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SUMMARY REPORT

A.01 Proposed general approach for granting transitional periods.

The Commission explained that the Regulations lowering or deleting maximum residue levels (MRLs) usually apply 6 months after the date of entry into force, providing already some time for food business operators to adapt to the new rules. In addition to this deferred application date, transition measures can exempt the products which were produced in the EU or imported into the EU before a given date from the need to comply with the new lowered MRLs. Such products have still to comply with the MRL previously in place. When a transition measure is introduced, it applies to all products for which information shows that a high level of consumer protection is maintained.

Member States agreed that a high level of consumer protection was not demonstrated when the international estimated daily intake (IEDI) or the international estimate of short-term intake (IESTI) exceeds the relevant toxicological reference value (the Acceptable Daily Intake (ADI) and/or the acute Reference Dose (ARfD), or when a toxicological reference value could not be established due to lack of data and consequently the consumer risk assessment could not be carried out.

One Member State suggested to follow a risk based approach and to provide transition measures even when a hazard is identified. Another Member State suggested the possibility to shorten the length of the deferred application period in cases of higher risk.

Discussions are still ongoing on the specific circumstances under which transition measures can be granted, e.g. in case of genotoxicity of the parent compound or one of its metabolites, as well as when the residue definition proposed by the European Food Safety Authority (EFSA) is provisional or when no residue definition can be proposed.

The Commission will distribute a questionnaire shortly after the meeting setting out different specific cases on which a decision is needed whether or not transitional measures can be granted. Member States are invited to comment on this document with a short deadline (29 June 2018 instead of 13 July 2018 as discussed in the meeting) in view of agreeing on an approach for the draft texts presented under C.05, C.06 and C.07 before SPS/WTO consultations are launched.

A.02 Art. 12 of Regulation (EC) No 396/2005 procedures:

The Commission received a letter from the European Crop Protection Association (ECPA) on possible improvements of the "new process" for MRL reviews under Article 12 of Regulation (EC) No 396/2005. Several Member States shared their experience with the new process. It was agreed that the topic would merit more time for discussion than possible within the agenda of this meeting. The issue will be taken up in a forthcoming meeting.
Member States and EFSA were invited to submit comments on the ECPA letter, as well as questions and observations on the new process, by 13 July 2018.

1. Priorities under Art. 12 – updated table:
   The Commission updated the table on substances prioritised under the Article 12 MRL review process and gave an overview to the Committee.

2. Substances for which the Art. 12 review follows the renewal procedure:
   There were no updates under this agenda point.

3. Confirmatory data Art. 12 follow-up:
   a. *Update of the Working Document on confirmatory data for MRL setting*
   The Commission will prepare a draft revision of the Working Document SANTE/10235/2016 on Art. 12 confirmatory data, based on suggestions received from EFSA.
   b. *Follow-up on footnotes in Art. 12 measures containing confirmatory data requirements*
   The Commission presented its planning on how to deal with open data gaps in Art. 12 Regulations for which the deadlines for submission of data have expired. Such deadlines were set in all Art. 12 measures requiring data to fill certain data gaps within two years of the date of publication of the Regulation.
   An initial screening shows that most data gaps that needed to be addressed by 2015 were addressed. For the data gaps that needed to be addressed by 2016 and 2017 the situation is different as many data gaps are still open. This is due to the fact that in the years 2014 and 2015 overall more Article 12 substances were assessed and more footnotes requiring confirmatory data per substance were introduced in the respective Regulations.
   Where data gaps were filled, this was done through different mechanisms, e.g. by subsequent draft Regulations following applications under Art. 6 of Regulation (EC) No 396/2005 or by new information coming in through renewal of approval process. In some cases the Commission was informed that the substance was no longer supported and no data would be submitted.
   The Commission intends to draft a measure in 2018 with a first batch of substances for which the MRL will be set to the limit of quantification (LOQ) since data gaps were not addressed. The coverage of further substances will follow a chronological order.

EFSA informed that several applications were received to address confirmatory data requested in the Article 12 review process and that there were many different situations to consider. The Excel table reporting the status of the Article 12 data gaps held by EFSA on the EFSA Document Management System (DMS) was recently updated.
One Member State asked to specify whether the "old" Evaluating Member State (EMS) (responsible for the initial Art. 12 review) or the "new" Rapporteur Member State (RMS) (assigned for the renewal exercise) should deal with the confirmatory data. The Commission replied that, in order to bundle the technical knowledge on a substance, the new RMS should deal with the confirmatory data. This had already been discussed and agreed in a previous meeting.
Member States were invited to complete/update EFSA's table reporting the Article 12 data gaps by 31 July 2018.

A.03 Dealing with non-approved basic substances.

The Commission informed that non-approved basic substances can in principle be included in Annex IV of Regulation (EU) No 396/2005 if justified. According to Art. 5 of this Regulation the pre-condition for including a substance in Annex IV is that it has been "evaluated". There is no requirement that the substance must have been approved. However, when including substances into Annex IV, it must be proven that such an inclusion is safe to consumers and the conditions set out in the "Guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) N° 396/2005" (SANCO 111/88/2013) are fulfilled.

The Commission presented an updated list of non-approved basic substances on CIRCABC with a proposal for follow up (either to include or not to include the substance in Annex IV). Member States were invited to submit comments on the proposed follow-up by 13 July 2018.

A.04 Feedback from Legislation Committee.

1. ***Toxicological reference values for iprodione and propargite:***
   On 21/22 March 2018, the Standing Committee on Plants, Animals, Food and Feed, section Phytopharmaceuticals - Legislation (SC PAFF – section Legislation) took note of the new toxicological reference values for iprodione and propargite.

