revision 10 of the MRL application form and informed the meeting of its intention to take note of this revision at the Committee meeting of 16/17 June 2016.

The Commission asked Member States to provide written comments by 18 March 2016, if any.

4. Thiacloprid/Honey

A Member State mentioned a problem with the MRL for thiacloprid in honey, which was lowered from 0.2 mg/kg to the limit of determination (LOD) of 0.05* mg/kg by Commission Regulation (EU) 2015/1200 (applicable since 12 February 2016) since no data were provided. As honey is not part of the PROFile, the issue was overlooked by all parties. The Member State had submitted an Article 6 application and the corresponding Reasoned Opinion by EFSA was favourable. On that basis it requested to re-instate the MRL as quickly as possible because otherwise the authorisations on rapeseed would need to be withdrawn and rapeseed honey could no longer be traded. The Commission proposed to set a level of 0.2 mg/kg based on the residue trials provided and confirmed also by the existing monitoring data on thiacloprid in honey that EFSA assessed. There was broad support among Member States for the level proposed and some Member States commented that residue trials are preferable over monitoring data as they would better capture real conditions. The Commision will now prepare a draft measure and plans to put it for vote at a future meeting of the Committee, as soon as possible. It also initiated a general discussion on how it could be avoided that necessary MRLs for honey are overlooked during the Article 12 review of existing MRLs and that no data are provided although they are available. It proposed to include honey in the PROFile by default. EFSA replied hat this was only possible once a guidance document was available on how to deal with residue trials on honey. The Commission indicated that it could not take on the work on the guidance document itself, but would facilitate the discussions if a Member State would take the lead. A Member State volunteered to continue the discussion on the honey guidance document that was abandoned some years ago for formal reasons. The Commission expressed its gratitude for this support and emphasised that in the meantime all parties should be vigilant to the issue on honey. Two other substances were mentioned for which it may be necessary to check the need for a specific MRL on honey: thiophanate-methyl and boscalid.

5. HCH (Hexachlorcyclohexane)

Currently four residue definitions are in place for hexachlorcyclohexane (HCH) which leads to inconsistencies regarding certain MRLs and to errors and confusion in the Member States' reporting of monitoring data for this substance. Therefore EFSA proposed changing these residue definitions. The Commission suggested to delete the residue definition "sum of all isomers except gamma" and to only keep the separate residue definitions for the alpha, beta and gamma isomers. The possibility of adding a

separate residue definition for the delta or epsilon isomers could be discussed. A Member State was in favour of adding a residue definition for the delta isomer. When amending the residue definition, at the same time the current MRLs could be adjusted to the most recent monitoring data and LOQs. The Commission invited the Member States to comment on the proposed residue definitions for HCH by 18 March 2016.

6. Cyazofamid

Cyazofamid was found to be completely degraded to form the metabolite 4-chloro-5-p-tolylimidazole-2-carbonitrile (CCIM), under pasteurisation, boiling and sterilisation conditions. Since the available toxicological data were not considered sufficient to address the toxicological properties of CCIM, additional information is requested to conclude whether the toxicological reference values set for cyazofamid also apply to CCIM.

The Commission recently asked the RMS to liaise with the applicant to obtain further information on the toxicological profile of the relevant metabolite.

7. Legal Service opinion on MRLs for veterinary medicinal products vs MRLs for plant protection products

The Commission's Legal Service was consulted on a proposal to align certain MRLs for the substances amitraz and coumaphos to the respective MRLs already established by Commission Regulation (EU) No 37/2010 on MRLs for pharmacologically active substances in foodstuffs of animal origin. The Legal Service agreed with the use of Article 14(l)(a) as a legal basis for a proposal. However, it considers that an opinion of EFSA should be sought in order to provide a scientific basis for such a modification of MRLs.

The Commission invited Member States to send comments by 31 March 2016 as regards possible other substances that need to be covered by such a proposal and to focus on those substances not covered by the Article 12 review of existing MRLs. For substances covered by an Article 12 review, MRLs established by other food legislation (e.g. for dual use substances) are in principle considered.

8. Processing factor for cold pressed lemon oil

The Commission received from a Spanish producers' association information on processing factors for cold pressed lemon oil (CPLO). The information was shared with the Member States on CIRCABC. The Commission clarified that there are currently no harmonised processing factors at EU level and that information received by stakeholders will be shared with Member States for their comments but not endorsed.

The Spanish delegate reported that Spain produces 15% of the world production of CPLO, mainly used in soft drinks. The information received shows that high residue levels of a number of different substances in lemon oil arise due to concentration during processing. One single agreed processing factor would be preferable. A complete document with more data is under preparation.

