

Minutes of the expert groups

Brussels, 26 February 2019

Minutes

ad-hoc meeting of the Advisory Group on the Food Chain, Animal and Plant Health on plant protection products

21 September 2018, CENTRE DE CONFÉRENCE ALBERT BORSCHETTES, Brussels

1. Approval of the agenda and of the minutes of previous meeting

2. Nature of the meeting

The objective of the meeting was to give the opportunity to interested parties to provide the Directorate General for Health and Consumers with comments and recommendations on guidance being developed or updated in the area of plant protection products and pesticide active substances.

3. List of points discussed

3.1 Welcome and opening

SANTE opened meeting by welcoming the participants and explaining that this ad-hoc meeting would be dedicated to various guidance documents related to the implementation of the Plant Protection Products Regulation. SANTE announced that such meetings would be organised more frequently in the future in order to improve the consultation process with stakeholders. SANTE informed that meetings like today could also be replaced by written consultation on specific documents

3.2 Overview on guidance documents currently under development or update and the consultation process

SANTE informed participants that guidance documents under development and finalisation in future are intended to be consulted via the Advisory Group on the food Chain and Animal and Plant Health. Stakeholders of the Advisory Group will be invited and the invitation will be extended also to ad hoc stakeholders, as for the meeting today.

The intent is to improve the consultation process. Previously guidance documents were adopted as SANTE staff working documents on SANTE website; in future they will be published as Commission Notice in the Official Journal.

SANTE clarified that when guidance documents are related to risk assessment they are done by EFSA. When the EFSA guidance is finalised it is presented to the SCoPAFF (Standing Committee of Plant, Animal, Food and Feed) for endorsement. So far, these were adopted by so-called note-taking procedure. From now on, they would be published in a Commission Notice. The guidance documents which had recently been noted by the SCoPAFF were mentioned.

ECCA asked about the legal status of the Commission Notice, which seems to make guidance documents legally binding vs. previous status of 'taking note'.

SANTE clarified that a draft Commission notice is not submitted to a vote in the SCoPAFF but it is adopted by the Commission. It will be subject to Inter-Service Consultation in the

Commission thus requiring the support of all other services, including the Legal Service. While a Commission Notice is also not binding, it gives a clear indication of what the Commission expects to be done for the subject matter of the guidance document. The 'note-taking' reflected a consensus position among the members of the SCoPAFF. Obviously the Commission will discuss draft Commission Notices in the SCoPAFF and will still strive to achieve consensus. Other documents like amendments to the Uniform Principles (Reg. 546/2011) require support by a qualified majority in SCoPAFF.

A - Draft Guidance Documents and Commission Notices – stakeholder consultation

3.3 Commission Communications on the data requirements for dossiers for active substances and plant protection products

SANTE presented the review of two Commission Communications on data requirements, including generation of studies, data, evaluation and interpretation of them. These two Communications listed the relevant guidance documents (GD) and tests methods, one for the active substances and one to build a good dossier for PPP authorisation. The first version was adopted back in 2013 when data requirements were reviewed. The plan is to have regular update of these two Communications to reflect the latest progress in chemical and microbial testing. There are now 4 tables: 1) methods for active substances, 2) GDs for active substances, 3) methods for PPP, 4) GDs for PPP,

The intent is to build up a database with all GD and test methods, in order to keep record of historical changes, so that it is possible for assessors to check whether the studies have been conducted according to the most up to date GD version.

The two Communications were published for comments: they cover all sections of a dossier and they address different areas of expertise.

In terms of the changes, it looked at some key elements, such as reduction of animal testing, promoting the use of in silico testing where possible. It was clarified when there was a change of GD and test methods, notably when one is outdated, a clear date application is provided in the Communications: the old guidance/method will still visible in the file but with clear indication of which one is valid in which time period. Comments are invited on the overall approach and the details, for instance information on new test methods which should be considered would be welcome.

Comments must be submitted using the template provided with the document for stakeholders to share their feedback in structured manner. Participants are invited to send their comments by 16 November 2018.

ECPA asked about some details regarding the database listing the test methods and guidance documents: although the tracking of GD appears to be fairly easy, there are a number of test methods which are work in progress, how would they be considered? SANTE explained that the database will only refer to test methods which have been validated (ring tested) to avoid confusion. A record of changes from one version to another of the Communications, will be provided.