2. ***Import tolerance requests containing new toxicological data in support of new or amended toxicological reference values, incl. substances that were never authorised in the EU:***
   The Commission outlined a proposed procedure to address import tolerance requests containing new toxicological data in support of new or amended toxicological reference values. This includes cases of substances that were never authorised in the EU but for which import tolerance requests are made. The below procedure was presented in the March meeting of SC PAFF – section Legislation:
   - The applicant submits the new toxicological data in support of the setting of new or amended toxicological reference values;
   - The EMS assesses the application containing the toxicological data and drafts an Evaluation Report (ER);

- The Commission forwards the ER to EFSA who delivers a Reasoned Opinion (RO) within 6 months;
- EFSA launches a Member States consultation on the ER with a focus on the toxicological assessment only (4 weeks);
- Following the comments received, EFSA may decide that there is a need to request additional data (stop-the-clock letter);
- Following submission of the updated ER and taking into account the comments received, EFSA considers the need to discuss the outstanding issues in a physical meeting or in an ad-hoc teleconference.

Following publication of the RO, the PAFF - section Legislation is responsible for taking note of the new toxicological reference values. The section on pesticides residues will be informed in the subsequent meeting. Once noted, the new reference values will be considered in MRL assessments.

3. New active substances currently under discussion in the PAFF section Legislation:

The following new active substances are currently under discussion in the SC PAFF – section Legislation:
Metschnikowia fructicola NRRL Y-27328, fenpicoxamid (XDE-777), *Pasteuria nishizawae Pn1*, Asulam, *Beauveria bassiana* strain PPRI 5339, *Bacillus subtilis* strain IAB/BS03.

A.05 Specific substances:

1. Lambda-cyhalothrin:

The Commission updated the Committee on the state of play on the draft Regulation on lambda-cyhalothrin (document SANTE 11228/2017) that was voted in a specific meeting of the SC PAFF - section residues on 22 March 2018 in the framework of the SC PAFF- section Legislation. The publication of the draft Regulation is expected in summer 2018. A mistake in the EFSA RO with regard to rye was signalled to the Commission. A correction of the RO will be made by EFSA. As a consequence of this change the Commission will now also be in a position to implement the Codex maximum residue limit (CXL) for rye in a forthcoming routine MRL proposal.
One Member State asked the Commission to publish the voted proposal (even if not yet applicable) in the Pesticides database. The Commission agreed to do this.

2. Imazalil:

The Commission informed the Committee that in the context of an application under Art. 6 of Regulation (EC) No 396/2005, new information was provided to EFSA during the stop-clock procedure raising additional concerns regarding the genotoxicity of imazalil. Given the horizontal nature of these concerns, the Commission will ask EFSA to revise the recently adopted Article 12 review for this active substance. A mandate under Art. 43 of Regulation (EC) No 396/2005 is under preparation.

3. ***Mepiquat (mushrooms):***

In Commission Regulation (EU) 2016/1003 of 17 June 2016, a temporary MRL (t-MRL) was set for mepiquat on mushrooms until 31 December 2018 to address possible cross-contamination from straw, which was lawfully treated with mepiquat. Additional data had to be submitted by April 2018, otherwise the MRL would decline to the limit of quantification (LOQ) on 1 January 2019. The applicant provided recent monitoring data and data on residue trials within the deadline and applied for the setting of a permanent MRL for mepiquat on mushrooms. EFSA and the Member States also collected monitoring data showing that the levels did not decrease since 2016. Hence, the validity of the current t-MRL of 0.09 mg/kg for should be further extended to allow more time for the evaluation of the proposed permanent MRL. The RMS indicated that it will evaluate the application for the permanent MRL by the beginning of 2019.

A draft Regulation extending the validity of the t- MRL will be presented for a vote in the SC PAFF – section Residues in September 2018 to avoid the automatic decrease of the MRL to the LOQ.

4. ***Dimethoate:***

The Commission reported about the extraordinary SC PAFF- section Residues which took place on 27 April 2018 in the framework of the SC PAFF - section plant health. In this meeting the French emergency measure on dimethoate in cherries had been discussed.

The detailed minutes of this meeting are published under the link below:
https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20180427_ppr_sum.pdf

One Member State reported a question from stakeholders asking whether a specific certificate was needed proving that there were no authorisations in that Member State. France answered that it would get back with an answer.

5. ***Fenpicoxamid:***

Fenpicoxamid is scheduled for a vote at the SC PAFF - section Legislation in July 2018. The Commission intends to present a draft measure setting MRLs to accommodate EU uses and import tolerances in September 2018. However, the Commission highlighted that the analytical standards still need to be made available.

6. ***Prochloraz:***

An Article 10 RO on the modification of the existing MRLs for prochloraz in various commodities was recently published. In parallel a draft RO on the Article 12 review is already available and was recently circulated by EFSA for consultation of Member States, but is not yet finalised. It is expected that some health concerns will be identified by EFSA. The Commission asked EFSA to particularly consider the existing CXLs in their assessment. Different stakeholders associations indicated that prochloraz was important for South American countries exporting exotic fruits into the EU (mango, papayas, avocados, passion fruits). The Commission investigated with specific manufacturers companies whether those uses were still supported, but got the initial feedback that this was not the case.

7. Dimethyl-naphtalene (1,4-DMN):

A Member State reported on the findings of 1,4-DMN in parsley and referred to the assessment carried out by another Member State in the framework of the approval of the active substance under Regulation (EC) No 1107/2009, where it was highlighted that there may be natural occurrences of the substance or occurrence of the substance in formulations of plant protection products (PPPs).

The purpose of this agenda point was to raise awareness of this issue among Member States and to invite them to share similar findings and experiences with a view to a possible follow up discussion in a forthcoming meeting.

8. Haloxyfop-P:

The Committee was informed on an ongoing import tolerance request on linseeds and which is still under the clock-stop procedure in EFSA as some of the required information had not yet been submitted by the applicant.

