Scientific Panel on Plant Protection Products and their Residues

Minutes of the 17th meeting of the Working Group on Cumulative Assessment Group of Pesticides

Held on 15th – 17th of April 2013, Parma (Agreed on 06 05 2013)

Participants

Working Group Experts:

 Susanne Hougaard Bennekou (Chair), Antonio F. Hernàndez-Jerez, Karen Ildico Hirsch-Ernst, Andreas Kortenkamp, Roland Solecki and Alberto Mantovani (only 16th – 17th)

Hearing Experts:

 Diane Benford and Josef Schlatter (by audioweb conference) and Bernadette Ossendorp (all only on the 17th a.m.)

• EFSA:

 Pesticides Unit: Charlotte Bergkvist (only on 15th and 17th), Federica Crivellente, Frederique Istace, Luc Mohimont (only on 15th and 17th), Hans Steinkellner, Andrea Terron, Manuela Tiramani (only on 17th) and Hermine Reich (only 17th)

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Alberto Mantovani.

2. Adoption of agenda

Two additional agenda points, on procedural matters and a session with hearing experts.

3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding

Page 1 of 2

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

4. Cumulative Assessment Groups for Pesticides **EFSA-Q-2009-00860**

Procedural matters on dealing with input from the Scientific Committee

The input received from the Scientific Committee was discussed and an agreement reached on how to address these comments in the opinion.

Discussion of comments received and update of opinion

The comments received from the Panel members were addressed and the opinion was updated accordingly.

Session with hearing experts

The reservations regarding the approach proposed by the PPR Panel were discussed. It was agreed that these need to be addressed in the opinion which might make a further extension of the deadline for its adoption necessary.

5. EFSA Scientific Report on Frameworks for Mixture Toxicity

The draft EFSA report on frameworks for mixture toxicity was discussed and it was agreed that it should be published together with the opinion.

6.	Any	other	business

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² http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf



Scientific Panel on Plant Protection Products and their Residues Minutes of the 16th meeting of the Working Group on Cumulative Assessment Groups of Pesticides

Held on 14-15 03 2013, Parma, Italy

(Agreed on 05 04 2013)

Participants

- Working Group Experts:
 - Susanne Hougaard Bennekou (Chair), Karen Ildico Hirsch-Ernst, Alberto Mantovani, Andreas Kortenkamp and Roland Solecki (by 12.00 on the first day)
 - Antonio Hernàndez Jerez has participated via teleconference the first day only
- Hearing Experts:
 - None
- European Commission and/or Member States representatives:
 - None
- EFSA:
 - Pesticides Unit: Hans Steinkellner, Frederique Istace, Charlotte Bergkvist, Andrea Terron
- 1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.



3. Declarations of interest

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes¹ and the Decision of the Executive Director implementing this Policy regarding Declarations of Interests², EFSA screened the Annual Declaration of interest and the Specific Declaration of interest) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest at the beginning of this meeting.

4. Agreement of the minutes of the 15th Working Group meeting held on 14-15 02 2013, Parma, Italy.

The minutes were agreed by written procedure on 27 02 2013 and published on the EFSA website 04 03 2013.

5. Scientific topic(s) for discussion

5.1 Cumulative Assessment Groups for Pesticides (EFSA-Q-2011-01020)

Grouping for Thyroid: the status on data collection and evaluation of substances were presented. Criteria for grouping were agreed.

Grouping for Neurotoxicity: changes to the last version and criteria for grouping were presented, discussed and agreed.

Chapter 2; Overview on grouping approaches for chemicals: a new text was provided, discussed with the Working Group and agreed.

Chapter 8; Uncertainties and limitations: a new text was provided, discussed with the Working Group and agreed.

Conclusions and Recommendations: a new text was provided, discussed with the Working Group and agreed.

Summary: a new text was provided, discussed with the Working Group and agreed.

6. Next meeting(s)

15th (pm) - 17th (am) April 2013

² http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf

¹ http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf



Scientific Panel on Plant Protection Products and their Residues

Minutes of the 15th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

held on 14 - 15 02 2013, Parma

(Agreed on 27 02 2013)

Participants

Working Group Experts:

Susanne Hougaard Bennekou (Chair), Alberto Mantovani, Antonio Hernandez Jerez, Andreas Kortenkamp, Karen Ildico Hirsch-Ernst and Roland Solecki

EFSA:

Pesticides Unit: Hans Steinkellner, Frederique Istace and Federica Crivellente

1. Welcome and apologies for absences

The Chair welcomed the participants. The participants introduced themselves.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. Cumulative Assessment Groups for Pesticides **EFSA-Q-2011-01020**

4.1. Discussion of all chapters of the draft opinion taking into accounts comments of the PPR Panel



The recommendations provided by the plenary meeting were taken into consideration when the different parts of the opinion were reviewed.

