

## MINUTES OF THE 29<sup>th</sup> PLENARY MEETING OF THE SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Held in Parma on 24-25 October 2007  
(adopted by written procedure on 14 November 2007)

#	Agenda
1.	Adoption of the agenda, apologies for absence, declaration of interest
2.	Presentation of the draft opinion on the new request on default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil
3.	Presentation of the project for updating the Guidance Documents on persistence in soil
4.	State of revision of the Guidance Document on risk assessment for birds and mammals
5.	Presentation of the draft opinion on cumulative risk assessment of pesticides in human health
6.	Presentation of the draft opinion on tritosulfuron
7.	Presentation of the draft opinion on buprofezin
8.	Update on new questions expected/new Guidance Documents to develop
9.	Miscellaneous: <ul style="list-style-type: none"> <li>• Feed-back from the Scientific Committee and Working Groups: Implementation of the INEX opinion</li> <li>• Questions to IT Department Extranet</li> </ul>

### PARTICIPANTS

#### *Members of the PPR Panel*

Mr. D. BARCELLO-CUILLERES, Mr. J. BOESTEN, Ms. C. BOLOGNESI, Mr. A. BOOBIS (Vice chairman), Ms. A. BUCHERT, Mr. E. CAPRI (on 24<sup>th</sup> only), Mr. D. COGGON, Mr. A. HARDY (on 24<sup>th</sup> only), Mr. A. HART, Mr. H. KÖPP, Mr. R. LUTTIK, Mr. M. LIESS, Mr. O. MEYER, Mr. M. MONTFORTS, Mr. A. MORETTO (on 24<sup>th</sup> only), Mr. M. MÜLLER (on 24<sup>th</sup> only), Ms. B. OSSENDORP, Mr. W. STEURBAUT, Ms. M. TASHEVA,

#### *Apologies*

Ms. S. MICHAELIDOU-CANNA, Ms. C. VLEMINCKX.

#### *EFSA*

PPR Panel secretariat: Ms. M. DUNIER-THOMANN, Ms. C. FÜLL, Mr. B. BERGER, Mr. M. EGSMOSE, Mr. I. SEBESTYEN, Ms. C. PERCIVALDI and Ms. I. RIHANI.

PRAPeR unit: Ms. M. TIRAMANI ad H. REICH for item 5 to 6.

## **Commission**

Mr. X. PAVARD (DG SANCO O3)

### **1. ADOPTION OF THE AGENDA, APOLOGIES FOR ABSENCE, DECLARATION OF INTEREST**

The agenda was adopted without changes, 2 apologies were received, the chairman and 3 other members were unable to attend on 25<sup>th</sup> October, and the meeting was chaired that day by the vice chairman A. BOOBIS.

The chairman introduced the new secretary I. RIHANI and wished good luck to B. BERGER in his new function as Head of the Scientific Cooperation Unit in the Scientific Cooperation & Assistance Department (SCA).

A. BOOBIS declared a new interest, he is now advising the company Sumitomo on a specific active substance, but not one under consideration by the PPR Panel.

M. TASHEVA informed the group she will move to a new position in the Ministry of Agriculture on 1st November.

### **2. PRESENTATION OF THE DRAFT OPINION ON THE NEW REQUEST ON THE DEFAULT Q10 VALUE USED TO DESCRIBE THE TEMPERATURE EFFECT ON TRANSFORMATION RATES OF PESTICIDES IN SOIL**

The rapporteur presented the status of the Q10 opinion. The Plenary discussed the possible outcome and it was suggested to provide clear guidance to risk-assessors on how to select the appropriate Q10 value(s). The Q10 working group had met on 23<sup>rd</sup> and 24<sup>th</sup> of October and discussed the comments and additions to the first draft. The working group will meet again on 14<sup>th</sup> and 15<sup>th</sup> of November to advance the draft opinion further. The opinion is scheduled for adoption at the 30<sup>th</sup> PPR Plenary meeting on 11<sup>th</sup> and 12<sup>th</sup> of December.

### **3. PRESENTATION OF THE PROJECT FOR UPDATING THE GUIDANCE DOCUMENTS ON PERSISTENCE IN SOIL**

The Draft Terms of References of the self-tasked question were discussed and agreed at the plenary. The rapporteur also presented the outline for the draft project plan for the revision of the Guidance Documents on Persistence in Soil. Some points were raised for clarification by the panel members and were addressed at the meeting. It is EFSA's intention to provide the outline for a web-consultation for stakeholders to respond when the project plan is further developed. The Working Group would meet on 25<sup>th</sup>-26<sup>th</sup> of October and on 15<sup>th</sup>-16<sup>th</sup> of November to consolidate the Working Group with *ad hoc* experts and further develop the project plan.