Stakeholder associations are concerned about the impact this delay has on international trade of linseed and believe that industry is not pushing forward this application due to the fact that it is a minor crop.

The Commission clarified that it will do its utmost to speed up the process, provided that the missing data is submitted. Moreover, this specific trade issue was selected as a case study for the REFIT evaluation to outline the complexity of international trade in relation to MRL setting.

9. Glyphosate:

EFSA had published two documents on glyphosate on 17 May 2018: a review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, and an evaluation of the impact of glyphosate and its residues in feed on animal health. The Commission thanked Member States and EFSA and acknowledged the substantial amount of work. DG SANTE is awaiting political validation in line with the Commission's Better Regulation Guidelines before work can start on a draft Regulation to amend the existing MRLs.

10. Copper:

The Commission presented to the Committee its first reflections on the way forward on the Article 12 RO on copper compounds published by EFSA in March 2018.

Copper is a natural element present in all plants and animal products and in the soil. It is not only used as active substance in plant protection products but also as micronutrient in feeding stuffs, in veterinary medicines and in fertilisers. All these different sources of exposure had been taken into consideration by the comprehensive risk assessment made by EFSA. The EFSA RO highlights an exceedance of the chronic exposure (109% of the ADI for WHO Cluster Diet B) due to endogenous levels and the different copper sources mentioned above. As a result, many of the existing EU MRLs for copper might need revision. A draft measure on MRLs is not yet prepared, as the Commission will first await the outcome of possible use restrictions currently under discussion in the SC PAFF-section Legislation (possible vote in autumn this year in view of the expiry of approval by 31 January 2019) and then carefully examine all possible risk mitigations options for MRL setting.

11. ***Acetamiprid:***

The Commission had asked EFSA to review the existing MRLs for acetamiprid considering the new toxicological reference values, which were formally agreed by the PAFF - section Legislation in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009.

EFSA identified consumer intake concerns for several products (apples, pears, peaches, head cabbages, Chinese cabbages, kales, lettuces, escaroles, spinaches, purslanes, chards and celeries). Member States were consulted to report potential fall-back Good Agricultural Practices (GAPs) that would not lead to an unacceptable risk for consumers. In its RO, EFSA therefore recommended lowering a number of MRLs. The draft measure will be notified to WTO via the SPS procedure for a commenting period of 60 days in view of the decrease of the MRLs.

In its RO, EFSA also addressed two applications which were submitted to increase the current MRLs in table olives, olives for oil production, barley and oats.

Member States were invited to provide comments on the draft measure and to report the missing data on the GAP for escaroles by 13 July 2018.

A.06 News from the European Food Safety Authority:

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

EFSA evaluations on 11 substances are currently ongoing under the "interim" process to be finalised during 2018. Evaluations of 27 substances are ongoing under the "new" procedure.

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

EFSA reported that 21 questions were addressed since the February 2018 PAFF meeting. 38 questions are ongoing and 15 will be finalised within the next weeks. 47 questions are on clock-stop. A table on long lasting clock-stops was presented and Member States were asked to provide feedback on the planned submission dates for the missing information or on the possible withdrawal of the respective applications by 6 July 2018. EFSA also informed that the overview Excel table on data gaps under Art. 12 had been recently updated by EFSA. Member States were requested to update the table by 6 July 2018 and send them directly to EFSA.

3. ***Update on Art. 43 mandates of Regulation (EC) No 396/2005:***

The reasoned opinion on acetamiprid was published. A mandate on imazalil (cf. agenda item A.05.02) is expected from the Commission soon. A technical report on iprodione and a scientific report on fipronil had been published as well. A revision of PRIMo 3.1. is planned to be finalised by summer 2018.

4. ***EFSA work programme on Art. 12 for 2018:***

The Committee agreed on the work programme as presented.

EFSA indicated that it is willing to provide support to Member States who are not familiar with the Article 12 MRL review.

5. ***EFSA opinion on food for infants and young children:***

EFSA gave a presentation on the main conclusions and recommendations of the EFSA scientific opinion on pesticides in foods for infants and young children. The Commission informed that the follow-up of this opinion would be discussed both in the SANTE Expert working group on foods for specific groups in charge of the legislation on foods for infants and young children and in the PAFF -

section Residues for technical aspects related to pesticides residues. A representative of the DG SANTE unit responsible for legislation on foods for infants and young children informed that the presentation had also been given in an expert working group on 11 June 2018. The Commission highlighted that it would be essential to establish good collaboration at Member State level between the respective experts of both groups. As regards the specific EFSA recommendations to lower the MRLs for infant formulae and follow on formulae for a group of substances with an Acceptable Daily Intake (ADI) below 0.0026 mg/kg bodyweight, the Commission will carefully assess the situation. Analytical feasibility and real exposure of infants and young children would need to be taken into account when reflecting about the follow-up. As regards the legislation on foods for infants and young children, currently Directive 2006/141/EC on infant formulae and follow on formulae is still applicable and will be replaced by a delegated act only in 2020 and in the case of protein hydrolysates in 2021 due to transitional measures laid down in the framework of Regulation 609/2013[1]. Any potential change of the legislation can therefore become applicable only as from 2020 and 2021 respectively. A Member State commented that in its view there was no issue with pesticides in infant formulae. Another Member States requested more details on the way the exposure assessment in the EFSA opinion was carried out.

A.07 EFSA Presentation of 2016 Monitoring Report and discussion on recommendations.