4.2. Discussion about further work to be carried out, allocation of tasks and setting of time lines

Further work will be carried out in order to review the different chapters of the opinion on the basis of the discussion within the working group. All the working group members agreed to contribute to a specific part of the opinion that will be provided to EFSA by March 7th.

5. Next meetings for 2013

- 14th(whole day) 15th (am) March
- 16th (pm) 17th (am) April



Scientific Panel on Plant Protection Products and their Residues

Minutes of the 14th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

held on 12 - 13 02 2013, Parma

(Agreed on 27 02 2013)

Participants

Working Group Experts:

Susanne Hougaard Bennekou (Chair), Antonio Hernandez Jerez, Andreas Kortenkamp, Karen Ildico Hirsch-Ernst and Roland Solecki

EFSA:

Pesticides Unit: Hans Steinkellner, Charlotte Bergkvist, Frederique Istace and Federica Crivellente

1. Welcome and apologies for absences

The Chair welcomed the participants. The participants introduced themselves. Apologies were received from Alberto Mantovani.

2. Adoption of agenda

The agenda was adopted after adding EFSA activities to the agenda.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

- 4. Cumulative Assessment Groups for Pesticides EFSA-Q-2011-0120
- 4.1. Presentation and discussion of data collection for neurotoxic substances not evaluated by RIVM (carried out by EFSA)



Data collection for neurotoxic substances carried out by EFSA was presented and the approach used was agreed.

4.2. Presentation and discussion of final list with CAGs for neurotoxicity

CAGs for neurotoxicity were presented, discussed and the approach agreed by all the members of the working group. Further work will be carried out by mid March to finalise CAGs on the basis of the approach agreed.

4.3. Presentation of progress on data collection on thyroid

An update of data collection for thyroid toxicity was presented and the approach used was agreed by all the working group members. Data collection will be finalised by mid March.

4.4. Discussion of the draft opinion with a particular emphasis on new and revised chapters

The new and revised chapters were reviewed. The working group agreed to further work on the opinion: different group members were identified as responsible for a specific part of the opinion.

5. Next meetings for 2013

- 14th (pm) 15th (am) February
- 14th(whole day) 15th (am) March
- 16th (pm) 17th (am) April



Scientific Panel on Plant Protection Products and their Residues

Minutes of the 13th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

held on 14 - 16 01 2013, Parma

(Agreed on 29 01 2013)

Participants

Working Group Experts:

Susanne Hougaard Bennekou (Chair), Alberto Mantovani, Antonio Hernandez Jerez and Roland Solecki

• EFSA:

Pesticides Unit: Frederique Istace, Hans Steinkellner, Charlotte Bergkvist, Federica Crivellente, Manuela Tiramani (present on the first day and first part of the second day) and Luc Mohimont (present on the first part of the second day)

1. Welcome and apologies for absences

The Chair welcomed the participants. The participants introduced themselves. Apologies were received from Karen Hirsch-Ernst and Andreas Kortenkamp.

2. Adoption of agenda

The agenda (rev.1) was adopted after adding "...adrenals..." to the agenda (no. 7) and "... allocation of tasks and timelines for presentation the draft opinion to the PPR Panel at the February Plenary" (no. 12).

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. Cumulative Assessment Groups for Pesticides EFSA-Q-2011-01020



4.1. Consolidation of hazard identification/characterisation (steps 1 and 2) for neurotoxicity and thyroid

The consolidated work provided was discussed and agreed.

4.2. Presentation and discussion of data collection for neurotoxity carried out by EFSA (substances not considered by RIVM)

EFSA presented a summary of the work carried out and the prioritisation that has been done. The WG agreed to the exercise.

4.3. Presentation and discussion of step 4 (final grouping) for neurotoxity

It was agreed to split the data collection into acute and chronic effects.

4.4. Discussion and agreement on hazard characterisation and identification (steps 1 and 2) for adrenals, eyes, reprotoxity, liver effects

It was agreed not to include these analyses in the opinion as they could not be completed.