### **4. STATE OF REVISION OF THE GUIDANCE DOCUMENT ON RISK ASSESSMENT FOR BIRDS AND MAMMALS**

The PPR Panel had received a request to revise the Guidance Document (GD) on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO/4145/2000-final of 25 September 2002). Subsequently, the EFSA Secretariat arranged a public consultation on the EFSA website in summer 2006, and four WG meetings took place between June and November 2006. Six Core Working Group meetings took place between December 2006 and October 2007. In addition, eight meetings of four different sub-Working Groups on specific topics and a telephone conference took place in 2007. A

workshop with Member States and industry on focal species and ecological parameters was held on 8<sup>th</sup> -11<sup>th</sup> May 2007 in Valencia/Spain.

The rapporteur presented the current version of the GD to the panel and explained the changes in the structure that were discussed during the 6<sup>th</sup> Core WG meeting, preceding the plenary meeting. He further explained which chapters of the GD are more or less finalised and which parts still need input. He continued in explaining the old/current concept of basic risk assessment and the intended changes in this concept in the revised GD. He outlined which new topics the revised GD will take up, thus also responding to the requests received during the public consultation.

The timetable for the further work was presented: all remaining contributions to the GD have to be sent to the EFSA Secretariat by 6<sup>th</sup> November 2007. The updated draft will be sent out to both the Core WG members and PPR Panel members for thorough reading. On 12<sup>th</sup> November 2007 another telephone conference of the Core WG will take place. The final draft should then go on the EFSA website for public consultation on 16<sup>th</sup> November. The consultation will be open for at least six weeks, but due to the Christmas period it might last later in January 2008. On 4<sup>th</sup>-5<sup>th</sup> December 2007 a meeting with Member States will take place to present the revised GD to them and to receive their initial feedback on the document.

It was suggested to accompany the public consultation with a text indicating the impact of the revised GD for notifiers (e.g. will there be increased data requirements, pass/fail rate, which compounds would come closest to the threshold etc.) but also what benefits there will be. Furthermore, the Core WG intends to elaborate an accompanying questionnaire.

A WG member gave an introduction to one of the Annexes submitted to the Plenary ("Alternative approaches for tier 1 avian acute assessment"). During the public consultation, feedback will be requested concerning the choice between two approaches, the TER approach and the LD50/sqm approach.

The discussions raised issues such as population modelling, the relative importance of the different exposure routes, non reproductive long term effects, reproductive effects, and residue unit doses. It was suggested to include a flow diagram in the GD showing applicants and risk assessors what steps they will have to take. Questions concerning statistical approaches were answered. Further feedback on the draft GD would be very much appreciated by the Core WG.

The next meeting (teleconference) of the Core WG will take place on 12<sup>th</sup> November 2007. The adoption of the revised GD by the PPR Panel is foreseen for April 2008.

## **5. PRESENTATION OF THE DRAFT OPINION ON CUMULATIVE RISK ASSESSMENT OF PESTICIDES IN HUMAN HEALTH**

To support EFSA in carrying out cumulative risk assessments in the future, the PPR Panel has self-tasked an opinion to evaluate the suitability of existing methodologies and, if appropriate, to identify new approaches for assessing cumulative and synergistic risks from pesticides to human health in relation to setting MRLs for those pesticides in the framework of Regulation (EC) No. 336/2995.

The rapporteur of the toxicology part explained the state of the quite advanced draft, which will be discussed further at the November Working Group Toxicology. The co-rapporteur for the exposure assessment aspect of the opinion reported back from the discussion on the opinion in the Working Group Residues on 23<sup>rd</sup>-24<sup>th</sup> October. It was emphasized that the opinion should be ready for adoption in April.

## **6. PRESENTATION OF THE DRAFT OPINION ON TRITOSULFURON**

The chair of Toxicology Working Group gave a thorough overview on a draft opinion regarding the toxicological relevance of the soil and ground water metabolite TBSA of tritosulfuron (a question from Commission).

The next revision of the draft opinion of tritosulfuron will be discussed during the meeting of the Toxicology Working Group in November 2007.