Another delegation replied that it does not consider the setting of one single processing factor for a range of substances appropriate due to the high variability of residue behaviour of different active substances.

The Commission considers work carried out by stakeholders useful and will facilitate the sharing of information among Member States. It invited the Member States to submit written comments by 31 March 2016 and will inform the producers association of the comments received.

9. Ombudsman report on confirmatory information

A Member State requested further information on the report of the European Ombudsman on confirmatory information. The Commission advised the Member State to raise the issue in the next meeting of the Committee's section on PPP Legislation.

10. Fluopyram

The RMS informed the Committee that two updated evaluation reports on fluopyram would be finalised before the end of February 2016.

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 abamectin, acequinocyl, acetamiprid, benzovindiflupyr, bromoxynil, fludioxonil, fluopicolide, fosetyl, mepiquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products (Article 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:

- Abamectin for the use on pome fruits, cucurbits with edible peel, Chinese cabbage, "lettuces and salad plants" of code 0251000, spinaches, beans and peas with pods and celery;
- Acequinocyl for the use on cherries and plums;
- Acetamiprid for the use on leafy brassica;
- Bromoxynil for the use on chives;
- Fluopicolide for the use on blackberries, spinaches and purslanes;
- Fosetyl for the use on blackberries, celeriacs and Florence fennels;
- Mepiquat for the use on cultivated fungi;
- Propamocarb for the use on celeriacs, purslanes, chards, celery leaves and Florence fennels;
- Proquinazid for the use on currants and gooseberries;
- Tebuconazole for the use on rye and wheat.

Two applications were submitted under Article 6(2) and (4) of Regulation (EC) No 396/2005:

- Fludioxonil on pineapples;
- Prohexadione for the use cherries.

For acetamiprid, the Committee's section on PPP Legislation endorsed maintaining the current toxicological reference values. On that basis, there are no concerns on consumer health identified for the proposed MRLs on leafy brassica. Following comments by several Member States, the Commission referred to the established procedure where the section on PPP Legislation is responsible for setting the toxicological reference values and that the work within the section on Pesticide Residues must reflect those decisions.

One Member State motivated its abstention by stating that the MRL proposal for acetamiprid in the commodity group “leafy Brassicas” should have been put on hold until the different views of EFSA and the Standing Committee regarding the acute reference dose (ARfD) have been clarified. Meanwhile it could not support any MRL recommendation where EFSA identified intake concerns for European consumers on the basis of the toxicological reference values proposed by EFSA. In addition to this, it also considered that one of the recitals of the proposal should better reflect the conclusions of EFSA's reasoned opinion.

Another Member State motivated its vote against the proposal by stating that it did not find the proposed MRLs for acetamiprid in leafy brassica - Chinese cabbage and kale - sufficiently protective for the consumers. It did not support the establishment of new MRLs exceeding the ARfD proposed by EFSA as the latter may be reduced in relation to the upcoming review of acetamiprid. In addition, it also considered that one of the recitals of the proposal should better reflect the conclusions of EFSA's reasoned opinion.

As regards mepiquat, recent monitoring data show that residues occur on untreated cultivated fungi at a level higher than the LOD. Such residues result from a cross-contamination with straw lawfully treated with mepiquat. EFSA proposed three different MRLs for those products, to be considered by the risk managers, which were based on the approaches recommended by the Food and Agriculture Organization of the United Nations (FAO) respectively for the setting of MRLs in spices and of extraneous MRLs.

Member States were consulted on the risk management decision. The Commission considers it appropriate to set the MRL at the level corresponding to the 99th percentile of all the sample results. This MRL is set as temporary, valid until 31 December 2018. After this date the MRL will be 0.02* mg/kg unless further modified by a Regulation in light of new information provided by 30 April 2018 at the latest.

The Commission further clarified that the amendment brought by the current proposal was already reflected in the Article 12 proposal reported under item B 04.00 of the agenda. The MRL for cultivated fungi was recalculated to "mepiquat chloride" using a molecular weight factor of 1.31. The level was therefore proposed be set at 0.09 mg/kg.

Two Member States abstained because they did not agree with the methodology used to derive MRLs for mepiquat in mushrooms. They opined that the highest residue should have been considered.

Another Member State abstained because the delegate had not received voting instructions.

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 to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carfentrazone-ethyl, ethofumesate, etoxazole, fenamidone, fluoxastrobin and flurtamone in or on certain products (Article 12).

The Commission presented the Rev. 4 of the document and the main changes introduced. The substance carfentrazone-ethyl was removed from the proposal in consideration of its ongoing peer review. The Commission will wait for the confirmation of the endpoints by the Committee's section on PPP Legislation and then mandate EFSA to update the Article 12 Reasoned Opinion. For ethofumesate, a new residue definition has been introduced and the LOQs have been adapted accordingly.