4.5. Discussion about final project report from ANSES/RIVM/ICPS in regard to quality of data collection for neurotoxicity and usability for grouping of neurotoxicity, reprotoxicity and liver effects and usability for grouping

The WG agreed on the decision that the data collection for neurotoxicity was complete and could be used for grouping.

4.6. Further data collections to be carried out by EFSA (thyroid)

EFSA presented the data collections already carried out and an estimate of the workload to finalise them.

4.7. Discussion about draft opinion (all chapters), allocation of tasks and timelines for presentation the draft opinion to the PPR Panel at the February Plenary

All chapters were discussed in detail.

- 5. Next meetings for 2013
 - 12th (pm) 13th (am) February
 - 14th (pm) 15th (am) February
 - 14th(whole day) 15th (am) March
 - 16th (pm) 17th (am) April



Pesticides Unit

Parma, 13th December 2012

SCIENTIFIC PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 12th meeting of the Working Group on Cumulative Assessment Groups of Pesticides Parma, 27th – 28th November 2012 EFSA/Pesticides Unit

Agreed by the WG on 13 December 2012

Participants

WG Experts Karen Hirsch-Ernst, Susanne Hougaard Bennekou (Chair), Alberto

Mantovani, Antonio Hernandez Jerez, Roland Solecki, Andreas

Kortenkamp (only present on the first day)

Hearing Experts ----Observers (eg.EC) -----

EFSA: Frederique Istace, Hans Steinkellner, Manuela Tiramani, Charlotte

Bergkvist, Luc Mohimont (only present on the first day)

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) and/or Specific Declaration of interest (SDoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. Overview about (amended) overall scope of the opinion and tasks to be carried out

The Chair presented the amended scope of the opinion and the activities to be carried out until adoption of the opinion. EFSA informed about further steps in implementing cumulative risk assessment.



Parma, 12th November 2012

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes Teleconference of the Working Group on Cumulative Assessment Groups of Pesticides

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Agreed on 12 November 2012

Date:	30 October 2012
Time:	14.00-17.00 CET
Place:	Teleconference

Participants:

WG Experts: Karen Hirsch-Ernst, Susanne Hougaard Bennekou (Chair), Alberto

Mantovani, Antonio Hernandez Jerez

EFSA: Frederique Istace, Hans Steinkellner, Manuela Tiramani

1. Welcome and apologies

The chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda (rev.1) distributed before the meeting was adopted.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

- 4. Scientific opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
- ♣ Further discussion about text for methodology (Chapter 6)

The methodology has been discussed and several amendments were agreed by the experts.



Reports from carrying out step 1 and 2 of the methodology for eye, thyroid, adrenals

The results from hazard identification and characterisation for eye, thyroid and adrenals were presented and discussed. Some changes were proposed but overall the work as carried out has been endorsed.

♣ Next step -data collection (step 3) for eye, adrenals and thyroid

It was agreed that data collection for the opinion will be carried out by the unit.

 Progress update from RIVM (i.e. interim outcome of outsourced data collection (step 3) for neurotoxicity)

EFSA reported about the progress on the project.

♣ Discussion about next steps until November meeting (e.g. carrying out step 1 and 2 for neurotoxicity, continuation/finalisation of step 3 for eye, adrenals, and thyroid) the workload incurred, distribution of work and setting of timelines (also for drafting of the other chapters)

Next steps wer discussed, tasks were allocated.

5. Miscellaneous

6. Next meetings

27(am) -28 (pm) November 2012, Parma

15 (am) -16 (pm) January 2013, Parma

12 (am) - 13 (pm) February 2013, Parma

16 (am) – 17 (pm) April 2013, Parma (to be confirmed!)



5. Discussion/agreement on presentation of hazard identification and characterisation (i.e. step 1 and 2 of methodology) in a harmonised format for adrenals, eye an thyroid

The WG agreed to the proposed methodology for the different organs, however, minor amendments were made.

6. Presentation of project progress of CFT/EFSA/PRAS/2012/07 -CT 01, 02 and 03 Toxicological data analysis to support grouping of pesticide active substances for cumulative risk assessment of effects on liver (Lot 2), on the nervous system (Lot 1) and on reproduction and development (Lot 3) (EFSA)

EFSA informed the WG about the progress achieved within the project.

7. Presentation of progress on data collection (step 3 of methodology) for eye, adrenals and thyroid (EFSA)

EFSA presented the progress of collecting data for the respective organs.

8. Discussion about response to question from PPR Plenary observer on Cumulative Risk Assessment

EFSA presented a draft response with was discussed and amended by the WG.

