SCIENTIFIC REPORT OF EFSA

Outcome of the Public Consultation on the existing Guidance Documents on Aquatic and Terrestrial Ecotoxicology under Directive 91/414/EC[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

EFSA's Panel on Plant Protection Products and their Residues (PPR Panel) has performed a public consultation on the existing Guidance Documents (GDs) for Aquatic Ecotoxicology (SANCO/3268/2001) and Terrestrial Ecotoxicology (SANCO/10329/2002) under Council Directive 91/414/EEC. These documents provide guidance to notifiers and Member States (MS) on how to conduct assessment of aquatic and terrestrial ecotoxicology in the context of the review of active substances for inclusion in Annex I of Directive 91/414/EEC. The public consultation was open from 20 October to 15 December 2008.

The public consultation on the existing GDs was held in order to collect input for the revision of the two GDs for which the PPR Panel received early 2009 the mandates (Aquatic Ecotoxicology EFSA-Q-2009-0001; and Terrestrial Ecotoxicology EFSA-Q-2009-0002). A total of 225 comments were received on the GD on Aquatic Ecotoxicology, and 199 comments on the GD on Terrestrial Ecotoxicology.

This report highlights the major issues addressed in the comments, provides response by the working group on some of these comments and lists in the Appendices all comments received. EFSA wishes to thank all stakeholders for their contributions.

KEY WORDS

Aquatic Ecotoxicology; Terrestrial Ecotoxicology; Public Consultation; Revision of Guidance Documents; stakeholder involvement;

1 On request of EFSA, EFSA-Q-2008-04987, issued on 20 November 2009.
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3 Acknowledgement: EFSA wishes to thank EFSA's staff members Stephanie Bopp, Christine Füll and Karin Nienstedt for the support provided to this EFSA scientific output.

Suggested citation: European Food Safety Authority; Outcome of the Public Consultation on the existing Guidance Documents on Aquatic and Terrestrial Ecotoxicology under Directive 91/414/EC. EFSA Journal 2009; 7(11):1375. [129 pp.]. doi:10.2903/j.efsa.2009.1375. Available online: www.efsa.europa.eu

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BACKGROUND

EFSA's Panel on Plant Protection Products and their Residues (PPR Panel) has performed a public consultation on the existing Guidance Documents for Aquatic Ecotoxicology (SANCO/3268/2001) and Terrestrial Ecotoxicology (SANCO/10329/2002) under Council Directive 91/414/EEC. These documents intend to provide guidance to notifiers and Member States on how to conduct assessment of aquatic and terrestrial ecotoxicology in the context of the review of active substances for inclusion in Annex I of Directive 91/414/EEC. The public consultation was open from 20 October to 15 December 2008.

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1. Introduction

In the context of the revision of the existing Guidance Documents (GDs) on Aquatic Ecotoxicology (SANCO/3268/2001) and on Terrestrial Ecotoxicology (SANCO/10329/2002), a public consultation was arranged for both GDs together. The public was invited to submit comments on these GDs via an online form available at www.efsa.europa.eu from 20 October to 15 December 2008. Risk assessors, risk managers, stakeholders and the scientific community were additionally informed via emails and via presentations at scientific events about the open public consultation.

Comments were received addressing both GDs in general or specifically one of the two GDs. The following report is structured to first give a brief statistical overview on the comments received and then to address comments common to both GDs (section 2.1), followed by comments to the GD on Aquatic Ecotoxicology (section 2.2) and comments on the GD on Terrestrial Ecotoxicology (section 2.3).

EFSA's PPR Panel Working Group (WG) "Ecotoxicological Effects", which started the work on the revision of the two GDs in beginning of 2009, scrutinised the comments, categorised and summarised them. Until end of 2009/early 2010, this WG is addressing general topics, common to both GDs. After that, individual sub-WGs will deal with more specific topics to which detailed comments were submitted during the public consultation. The comments received will then be taken into account specifically. In the following sections, summaries of comments are given and response from the working group to the comments (if already available) is shown in italics.

2. Screening and evaluation of the comments received[4]

A total of 225 comments were received for the GD on Aquatic Ecotoxicology, and 199 comments on the GD on Terrestrial Ecotoxicology. All comments received were scrutinized and subsequently tabulated with reference to the author(s) and the section of the Guidance Document to which the comment referred. Duplicate comments received from the same contributor appear only once in the table and comments submitted by individuals in a personal capacity are listed anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization. All original comments received are listed in the end of this report in Appendix A (Aquatic Ecotoxicology) and Appendix B (Terrestrial Ecotoxicology).

In the following, statistical details on the comments received are provided in the tables 1-5. Then, the issues most frequently addressed, are presented. Comments are not answered individually in this report.

However, all comments were noted and will be considered during the revision process.

Table 1. Comments received on the GDs per stakeholder category

stakeholder category	GD Aquatic Ecotoxicology	GD Terrestrial Ecotoxicolgy	Total
authority	195	132	327
academia	5	5	10
agrochemical industry / ECPA	13	0	13
individuals	8	24	32
associations	4	38	42
consultancy	0	0	0
TOTAL	**225**	**199**	**424**

[4] Please note that the European Food Safety Authority may have considered some comments to be outside the instructions provided for in the terms of use of the public consultation.

Table 2. Comments received on the GD on Aquatic Ecotoxicology per organisation

Institution	Country	Number of Comments
Alterra / WUR (Wageningen University and Research Centre)	NL	3
AGES (Austrian Agency for Health and Food Safety)	AT	15
BASF SE	DE	13
CTGB (Board for the Authorisation of Pesticides)	NL	20
Centre for water management	NL	4
Danish EPA (Environmental Protection Agency)	DK	10
FURS (Phytosanitary Administration of the Republic of Slovenia)	SI	9
ICPS (Internat. Centre for Pesticides and Health Risk Prevention)	IT	1
Individual	DE	8
INIA (Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria)	ES	15
PAN-Europe (Pesticide Action Network International)	NL	4
PSD (Pesticide Safety Directorate)	UK	38
RIVM (National Institute for Public Health and the Environment)	NL	1
Swedish Chemicals Agency	SE	36
UBA (Federal Environment Agency)	DE	38
US EPA OPP/EFED (US Environmental Protection Agency)	US	10

Table 3. Comments received on the GD on Terrestrial Ecotoxicology per organisation

Institution	Country	Number of Comments
AGES (Austrian Agency for Health and Food Safety)	AT	10
COPA-COGECA WP on Honey (European farmers - European agri-cooperatives)	BE	8
CTGB (Board for the Authorisation of Pesticides)	NL	8
Danish EPA (Environmental Protection Agency)	DK	5
EPBA (European Professional Beekeepers Association) & DBIB (Deutscher Berufs and Erwerbs Imker Bund e.V)	DE	17
FUAL (Fédération des Unions d'Apiculteurs du Grand Duché du Luxembourg)	LU	1
FURS (Phytosanitary Administration of the Republic of Slovenia (PARS))	SI	11
ICPS (International Centre for Pesticides and Health Risk Prevention)	IT	1
Individuals	DE, BE, FR	24
INIA (Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria)	ES	10
Inter-Environnement Wallonie	BE	5
Mellifica asbl	BE	1
PAN-Europe (Pesticide Action Network International)	NL	2
PSD (Pesticide Safety Directorate)	UK	17
RIVM (National Institute for Public Health and the Environment)	NL	2
Royal Federation of Flamish Beekeepers	BE	3
RWTH Aachen University	DE	1
SNA (Syndicat National de l'Apiculture)	FR	1
Swedish Chemicals Agency	SE	16
UBA (Federal Environment Agency)	DE	48
University of Liège	BE	1
US EPA/OPP/EFED	US	7

In the following tables 4 and 5, the comments are listed per chapter of the two GDs. Table 4 and 5 vary in the level of detail of subchapters which is due to the different structures of the two GDs.

Table 4. Comments received on the GD on Aquatic Ecotoxicology per chapter

Main Subchapters	Total
0. GENERAL COMMENTS	30
1. INTRODUCTION	1
1.1 Status and purpose of this document	2
1.2 Legislative background	1
1.3 Protection aims	4
1.4 Structure of this document	1
2. DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FORMULATIONS AND THEIR USE IN STANDARD RISK ASSESSMENTS	4
2.1 General issues in toxicity test design	12
2.2 Toxicity testing with fish	10
2.3 Studies with aquatic invertebrates including sediment-dwelling organisms	17
2.4 Studies with Aquatic Plants (including algae and macrophytes)	15
2.5 Study requirements for formulations (Annex III point 10.2)	4
3. EXPOSURE ASSESSMENT	3
3.1 Exposure calculations and the implementation of FOCUS Surface Waters	17
3.2 Specific exposure scenarios	2
3.3 Use of time weighted concentrations (PECtwa)	8
4. STANDARD RISK ASSESSMENT	3
5. HIGHER-TIER RISK ASSESSMENT	5
5.2 Higher-tier acute risk assessment	5
5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	5
5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point 10.2.2)	23
5.5 Risk assessment on the basis of higher tier data	11
5.6 Probabilistic Risk Assessment	6
5.7 Higher-tier risk assessment for compounds which have a considerable potential to bioaccumulate	11
6. METABOLITES	4
6.2 Definitions	1
6.3 Potential routes of entry	1
6.4 Data Requirements	2
6.6 Requirements for Aquatic Organism Testing with Metabolites	2
6.8 Defining ecotoxicological relevance	1
7. RISK MANAGEMENT	3
8. OTHER ISSUES	
8.1 Definition of ecotoxicologically significant residues - aquatic life (Annex VI, 2.6.2)	1
8.3 Endocrine Effects	5
9. REFERENCES	1
10. ANNEX	1
10.1 Annex 1 - Worked examples regards sediment-dwelling organisms	1
10.3 Annex 3: Testing requirements for active substances	2

Table 5. Comments received on the GD on Terrestrial Ecotoxicology per chapter

main chapters	number of comments
0. General Comments	17
1 Introduction	1
2 General issues	51
3 Terrestrial vertebrates	9
4 Bees [(a)]	46
5 Other arthropods	34
6 Soil organisms	33
7 Non-target plants	8

(a): Several comments for bees were submitted with the same text by different institutions and individuals. They appear all as separate comments in the statistical tables.