A Member State enquired about the availability of reference standards and the validation of analytical methods for the metabolites introduced in the residues definitions of ethofumesate and fluoxastrobin. The Commission replied that the EURLs did not identify any problem in this regard.

Another Member State expressed concerns about the proposed LOQ of 0,01* mg/kg for fluoxastrobin. The Commission considered that it was possible to enforce this limit based on the information received.

One Member State abstained because the delegate had not received voting instructions.

Vote taken: Favourable opinion.

B.03 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 AMTT, diquat, dodine, glufosinate and tritosulfuron in or on certain products (Article 12).

The Commission outlined the comments received in the framework of the SPS notification and how they have been taken into account in the current proposal.

Several Member States submitted comments to the Commission expressing their concerns on the low values proposed for metabolite 2-amino-4-methoxy-6-

trifluoromethyltriazine (AMTT), which is resulting from the use of tritosulfuron. Moreover, the EURLs recently confirmed that analytical methods to achieve the lowest possible LOD need to be developed for AMTT.

The Commission proposed to set all MRLs at the default value except for those products for which EFSA identified a health concern (i.e. sweet corn, cereals and milk). It proposed to lower the MRLs for those products to 0.001 mg/kg. At the meeting, EFSA highlighted that there may be issues also regarding rotational crops. The Commission believes it is appropriate to address sweet corn, cereals and milk at this stage and to review the situation once the analytical methods are available. This approach was also reflected in the relevant recital of the proposal.

A Member State highlighted that MRLs were not set in the past in the Annexes to Regulation (EC) No 396/2005 and that also the default value was not applicable for the metabolite AMTT. This was reflected in the relevant recital.

One Member State abstained because the delegate had not received voting instructions.

Vote taken: Favourable opinion.

B.04 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 as regards maximum residue levels for 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim in or on certain products in or on certain products (Article 12).

The Commission introduced the draft and presented its contents.

Comments were received from the United States and Syngenta on the MRL proposals for several crops. The Commission explained that since in all these cases the data supporting these MRLs had not been submitted to EFSA prior to the drafting of the reasoned opinion, they could not be taken into account. However, if the concerned MRLs are considered necessary, an application can be made under Article 6 of Regulation (EC) No 396/2005.

A Member State enquired about the possibilities of consulting applicants regarding the GAPs that are notified under the Article 12 review. Due to workload restraints, EFSA considered a third party consultation not an option and pointed to the responsibility of Member States to ensure that all the necessary GAPs are notified to EFSA.

A Member State commented on the LOQs proposed for fuberidazole and mepiquat. The Commission explained that these MRLs were based on the most recent scientific information, received from the EURLs.

One Member State abstained because the delegate had not received voting instructions.

One Member State abstained to be consistent with its vote on the draft act presented under agenda point B.01 (where it did not agree with the methodology used to derive MRLs for mepiquat in mushrooms).

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 2017, 2018 and 2019 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.

A Member State requested an additional footnote regarding the sampling of fat. The Commission explained that the provisions listed in Directive 2002/63/EC are sufficiently clear.

A Member State requested an evaluation of findings in all commodities to be analysed for substances that are determined with single residue methods, with the aim of assessing the relevance of such pesticide-commodity combinations in the EU multiannual control progarmme. The Commission explained that a general review would not be possible due to resource restraints. However, comments on specific pesticide-commodity combinations can be discussed in the 2016 expert group on pesticide residue monitoring.

A Member State requested to amend the footnote for husked rice grain that states that 'where appropriate polished rice can be analysed'. It proposed to indicate that only polished rice should be sampled when it was not possible to sample husked rice. The Commission explained that the proposed phrasing was agreed during the Committee meeting of 30 November/1 December 2015 because in some Member States husked rice is hardly consumed.

A Member State proposed some editorial changes that were included in revision 5.

One Member State abstained because the delegate had not received voting instructions.

Vote taken: Favourable opinion.

B.06 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 *Streptomyces* K61 (formerly *S. griseoviridis*), *Candida oleophila* strain O, FEN 560 (also called fenugreek or fenugreek seed powder), Methyl decanoate (CAS 110-42-9), Methyl octanoate (CAS 111-11-5) and Terpenoid blend QRD 460.

The Commission introduced the draft and presented its contents. It informed the Committee of its intention to include all approved fatty acids separately in Annex IV to Regulation (EC) No 396/2005.

One Member State abstained because the delegate had not received voting instructions.

Vote taken: Favourable opinion.