9. Discussion about first consolidated draft of new opinion

The structure of the opinion was amended according to the revised scope of the opinion. Text in the different chapters was discussed and amended where necessary.

10. Information and discussion about inclusion of active substances not approved in EU, but present as residues in food commodities, in Cumulative Assessment Groups

EFSA informed briefly about internal discussions on including further substances in the assessments.

11. Next meeting dates

2013 January 14 pm -16 am

2013 February 12 pm - 13 am

12. Any other business



Parma, 22th October 2012

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes

of the 10th and 11th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

(Agreed in a written procedure on 19th October 2012)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	2 – 3 and 4 – 5 October 2012
Time:	14.00-18.00, 09.00-13.00 CET
Place:	Meeting Room M01 EFSA, Via Carlo Magno 1/a, Parma

WG Experts: Karen Hirsch-Ernst, Susanne Hougaard Bennekou (Chair), Alberto

Mantovani, Antonio Hernandez Jerez

EFSA: Frederique Istace, Luc Mohimont, Hans Steinkellner

1. Welcome and apologies

The participants introduced themselves. No apologies were received.

2. Adoption of agenda

The agenda was adopted without comments.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

4. Scientific opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile



♣ EFSA objective regarding the implementation of CRA.

EFSA introduced the strategy for the work on cumulative risk assessment and reported also that the PPR Guidance on probabilistic exposure assessment developed in support of CRA has been published recently.

♣ Discussion on the updated methodology to derive cumulative assessment groups of pesticides. Criteria for selecting specific effects relevant for combined toxicity, characterization of specific effects and grouping of pesticides in cumulative assessment groups (possibly practical example with eye effects prepared by the Pesticides unit)

The experts discussed the methodology and a series of amendments were made.

Scientific report of the Danish Technical University on the Identification of cumulative assessment groups of pesticides.

The new WG members have been updated on the report.

Update on the ongoing outsourced activities on the effects on liver, on the nervous system and on reproduction and development.

EFSA informed that a kick-off meeting on the new outsourced project took place 3-4 September. A final report will be available on 15th December.

Quantitative estimation of the workload and fitting of the resources to a realistic workplan.

Agreed to address the issue on resources to be addressed at the next meeting (teleconference).

External expertise needed and composition of the WG.

It was agreed to revisit this agenda point when appropriate.

♣ Timelines, list and repartition of practical tasks.

It was agreed to carry out hazard identification and hazard characterisation a laid down in the new methodology for several organs by by the 26th October which should then be discussed at the teleconference on the 30th October.

♣ Cooperation between the Working group, the Pesticides unit and the contractors.

This agenda point was not discussed in particular but is reflected throughout all the other agenda points.

Content and structure of the opinion

A new structure for the opinion was agreed.

5. Miscellaneous

6. Next meetings

30 October 2012, 14.00 – 17.00, Teleconference



27(am) -28 (pm) November 2012, Parma

15 (am) -16 (pm) January 2013, Parma

12 (am) - 13 (pm) February 2013, Parma

Hans Steinkellner



Parma, 15th June 2012

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 9th meeting of the Working Group on Cumulative Assessment Groups of Pesticides

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

(Agreed on 14th June 2012)

Date:	29-30 May 2012
Time:	14.00-18.00, 09.00-13.00 CET
Place:	Meeting Room M05
	EFSA, Via Carlo Magno 1/a, Parma

WG Experts: Maria Tasheva (Chair), Kyriaki Machera, Karen Hirsch-Ernst,

Susanne Hougaard Bennekou, Andreas Kortenkamp, Claudia

Bolognesi, Roland Solecki and Christiane Vleminckx

EFSA: Frederique Istace, Hans Steinkellner;

Only on the second day: Hermine Reich, Luc Mohimont and

Manuela Tiramani

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Alan Boobis

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No



conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.

- Scientific opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
- 4.1. Discussion about main text of the draft opinion and
- 4.2. Discussion about CAGs for all organs (besides those outsourced)

WG members again expressed their concerns about the scope and the timelines for this opinion.

It was suggested that, since information on MoA was generally lacking structural similarity could be used instead for refinement and narrowing down the groups.

EFSA also presented their progress in grouping for cardiovascular effects and urinary bladder. The outcome of this preliminary grouping was discussed by the experts.

4.3. Discussion about overall scope of the opinion in the context of EFSAs work on cumulative risk assessment for pesticide residues in the diet (Wednesday morning)

For this agenda point also Luc Mohimont, Manuela Tiramani and Hermine Reich (Team Leader Pesticide Unit MRL team) participated.