2.1. Summary of comments received regarding both GDs

2.1.1. Consideration of revision of Annexes II and III and upcoming new regulation

It was mentioned in 24 comments that the revision of the two GDs on Ecotoxicology should take into consideration the ongoing revision of the Annex II and III to Directive 91/414/EEC as well as the development of the new regulation which will replace Directive 91/414/EEC.

The WG Ecotoxicological Effects is aware of the ongoing changes and tries to align the revised GDs to the new developments. Additionally, the PPR-Panel was already consulted regarding the Annex II and III revision and issued two scientific opinions in the context of Ecotoxicological studies (EFSA 2007, EFSA 2009b).

2.1.2. Updating of references within the GDs

Nine comments referred to a general need for updating the references in the two GDs. Links to e.g. test guidelines, such as from OECD, or to FOCUS guidance etc. should refer to the latest documents.

The WG Ecotoxicological Effects will take into account new developments of test guidelines and will cite the most recent relevant documents replacing obsolete references.

2.1.3. Harmonisation between the two GDs

It was raised in four comments, that the revision of the two GDs should be harmonised to come to a coherent approach (e.g. regarding protection levels, recovery, tiered approach, risk assessment quotients, etc.).

The two GDs are revised in parallel with the intention to harmonize them as far as possible. The joint WG Ecotoxicologial Effects currently works on general issues relevant for both GDs under revision in order to ensure as far as possible a coherent approach.

2.1.4. Harmonisation with other legislations

In four comments, a harmonisation with approaches in other legislative frameworks was proposed, such as e.g. with the directive/regulation on REACH, biocides, POPs, etc.

The WG Ecotoxicological Effects prepared an overview on relevant related legislative frameworks to take other approaches into account. At present, the WG is considering these in the context of the mandate received by EFSA for the definition of protection goal options (EFSA-Q-2009-00861).

2.1.5. Clearly defined protection goals

The revised GDs should both still include a chapter on protection aims. The protection goals should be clear about distinguishing in crop and off-crop risk assessment, and functional and structural protection goals, which is currently not harmonised between the two GDs.

A mandate has been received by EFSA for the definition of protection goal options (EFSA-Q-2009-00861). The WG Ecotoxicological Effects is currently discussing protection goal options for the different organism groups and plans to consult Risk Managers (RMs) at an early stage on the developed proposal. It is also intended to consult stakeholders.

2.1.6. Multiple exposure

Multiple exposure was highlighted as an important issue in more than 30 comments. Hereby, multiple exposure can refer to different aspects, e.g. multiple consecutive applications, multiple applications in adjacent fields, tank mixtures, formulations with more than one active substance, mixtures with metabolites, consideration of interactions with other non-pesticide environmental stressors, etc. The impact of multiple exposure should be considered in the risk assessment (RA) especially when thinking about recovery. Many stakeholders who submitted related comments were aware of the difficulties considering multiple exposure, e.g. stating a direct inclusion in the RA scheme is not feasible, however, some considerations regarding safety factors and refinements were required.

The issue of multiple exposure is under discussion in the WG Ecotoxicological Effects and was also addressed in a questionnaire to Risk Managers in the Member States (circulated and evaluated end of 2008) to collect their views and current practical approaches on this.

2.1.7. Inclusion of additional and more sensitive organisms in the RA scheme

For both GDs, it was pointed out that the tests should include sensitive organisms and vulnerable life-stages. In addition, different organisms and organism groups were proposed to be included in the RA scheme in order to cover different routes of exposure and avoid a lack of representativeness of standard test species.

For the GD on Aquatic Ecotoxicology, it was suggested to include e.g. amphibians, estuarine and/or marine species (i.e. fish and invertebrates), and mysid shrimp.

For the GD on Terrestrial Ecotoxicology, it was suggested to include e.g. amphibians, reptiles, bats, molluscs, ferns, mosses, lichen, butterflies, grasshoppers, and moths. Furthermore, it was proposed to replace the part on bees with pollinators in general.

EFSA has commissioned six literature reviews related to these topics and will analyse the application of the results on the updated GDs. The reviews are published on www.efsa.europa.eu as external reports (Fryday and Thompson, 2009a; Fryday and Thompson, 2009b; Jarrat and Thompson, 2009; Brown et al, 2009; Duncan and Hinchcliff, 2009; Taylor and Blake, 2009).

2.1.8. More guidance on statistical analyses required

Five comments highlighted a need for more/better guidance on statistical analyses in test evaluation. Especially higher tier assessments and field studies with higher uncertainties need clear rules for their evaluation and presentation.

The revised GDs will contain sections on how to deal with uncertainties in risk assessment.

2.1.9. Preference of EC_x over NOEC

It was recommended in five comments to use consistently EC_x values instead of NOEC values since the EC_x approach is judged to be more scientifically sound. Reference was made to a PPR opinion

suggesting the same (EFSA 2007). If EC_x is recommended, however, also confidence intervals should be required.

These comments are in line with previous recommendations of the PPR Panel (EFSA 2007, EFSA 2009b) and will be considered during the GDs revision process.

2.2. Summary of comments received on the GD on Aquatic Ecotoxicology

2.2.1. Additional information to consider during the revision

A total of 34 comments suggested additional sources of updated information to be taken into account during the revision. Stakeholders referred to workshops like AMRAP, ELink, AMPERE, LEMTOX, EUPRA, ECOFRAM, WEBFRAM, Harap etc. New OECD guidelines were highlighted in the relevant subchapters and also individual scientific publications of relevance were suggested.

The WG Ecotoxicolgical Effects gathered all the provided information, reports, and executive summaries and will take these as well as further upcoming information into account during the revision process.

2.2.2. Definition and harmonisation of triggers

Eight comments pointed out that clearer definitions and harmonisation are needed for triggers, such as e.g. DT_{50} for chronic fish studies, mammalian toxicology results as trigger for assessing endocrine disruption / fish studies, DT_{90} for bioaccumulation in fish, trigger for chronic *Daphnia* tests.

2.2.3. Endocrine disruption

Endocrine disruption was addressed in six comments. New tests should be considered in the revision. Therefore, activities of OECD and EPA should be taken into account in order to avoid duplication in vertebrate testing. The use of mammalian toxicology studies to trigger fish studies concerning endocrine disruption was questioned.

EFSA is following closely these activities and will take them into account in the revision process as appropriate.

2.2.4. Recovery

Attention was drawn to the recovery issue in four comments. If recovery is considered, there needs to be clear (scientifically based) guidance on time periods to consider, on extrapolation of recovery from mesocosms to field situations, on the interference of multiple exposure with recovery, on the influence of climatic conditions, etc.

2.2.5. Mesocosm studies

Six comments highlighted that mesocosms are valuable studies, but do not necessarily represent all natural ecosystems. Especially the related uncertainties and statistical power of results from mesocosms should be taken into account. More guidance should be provided also regarding summarising and evaluation of micro- and mesocosm studies

2.2.6. Metabolites

Metabolites should be taken into account in the RA, with special emphasis on bioaccumulation, RA regarding mixtures, and in sediment studies where metabolites can sum up to bigger fractions.

2.2.7. Exposure calculations

There were several comments on different aspects related to FOCUS models. Comments included the need to update references referring to revised models, to validate FOCUS models, to prove the suitability of FOCUS models throughout whole EU and candidate countries also considering climate change, etc. When referring to FOCUS PEC values (Predicted Environmental Concentrations) in the GD, it should be always clear which type of PEC (max., twa, FOCUS step 1-4) is meant. Furthermore, it was highlighted that there should be a better link between exposure and effect assessment.

2.2.8. Studies with aquatic plants

Several comments addressed the need for a clearer guidance regarding the endpoint to be considered in tests with aquatic plants. It was recommended to use the inhibition of growth rate as endpoint instead of biomass, since growth rate seems to be the more robust measure and is also recommended by the OECD. For further issues on aquatic macrophytes it was suggested to consider the AMRAP workshop results.

The WG gathered the suggested information and will take these as well as further upcoming information into account during the revision process.

2.3. Summary of comments received on the GD on Terrestrial Ecotoxicology

2.3.1. Additional information to consider during the revision

Also for the GD on Terrestrial Ecotoxicology several publications and workshops were suggested in 15 comments to be considered during the revision process: the workshops PERAS, EUFRAM, the currently ongoing SETAC working group NTTP (non-target terrestrial plants), several publications such as e.g. on bee brood feeding test, earthworm field studies, etc.

The WG Ecotoxicological Effects gathered all the provided information, reports, and executive summaries and takes the information into account during the revision process.