EFSA made a presentation of the main conclusions and recommendations of the 2016 annual monitoring report which will be adopted soon. Overall, the monitoring data show that the situation is well under control and the system is effective in detecting non-compliances. Many of the non-compliances could be explained with well-known issues, such as the change of the MRLs for chlorpyriphos in 2016, the detection of chlorate levels above the default value of 0.01 mg/kg, residues of copper (used widely in conventional but also organic agriculture) and of fosetyl-aluminium linked to the use of fertilisers. The Member State asked why conversion factors between the residue definition for monitoring and risk assessment were not used in the risk assessment. EFSA replied that a harmonised list of conversion factors at EU level does not yet exist, but that such factors could indeed be considered in forthcoming programmes. A discussion took also place on the usefulness of presenting data that are detected but not quantified. EFSA, supported by a Member State, considered this useful to refine exposure assessments, e.g. also with a view to future cumulative risk assessment. Another Member State commented that this was not needed and would increase workload for laboratories. A Member State requested to present middle-bound data in addition to upper and lower bound data. Another one recommended to further investigate organic samples.

[1] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009

A.08 Project on data collection dithiocarbamates.

The Commission reported that 8 Member States got access in the "Pestipedia" application managed by the EU Reference Laboratory for Single Residue Methods (EURL-SRM). One Member State already inserted an estimation of the number of organic samples to be analysed. The Commission invited Member States to register and upload their estimations. The Commission recalled the purpose of the project aiming at the collection of dithiocarbamate background levels in certain commodities to assist EFSA in the future MRLs review on dithiocarbamates. Therefore organic samples should be taken. The Commission clarified once again that the procedure proposed in the previous SC PAFF meeting of February 2018 (data collection co-ordinated by EU RL SRM) had been agreed with EFSA who was involved in the preparation of the list of commodities to be analysed. One Member State expressed its concern that input to this project would only come from very few Member States and requested the list of commodities for which data would be needed. EFSA encouraged the participation of as many Member States as possible. The Commission informed that the list of commodities had been presented at the last meeting and was visible when entering the application. One Member State asked whether data should only be collected for commodities where no authorisations were available. EFSA replied that the authorisation status of a substance would not matter as organic samples should be taken to get background levels of carbon disulfide resulting from natural sulphurous compounds.

A.09 Honey - Technical guidelines.

The draft Technical Guidelines for Honey (SANTE/11956/2016 rev. 6) had been updated with comments from 5 Member States, EFSA and ECPA and rev. 7 uploaded on CIRCABC for discussion. The comments received had been collated in an overview table and it was indicated how/if they were taken into account. As at this late stage not all comments could be considered, the overview table will serve as a basis to inform a future revision after some time of implementation in order to gain experience. The Commission considered it important to finalise the document and take not of it in the SC PAFF- section Residues in September 2018. The Commission proposed to set 1 July 2019 as implementation date for the Technical Guidelines.

As regards the content, some clarification was provided on the definition of melliferous crops and residue data collection on such crops. It was also clarified that the decision-making scheme does not cover MRLs set on the basis of monitoring data according to Art. 16 of Regulation (EC) No 396/2005 as such MRLs would be of temporary nature by definition.

One Member State asked whether propolis was covered. The Commission clarified that this was not the case and that only honey was covered as the consumption of the other bee products such as propolis was very low. The exact scope is set out in the beginning of the document.

Member States were invited to submit comments by 13 July 2018.

A.10 State of play on cumulative risk assessment.

The Commission informed the Member States of the public consultation launched by EFSA on the draft EFSA Scientific Report on cumulative assessment groups for the effects of pesticides on the nervous system. The Commission also informed of the expert working group meeting on cumulative risk assessment back-to-back to this SC PAFF - section Residues on 15 June 2018 for which many participants had registered.

A.11 Work organisation for next monitoring exercise 2020, 2021, 2022.

The Commission reminded of the expert working group meeting on Monitoring of Pesticide Residues due to take place in Brussels on 12 October 2018 and invited Member States to nominate their experts for the meeting until 7 September 2018 at the latest.

A.12 Screening exercise on temporary MRLs in Regulation (EC) No. 396/2005 that will expire in 2018-2020.

The Commission gave an update on the state of play. For difluoroacetic acid and flupyradifurone data were submitted in the framework of an import tolerance request and will be assessed in this context. As regards mepiquat /mushrooms see agenda item A. 05. 03.

A.13 International Matters:

1. ***Feedback from the 50th session of the Codex Committee on Pesticide Residues (CCPR 50) meeting in April 2018:***

   The Commission informed the Member States of the outcome of CCPR 50 in April 2018.

   The Commission thanked the Member States for their active participation and outlined the progress made on specific issues such as the revision of the classification system for food and feed, the Codex schedule of priority lists, as well as the work on the Internationally Estimated Short Term Dietary Intake (IESTI) equation.

   Reservations to the advancement of proposed draft CXLs had been made for around one third of the proposed CXLs. Reservations were mainly due to discrepancies in the risk assessment carried out by the JMPR and EFSA, e.g.: use of different residue definitions, different number of trials needed to derive MRLs, but also pending EFSA risk assessments.

   Following a request made by Chile, the CCPR had agreed to establish an electronic working group (EWG) on biopesticides. Equally, the request from Canada to establish an EWG to consider the participation of the JMPR to an international joint review of new compounds, and a request from Iran to establish an EWG on a possible Revision of the Guidelines on the use of mass spectrometry had both been accepted. Following the discussion on a database of national registrations, the CCPR decided to set up a new EWG chaired by Germany and co-chaired by Australia to explore this issue further. The CCPR did not agree to a request from India to start working on risk management recommendations on endocrine disruptors.