It was clarified that the mandate of this WG is confined to developing criteria for grouping and to set up cumulative assessment groups considering all authorised pesticide active substances (as of 31st December 2011), using the scientific methodology described in the opinion of 2008.

5. Miscellaneous

6. Next meetings

2 (p.m.) - 3 October (a.m.) 2012, EFSA, Parma



Parma, 13th April 2012

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 8th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

(Agreed on 12th April 2012)

Date:	8-9 March 2012
Time:	14.00-18.00, 09.00-13.00 CET
Place:	Meeting Room M03
	EFSA, Via Carlo Magno 1/a, Parma

WG Experts: Ms. Maria Tasheva (Chair), Ms Kyriaki Machera, Mr. Alan Boobis,

Ms. Karen Hirsch-Ernst, Ms. Susanne Hougaard Bennekou, Mr. Andreas Kortenkamp, Ms. Claudia Bolognesi Mr. Roland Solecki

and Ms. Christiane Vleminckx

EFSA: Ms Frederique Istace, Mr. István Sebestyén, Mr. Hans Steinkellner

1. Welcome and apologies

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



- 4. Scientific opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
 - a. Discussion of the new version of DTU report and its impact on the work already done

The WG agreed that a clear terminology needs to be applied throughout the opinion. Agreed that IPCS terminology should be applied throughout the entire opinion. It was agreed to insert a new chapter on terminology.

b. Discussion of the use of the report of the outsourced project on dissimilar mode of action

A presentation was given about the project on the relevance of dissimilar MoA for Cumulative Risk Assessment (final report already published on EFSA webpage).

c. Discussion of the CAGs not covered by the new outsourced activities, with particular attention to parathyroid, cardiovascular system, eye, urinary bladder

It was reported that that grouping for parathyroid and eye has already been finalised other groups are currently being finalised.

Discussion of the new template

The new template for grouping as agreed at the last Plenary by means of the already (partly) filled template for effects on the urinary bladder. Several experts noted that the template needs to be simplified.

d. Discussion of the practical and scientific questions arising during the data collection and evaluation of substances for inclusion/exclusion to different CAGs

See above.

e. Discussion of the EXCEL table of new substances prepared by EFSA

It was noted that the Excel sheet giving indications of specifiec effects caused by the substances included in addition to those scrutinised by the contractor provided by EFSA is very useful.

There was general agreement among the WG members that it is of high importance to make clear to the public that a list with CAGs in the opinion will not constitute a final list.

f. Discussion of the current state of the draft opinion in particular the general chapters: Chapter 1 (Introduction), Chapter 2 (Relation with other activities and literature review), Chapter 3 (Summary of previous



opinions – lessons learnt), Chapter 4 (Grouping approach). Deadlines for individual contributions to be agreed in accordance with the Work plan.

The experts discussed the draft and several amendments were proposed.

5. Miscellaneous

6. Next meetings

29 (am) - 30 (pm) May, 2012 - EFSA, Parma



Parma, 9th January 2012

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes

7th Meeting of the Working Group on Cumulative Assessment Groups of Pesticides

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

(Agreed on 8th February 2012)

Date:	16-17 January 2012
Time:	14.00-18.00, 09.00-13.00 CET
Place:	Meeting Room M04 EFSA, Via Carlo Magno 1/a, Parma

WG Experts: Ms. Maria Tasheva (Chair), Mr. Alan Boobis, Ms. Karen Hirsch-

Ernst, Ms. Susanne Hougaard Bennekou, Mr. Andreas

Kortenkamp, Ms. Claudia Bolognesi Mr. Roland Solecki and Ms.

Christiane Vleminckx

EFSA: Mr Herman Fontier (only beginning of the meeting and second day

in the morning) Ms Frederique Istace, Mr. István Sebestyén, Mr.

Hans Steinkellner, Mr. Edgars Felkers

1. Welcome and apologies

Herman Fontier welcomed the participants. He pointed out that the successful finalisation of the mandate in time was a top priority for the Authority.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



- 4. Scientific opinion of the PPR Panel on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
 - a. Finalization/validation of the criteria for identifying toxicological effects relevant for combined toxicity and of the methodology for grouping

The draft criteria that have been sent to the WG before the meeting have been discussed and agreed.

b. Re-allocation of organs/tissues not covered by the new outsourced activities to WG members and EFSA Staff for the establishment of CAGs

The WG members responsible introduced their cumulative assessment groups. Overall the experts responsible for the organs (which were the starting point for grouping) confirmed that their analyses would fit to the criteria.