2.3.2. Reference to other Guidance Documents

In ten comments, it was suggested to take the parts referring to terrestrial vertebrates in the current GD on Terrestrial Ecotoxicology completely out, since they should be covered under the updated GD on Birds and Mammals. Also for the part on Persistence, the need for harmonisation with the GD on Persistence in Soil, which is currently under revision, was pointed out.

The revision of the above-mentioned GDs is taken into account in the WG Ecotoxicological Effects. Scientific Opinions related to the revision of these two GDs are published on the EFSA webpage (EFSA 2008, 2009a).

2.3.3. Endocrine disruption

Endocrine effects were discussed in six comments since a need for clear guidance was identified. It was requested to consider new up-to-date information and results of specific working groups such as the OECD EDTA task force. It was proposed to harmonise with the approach followed for in the GD on Birds and Mammals.

2.3.4. Routes of exposure

It was particularly highlighted in 16 comments that the revised GD needs to cover all possible routes of exposure, explicitly mentioning seed treatments, soil treatments and fumigation.

These comments are partly already addressed in the Scientific Opinion of the PPR Panel on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the

assessment of ecotoxicological effects (EFSA, 2009a) and will be considered during the GDs revision process.

2.3.5. Comments on RA for bees

As mentioned in Table 5, 46 comments were received on the chapter covering bees. Many comments addressed the current RA for bees in general, but also very specific proposals were submitted. The main issues addressed were the consideration of seed and soil treatments, consideration of off-crop risk for bees, the inclusion of a new bee brood feeding test and special bee tests for systemic plant protection products and applying oral exposure, and the broadening of the RA scheme to pollinators in general since e.g. bumblebees or wild bees might be more sensitive. The current activities of ICPBR regarding the update of EPPO risk assessment schemes were mentioned and recommended to be taken into account.

2.3.6. Other arthropods (Non-Target Arthropods - NTA)

A total of 34 comments were received for the chapter on other arthropods of the current GD. Eight comments addressed the fact that the use of different RA quotients (TERs and HQ) for different groups of organisms is confusing. In particular, the use of HQ for NTA is not supported in comparison to the TER quotient used in general in ecotoxicology.

The issue highlighted in the comments was already addressed in the Scientific Opinion of EFSA on updating the opinion related to Annex II & III: Ecotoxicological studies (EFSA 2009b) and will be further considered during the current revision of the GDs on Ecotoxicology.

Additionally, eight comments addressed the need of revising the conclusions stated in ESCORT II. The comments ranged from specific topics which have not been considered in ESCORT II, disagreements with the scientific conclusions of ESCORT II, but also on the transparency and documentation of the decision making during this workshop and to the undocumented uncertainties of the results.

EFSA will consider the specific issues that arose in this public consultation when working specifically on the issue of non-target arthropods which will follow later during the revision process. In general, EFSA's policy for issuing scientific opinions and guidance includes maximum transparency, accountability of uncertainties during the process, and an open involvement of experts accounting for any potential conflicts of interests, and repeated consultation of public and stakeholders during the process via e.g. public consultations, stakeholder workshops, and publication of meeting minutes on EFSA's website.

2.3.7. Soil organisms

The RA scheme for soil organisms was addressed in 33 comments. The major issues were the definition of protection goals (structural or functional), the differentiation in the current RA scheme between soil organisms and others (which might be difficult for organisms with life stages in and on soil), the controversy related to the litter bag study, the evaluation of earthworm field studies which needs clearer guidance, and the exposure measure to use ($PEC_{intitial}$, $PEC_{plateau}$, PEC_{twa}, total content or pore water concentrations).

Under the currently ongoing work on the update of the GD on Persistence in Soil the "Scientific Opinion on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects" was adopted by the PPR Panel December 2008 (EFSA, 2009a). The recommendations of this opinion will be considered for the update of the GD on Terrestrial Ecotoxicology.

Additionally, the WG Ecotoxicological Effects is currently discussing protection goal options for the different organism groups and plans to consult Risk Managers (RMs) at an early stage on the developed proposals. It is also intended to consult stakeholders (EFSA-Q-2009-00861).

2.3.8. Non-target plants

A total of eight comments addressed the chapter related to non target plants, highlighting open issues, the current RA practice, or ongoing activities in the field.

INCORPORATION OF COMMENTS

Due to the large number of comments received and the revision process being still in the beginning, comments cannot be answered individually. However, the comments from the public consultation on the existing Guidance Documents were discussed by the EFSA Working Group Ecotoxicological Effects. The comments and the proposed literature from stakeholders will be re-consulted during the revision of the two Guidance Documents.

Comments received were very appropriate and of high value for the PPR Panel and the Working Group Ecotoxicological Effects. EFSA thanks all stakeholders for their contributions.

REFERENCES

Brown, K., J. Tomlinson, J. Duncan, A. Hinchcliffe. 2009. Lot 4: Critical comparison of available and potential higher tier testing approaches for the risk assessment of plant protection products, considering at least field and semi-field experimental designs, extrapolation from dose-response relationship, and increased dosages (aquatic and terrestrial). Literature reviews on ecotoxicology of chemicals with special focus on plant protection products. CFT/EFSA/PPR/2008/01. Exponent. UK.

Duncan, J., A. Hinchcliffe. 2009. Lot 5: Evidence of potential long term effects in (aquatic and terrestrial) invertebrates after short term pulsed exposure. Literature reviews on ecotoxicology of chemicals with special focus on plant protection products. CFT/EFSA/PPR/2008/01. Exponent. UK.

EC (European Commission), 2000. Guidance Document on Persistence in Soil under Council Directive 91/414/EEC. SANCO/9188VI/1997 rev 8 of 12 July 2000.

EC (European Commission), 2002. Guidance Document on Aquatic Ecotoxicology under Council Directive 91/414/EEC. SANCO/3268/2001 rev.4 final.

EC (European Commission), 2002. Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final.

EC (European Commission), 2002. Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC. SANCO/4145/2000 – final 25 September 2002, pp 74.

EFSA Panel on Plant protection products and their Residues (PPR), 2007. Scientific Opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Ecotoxicological studies, on request from the Commission. *EFSA Journal (2007) 461, 1-44.*

EFSA Panel on Plant protection products and their Residues (PPR), 2008. Scientific Opinion of the Panel on Plant protection products and their Residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. *EFSA Journal (2008)* 734, 1-181.

EFSA Panel on Plant protection products and their Residues (PPR), 2009a. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects. *EFSA Journal (2009)* 922, 1-90.

EFSA Panel on Plant protection products and their Residues (PPR), 2009b. Scientific Opinion of the Panel on Plant Protection Products and their Residues updating the opinion related to Annex II & III: Ecotoxicological studies, on a request from EFSA. *EFSA Journal* (2009) 1165, 1-25.

Fryday, S., H. Thompson. 2009. Exposure of reptiles to plant protection products. A report to EFSA CFT/EFSA/PPR/2008/01 Lot 1. FERA. The food and environment research agency. UK.

Fryday, S., H. Thompson. 2009. Compared toxicity of chemicals to reptiles and other vertebrates. A report to EFSA CFT/EFSA/PPR/2008/01 Lot 2. FERA. The food and environment research agency. UK.

Jarratt, N., H. Thompson. 2009. Comparison between the sensitivity of Enchytraeids and Lumbricidae to chemicals, in particular plant protection products. A report to EFSA CFT/EFSA/PPR/2008/01 Lot 3. FERA. The food and environment research agency. UK.

Taylor, S., N. Blake. 2009. Lot 6: Available protocols for testing the effects of chemical against aquatic invertebrates other than Crustacea. Literature reviews on ecotoxicology of chemicals with special focus on plant protection products. Cambridge Environmental Assessments – ADAS. UK.

APPENDIX A – COMMENTS ON THE EXISTING GUIDANCE DOCUMENT ON AQUATIC ECOTOXICOLOGY

This compilation contains the comments received via the electronic form after the public consultation which closed at December 15th, 2008. This compilation contains all comments received regarding the existing Guidance Document on Aquatic Ecotoxicology. Duplicated comments received from the same contributor appear only once and comments submitted by individuals on personal capacity are published anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization.

Table 7: Comments received on the existing Guidance Document on Aquatic Ecotoxicology

Contributor	Section	Comment
Danish EPA	0. GENERAL COMMENTS	In several places it is implied that acute toxicity is correlated to chronic toxicity. This has been debated frequently. We have often asked for this to be documented but have to date never received any. On the contrary (albeit on birds and mammals in the material produced by the UK and submitted for the workshop in Woudschouten) it was demonstated that no correlation existed. So in our opinion this argument should no longer be used unless it is based on solid evidence as to its appropriateness.
Danish EPA	0. GENERAL COMMENTS	In plases where triggers are used (e.g. persistency, bioaccumulation etc.) clear definitions should be given - and a better harmonisation should be sought.
ICPS	0. GENERAL COMMENTS	Update aquatic macrophytes taking into consideration the outcome of AMRAP workshop Update exposure assessment etc. taking into consideration the ELINK workshop outcome Update mesocosms taking into consideration to the AMPERE workshop
BASF SE	0. GENERAL COMMENTS	Considering that there is a revision of directive 91/414 in preparation, I wonder how the revision of the guidance document will either depend on this revision or whether the comments on this guidance document might be reflected in the above mentioned revision of the directive?
Austrian Agency for Health and Food Safety	0. GENERAL COMMENTS	A risk assessment scheme for indoor uses should be developed (incorporation of the output of the guidance document on emissions from protected crop systems which is currently developed).
Austrian Agency for Health and Food Safety	0. GENERAL COMMENTS	The panel opinions are generally for specific substances and sometimes it is hard to find out from the text in how far an opinion can be used for other substances. We therefore think that existing scientific panel opinions, which were already repeatedly discussed in PRAPeR meetings, should be incorporated into the text of the guidance document as far as possible and not only be referred to. Additionally panel opinions are not "peer reviewed" and therefore the reference to such a document is seen critically. Generally it would be very helpful if MS had the possibility to forward questions regarding a panel opinion to the authors to get help in using a panel opinion "correctly" for other substances (we are aware that this is not an issue of the revision of this guidance document; however it is a possibility to post such a proposal).