2. Follow-up to CCPR 50 (2018):

a. *Concern forms*

Given the ongoing regulatory initiatives setting the MRLs to the limits of quantification (LOQs) for the active substances buprofezin, diflubenzuron, iprodione and picoxystrobin, the Commission requested the respective RMSs to submit draft concern forms summarising any health concerns for these active substances.

b. *Submission of additional information supporting the public health concerns for aldicarb, amitraz, azinphos-methyl, bromopropylate, dicloran, fenarimol and phosalone*

Regarding the concern forms already submitted for aldicarb, almitraz, azinphos-methyl, bromopropylate, dicloran, fenarimol and phosalone, the Commission requested EFSA to identify the key studies leading to the concerns outlined in the forms, as requested by the Joint FAO/WHO Meeting for Pesticides Residues (JMPR).

EFSA indicated that concerning bromopropylate, the concern was not due to a particular study but due to the absence of an evaluation during the last 25 years. As no ARfD was set for this substance, EFSA used the ADI as a surrogate for the ARfD, showing high exceedances of the toxicological reference value for many commodities.

EFSA will answer directly to JMPR for bromopropylate, as the request is urgent. The Commission will coordinate the reply concerning the other active substances.

c. *Coordination of the EU Member States' contribution to EWGs*

A Member State suggested attributing a Member State to each of the various EWGs established by the CCPR, to follow the discussions and give feedback to the SC PAFF, without in any way preventing the active participation of other Member States. The following attributions were agreed:

- EWG on the revision of CAC/GL 56-2005: France
- EWG on bio-pesticides: France
- EWG on revision of the classification: the Netherlands
- EWG on review of the IESTI equation: the Netherlands
- EWG on priorities and management of unsupported compounds: Germany
- EWG on the national registrations database: Germany
- EWG on JMPR participation in international reviews: awaiting confirmation

d. *Development of an EU position on a proposal expected for the CCPR 51 (2019) meeting regarding a request for a JMPR pilot project to leverage on national/regional reviews*

The Commission provided background information and raised awareness among Member States on this possible future topic of discussion.

e. *Avenues to promote EU policies related to MRL setting vis-à-vis third countries and especially developing countries*

A Member State suggested exploring avenues to promote EU policies related to MRL setting vis-à-vis third countries. There are several existing training opportunities third countries can benefit from, including TAIEX projects and the Better Training for Safer Food (BTSF) Programme. However, there is insufficient communication of such positive initiatives.

The Member State proposed to present such training opportunities at a side event at the CCPR 51 (2019) meeting.

3. Preparations for the Codex Alimentarius Committee (CAC) 2018:

The Commission informed Member States that the reservations made by the EU in CCPR 50 and recorded in the CCPR 50 report would be maintained for the Codex Alimentarius Commission (CAC) 2018 meeting that takes place in Geneva in July 2018, as agreed at the Council Working Party on 5 June 2018.

4. Principles for EU positions:

During the preparation of the CCPR 50, several issues were discussed regarding the guiding principles for establishing EU positions:

a. Minimum number of trials for minor/major crops and considerations on homogeneity, other uncertainty factors

One Member State proposed to consider 6 or 7 trials for major crops as a minimum instead of 8 trials required by EU standards. This proposal was supported by the Committee. Regarding minor crops, it was reminded that the Codex Guidance on Minor Crops that was supported by the EU, would be applicable at the 2019 CCPR51 meeting and that the minimum number of trials was specified in that guidance.

b. Cases where recommended CXLs are lower than EU MRLs

The Committee discussed whether action was required in cases where the draft CXLs recommended by JMPR were lower than the EU MRL, which may reduce the opportunities for EU producers to export to third countries. While the problem is understood, there are several practical and resource constraints to overcome before this could be addressed systematically. The Committee agreed to revisit this issue only if it is demonstrated that the economic interest would justify a comprehensive approach to address it.

c. Cases where new adverse information was evaluated by EFSA but is not yet available to JMPR

If new adverse information is available in the EU on a substance, it should be brought to the attention of the JMPR and CCPR through the submission of a concern form.

d. Extrapolation rules/representative crops for setting group MRLs if different in the EU from the Codex system – (EU Extrapolation Guidance versus Codex classification)

A Member State proposed certain clarifications as to which extrapolation rules should be applied in developing an EU position, depending on whether the use in question is authorised in the EU or not. Other Member States were not in favour of differentiating the EU position based on the country of authorisation. The Commission observed that there was agreement in the Committee that for non-EU uses, flexibility as regards the appropriate representative crop can be applied. Some flexibility is foreseen in the Codex tables establishing representative crops to deviate from the representative crop if an acceptable justification is given. It further observed that for EU uses, it was very likely that trials would be available for the representative crops indicated in the EU Extrapolation Guidance, given that they are chosen based on comparable residue behaviour and contribution to consumption as well as economic importance for production in the EU.

5. Other International issues, e.g. OECD issues:

a. Revision of the OECD guidance document on the residue definition for risk assessment

The Commission informed the Committee that a majority of Member States supported the option previously discussed by which the impact of the EFSA Guidance Document (EFSA GD) on the Residue Definition for Risk Assessment should be assessed before implementation by developing a set of cases studies.

In parallel, discussions are taking place at international level to update the OECD guidance document on the residue definition. There had already been a meeting of the Residue Chemistry Expert Group dedicated to this issue.

The Commission believes that the contents of the EFSA GD should feed into the section on the residue definition for risk assessment of the OECD guidance. However, it is currently too early to understand to which extent this can be done and also to predict an indicative timeline. Further information on case studies is still expected to be provided by ECPA. EFSA asked how OECD guidelines are adopted at EU level. The Commission will clarify this bilaterally.

b. Publication of OECD Guidance Document on residues in rotational crops

The Commission informed the Member States about the publication of the OECD Guidance Document on residues in rotational crops. The document was uploaded on CIRCABC. The very last draft of that document was presented for comments in the February PAFF meeting and no comments had been received from Member States.

A.14 Info on substances falling under the cut – off criteria in Regulation (EC) 1107/2009 and follow up on MRL side.