POLLINIS noted that there were some blanks with respect to test methods for bees although some are available. Commission confirmed that comments are welcome in particular to flag new internationally validated methods which are available and which might have not been yet included in the drafts. “Validated at international level” is interpreted as ring tested in different countries, as a minimum. Two additional columns have been added in the

Communications as they should provide an expiry date or a starting date for the GD. Sometimes it may not be applicable (new GD) and so there are empty spaces.

PAN asked whether it would be possible to raise questions during the consultation process to seek clarifications? Although it is possible, it is recommended to use the consultation for raising points, which would deserve further clarification.

Eurogroups for animals asked for a regular time period for review of GD rather than on an ad hoc basis. SANTE clarified that updates would be regular, however it is difficult to fix a timeline as it depends on the needs and priorities.

EFFAT noted that there was a lack of coordination across DGs, notably with DG EMPL, some risks for users seems not to be taken care of, the focus should not only be on exposure of chemicals and their structure, but also on technical exposure.

SANTE clarified that data requirements for the safe use of the product have not changed and the Uniform Principles still apply, and that guidance is already available which specifically considers also assessment of risk to operators, workers, bystanders and residents. In the revised draft Communications, these more recent test methods and guidance documents are listed. The Communications will be subject to Inter Service Consultation and DG EMPL will be involved, as usual.

3.4 Amendments of the Joint Template for Assessment Report and CLH Report

SANTE explained that the template in question is aiming at helping the RMS to report on the risk assessment for an active substance and the classification of active substances according to the CLP regulation (Classification, Labelling and Packaging of substances and mixtures, Reg. 1272/2008). This template needs to be updated to reflect the new criteria for the identification of substances with endocrine disrupting properties, which have been recently adopted. Volume 1 of the DAR/RAR provides a summary of the full detailed assessment but also the RMS proposed decision on the approval for the active substance and the endocrine disruptive potential is one of the criteria for decision.

The amendment to the template is very specific as it related to the section on criteria for decision.

Participants are invited to send their comments by 19 October 2018; Comments must be submitted using the template provided with the document.

3.5 Commission Notice – Guidance on Seed Treatment

SANTE presented this Commission Notice, which has been under development since 2010 on how to address risk mitigation measures for seed treatments. A dedicated working group (WG) is in place and is chaired by Belgium. The document is considered as draft final by the WG, hence it is now subject to internal consultation with EFSA and MS.

The document covers anything related to seed treatment, art. 49 of the Regulation 1107/2009 on the evaluation because of the specificity of the seed treatment. A background document prepared by EFSA is provided with the draft Commission Notice which outlines all the science supporting the guidance.

Participants are invited to send their comments by 16 November 2018, Comments must be submitted using the template provided with the document. Nota Bene: the background document is NOT open for comments.

IBMA asked whether microorganisms have been considered as part of seed treatment. SANTE clarified that the draft document is currently focused on chemical properties of the formulation, such as stickiness. At this stage, it is uncertain that all points would be relevant for microorganisms; it would be reconsidered in the future once experience would have been gained.

ESA asked about a potential date for the adoption of the document. SANTE indicated that it would depend of the feedback received. It should be noted that the background document is equivalent to an EFSA opinion to provide some clarification in order to understand the reasoning behind the guidance. However only the Guidance document is going to be applicable. It has not been finally concluded whether the Guidance document would become a Commission Notice or a Guidance adopted by the SCoPAFF.

EFFAT asked whether there was a risk assessment for the work place included. SANTE clarified that there is a section on non-dietary exposure, in the company treating the seeds or at the step of using seeds, handling the seeds, filling the sewing machine or carrying the bags.

IBMA and ECCA inquired about the process for consultation. SANTE mentioned that the documents would be available on the webpage of the advisory forum. A dedicated email address is provided to which comments should be sent.

ECPA inquired whether the comments be shared with the working group which drafted the GD or only with SANTE? SANTE explained that most of the documents have been subject to early consultation with stakeholders. These documents are considered as final draft by the working groups, so SANTE is intending to proceed swiftly with their adoption. Only if fundamental comments were identified there might be a need to go back to the working group.

EFFAT explained the risk to agricultural workers should be considered in the document, CHAFEA (Consumer, Health and Food Executive Agency) develops risk management procedures for these workers but it does not seem they have been involved in the drafting process for the guidance.