Contributor	Section	Comment
Austrian Agency for Health and Food Safety	0. GENERAL COMMENTS	Wherever PECs are referred to in the whole guidance document it has to be made clear, which PECs (FOCUS step 1 – 4, global max., twa?).
UBA	0. GENERAL COMMENTS	COMMENT ON THE PROCEDURE/WEB INTERFACE: Entering a larger number of comments in consecutive order of chapters is tedious, because the highlighting under "Chapter/Section" always jumps back to "0. GENERAL COMMENTS" after sending of each comment. Could this be improved for future commenting exercises?
Swedish Chemicals Agency	0. GENERAL COMMENTS	In the present guidance document there is a lack of guidance on how to assess the exposure resulting from private use (non agricultural use, e.g. in home gardens and parks). This is needed in the revised guidance document
Swedish Chemicals Agency	0. GENERAL COMMENTS	Please ensure that sections dealing with the same issues in the aquatic and terrestrial guidance document cohere.
Swedish Chemicals Agency	0. GENERAL COMMENTS	Preferably, the guidance document should not repeat information and guidance from the test guidelines. A reference to the relevant TG would be sufficient. This would allow for future revisions of the TG without the need to update the guidance document.
Swedish Chemicals Agency	0. GENERAL COMMENTS	Over the last years we have found the current Guidance Document helpful in many ways (interpretation of data requirements, how to proceed from tier one risk assessments etc.). It is important that any revised guidance document also provides clear guidance. In this context it is of importance to note that a substantial part of the current Guidance Document reflects policy and guidance on various decisions by risk managers. It is desirable that guidance on these matters is not excluded from the revised guidance document. It is recognised that such matters are out of the scope of the EFSA"s activity. A task for the Commission and for the Member States can therefore already at this stage be identified; to take the outcome of the EFSA"s revision on board for development of a new guidance document. It may be helpful for the further work and the division of work (scientific vs policy and risk management related) if EFSA during their revision clearly identifies those issues (included in the current guidance document) that are put aside and not addressed or developed further during the revision because they are not purely scientific in nature.
Swedish Chemicals Agency	0. GENERAL COMMENTS	For the various groups of organisms discussed in the current guidance document, we lack clear guidance on how to assess the risk from formulations containing more than one active ingredient.
Swedish Chemicals Agency	0. GENERAL COMMENTS	The section on data requirements should be in line with the agreements so far during the work with the Annex II and III revisions (rev. 8). We are aware that the new versions are not formally adopted, but there have been thorough discussions and the major part of the changes is already agreed upon.

Contributor	Section	Comment
Swedish Chemicals Agency	0. GENERAL COMMENTS	Throughout the document text which make reference to other documents needs to be updated (e.g. to OECD guidelines/guidance documents, FOCUS etc.).
Swedish Chemicals Agency	0. GENERAL COMMENTS	Any revision of the guidance document should make use of experience gained in the discussions in PRAPeR meetings as well as in PPR Opinions, to discuss and where appropriate include as general guidance in the document.
Swedish Chemicals Agency	0. GENERAL COMMENTS	When developing refinment procedures it should be recognised that the use of plant protection products will result in multiple exposure of pesticides which may cause synergistic and cumulative adverse effects. Hence we should not develop too sofisticated refinement methods which mainly serves to reduce the risk (modelling population/community level effects, including recovery etc.), without taking multiple exposure also into account. However, we believe that it is not feasible to include multiple exposure in a regulatory risk assessment under 91/414. This should be considerd when developing refinemnt methods, and may be the assessment should remain fairly “crude” in order to balance this lack of realism.
Swedish Chemicals Agency	0. GENERAL COMMENTS	An appropriate risk assessment approach for amphibians should be developed. We do not consider that this group of organisms is covered by the current risk assessment procedure. I addition many amphibian species are “red listed” and thus their protection need extra attention. This was also proposed by PPR in their opinion on Annex II.
US EPA OPP/EFED	0. GENERAL COMMENTS	It is unclear why the EU does not require acute and chronic data for estuarine/marine fish and invertebrates, especially if pesticide exposure to estuarine/marine organisms is possible.
US EPA OPP/EFED	0. GENERAL COMMENTS	It appears that the EU criteria for requiring sediment toxicity testing with invertebrates are based on the results of the chronic daphnid test (i.e., NOAEC < 0.1 mg/L) and the presence of the material in sediment at >10% of applied radioactivity at or after day 14. In contrast, EPA/OPP/EFED requires acute data if the half-life of the pesticide in the sediment is =10 days in either the aerobic soil or aquatic metabolism studies, and if any of the following conditions exist: • The soil partition coefficient (Kd) is > 50. • The log KOW is > 3. • The KOC is > 1,000.
US EPA OPP/EFED	0. GENERAL COMMENTS	Chronic data are required if the EEC in sediment is >0.1 of the acute LC50/EC50 values, the half-life of the pesticide in the sediment is > 10 days in either the aerobic soil or aquatic metabolism studies, and if any of the following conditions exist: • The soil partition coefficient (Kd) is > 50. • The log KOW is > 3. • The KOC is > 1,000.
US EPA OPP/EFED	0. GENERAL COMMENTS	In addition to the current EU data requirements for sediment toxicity testing with invertebrates, the EU should also consider inclusive of Kd, Kow, and Koc triggers to account for the soil-binding capacity and persistence of the pesticide.

Contributor	Section	Comment
		Also, it is important to note that EPA/OPP/EFED prefers sediment toxicity testing with "spiked sediment" rather than "spiked water" to assess the potential exposure of sediment-sorbed pesticides to benthic invertebrates. At this time, the Agency does not have a formal position on the limit concentration needed for a difficult to synthesize degradate. The selection of 10 mg/L by the EU appears to be arbitrary. A more reasonable test limit may be the maximum estimated environmental concentration when the normal limit of 100 mg/L could not be readily tested. The guidance suggests that additional acute testing may be required to document sublethal effects not captured by current testing of both fish and invertebrates. It's unclear what this would entail and how these tests might link the measurement endpoints to assessment endpoints of acute mortality. The statement that fish full life cycle (FLC) and early life stage (ELS) toxicity test results do not differ significantly is misleading. It is accurate to say that FLC studies can be difficult to conduct and tend to have higher variability than ELS studies; however, the FLC studies provide much greater insight into reproductive and transgenerational effects. Also, at this time, the Agency does not rely on mammalian endpoints indicative of impacts on endocrine-mediated processes as a trigger for FLC studies. The EU only requires data on a compound that is stable; however, it does address data needs if a compound degrades to stable form. The EU suggests that additional aquatic insect testing may be required if the mode of action makes it likely that Daphnia will not be sensitive indicators. At this time, EPA does not have similar guidance; however, it is a reasonable consideration. Although the EU guidelines indicate that acute toxicity testing with chironomids is not required if long-term toxicity data exist, the acute toxicity data are of utility particularly if the chironomid chronic endpoint proves to be more sensitive than the daphnid chronic toxicity endpoint. The EU guidance indicates that spiked sediment toxicity tests may estimate exposure concentrations in sediment using partition coefficients, EPA prefers measured pore water concentrations.
FURS	0. GENERAL COMMENTS	Please take notice of guidance used in the assessment of other chemicals such as biocides. It often concerns the same active substances and consistency should be achieved whenever possible. Also the POP criteria should be covered. The Technical Guidance Document on Risk Assessment (ECB, 2003) better reflects the current scientific views on aquatic hazard and risk assessment in a number of areas.
INIA	0. GENERAL COMMENTS	Other considerations ELINK workshop 1) At EU level, spray drift was considered the principal entry of pesticides in surface water, however with FOCUS scenarios drainage and runoff are also important via of entry on water-bodies. To deal with this, recently an EU Workshop on Linking Aquatic Exposure and Effects in the Registration Procedure of Plant Protection Products has been organised. Interesting proposals on how to link exposure and effects are depicted. 2) Use of ecological field data as step further for refinement has been introduced and discussed on the ELINK workshop. The outcome of this workshop should be considered for the revision of SANCO/3268/ guidance.