Agreed that once a template for grouping was available (to be provided by EFSA) the experts will edit their analyses accordingly.

c. Discussion and agreement on the table of contents of individual reports on CAGs

A draft table of contents for the individual reports (i.e. grouping template) has been agreed and will be distributed to the WG after the meeting

d. Discussion about the list of substances to be evaluated

EFSA has distributed the list of further substances to be considered for grouping. EFSA will also provide a final list with substances to be considered (deleting those irrelevant for CAGs) for commenting by the WG.

e. Discussion of the work plan

The work plan was presented.

f. Discussion and agreement on the revised structure of the opinion, tasksharing and deadlines for drafting.

EFSA presented a table with the proposal for a revised structure of the opinion and the responsible experts for the chapter which was discussed by the experts. The experts agreed to the new structure.

5. Miscellaneous

6. Next meetings

The following meeting dates were agreed:



 $27^{th}(pm) - 28^{th}$ (am) November 2012, EFSA, Parma

In addition, 1 - 2 teleconferences will be held, dates tbd

Hans Steinkellner/Istvan Sebestyen



Parma, 22 December 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 6th meeting of the Working Group on Cumulative Assessment Groups of Pesticides

(Agreed in a written procedure)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	22-23 November 2011
Time:	14.00-18.00, 09.00-13.00 CET
Place:	22 Nov.:Palazzo Ducale, meeting room Umberto I,
	Strada delle Fonderie, Parma
	23 Nov.:EFSA DUS D 00/002
	Largo N.Palli 5/A - Parma

WG Experts: Ms. Maria Tasheva (Chair), Mr. Alan Boobis, Ms. Karen Hirsch-

Ernst, Ms. Susanne Hougaard Bennekou, Mr. Andreas

Kortenkamp (on 22 November) and Ms. Christiane Vleminckx

EFSA: Mr. István Sebestyén, Mr. Hans Steinkellner, Mr. Edgars Felkers,

Ms Frederique Istace

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Ms. Claudia Bolognesi and Mr. Andreas Kortenkamp (on 23rd November)

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



4. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile

The group reviewed the CAGs proposed by the contractor and deletion/revision of severa; groups was discussed and agreed.

A consolidated version of the draft opinion containing all comments was circulated before the WG meeting and discussed by the members of the WG. The WG members agreed to provide draft CAGs documenting clearly reasoning for excluding effects (non relevance, non specificity). It was agreed to that in the opinion the options for further refinement of grouping, limitations of the approach followed and the uncertainties should be clearly described in a separate chapter of the opinion as this was information of highest importance for the risk managers to take decisions. An updated version of the opinion will be distributed on 5th January 2012.

5. Miscellaneous

6. Next meetings

- 16/17 January 2012 pm/am WG meeting in Parma
- 8/9 March 2012 pm/am, WG meeting in Parma

Hans Steinkellner/Istvan Sebestyen



PPR UNIT

Parma, 18 October 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 5th meeting (Teleconference) of the Working Group on the Cumulative Assessment Groups of Pesticides

(Agreed in written procedure on 18 October 2011)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	7 October 2011
Time:	10.00-13.00 CET
Place:	Teleconference

WG Experts: Ms. Karen Hirsch-Ernst, Ms. Susanne Hougaard Bennekou, Mr.

Andreas Kortenkamp, Mr. Roland Solecki, Mr Alan Boobis, Ms.

Maria Tasheva (Chair) and Ms. Christiane Vleminckx

EFSA: Mr. István Sebestyén (PPR), Mr. Hans Steinkellner (PPR), Mr.

Edgars Felkers (PPR)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Ms. Claudia Bolognesi.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting



4. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

The experts discussed the content on a letter from the Commission on possible risk management issues in regard to Cumulative risk assessment an its impact for this WG. Also the outcomes of the case study on acute developmental CAGs and on chronic thyroid CAGs were discussed.