SANTE mentioned that the draft Assessment Report prepared by the MSs is open for public consultation at the time it is received by EFSA and that risk assessment of products for the workers is included.

SANTE also reminded participants that back in 2014, the advisory forum was consulted on the exposure of workers, residents, bystanders on a draft guidance document. SANTE also reminded that a dedicated EFSA GD on exposure to humans is available, and that this GD was subject to public consultation. EFSA pointed out the existence of the EU agencies forum where there is full cooperation between the different relevant committees.

PAN commented that post monitoring data of workers exposure was not provided so far, this point would be reflected in their comments on data requirements.

ECCA answered by referring to the human biomonitoring project sponsored by the European Commission. Also, it was noted that Art. 56 of Reg. 1107/2009, includes provisions where the monitoring is mandatory to report on potential adverse reactions.

EFFAT insisted that Article 153 of the TFEU (Treaty on the Functioning of the EU) calls for a dedicated consultation on workers safety and cannot be covered by a general consultation.

Risk assessment at the work place is a dedicated instrument of the EU Commission and is not reflected in the risk assessment of the Reg 1107/2009. SANTE acknowledged the point raised and the need for consistency with other legislation and confirmed that the provisions for risk assessment were addressing concerns raised.

SANTE encouraged participants to use the template provided to share comments in order to ensure an efficient handling of the comments received which would smoothen the revision process and a timely adoption of the final documents. As much as possible comments should be supported with justification. In case of lack of clarity, suggestions for alternative rewording would be welcome.

B - EFSA GD to be implemented (update)

3.6 Commission Notice on the time-frame for the use of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees)

SANTE provided an update about the status of the Commission Notice on the EFSA Bee guidance. Many comments were received with divergent opinions expressed by different stakeholders and MSs. It was agreed to take a stepwise approach and that acute and chronic risk for honey bees would be implemented in the first place.

This Commission Notice goes together with a revision of the Uniform Principles on bees. It needs to go through Inter Service Consultation in the Commission. When this will be concluded it will be taken to SCoPAFF.

ECPA asked whether it would be possible to receive the draft Commission Notice and the amendment of the Uniform Principles for consultation. SANTE explained that it has not been concluded yet if the Uniform Principles would be subject to feedback mechanism, this will be confirmed through the Inter Service Consultation.

IBMA asked for further clarification about the general and specific changes to the Uniform Principles. SANTE explained that the changes in the Uniform Principles were based on the guidance document and can be found in there.

POLLINIS asked whether the 2013 document would be proposed for implementation or if it would be updated. SANTE mentioned that the 2014 document would be implemented.

3.7 Commission Notice – EFSA/ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

SANTE summarised the development of the guidance and the process followed for the adoption of the Commission Notice. SANTE explained the approach taken with respect to the application of the GD on the dossier under evaluation.

ECCA asked about the case where EFSA would issue a conclusion where the ED (Endocrine Disruptive) profile could not be concluded on after 10 November 2018. SANTE explained that it is always case by case and that if there would be reasons (other than ED potential) not to approve the active substance, SANTE would proceed with a non renewal proposal.

In case of doubt, a mandate could be sent to EFSA to conduct appropriate review; decision to send a mandate will be made on a case by case basis. The clock stop will be of minimum 3

month and maximum 30 months depending on the identified need for further data. This will imply extending expiry dates of approvals.

In some cases, as an alternative to send the mandate and stop the clock, requests for confirmatory information could be considered.

PAN pointed out that some of the substances have been approved a long time ago so this might be an opportunity for the Commission to trigger an Art 21 (Reg. 1007/2009) on the review of approval. SANTE confirmed that this is always possible, but that many of these substances are already subject to renewal and therefore would be reviewed according to the new ED criteria. An assessment has been performed and triggering an article 21 would not add benefits in term of timing with respect to the ongoing or forthcoming renewal assessment.

IBMA mentioned that some pheromones have been flagged as possibly meeting the criteria for identification as endocrine disruptors. SANTE suggested that if it would be the case, the applicants, when requested to submit additional information on the ED properties of those substances, could clarify that pheromones are by definition not endocrine disruptors since they are secreted outside the organism.