Contributor	Section	Comment
PAN-Europe	0. GENERAL COMMENTS	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request and are happy to supply more scientific articles or background information on our positions here if necessary. The points are: 1. Risk is a poor approach to protect the (aquatic) environment. Risk assessment is a very poor approach in understanding biodiversity and the complex relations of ecosystems. Testing a few organisms give some indication of toxicity of a chemical but no good picture at all of the effects on water ecosystem and biodiversity. Further to that testing only lets you find what you are looking at, and what is looked at is very limited. Risk assessments never showed the endocrine disrupting effects on waterorganisms like alligators or fish and risk assessment never preventing the massive dying of amphibians we are witnessing now. So risk assessment should be done only with those chemicals having no very hazardous inherent properties because risk assessment is too "blind" for the many unexpected effects, unknown exposure routes in the environment and organisms. Additionally to risk assessment we need a hazard approach for the most hazardous chemicals and focus only on banning and substituting those ones. For the rest risk assessment might be the least worse approach on the monent but only if safety factors (never less than 10x10xNOEC) are taken into account.
Individual	0. GENERAL COMMENTS	Effects of complex application patterns and mixture toxicity: Surface waters with agricultural dominated catchment areas are often exposed to mixtures of pesticides caused by coincident pesticide applications of different farmers within the same catchment area. Surface water monitoring results clearly demonstrate that mixtures of multiple pesticide compounds occur much more often than one single compound (e.g. Gilliom 2007 Environ. Sci. Technol. May, 15: 3409-3414; Donald et al. 2007 Environ Health Persp 115: 1183-1191). The neglect of pesticide mixtures in surface waters leads to an underestimation of toxicity when assessment is based on individual compounds like in the current European aquatic risk assessment procedure. Further on, contemporaneous application of the same pesticide by different farmers within the same catchment area may lead to peak exposure sequences in surface waters with no or only very less time for recovery periods. This repeated exposure pattern may also occur even if the proposed use of an active ingredient is only once per season. I therefore strongly recommend to include these facts into the European pesticide risk assessment procedures and to cover the effects of mixture toxicity and complex exposure patterns typical for agricultural surface waters by higher uncertainty factors within the effect assessment of standard and higher-tier risk assessment.
UBA	0. GENERAL COMMENTS	Over the last months it has turned out that seed treatments pose a much higher risk to non-target life than expected (e.g., due to abrasion of active substances before or during sowing). There is a need to address this type of risks in the new GD.
psd	0. GENERAL COMMENTS	Further Candidate MS are due to accede to the EU in 2010. Whilst possibly outside of the scope of the Aquatic GD, it would be useful for EFSA, the Commission and MS to give some thought to revisiting the FOCUSsw models and scenarios to consider the applicability of these to the enlarged EU, in a similar manner to that recently conducted with FOCUS groundwater models (but recognising that the new groundwater report does not address the latest group of countries hoping to accede). It is understood that the pesticide industry may have already commissioned some work on this aspect.

Contributor	Section	Comment
Pesticides Safety Directorate	0. GENERAL COMMENTS	0 Guidance would be useful on how to deal with risk assessments for products which contain more than one active substance or have metabolites which are toxic. For instance should a combined assessment be done if they are predicted to enter surface water simultaneously?
Alterra, Wageningen UR	0. GENERAL COMMENTS	Please note that recenty new ideas have been developed as a result of the ELINK workshops how to link exposure and effects in the risk assessment procedure of plant protection products. Please see the Ececutive Summary that was send to EFSA via normal E-mail. I did this since the ELINK Executive summary was to large to place here
Pesticides Safety Directorate	1. INTRODUCTION	We understand that the new draft regulation has yet to be finalised and that there are significant changes proposed to Annex II and III (Fate and Ecotox) as well as the revised Annex VI (previously know as the uniform principles). We believe that Annex VI for fate has been worked on but we do not believe that similar work has yet been undertaken on Annex VI for ecotox. In view of the changes in end points proposed e.g. from EC50 values to NOEC in Annex II/III we hope that this will also be revised to ensure that all the parts referring to ecotox tie in together. The guidance document should be amended to reflect any agreed changes. We believe that it is very important that all the relevant documents tie together. We believe it is important that use is made of initiatives such as ELINK, ampere, amrap etc. For instance ELINK provided a very useful forum for discussions on how to link exposure and effects in the light of the types of exposure profiles now being predicted from FOCUS EFSA should be requested to consider including appropriate references to relevant PPPR opinions (e.g cyprodinil, dimoxystrobin). We believe the guidance documents should reflect a pragmatic and regulatory approach based on good current science to ensure that decisions consistent between actives and so the approach is clear and transparent and not ad hoc. We believe the guidance should provide a clear and consistent basis for regulation. There have been a number of European initiatives that could provide a good basis for guidance. For example ELINK examined how exposure and effects should be examined in the light of FOCUS predictions for surface water e.g. duration or exposure, pulses etc. We believe this was a very useful initiative and could form a useful basis for the guidance. Similarly information and guidance from workshops such as Ampere, Amrap etc could be considered. Feed in comments from ELINK , ampere, amrap etc. – something gall MSs agree A major future issue is likely to be the role of non standard studies to address the complexity of exposure scenarios. Clear guidance on the best approaches to use would be useful e.g. good science, sufficient replication etc. Also guidance should be given on when a refined approach is used for one sensitive species i.e. how this can be related to other organisms etc. We wonder if in view of climate change we need to be consider this aspect in any way? For example are the temperature data for FOCUS still appropriate?
INIA	1.1 Status and purpose of this document	1.1 Status & purposes of third document A review of the state of the art is welcome. It is desirable to include lessons learnt during the Peer Review programme and limitations and challenges of the current approach. The purpose of the guidance document should be in agreement with the new advances and data requirements included in the new regulation for the commercialization of PPP in EU

Contributor	Section	Comment
Board for the Authorisation of Pesticides	1.1 Status and purpose of this document	This chapter should be updated taking into account the current situation.
INIA	1.2 Legislative background	1.2 Legislation background A comparison of annexes II and III data requirements of the current directive and the new regulation is welcome.
Danish EPA	1.3 Protection aims	As for the last paragraph on direct aquatic application or in-crop uses we find these statements questionable and not in line with other areas of assessment – e.g. for the terrestrial “in crop” assessment for soil organisms and non-target arthropods we do not only assess the effects on function. Consistent approaches across areas should be taken.
BASF SE	1.3 Protection aims	The protection aims in the present document do already provide some very useful details and may eventually need to be extended. (Instead the derived protection goals as mentioned for example in the PPR opinion "...on lowering the assessment factor..." are not considered to properly reflect the principle protection goal "no unacceptable impact" on the environment and no "long-term repercussions for the abundance and diversity of non-target species", as provided in 91/414.) Being aware that any (human) activity does have an impact - even if very small, "negligible" - on the environment, it is obvious that a "nof effect" does not exist and that a certain level of impact must be accepted. It is recommended that ecotoxicologists, ecologists develop parameters for an "acceptable" impact in the sense that this level of effect will be well within the limits of "normal, usual" perturbations and fluctuations of an ecosystem and its populations and function and that this level will likely not cause an impact on the sustainability of ecosystem function and structure, respectively no "long-term repercussions for the abundance and diversity of non-target species". This has been partly covered in chapter 1.3 already, also refering to recommendations gathered at workshops such as HARAP and CLASSIC and could be developed further, to provide clear guidance to regulators and notifiers. As mentioned above, the present guidance document does already reflect such ideas and might eventuall be extended and updated based on current knowledge. If an impact is likely to reach levels beyond those considered to be of little relevance for the ecosystem, even if appropriate mitigation measures have been considered, in addition a risk-benefit analysis should be conducted before deciding whether authorisation should be granted or not . This should consider the risks associated with the use of a product in comparison to the benefits of this use and should at the same time consider the respective risks and benefits of alternative measures. (It has to be considered that the outcome of a risk benefit analysis is likely to differ in space and time.)
Swedish Chemicals Agency	1.3 Protection aims	We suggest the topic covered in this section (Protection aims) needs to be included also in a revised guidance document.

Contributor	Section	Comment
INIA	1.3 Protection aims	1.3 Protection aims Regarding to the protection of biodiversity, it should taken into account that extrapolation of results from test batteries to ecosystems may be limited because aspect of community ecology competition and food web interactions) and community structure of the ecosystems are not reflected in tests using a single species.
INIA	1.4 Structure of this document	1.4 Structure of this document Not references and/or protocols are available to deal with the risk assessment of sewage water treatment plants. In many cases plant protection products can reach the sewage treatment plants and therefore this needs to be assessed.
Austrian Agency for Health and Food Safety	2. DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FORMULATIONS AND THEIR USE IN STANDARD RISK ASSESSMENTS	The whole chapter has to be adapted to the revised data requirements set in the revised Annexes II and III of Directive 91/414/EEC (or the new Regulation).
Swedish Chemicals Agency	2. DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FORMULATIONS AND THEIR USE IN STANDARD RISK ASSESSMENTS	Considering tank mixing of several products, we would also appreciate discussions of these gaps in our risk assessments. Today only one product at a time is risk assessed not the entire tank content in a worst-case/realistic situation.
PAN-Europe	2. DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FORMULATIONS AND THEIR USE IN STANDARD RISK	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request and are happy to supply more scientific articles or background information on our positions here if necessary. The points are: 2. Risk assessment of one chemical at a time is totally unscientific. Doing risk assessment of one chemical and pretending organisms and the environment are completely clean and unstressed is a fundamentally flawed way of working. In horticulture areas for instance dozens of pesticides are found in ditches and canals at the same time as well as other chemicals and stress factors. Establishing maximum toxicity levels for chemicals for every chemicals and applying these in agriculture dominated areas is a shame. In a risk assessment other chemicals and stress factors