The Commission informed the Committee that following its exchanges with Member States, it had reconsidered its approach on how to handle import tolerance (IT) requests for active substances falling under the cut-off criteria of Regulation (EC) No 1107/2009.

As a consequence of the non-renewal of such active substances or their expiry of approval (no renewal procedure initiated), existing MRLs for such active substances should be deleted once Member States withdraw the authorisation of plant protection products containing these active substances.

Import tolerance requests concerning these active substances will undergo systematically the procedures laid down in Regulation (EC) No 396/2005, including a risk assessment by an Evaluating Member State and a scientific opinion by EFSA. Consequently, the granting of the IT will be considered on a case-by-case basis taking into account all relevant factors.

The Member States thanked the Commission for its flexibility to revise the initial approach and generally supported the revised approach with some comments on its practical implementation. The Commission and Member States will now follow the proposed approach.

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

The United Kingdom (UK) informed the Committee on an emergency use of flonicamid on carrots for which it requested a temporary MRL of 0.3 mg/kg. Residue trials show that the existing MRL of 0.03* mg/kg will be exceeded. That Member State allows food and feed with levels above the EU MRL to circulate nationally in line with the procedures set out in Art. 18 (4) of Regulation (EC) No 396/2005, but prohibits the export of any treated crop and of processed products for the time being. A regular application for the same use is already ongoing and the evaluation is under preparation.

A Member State asked whether EFSA could combine this assessment with another ongoing application for the use on radishes. The Commission clarified that this should be done only if the assessment of the emergency use was not delayed.

A.16 Designation of Member States for maximum residue levels (MRL) applications.

1. ***Import tolerance application for propiconazole:***
   An application for an import tolerance (IT) for propiconazole was made to Finland. The UK was asked by Finland to assess it and agreed to this giving assurances that the work will be finalised before March 2019. While the other Member States had no comments on this change, the Commission stated that it was not much in favour of such bilateral transfers of dossiers to the UK as this was running counter its current efforts to re-allocate dossiers from the UK to other Member States (cf. point A.22 – Preparation for Brexit).

2. ***Application for an import tolerance request for iprodione on tree nuts and coffee:***
   An application for an IT for iprodione on tree nuts and coffee was made to the Netherlands who accepted it. Previously the same IT request had been rejected by two Member States. The first (the RMS) because the substance falls under the cut-off criteria, the second because the Member State was not the RMS. The Commission clarified that according to the provisions of Regulation (EC) No 396/2005 (Art. 8) it is legally not possible for a Member State to simply reject an IT request. It however acknowledged, that this had been initially proposed in a draft working document prepared by the Commission on how to handle import tolerances, but then abandoned due to legal reasons. The respective MS clarified that its rejection was made at the time of discussion of the initial Commission proposal.

3. ***Application for an import tolerance for tioxazafen:***
   An application for an IT request for tioxazafen was made to the Netherlands who accepted it. No Member State commented on this issue.

A.17 State of play of evaluation of Reg. (EC) No. 396/2005 and Reg. (EC) No. 1107/2009.

The Commission updated the Committee on the outcome of the second REFIT workshop held on 16 May 2018 which was well attended by Member States, EFSA, a wide range of stakeholders and the Commission. The preliminary findings of the evaluation study were presented by the contractor conducting the external study and discussed together with the participants. The main points discussed were the number of active substances available versus the variety of uses they should cover, the use of

emergency authorisations and their impact on human health and environment, and issues concerning minor uses.

The Commission informed that the external study was expected to be finalised during summer. The final report (Staff Working Document) that will be drafted by the Commission is expected to be published during the first half of 2019.

A.18 Update on the technical guidelines for MRL setting.

The Commission presented the various changes which were brought to the Technical Guidelines. The intention is also to consult stakeholders and endorse the new revision at the PAFF - section Residues in September 2018. The revised version will also contain a chapter outlining the approach presented under agenda item A.14 on how to handle substances falling under the cut-off criteria.
Member States were invited to submit comments by 13 July 2018.

A.19 Decision of the European Ombudsman in case 2000/2015/ANA on the European Commission's compliance with the rules on the approval of plant protection products.

The Commission informed about the outcome of a complaint made by ECPA to the European Ombudsman (case 2000/2015/ANA) in 2016 with regard to the Commission's practice to set MRLs for new substances shortly after the approval of that new substance but not before. The Ombudsman had weighed all arguments brought forward carefully and came to the conclusion that there was no maladministration on the Commission's side.

A.20 Info on rules of procedure Standing Committees.

The Commission reminded of the existing rules of procedure of the Standing Committee according to which observers attending the Committee must leave the room at the moment of voting. This concerns representatives from Norway, Switzerland and also colleagues from EFSA.

A.21 Exchange of experiences with EFSA PRIMo rev. 3 (request from DE)

The points was put on the agenda on request of two Member States who asked for an exchange of experiences with the other Member States on how to handle specific cases in view of the recent introduction of PRIMo revision 3 (applicable since 1 February 2018). The question whether it would be more appropriate to already apply the new version to existing applications (submitted before the application date 1 February 2018) was raised again. The Commission clarified its willingness to discuss specific practical cases, but stated that the discussion on the application date took place twice, in November 2017 and February 2018 and should not be re-opened. Due to lack of time the discussion will be re-tabled at the next meeting. Member States were invited to forward examples of cases they would like to discuss and to reply to those questions already presented by other Member States and uploaded on CIRCABC.

A.22 Preparation for Brexit

The Commission proposed the designation of Member States as back-up, for files (applications and other evaluations under Regulation (EC) No 396/2005 and 1107/2009) currently processed by the UK. It outlined the approach and referred to the document on CIRCABC for the individual designations per file.