5. Next meetings

22-23 November 2011 (pm/am), WG meeting in Parma
Teleconference (tentative) on 15th December 2011 from 10:30 to 13:00.
16-17 January 2012 (pm/am) WG meeting in Parma

Hans Steinkellner/Istvan Sebestyen



Parma, 26 August 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 4th meeting of the Working Group on the Cumulative Assessment Groups of Pesticides

(Agreed in a written procedure)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	22 August 2011
Time:	10.00-18.00 CET
Place:	Regus Vienna Office Park Airport
	Office Park I, Top B02 Vienna, Austria

WG Experts: Ms. Claudia Bolognesi, Mr Alan Boobis, Ms. Karen Hirsch-Ernst,

Ms. Susanne Hougaard Bennekou, Mr. Andreas Kortenkamp, Mr. Roland Solecki, Ms. Maria Tasheva (Chair) and Ms. Christiane

Vleminckx

EFSA: Mr. István Sebestyén, Mr. Edgars Felkers

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



4. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile

<u>Discussion of the report of the outsourced project and the possible content of the chapter 4</u> of the opinion

The WG agreed that the approach based on phenomenological effects as applied in the Report is an alternative approach for grouping. The group agreed that the known modes of action should be listed in the chapter 6 of the opinion. Carcinogenicity can be considered as possible basis of a new CAG.

<u>Discussion on the concept of the case study for developmental toxicity for acute CAG</u> (malformations)

The group agreed that the EXCEL datasheet should be improved and suggested some amendments.

<u>Discussion on concept proposal for performance of a case study on elaboration of CAGs, based on toxicity towards the thyroid hormone system</u>

 A proposal for a cas study was presented. For further refinement, mechanistic data, if available, might be used.

Discussion on Chapter 2 Relation with other activities

It was agreed that publications from 2008 onwards should be included in this review.

5. Miscellaneous

6. Next meetings

- 7th October 2011 from 10:00 am to13:00 a teleconference will be organized to discuss the new versions of documents listed in Actions point and the results of the case studies.
- 22/23 November pm/am WG meeting in Parma
 16/17 January 2012 pm/am WG meeting in Parma
 8/9 March pm/am WG meeting in Parma



PPR UNIT

Parma, 15th June 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 3rd meeting of the Working Group on the Cumulative Assessment Groups of Pesticides

(Agreed in written procedure on 10 June 2011)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	16 May 2011
Time:	09.00-18.00 CET
Place:	Regus Brussels Airport Meeting Centre 4th Floor of the Airport Terminal

WG Experts: Ms. Claudia Bolognesi, Ms. Karen Hirsch-Ernst, Ms. Susanne

Hougaard Bennekou, Mr. Andreas Kortenkamp, Mr. Roland Solecki, Mr Alan Boobis, Ms. Maria Tasheva (Chair) and Ms.

Christiane Vleminckx

EFSA: Mr. István Sebestyén (PPR), Mr. Hans Steinkellner (PPR)

1. Welcome and apologies

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting



4. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile

<u>Discussion of the first draft version of the opinion prepared by the rapporteur, of a concept for guidance for grouping and of the draft proposal on scientific issues for inclusion of a new substances in a CAG</u>

Discussion about overall structure of the opinion

Agreed to add a short description of content and structure of opinion to be added to the introduction.

Discussion of the usability of the database

The WG discussed the general principles to be applied for grouping. A problem is that for many substances mechanistic data was lacking. It was proposed to focus in the discussions on the procedures for establishing CAGs. It was noted that the final outcome of the opinion should be a list with CAGs that should be accepted EU wide. Following the opinion a guidance document should be drafted for grouping pesticides for CRA. It was agreed that it was a good idea also to carry out several case studies.

Discussion about the Grouping approach

Agreed that in regard to the principles of grouping the extent on knowledge on MoA was crucial and should be clearly documented. Relevance of different MoAs for humans had to be considered as well. Justification for the grouping approach(es) taken has to be provided. Criteria for grouping have to be clearly explained.

Timeline for delivery of contributions

Draft opinion to be ready for public consultation by end of March 2012.

Opinion to be adopted end of June 2012.

5. Next meetings

Friday, 1st of July, 10.00- 13.00, teleconference (to be confirmed) Monday, 22nd of August, full day, Vienna

István Sebestyén/Hans Steinkellner



PPR UNIT

Parma, 8 June 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 2nd meeting of the Working Group on the Cumulative Assessment Groups of Pesticides (Agreed in written procedure on 3rd May 2011)

Mandate: Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Date:	14 April 2011
Time:	10.00-13.00 CET
Place:	Teleconference

WG Experts Ms. Claudia Bolognesi, Ms. Karen Hirsch-Ernst, Ms. Susanne

Hougaard Bennekou, Mr. Andreas Kortenkamp, Mr. Roland

Solecki, Ms. Maria Tasheva (Chair) and Ms. Christiane Vleminckx,

EFSA: Mr. István Sebestyén (PPR), Mr. Hans Steinkellner (PPR)

1. Welcome and apologies

The Chair welcomed the participants. Apologies were received from Alan Boobis.