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	ASSESSMENTS	have to be taken into account. Neglecting the many pesticides being neurotoxic and having cumulative effects won"t be defended by any professional. Doing risk assessment and "forgetting" about cumulative, synergistic effets and not taken into account other stress factors (low oxygen, fertilizers, etc.) gives a false signal of safety to society.
Individual	2. DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND FORMULATIONS AND THEIR USE IN STANDARD RISK ASSESSMENTS	In my opinion, the representativeness of the standard test organisms used in acute and chronic standard risk assessment should be reconsidered. It is questionable, if toxicity data derived from test with crustaceans, fish and aquatic insects are sufficiently representative for the extrapolation of the effects to other aquatic organism groups like - for example - amphibians. The application of pesticides in the springtime and early summer coincides temporally with the development of amphibian spawn and tadpoles in small ponds located within the agricultural landscape. There is a lot of evidence in the literature that pesticides reaching a pond during or after application, affect these sensitive life-stages and amphibian reproduction and survival. Recent studies demonstrate lethal and sublethal effects of pesticides on adult amphibians and larvae (e.g. Relyea 2005, Arch. Environ. Contam. Toxicol. 48: 351–357) raising the question why there is no risk assessment for amphibians within the European pesticide directive 91/414/EEC although amphibians are widespread in agricultural surface waters. This lack of standard test organisms' representativeness is questionable not only for amphibians but also for other aquatic species not considered within European pesticide risk assessment.
Swedish Chemicals Agency	2.1 General issues in toxicity test design	We believe the topics covered here (limit-tests, poorly soluble substances, analytical measurements etc.) need to be covered also in a revised document (but see more detailed comments below).
BASF SE	2.1.2 Poorly soluble substances	The US are very hesistant with regard to the use of solvents. Therefore, it is suggested to omit and change sentences within this chapter: "It is generally not sufficient to test the maximum water solubility of the substance because this is usually determined in studies with pure water under sterile conditions. Attempts should be made to reach the maximum solubility level expected under the test conditions, using either an appropriate solubilizer, auxilary solvent or dispersing agent." Omit the first sentence and add at the end of the second sentence: "...or using "saturation collumns" in order to achieve the maximum solubility under test conditions".
Swedish Chemicals Agency	2.1.2 Poorly soluble substances	Aquatic tests in the presence of sediment are proposed as an option for poorly soluble substances. This is a questionable approach, since these tests do not add further information on the intrinsic toxicity, but only on the exposure pattern of the compound. Especially when the tested species does not normally get in contact with the sediment or if the test design prevent free access to the sediment these tests does not represent worst case conditions. This was discussed by PPR in their opinion on dimoxystrobin.
FURS	2.1.2 Poorly soluble substances	Please include a remark that if poorly soluble substances are tested far above their solubity limit, homogeneity of the test media should be at least demonstrated.

Contributor	Section	Comment
Swedish Chemicals Agency	2.1.3 Analytical measurements	In the last paragraph, it is proposed that analytical measurements do not need to be required for older studies if it is not from the most sensitive species. We feel that this revision of the guidance document is an opportunity to update the requirements in order to meet the most recent guidelines and thereby increase the quality of the available data. Hence, we think that analytical verifications of the test levels should always be required.
BASF SE	2.1.4 Calculation of test endpoints	It would generally be helpful to clearly state for static, semi-static and flow-through experiments how the results should be expressed also considering possible differences between active ingredient and formulation studies and differences between acute and chronic studies. There is some inconsistency in this paragraph with respect to the first sentence of the 2nd paragraph and the following bullet points. Mean measured concentrations may be used in acute tests. However, to cover substances which are highly unstable in water the following bullet point should be added: • for very unstable compounds (DT50< 1 day and with stability under test conditions similar or higher than those likely to occur under realistic natural conditions) results should be based on initial measured concentrations. Finally, the match between study endpoints and PECsw should be discussed (e.g. initial measured in acute, static test and PECsw ini).
Swedish Chemicals Agency	2.1.4 Calculation of test endpoints	We would like to see inclusion of clear guidance on statistics in aquatic testing, without repeating what is already included in test guidelines. Preferably any guidance included should not deviate from the OECD Guidance Document on Statistical Analysis of Ecotoxicity Data (OECD Series on Testing and Assessment No 54). We would prefer if ECx (the value of x needs to be agreed on) could be used as a starting point for the risk assessment instead of the NOEC. NOEC depends on the choice of test concentrations and number of replications and rewards poor experiments, i.e., high variability, with high NOEC values. The PPR panel suggests in the opinion on the data requirements to open up the text in the annex II and II for this possibility by using the wording “reference point” instead of NOEC. Thus a discussion of how to calculate ECx or similar reference points is needed in this guidance document. We would also appreciate a discussion of the possibility to include the information in the confidence intervals around an ECx into the risk assessment. This would encourage the development of better data since more narrow confidence intervals would result in a higher “reference point”. Furthermore, we need to agree on the multivariate statistics that should be used for evaluating higher tier studies (i.e PRC) and clear guidance on these methods is needed.

Contributor	Section	Comment
US EPA OPP/EFED	2.1.4 Calculation of test endpoints	1. Section 2.1.4: Calculation of test endpoints: The guidance states that nominal test concentrations should be used to calculate toxicity endpoints unless measured concentrations are < 80% or >120% of the nomimal, in which case initial measured concentrations should be used. This guidance may result in the selection of different toxicity endpoints than those selected by EPA/OPP/EFED, given that we generally base endpoint selection on mean-measured or time-weighted average (if applicable) concentrations. High variability in measured concentrations can be used as a rationale to invalidate studies if treatment groups are not statistically different.
Pesticides Safety Directorate	2.1.4 Calculation of test endpoints	2.1.4 We proposed that this section is revised as it is a bit confusing. We propose that it is clearly laid out what you do for different types of studies e.g. flow through, semi static, static when a concentration is not maintained. Also it would be helpful if a little explanation was given as to why the approach is used e.g. for static studies active substance may be taken out of the solution e.g. by algae and so later measurements may be less than nominal. As this is likely to be what will happen in the environment then it is acceptable to use initial measured concentrations when the concentration is <80% at initial measurement. This is the best available figure because as indicated at later stages the active may have been absorbed on to the algal material and so be <80% but the initial measured concentration is still a good reflection of what is going on.
Board for the Authorisation of Pesticides	2.1.4 Calculation of test endpoints	It is not clear what to do in the case of static tests in which the measured concentrations fall below 80% during the test. CTGB prefers to express the toxicity values as mean measured concentrations. Further it is not clear what to do in the case that in a static test the compound disappears so fast that at the end of the test the compound can't be measured anymore. More guidance is needed on this point. Also more guidance is necessary what to do in the case of tests with formulations with two or more active substances. Those active substance have different dissipation rates and measured concentrations will be different. How to express the toxicity value (nominal/initial/mean measured)?
Swedish Chemicals Agency	2.1.5 Acceptable guidelines	Companies are obliged to do a literature search and submit information which may be of relevance to the risk assessment. However, we regularly find important information, available in the "open literature" that is not submitted. Today, the notifier may discard a study since it is not a GLP study or does not follow a guideline. Nonetheless, the information may be of importance and this decision should not be subjected to the notifier. We therefore propose that the notifier should make a very short summary of the study and thereby the authority can decide whether it may be of importance. Guidance on how to make this summary is needed in the guidance document; this is a general point which should be considered during revisions of guidance document in all sections.
Pesticides Safety Directorate	2.1.5 Acceptable guidelines	2.1.5 Acceptable guidelines: guidance should be given on what should be done when an agreed guideline is not used to allow an effects study to more realistically reflect exposure predicted by FOCUS (see our comments in the introduction).
Board for the Authorisation of Pesticides	2.2 Toxicity testing with fish	This paragraph should be adjusted based on the new proposals for Annex II and III data requirements.
BASF SE	2.2.2 Long-term/chronic toxicity tests	P 11, 5th paragraph: Proposal to change the following sentence to target specific effects "If specific effects on reproduction (i.e. when the NOEL for reproduction is 10-fold lower than the NOEL for other signs of toxicity) or the endocrine system could be anticipated (e.g. based on data from mammalian toxicology studies), the need for a FLC-test should should be carefully