This topic will also be presented to the section SC PAFF – section Legislation at its next meeting planned for 19/20 July 2018. Endorsement is envisaged to take place at the meeting of the PAFF – section Legislation on 23/24 October 2018.

A Member State raised a concern regarding their budget allocation.
Member States were invited to submit a co-ordinated reply (co-ordinated with Member State representatives in PAFF – section PPP Legislation) by 24 August 2018.

B.01 Exchange of views and possible opinion of the Committee on a draft Commission Regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for abamectin, acibenzolar-S-methyl, clopyralid, emamectin, fenhexamid, fenpyrazamine, fluazifop-P, isofetamid, Pasteuria nishizawae Pn1, talc E533B and tebuconazole in or on certain products (Art. 10).

The Commission introduced the draft measure and presented its content.

The following MRL applications had been submitted under Article 6(1) of Regulation (EC) No 396/2005 (EU uses):

- abamectin for the use on citrus fruits;
- acibenzolar-S-methyl for the use on aubergines and cucurbits;
- clopyralid for the use on spring onions and leeks;
- emamectin for the use on leafy brassica, beans (with pods) and peas (with pods);
- fenhexamid for the use on plums, blueberries, cranberries, currants, gooseberries and beans (with pods);
- fenpyrazamine for the use on lettuces, salad plants, spinaches and similar leaves;
- fluazifop-P for the use on tomatoes;
- isofetamid for the use on tomatoes, peppers, aubergines, okra and cucurbits;
- tebuconazole for the use on olives, rice, 'herbs and edible flowers' and herbal infusions from flowers, leaves and herbs.

As regards abamectin and tebuconazole, the applicants submitted validated analytical methods for the relevant crop matrices. The Article 12 footnotes were therefore deleted from Annex II to Regulation (EC) No 396/2005.

The draft measure included *Pasteuria nishizawae* Pn1 (low-risk active substance) and Talc E533B (basic substance) into Annex IV to Regulation (EC) No 396/2005.

A Member State pointed out that for isofetamid MRLs were recommended for tomatoes, peppers, aubergines and okra, but also other Solanaceae and Malvaceae (code 0231990) should be covered. The Commission proposed to set the same value applied to peppers and okra (i.e. 3 mg/kg). This is in line with the approach taken for benzovindiflupyr in the framework of Regulation (EU) 2018/687.

Vote taken: favourable opinion.

B.02 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 diphenylamine and oxadixyl in or on certain products (Art. 10).

The Commission introduced the draft measure and presented its content.
There was no discussion on the content or the specific MRLs but a discussion took place on the wording used in Article 2 for products imported into the Union.

Two Member States felt that the amended wording used in Article 2 of the draft text setting transitional measures would discriminate imports from third country vis-à-vis European products and announced they would abstain if the wording was maintained. They stated that products such as wine are treated and produced much in advance of being placed on the market and that transitional measures should apply given there were no health concerns. For those Member States the term "produced" should be widely interpreted as "treated".

Two Member States remarked that the term "produced" should be replaced by "placed on the market" as they believe that the term "produced" should not be interpreted as "treated". Another Member State mentioned the issue of post-harvest treatments (e.g. of cereals) which would need to be considered separately. This was supported by another Member State.

The Commission clarified that the discussion on the interpretation of the term "produced" had been abandoned in 2016 since there was no agreement on the interpretation. The Commission confirmed its view that the term should be interpreted as "placed on the market" in line with the definitions of the General Food Law. The wording "produced" was however maintained given the lack of an agreed interpretation. The Commission indicated that, if requested by Member States, this broader discussion could be re-opened at some other stage.

It further clarified that the issue of imported products was a different one and that comments had also been received by two third countries on this point. The Commission stated that imported products should be compliant with EU MRLs at the moment of import into the EU as only from that point onwards enforcement authorities in the EU have the means to check them for compliance with EU legislation. There is no means for EU enforcement authorities to control the compliance with EU legislation at the time of production in the third country, hence a wider interpretation could weaken consumer protection.

The amended wording of Article 2 clarifies the issue since questions were received frequently on this point.

The Commission also confirmed that in previous discussions with Member States it was acknowledged that post-harvest treatments would need to be considered separately.

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 penoxsulam, triflumizole and triflumuron in or on certain products (Art.12).

The Commission presented rev. 2 of the document clarifying that only some changes in the Recitals had been introduced following the Commission's internal consultation procedures. The MRLs remained the same as those already presented in rev. 1 at the February 2018 SC PAFF meeting.

One Member State noted that due to the introduction of footnotes clarifying provisions for ginger and horseradish into the Annex I to Regulation (EC) No 396/2005, the specific footnotes were no longer necessary in specific Regulations. Consequently, a rev. 3 in which footnotes on ginger and horseradish were deleted was put forward for vote.

Vote taken: favourable opinion.

C.01 Exchange of views of the Committee as regards maximum residue levels for bromadiolone, etofenprox, paclobutrazol, and penconazole (Art. 12).

The Commission informed the Committee that imazalil was withdrawn from the scope of this draft due to the pending revision of the EFSA Article 12 review of this active substance (cf. point A.05.02), and that the revised draft had been notified to the World Trade Organisation (WTO) under the SPS procedure (commenting period of 60 days).

C.02 Exchange of views of the Committee as regards maximum residue levels for bromuconazole, carboxin, fenbutatin oxide, fenpyrazamine and pyridaben (Art. 12).

The Commission gave an update of the status of the draft Regulation and presented the comments that had been received. One Member State commented on the extrapolation approach used by EFSA merging trial data for mandarins and oranges that were statistically not compatible based on the Mann-Whitney (U-test). One Member State commented that this test was not included in the Extrapolation Guideline and hence should not be used as a criterion. Several other Member States supported this view and considered the use of one single MRL as more appropriate for citrus varieties, since for example some mandarins can be as large as oranges. The Commission therefore proposed to maintain the MRL value as recommended by EFSA combining the trials for mandarins and oranges in line with the Extrapolation Guidance Document.