2. Adoption of agenda

The agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



4. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

EFSA informed that the final report from the outsourced work was further delayed.

<u>Discussion of the workplan for the preparation the first draft of the chapters 1, 2, 3 and 5</u> (chapters that are not directly depending on the outcome of the DTU report.

Drafting of the different chapters was allocated to different WG members.

<u>Development of a concept for guidance for grouping - discussion on the content of the chapter, allocation of tasks.</u>

It was agreed that selection criteria for index compounds will be provided and that a concept for discrimination between acute and chronic CAGs will be developed. It was agreed that a key step for grouping was the determination of the common mode of action. Similar mode of action and dissimilar mode of action have to be defined clearly.

<u>Timeline for delivery of contributions</u>

It was planned that the opinion should be delivered within 12 months after acceptance of the final report envisaged for mid of June 2011, i.e. mid of June 2012.

5. Miscellaneous

6. Next meetings

Brussels (airport), 16th of May 2011, full day

István Sebestyén/Hans Steinkellner



PPR UNIT

Parma, 8 June 2011

PANEL ON PLANT PROTECTION PRODUCTS AND THEIR RESIDUES

Minutes of the 1st Meeting of the Working Group on the Cumulative Assessment Groups of Pesticides

(Agreed on 21st December 2010)

Date:	23-24 November 2010
Time:	14:00–18:00, 09:00-13:00
Place:	EFSA
	Largo N. Palli 5/A, I-43121 Parma, Italy
	DUS D 00/016

Participants

WG Experts Ms. Claudia Bolognesi, Ms. Karen Hirsch-Ernst, Ms. Susanne

Hougaard Bennekou, Mr. Angelo Moretto, Ms. Maria Tasheva and Ms. Christiane Vleminckx, Mr. Roland Solecki, Mr. Alan Boobis

(only Wednesday)

EFSA: Mr. István Sebestyén (PPR), Mr. Hans Steinkellner (PPR)

1. Welcome and apologies

EFSA welcomed the participants. Apologies were received from Andreas Kortenkamp. The participants then briefly introduced themselves.

2. Adoption of agenda

The draft agenda was adopted without changes.

3. Declarations of interest

In accordance with EFSA's Policy on Declarations of Interests, EFSA screened the Annual Declaration of interest (ADoI) filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the beginning of this meeting.



4. Appointment of a Chair for the Working Group

Maria Tasheva was appointed chair of the WG. Panel.

5. Scientific opinion of the PPR Panel on identification of pesticides to be included in cumulative assessment groups on the basis their toxicological profile

Maria Tasheva reported on the current state of the works in regard to the preparation of the CAG opinion. Preparatory work was outsourced and was delayed. A preliminary final report will be available in February. EFSA gave a presentation on the regulatory background of the opinion.

In the discussion after the presentation the experts agreed that establishing the CAGs should be well described in the opinion to obtain wide acceptance for the criteria applied. It was noted that cumulative risk assessment for operators, workers and bystanders should be carried out as well. EFSA informed that another call for outsourced work for the preparation on an opinion on cumulative non-dietary risk assessment had been launched.

Angelo Moretto presented briefly the outcome and conclusions of the first PPR opinion on cumulative risk assessment where relevant existing methodologies had been investigated.

It was agreed that acute and chronic effects had to be considered in parallel.

Maria Tasheva gave a presentation on lessons learnt from the first two opinions on CRA with an emphasis on toxicology since that was important also for the present opinion. She pointed out that the triazole opinion was not an assessment of substances per se but a tryout of the principles established in the first opinion.

The group then discussed the risk management elements possibly contained in the future guidance document. It was agreed that the context of the mandate, legal requirements, background of the opinion were already defined in the Terms of Reference, and will be reflected in the introduction. An overview on relevant EC activities should also be presented in the opinion. A draft structure of the opinion was discussed and agreed upon as well.

A detailed workplan will be discussed once the final report from the outsourced work is available.

6. Miscellaneous

7. Next meetings

February 2011 - Teleconference
15/16 March 2011 pm/am in Parma
16 May 2011 all day Brussels airport
30 June/1 July 2011 pm/am Parma
7 October 2011 Teleconference
22/23 November 2011 pm/am Parma
Hans Steinkellner/Istvan Sebestyen