Contributor	Section	Comment
	(Annex II point 8.2.2)	considered (see section 8.3)." It should be clarified with more precision (in 8.3) which endpoints from mammalian toxicology studies are indicative for endocrine disruption and would trigger a specific fish test. Fish testing for ED should be conducted in a tiered approach starting with a 21-d fish screening test. When this test indictes ED effects it should be considered if a fish sexual development test (FSDT) has to be conducted. The FLC test presents the highest tier in chronic fish testing (for ED); if this test is conducted, no other chronic fish tests are needed.
US EPA/OPP/EFED	2.2.2 Long-term/chronic toxicity tests (Annex II point 8.2.2)	Section 2.2.2; p. 11 (OECD Test 204): Based on current EPA/OPP/EFED ecological effects data requirements, use of the OECD 204 test would not be considered an acceptable substitute for a chronic toxicity study with fish for the reasons stated in the EU Aquatic Ecooxicology Guidance document (i.e., lack of sublethal endpoints, 21-d duration).
US EPA/OPP/EFED	2.2.2 Long-term/chronic toxicity tests (Annex II point 8.2.2)	6. Section 2.2.2; p. 12 (Use of Mesocosm/Microcosm Tests): While EPS/OPP/EFED agrees that microcosm and mesocosm tests have many strengths for evaluating chronic toxicity to aquatic organisms, our experience is that such tests may also contain significant limitations. One such limitation can be their much reduced statistical power due to factors such as fewer replicates and greater biological variability among replicates relative to laboratory toxicity tests. We recommend that consideration and evaluation of microcosm and mesocosm tests explicitly consider statistical power of the study.
UBA	2.2.2 Long-term/chronic toxicity tests (Annex II point 8.2.2)	This chapter should be amended by the state-of-the-art in endocrine specific fish testing (see also comment on chapter 8.1 Endocrine disruption). Guidance is especially needed in order to decide which protocol for chronic fish testing is most appropriate in individual cases. While standard chronic fish guidelines (OECD 204, 210 and 215) do not adequately cover endocrine specific endpoints (sexual development, reproduction), there is also limited experience until now with the different endocrine-specific fish test protocols (fish screening assay, fish short-term reproduction assay, fish sexual development test, fish full life cycle test) currently under development at OECD level. However, we strongly propose not to wait until a broader consensus on the OECD level on endocrine-specific testing and assessment is achieved, but to give as much guidance as currently possible in this respect. (It is unfortunate that the OECD efforts already took an undue long time, while decision-making has to be done today on national level).
Pesticides Safety Directorate	2.2.2 Long-term/chronic toxicity tests (Annex II point 8.2.2)	2.2.2 We believe it would be useful to consider whether or not the DT50 should be used to trigger the need for chronic studies in the light of the FOCUS based exposure scenarios which may predict longer exposure durations. We understand that this was discussed for the current guidance document and this was considered a simple approach especially as some member states do not use FOCUS. It would be useful to consider if this remains the best approach. Further guidance repeat acute exposure and how this might be more satisfactorily addressed would be very useful. The discussion on which chronic fish study to use could be better presented as a flow diagram or reference made to Annex 3 which is useful but never seem to be really referenced.
US EPA/OPP/EFED	2.2.3 Triggering of a fish bioconcentration study (Annex II Point 8.2.3)	Section 2.2.3; p. 13. (BCF Trigger). The proposed BCF trigger should be applied not only to the parent compound(s), but also the metabolites of concern.

Contributor	Section	Comment
UBA	2.2.3 Triggering of a fish bioconcentration study (Annex II Point 8.2.3)	Page 13 from line 6 till 10 (referring stability of the substance): The substance is considered stable if there is less than 90% loss of the original substance over 24 hours via hydrolysis (in accordance with draft revision 8 of Annex II and II to Council Directive 91/414/EEC (ecotoxicology section, September 2007).
Pesticides Safety Directorate	2.2.3 Triggering of a fish bioconcentration study (Annex II Point 8.2.3)	2.2.3 Triggering of fish bio-concentation study. The current guidance states that bioconcentration would not be expected where a 'substance is not stable in water'. However, many substances with high bioaccumulation potential move rapidly out of the water phase into living organisms and sediment - such that their stability in the water phase is not a critical issue. Please also see comments under Section 4.3 regarding the appropriateness of the use of the standard BCF study.
Pesticides Safety Directorate	2.2.3 Triggering of a fish bioconcentration study (Annex II Point 8.2.3)	2.2.3 Again as per our previous comment it would be useful to discuss if the DT50 value is the best trigger for the need for additional studies such as the fish BCF.
Board for the Authorisation of Pesticides	2.3 Studies with aquatic invertebrates including sediment-dwelling organisms	This paragraph should be adjusted based on the new proposals for Annex II and III data requirements.
Danish EPA	2.3.1 Studies with Daphnia (Annex II point 8.2.4 and 8.2.5)	The "persistency" trigger for a chronic daphnia study should be reconsidered – in our view a reproduction study should always be required. The acute test is only a 2 day test and using a DT50 trigger of 2 days means that there can still be a significant exposure after the test period of the acute test – and sublethal/reproductive effects can not be out-ruled on this basis. The second paragraph has nothing to do with data requirements and does not belong in this section. Furthermore we de not agree to the text and find that it should be totally removed. The text is rather speculative and we do not agree that daphnids are always among the most sensitive species. There are examples where daphnids are sometimes (also for pesticides) the least sensitive . As for the Brock reports they are based on a comparison between lab. and mesocosm studies and therefore there is a bias in the data in that mesocosm will usually be performed if daphnia are very sensitive (and a risk is indicated in tier 1). Also the conclusions build on the assumption that mesocosms are representative for all natural ecosystems and all species – which we do not accept.

Contributor	Section	Comment
US EPA OPP/EFED	2.3.1 Studies with Daphnia (Annex II point 8.2.4 and 8.2.5)	2. Section 2.3.1: Studies with Daphnia (2nd par): The EU guidance specifies the use of uncertainty factors of 100 and 10 for acute and chronic freshwater invertebrate endpoints, respectively, to account for potential inter-species sensitivity. Given that EPA/OPP/EFED does not use uncertainty factors in the derivation of toxicity endpoints, this guidance may result in EU selection of freshwater invertebrate endpoints that are one to two orders of magnitude more sensitive than those selected by EPA/OPP/EFED. It is unclear whether the "safety factor" is analogous to the 20X factor used for determining acute risk to listed species LOCs. The EU has not provided sufficient support though for the selection of a 100x safety factor but rather has suggested that such a factor cannot be substantiated at this time.
UBA	2.3.1 Studies with Daphnia (Annex II point 8.2.4 and 8.2.5)	P. 13, comment to "A recent review paper (WOGRAM & LIESS, 2001) has clearly demonstrated that for organic chemicals including a range of pesticides, Daphnia magna is usually among the most sensitive species. Even when there are more sensitive groups, these are generally less than an order of magnitude more sensitive than Daphnia.": The findings in this paper are misinterpreted. Even though there seems to by a significant bias towards higher sensitivity of D. magna for organic chemicals in general, there is a considerable variation between different classes of substances. Thus, in a certain percentage of substances, other species will be considerably more sensitive than D. magna.
UBA	2.3.1 Studies with Daphnia (Annex II point 8.2.4 and 8.2.5)	P. 13, comment to "The Annex VI trigger values for further assessment have also been validated in a major review study by BROCK et al. (2000 a and b) which compared sensitive endpoints from laboratory studies with insecticides and herbicides to the results of field studies. For these compounds, the Annex VI trigger values were clearly demonstrated to be protective for invertebrates when comparing with the NOEC and LOEC values found in micro- and mesocosm studies.": Agreed that a comparison of Tier 1 and higher tier micro- and mesocosm studies (not: field studies!) is suggestive for an assessment of the level of protection of a tier 1 risk assessment. However, it should be kept in mind that the results of state-of the-art mesocosm studies still comprise a certain level of uncertainty in terms of their statistical power and their representativeness for situations in the field (extrapolation to semi-/univoltine invertebrate species etc.). Note that an uncertainty factor is used in the majority of cases in the higher tier risk assessment based on mesocosm studies, which has not been considered in the cited paper. If tier 1 and higher tier data are compared, it might be reasonable to compare Tier 1 RAC values to generally accepted higher tier RAC/EAC values rather than to higher tier test endpoints (NOEC, NOEAEC).
Pesticides Safety Directorate	2.3.1 Studies with Daphnia (Annex II point 8.2.4 and 8.2.5)	2.3.1 Relevance of DT50 > 2 day trigger for chronic Daphnia study. Again please see our comment regarding if DT50s are the best triggers.

Contributor	Section	Comment
BASF SE	2.3.2 Studies with additional invertebrate species (Annex II point 8.2.4 and 8.2.5)	P 14, 3rd paragraph. A guideline for an water-only acute immobilisation study with 1st instar Chironomus riparius larvae has been described by Rufli et al. (under submission). Rufli, H., Weltje, L., Heimbach, F., Wheeler, J., Vervliet-Scheebaum, M. and M. Hamer (under submission) The chironomid acute toxicity test: development of a new test system. P 14, 5th paragraph. Neonate daphnids molt during a 48-h acute test (see e.g. Olmstaed and LeBlanc, 2001), hence effects of some IGRs (such as benzoylureas) will be visible in an acute Daphnia test. IGRs acting as juvenile hormones may not express their toxicity in a 48-h test. Olmstead, A.W. and G.A. LeBlanc (2001) Low exposure concentration effects of methoprene on endocrine-regulated processes in the crustacean Daphnia magna. Toxicological Sciences, 16: 268-273.
Swedish Chemicals Agency	2.3.2 Studies with additional invertebrate species (Annex II point 8.2.4 and 8.2.5)	Updated guidance is needed on the selection of a second aquatic invertebrate species to be tested, taking developments of new guidelines into account. Regarding the choice of a second species for testing the Panel suggests that the second test should always be conducted with a species that does not live in the sediment. However, we consider that the selection of test species should be guided on the expected behaviour of the chemical. We think that for substances that may be expected to be distributed to the sediment, there should be a possibility to require specific ecotoxicity studies on sediment living detritus feeding organisms, such as the Lumbricus, for which there is an ongoing OECD project. In any case, we suggest that recommendation on the selection of the second test species could be given in this guidance document
UBA	2.3.2 Studies with additional invertebrate species (Annex II point 8.2.4 and 8.2.5)	P. 14, comment to: “Consequently, for uses where a direct application is made to water, the notifier should make a reasoned case as to why gastropod mollusc data should not be required. This could include acute toxicity data demonstrating the relative sensitivity of molluscs to the active substance.": It has been shown that chemicals with a potential for endocrine disrupting effects on birds and mammals might also affect the endocrine system of gastropods (e.g., the fungicide fenarimol). Thus, it should be considered in the review of the guidance document that acute studies with snails might not always address the risk to gastropods.
UBA	2.3.2 Studies with additional invertebrate species (Annex II point 8.2.4 and 8.2.5)	P. 14, comment to “Information on the mode of action of insecticides (from efficacy and non-target arthropod data) should be considered before deciding whether testing on an insect species is required. If the toxicity of an insecticide to Daphnia is low (48 h EC50 > 1 mg/l, 21 d NOEC > 0.1 mg/l), this may indicate selectivity. An acute toxicity test should then be carried out with first instar (2-3 d old) Chironomus riparius (48 h water-only study).”: According to current proposals for the amendment of Annex II and III of Directive 91/414 EEC, an acute test with Chironomus should become mandatory in the case of insecticides, irrespective of their mode-of-action.
UBA	2.3.2 Studies with additional invertebrate species (Annex II point 8.2.4 and 8.2.5)	P. 14, comment to “If a long-term/chronic study on insects is already available there is no need to require additionally an acute one.”: This proposal should be critically reviewed as the OECD chironomid studies in a water/sediment system do not feature a chronic or repeated exposure in the water phase of natural water bodies. As a consequence, in some cases the 48 h EC50 values from acute water-only chironomid studies are lower than the 28 d NOEC values from regular OECD chironomid studies! In the review of the guidance document, the representativeness of the fate characteristics in the OECD chironomid test for typical edge-of-field water bodies should be assessed. If the influence of the sediment in the system is considered to confine to level of representativeness, it might be considered if a deviation in the composition of the sediment as described by Hahn et al. (use of