PAN asked whether the proposal to amend the clause on negligible exposure could have an impact on the submission of additional data on the ED properties. SANTE clarified that the proposal is still under discussion. If endorsed in the future, transitional measures would apply. Therefore, it will likely not apply in the near future. PAN asked whether a feedback mechanism would be launched on that amendment. SANTE recalled that a feedback mechanism was already held in 2016 and that measure has not changed in text from that date.

ECPA asked whether it would be possible in the future, for new guidance developed, to organise dedicated workshops to have and exchange views on practical cases, similarly to what was done for the application of the ED-guidance in February 2018. EFSA mentioned that those type of discussions with Member States are routinely organised via the Pesticide Steering Network. What was new with the workshop on the ED-guidance, was the involvement of stakeholders and that there is currently discussion with SANTE to even have a dedicated training session for Member States on the ED-guidance.

ECPA commented that workshops with case studies where the MSs tested the guidance, like performed in February 2018, proved to be helpful also for stakeholders and should be renewed for other areas. EFSA responded that other opportunities for such a process are under consideration, as part of the on - going interaction with representative parties.

C --Foreseen stakeholder involvement and consultations

SANTE provided an overview on various documents at an early drafting stage, which would be subject to consultation in the near future.

3.8 Development of Specific Protection Goals for Guidance documents for environmental risk assessment under Regulation (EC) No 1107/2009

SANTE indicated that the Commission intends to progress in a stepwise approach, which would take about 2 years. Stakeholders should be involved since the beginning. An outline-plan was presented in July 2018 at SCoPAFF and a status update is expected to be provided during the upcoming SCoPAFF meeting in October 2018.

SANTE invited stakeholders to look already at EFSA documents of 2010 and 2016 dealing with protection goals in order to prepare for the consultation.

3.9 Risk Mitigation of PPPs

SANTE indicated that activities on this topic will be initiated and are in the planning phase. The input from stakeholders on these elements will be crucial. Once more concrete proposals would be available, the Commission would approach stakeholders via the Advisory Group.

3.10 Commission Notice – Guidance on Zonal Assessments and Mutual Recognition

SANTE mentioned that the work started 3 years ago and that four areas were revised:

- Section on Mutual Recognition Process: the document addresses the process at MS level, how the zonal evaluation works for the granting of an authorisation.
- Generic products section have been biffed up
- Provision on low risk products have been included
- Clarification of the section on general interest.

In some cases, those changes should help dealing with minor uses.

The document was discussed in WG and is considered as almost finalised pending some fine-tuning. The stakeholders would receive a message clearly mentioning expectations with respect to the documents shared.

Tentative consultation date : Q1 2019

ECCA commented that before starting a discussion in a WG, views of stakeholders should be sought in order to inform the discussion of the MSs.

SANTE agreed to this, but explained that the revision of this document had been initiated back in 2016. As there was an evolution on the topic over the last two years, SANTE indicated that for those documents where revision has already started, SANTE is willing to progress for reasons of efficiency.

ECCA indicated that would provide views ahead of the consultation on the list of documents provided by the EU Commission.

3.11 Commission Notice – Guidance on Renewals of Authorisation according to Article 43 of Regulation (EC) No 1107/2009

SANTE explained that applicants and regulators were still in a learning phase. The revision includes clarification on role and responsibilities (RMS vs Zonal RMS), timelines and other elements.

Documents still work in progress and under debate in the WG

Target consultation date: 2H 2019

3.12 Commission Notice – Guidance on Metabolites produced by Micro-Organisms

SANTE explained that this draft document should be looked at in relation with the OECD draft guideline on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents , the later one is currently subject to declassification process and should to be made publicly available in the near future.

The draft guidance is still under discussion at the level of the Biopesticides WG and would provide a step wise approach.

Target consultation date: summer 2019

3.13 Commission Notice – Guidance on Antimicrobial Resistance in Micro-Organisms approved according to Regulation (EC) No 1107/2009

SANTE mentioned that this document would be a new guidance, for defining if microorganisms which should be approved according to low risk criteria because they do not trigger Anti Microbial Resistance. Reference is made to the existing EFSA guidance on the characterisation of microorganisms used as feed additives or as production organisms. The work is still on going in the Biopesticides WG.

Target consultation date : summer 2019

IBMA asked how the draft guidance would be considered during the renewal process of microorganisms and the evaluation of low risk criteria. SANTE explained that although the guidance would not be available, it does not prevent assessing the dossier according to low risk criteria currently available.