The adoption of the tritosulfuron opinion is planned for the Plenary meeting in December 2007, thus before the deadline negotiated and agreed with the Commission.

## **7. PRESENTATION OF THE DRAFT OPINION ON BUPROFEZIN.**

The rapporteur gave a detailed overview on a question regarding the genotoxic and carcinogenic potential of buprofezin in the context of the human risk assessment with a thorough explanation of the results of toxicological studies with buprofezin.

The first draft opinion has been circulated. The first thorough discussion on the draft opinion on buprofezin took place during the WG Toxicology meeting on 12<sup>th</sup>-13<sup>th</sup> September. The next discussion will take place in November at the WG Toxicology meeting.

The adoption of this opinion is envisaged for December 2007.

## **8. UPDATE ON NEW QUESTION EXPECTED/NEW GUIDANCE DOCUMENTS TO DEVELOP**

M. DUNIER-THOMANN gave a short overview of the future work of the Panel. A new question is expected from the Commission in the area of toxicology by end of the year and should be presented at the next plenary.

The priorities of the PPR Panel for the development of new Guidance Documents on risk assessment and the updating of existing ones in 2008 are listed hereafter:

- As the selection procedure of the call under Article 36 of European Parliament and Council Regulation N° 178/2002 for "Preliminary work in view to develop the GD for pesticides exposure assessment for workers, operators, bystanders and residents" is almost over, the contract should be signed by early December, and more details will be given at the next Plenary. Discussion will take place at the November Toxicology Working Group meeting about the composition of the Steering group.

- A new self-task opinion, to produce an example of a cumulative risk assessment for triazoles with a view to test the methodologies, will be soon launched. The Panel members discussed and agreed the Terms of Reference, the discussion were whether to carry out such cumulative risk assessment for chronic and/or acute risk, as well as which residue values to use in the exposure assessment (monitoring results or MRL values). The Panel members confirmed a rapporteur. EFSA is in the final phase of the evaluation of the proposals from the call for tender regarding the exposure part of this opinion (a 6 months contract). The composition of the Steering group, including toxicologists and residue experts, was established; the first meeting should take place in December and ensure a consistent approach between the exposure and toxicology aspects.

- A new GD on environmental exposure in greenhouses, is intended to be developed by the Panel from 2008 onwards. The workplan and possible externalisation of the preliminary work will be further discussed at the WG on 25<sup>th</sup>-26<sup>th</sup> October and presented at the next Plenary.

## **9. MISCELLANEOUS**

- Feedback from the Scientific Committee

Tony HARDY reported briefly the progress on the activities of the last Scientific Committee which took place on 17<sup>th</sup>-18<sup>th</sup> September and on its various WGs. He attended the Transparency WG on 25<sup>th</sup> October.

A new WG on nanotechnology will be created; volunteers were requested from all Panels. T. HARDY will circulate the information to contact the relevant colleagues of some Panel members.

A. BOOBIS reported on progression of work in the Working Group on use of the Benchmark Dose Approach in Risk Assessment.

O.MEYER reported on the work in the Animal Welfare Working Group (next meeting on 8<sup>th</sup> November).

T. HARDY informed on a presentation he gave on 15<sup>th</sup> October in Glasgow at the International Plant Protection Congress on "How safe is our food? Whom do you trust?".

The "Internal and External Review" opinion, adopted by the SC in August, should now be implemented in all Panels. The self-review check list (in the Annex) should be applied for each opinion before adoption. Some Panel members expressed their concerns on the delay in publishing the opinions in case of internal scientific review in EFSA. Details of the external scientific review were also questioned and Panel members recommended EFSA to use it with discernment.

- Questions to IT Department on Extranet

Some questions were raised on the functioning of the PPR Extranet. A demo at the next meeting might be useful.

- The secretariat informed that the Chairs of the Working Group and Plenary meetings will receive a special indemnity of 300 E per meeting (not per day) from 11<sup>th</sup> September onwards.

The next **PPR Plenary meeting** will be on **11<sup>th</sup>-12<sup>th</sup> December 2007**, starting at 14h00 on 11<sup>th</sup> and the whole day on 12<sup>th</sup>. The Executive Director will give the opening speech and the new Head of the Risk Assessment department Riitta MAIJALA should attend the first afternoon of the plenary.

As 3 adoptions are foreseen, the chairman asked the Panel members to do their best to be present in order to obtain a quorum for adoption.