Member States were invited to submit comments by 13 July 2018.

C.03 Exchange of views of the Committee as regards maximum residue levels for bispyribac, denathonium benzoate, fenoxycarb, flurochloridone, quizalofop-P-ethyl, quizalofop-P-tefuryl, propaquizafop and tebufenozide (Art. 12).

The Commission presented an overview of the substances that will be included in a forthcoming Article 12 review and referred to the Explanatory Note and the LOQ table already uploaded on CIRCABC.

The Commission drew the attention of the Member States to the ester variants of quizalop-P and informed them that the approach followed is consistent with the RO of EFSA where MRLs are reported under one residue definition which includes not only quizalofop-P but also its ester variants, metabolites and conjugates.

One Member State requested clarifications regarding the merging of quizalofop and propaquizafop.

Member States were invited to submit comments by 13 July 2018.

C.04 Exchange of views of the Committee as regards maximum residue levels for chlorate.

The Commission confirmed its intention to revise chlorate MRLs on the basis of monitoring data and presented new monitoring data covering the period 2014-2017. The preliminary statistical analysis showed that, compared with the data collected in 2013-2014, chlorate concentration were considerably reduced in many food commodities.

Answering to questions from Member States, the Commission clarified that:

- the analysed data were only the data provided by Member States to EFSA, but that stakeholders data were also confirming this evolution,
- key geographical areas were covered, including the areas where the highest levels of chlorate were found in food so far; and
- exchanges with the relevant trade associations showed that this decrease was the result of actions put in place in order to reduce chlorate contamination.

While these new data showed that a decrease was achievable, the Commission acknowledged that the margin of manoeuvre available for further reduction was now more limited than in 2014.

Some Member States noted that the use of chlorinated solutions for the washing of fresh products or for the blanching of products before freezing were legitimate practices allowed under their national legislation, and that MRL legislation was not an adequate legal tool to regulate their use. The Commission answered that recommendation on good hygiene practices in order to reduce chlorate levels resulting from use of chlorinated disinfectants was part of an action plan supported by the heads of national food safety agencies, and that the Commission guidance on addressing microbiological risks in fresh fruits and vegetables had already been amended to include such recommendations.

Some Member States recalled that drinking water was by far the main contributor to chlorate intakes and that chlorate concentration should first be reduced in drinking water before new MRLs were set for foods. One Member State also asked for a stricter maximum level of chlorate in drinking water. The Commission recalled that given the health issue at stake, waiting for the end of the legislative procedure for the adoption of the revised Drinking Water Directive before taking a decision on MRLs for food was not an option.

The Commission also recalled that the proposal tabled for the revision of the Drinking Water Directive proposed a maximum level of chlorate at 0.25 mg/l, a level already 3 times lower than the current guideline level by the World Health Organization (WHO) of 0.7 mg/l. The Commission invited Member States to comment on the proposed maximum level of chlorate in drinking water in the Council working group dedicated to the discussion on the proposal.

The Commission also announced that it will ask EFSA for an in-depth statistical evaluation of these more recent data and modify its draft Regulation accordingly.

On the percentile to be used, a Member State requested to use the 95th instead of the 90th percentile. The Commission signalled that it was open to re-discuss this point in the light of the new data and statistical analyses that will be prepared by EFSA.

C.05 Exchange of views of the Committee as regards maximum residue levels for linuron.

As a consequence of the conclusion reached under agenda item A.01, and due to the absence of toxicological reference values advised by EFSA in the peer-review of that active substance, the Committee agreed to withdraw the transition measures initially foreseen for this draft Regulation setting the MRLs for linuron to the LOQs.

C.06 Exchange of views of the Committee as regards maximum residue levels for iprodione.

On request of the Commission, EFSA had published in a technical report the results of a risk assessment of iprodione MRLs carried out with the new toxicological reference values recommended in the peer-review and endorsed by the PAFF Committee – section Legislation on 24 and 25 May 2018. Acute health risks were identified for the MRLs of certain commodities, and these MRLs were withdrawn from the scope of the transition measure.

Given that a genotoxic concern could not be excluded for the major residue metabolite RP 20228 in the EFSA peer-review and the still ongoing discussion of the Committee on the principles for setting transitional periods under agenda item A.01, no decision was taken yet on transitional measures for iprodione. A Member State mentioned dried products such as raisins with a long shelf-life that would need to be looked at in more detail as their consumption would be very low. The Commission stated that this specific issue would be examined, but that it was not ready to set an unwanted precedent for any possible processed products.

Member States were invited to submit comments by 13 July 2018.

C.07 Exchange of views of the Committee as regards maximum residue levels for buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim.

The Commission introduced the draft and replied to written comments from Member States. The draft provisions on transitional measures may be amended at a later stage, further to consideration of the issues discussed under agenda item A.01.

The Commission provided clarifications on questions raised by Member States on the appropriate LOQ for certain substance/commodity combinations, and on the interplay between grace periods provided for in the implementing act non-approving a substance or amending its approval conditions on one hand, and the application date and transitional measures provided for in the act amending the MRLs on the other hand.

M.01 Fluoxastrobin fast-track procedure.

The item was added to the agenda by the chair on request of one Member State. That Member State proposed to extrapolate the MRL currently set for bulb onions to garlic. A "light" version of the Evaluation Report was drafted for this purpose by including basic elements such as the MRL application, reference to the previous EFSA assessment on the major crop, the GAP table and the PRIMO model. The Commission proposed to use this version of the ER as a template for future similar cases and invited the Member States to submit comments on the template by 13 July 2018.