D – General discussion

General discussion and feedback from stakeholders on other area where new or updated guidance would be needed

SANTE invited participants to share views on areas of concerns with GD but also on topics of interest for further work.

ECPA welcomed the opportunity to be consulted but indicated that a review of draft Commission Notice on the time-frame for the use of the EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees would be welcome. The set up of dedicated workshop on this guidance would be of much help.

PAN noted that it is difficult to handle the review of the various guidelines or requirements in particular because the Sustainable Use Directive (Dir. 2009/128/EC) would bring another perspective to the draft documents and should be considered. SANTE stressed that there is a good cooperation with colleagues working on the Sustainable Use Directive to reflect on these aspects.

ECCA referred to the document on data protection tabled at the last SCoPAFF meeting and asked for an update on the status of the document. SANTE explained that today's meeting is part of an improved process for consultation of stakeholders, although for this particular Commission Notice on data protection the process was closed and there is a need to progress swiftly. In addition, some provisions are already enshrined in other documents. Comments are still possible, but a forthcoming consultation would occur for the next revision of the guidance as the topic is evolving fast; hence a consultation of stakeholders on the revised guidance will be scheduled at an early stage.

ECCA noted that any minor change to the guidance would have a major impact for generic industry and complained of the lack of consultation of stakeholder. ECCA indicated that they asked for the document under the formal Access to Documents process and was denied access. SANTE indicated that the EU Commission would reflect on this point and would

come back to stakeholders on the potential for a short consultation or go for adoption by the SCoPAFF.

ECCA commented that the development of GD on data sharing would benefit from clarification (art. 61 and art. 62) because there is still a lot of confusion.

POLLINIS asked whether the Commission would foresee a specific mechanism about conflict of interest. SANTE indicated that EFSA has a guideline on conflict of interest in the context of risk assessment.

4. Conclusions/recommendations/opinions

The Commission thanked the participants for their contribution and the fruitful discussion. The various timelines will be reminded in an email. Slides will be made available to participants confirming the email address where to send comments.

5. Next steps

SANTE would provide an update on the work in progress in 2019.

6. Next meeting

Organisation of future meeting will be considered depending of the progress with the various documents.

7. List of participants

<i>Organisation</i>	<i>Name</i>
CELCAA European Liaison Committee for the Agricultural and Agri-food Trade	Paul Rooke
COCERAL European Association of cereals, rice, feedstuffs, oilseeds, olive oil, oils and fats and agrosupply trade	Lucia Castillo
COPA European farmers COGECA European agri-cooperatives	Lucas Peeters
ECPA European Crop Protection Association	Laurent Oger
ECPA European Crop Protection Association	Ornella Cosomati
ECPA European Crop Protection Association	Aurélie Dhaussy

EFFAT European Federation of Food, Agriculture and Tourism Trade Unions	Arnd Spahn
ENA European Nurserystock Association	Josep M. Pagès
EUROGROUP for ANIMALS	Luisa Bastos
FACE Federation of Associations for Hunting and Conservation of the EU	Angela Popovic
FoodDrinkEurope	Rebeca Fernandez
FRESHFEL Freshfel Europe - the forum for the European fresh fruits and vegetables chain	Natalia Santos-Garcia Bernabe
IFOAM EU GROUP International Federation of Organic Agriculture Movements EU Regional Group	Isabella Lang
PAN EUROPE Pesticide Action Network Europe	Angeliki Lysimachou
PAN EUROPE Pesticide Action Network Europe	Constantin Muraru
PFP Primary Food Processors	Celine Benini

Permanent Observers

ECCA European Crop Care Association	Hans Mattaar
ECCA European Crop Care Association	Steve Kozlen
ECCA European Crop Care Association	Manuel Duarte
ESA European Seed Association	Amalia Kafka

Additional Stakeholders

C.I.B.E. International Confederation of European Beet Growers	Alex Krick
FEDIOL EU vegetable oil and proteinmeal industry association	Julie Roiz
FRUCOM European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey	Anna Boulova
IBMA International Biocontrol Manufacturers Association	David Cary
IBMA International Biocontrol Manufacturers Association	Willem Ravensberg
IBMA International Biocontrol Manufacturers Association	Ulf Heilig
POLLINIS	Barbara Berardi Tadie
POLLINIS	Clémentine Bonvarlet