Contributor	Section	Comment
		quartz sand) should be proposed in the revised guidance document.
Austrian Agency for Health and Food Safety	2.3.3 Available data on estuarine/marine invertebrates (Annex II point 8.2.4 and 8.2.5)	It should be made clear, how marine organisms are dealt with in a risk assessment.
UBA	2.3.3 Available data on estuarine/marine invertebrates (Annex II point 8.2.4 and 8.2.5)	P. 15. According to Maltby et al (2005), existing data indicate that there is no basic difference in the sensitivity of marine and freshwater organisms. If this finding is considered to be representative, existing test results with marine organisms should be used as a default in the risk assessment.
Pesticides Safety Directorate	2.3.3 Available data on estuarine/marine invertebrates (Annex II point 8.2.4 and 8.2.5)	2.3.3 It could be considered if there is now sufficient information available in the scientific literature to address the issue of species sensitivity. Additionally we understand the mysid shrimp is likely to be included as a core species.
BASF SE	2.3.4 Tests with sediment-dwelling invertebrates (Annex II point 8.2.7)	P 16, A life cycle method has been published by Taenzler et al. (2007) and is currently a working item on the OECD list. Taenzler, V., Bruns, E., Dorgerloh, M., Pfeifle, V. and L. Weltje (2007) Chironomids: suitable test organisms for risk assessment investigations on the potential endocrine disrupting properties of pesticides. Ecotoxicology, 16: 221-230. P 18, 1st paragraph. The option to calculate a (preliminary) NOEC for sediment from a spiked water test or alternately a (preliminary) NOEC for water from a spiked sediment test should be mentioned. Prerequisite is the availability of measured values in the time that the animals are present in the test vessels, i.e. from the day of introduction of the larvae up until day 21. These values may help in completing the aquatic risk assessment or to decide if the complementary test (i.e. spiking the other compartment) is needed.
UBA	2.3.4 Tests with sediment-dwelling invertebrates (Annex II point 8.2.7)	For some substances, metabolite fractions are formed with each single metabolite <5% but total amount of all metabolites in the sediment far above 10% because of the large number of minor metabolites. For minor metabolites, ecotoxicological data is not necessarily available, and therefore the cumulative occurrence of structurally similar minor metabolites with ecotoxicological relevance cannot be excluded. We propose that risk from high fractions of co-occurring minor sediment metabolites should be assessed by a case-by-case decision depending for instance on information on probable toxicity profile, time of formation, time trend of occurrence and so on.

Contributor	Section	Comment
Pesticides Safety Directorate	2.3.4 Tests with sediment-dwelling invertebrates (Annex II point 8.2.7)	2.3.4 – We believe OECD 209 was adopted in 2004. As a general point it could be checked that the latest guidance is referred to.
Austrian Agency for Health and Food Safety	2.4 Studies with Aquatic Plants (including algae and macrophytes)	In the revised guidance document the acceptable endpoints for risk assessment have to be defined.
INIA	2.4 Studies with Aquatic Plants (including algae and macrophytes)	2.4. Studies with Aquatic Plants (including algae and macrophytes) Toxicity endpoints growth rate versus biomass According to SANCO 3268 both Biomass or growth rate endpoints from algae and aquatic plants should be reported and the more sensitive endpoint used for RA besides “there is not clear evidence to indicate which the most relevant endpoint for the field situation is”. A very frequent justification provided by notifier is that “"growth rate" is more ecological relevant for the population than final biomass, and should be an acceptable endpoint for field situation. However, at EU level always EbC50 (biomass) is the endpoint used for RA. However, in the "Technical Guidance Document for Risk Assessment" (2003) for biocides and chemicals which deal with the endpoints of algal studies. http://ecb.jrc.it/documents/TECHNICAL_GUIDANCE_DOCUMENT/EDITION_2/tgdpart2_2ed.pdf, TGD, part II, page 187, it is indicated that ErC50 (growth rate) should be used (see text below): Algal testing Algae toxicity test (EU Annex V C3, OECD 201, 1984a) The algal growth inhibition test measures the inhibition of growth during the exponential phase under optimum standard conditions of light, temperature and nutrient concentrations. The test produces an EC50 that can be considered equivalent to a short-term L(E)C50. Often both ErC50 (estimated from specific growth rate) and EbC50 (estimated from biomass growth) are available, however the latter should not be used. The reason is that direct use of the biomass concentration without logarithmic transformation cannot be applied to an analysis of results from a system in exponential growth. Where only the EbC50 is reported, but primary data are available, a reanalysis of the data should therefore be carried out to determine the ErC50. It would really appreciate to incorporate clear guidance indicating which the most relevant endpoint for the field situation is.

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Danish EPA	2.4.1 Species for algae tests (Annex II point 8.2.6)	last paragraph: OECD has, based on a solid scientific assessment, decided to base the classification and assessment on growth rate endpoint. This should now be harmonised.
BASF SE	2.4.1 Species for algae tests (Annex II point 8.2.6)	P 19, 1st para: In accordance with the newest guidelines (e.g. OECD guideline 201) the EC50 should be given for growth rate and biomass. The more relevant and scientifically sound endpoint is based on growth rate; however, to fulfil some traditional national requirements (US), the measurement of yield is also mentioned. The OECD guideline 201 (23 March 2006) states the following: "It should be noted that toxicity values calculated by using these two response variables are not comparable and this difference must be recognised when using the results of the test. ECx values based upon average specific growth rate (ErCx) will generally be higher than results based upon yield (EyCx) if the test conditions of this Guideline are adhered to, due to the mathematical basis of the respective approaches. This should not be interpreted as a difference in sensitivity between the two response variables, simply that the values are different mathematically. The concept of average specific growth rate is based on the general exponential growth pattern of algae in non-limited cultures, where toxicity is estimated on the basis of the effects on the growth rate, without being dependent on the absolute level of the specific growth rate of the control, slope of the concentration-response curve or on test duration. In contrast, results based upon the yield response variable are dependent upon all these other variables. EyCx is dependent on the specific growth rate of the algal species used in each test and on the maximum specific growth rate that can vary between species and even different algal strains. This response variable should not be used for comparing the sensitivity to toxicants among algal species or even different strains. While the use of average specific growth rate for estimating toxicity is scientifically preferred, toxicity estimates based on yield are also included in this Guideline to satisfy current regulatory requirements in some countries." Accordingly, it is recommended to use the parameter growth rate as assessment endpoint. Particularly in a higher tier assessment it is necessary to apply this parameter. HC5 calculations, for example, cannot correctly be performed with biomass endpoints. This is because the biomass endpoints do not allow comparison between species, different experimental durations or differing experimental conditions. In contrast to "growth rate" the "biomass" endpoint depends on: a) Species specific maximum growth rate; faster growth results in lower EbC50 values, b) Test conditions; conditions causing better growth result in more biomass inhibition than those where growth is slower (similarly to "a"), c) Duration of the experimental phase; longer test duration results in lower endpoints, d) Slope of the curve; differences between biomass and growth rate are smaller for steeper concentration/response curves and vice versa. The parameter "growth rate", however, is independent of all these factors and may thus be used for comparison between species, for modelling and for extrapolation to other situations than those specific ones of the respective laboratory studies. As mentioned above, the parameter growth rate will generally provide higher numerical values as compared to the parameter biomass. However, similar to the conclusion reached by Brock et al. (2000) a scientific evaluation of relevant data allows to confirm that the use of ErC50 values in combination with the present TER of 10 is sufficient to exclude unacceptable risk to algae and aquatic plants in the environment (Bergtold & Dohmen (2009). Biomass or growth rate: relevance for the aquatic risk assessment of herbicides. In preparation).

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FURS	2.4.1 Species for algae tests (Annex II point 8.2.6)	Biomass endpoints from algal tests are not relied upon in other regulatory frameworks. Consistency with assessment of other chemicals on what is the appropriate endpoint from an algae test would be welcomed.
Pesticides Safety Directorate	2.4.1 Species for algae tests (Annex II point 8.2.6)	2.4.1 Very clear guidance needs to be drafted on what end point should be used from algae studies. We understand that the revised AII/III now refers to the use of NOEC rather than EC50s. It is therefore important that the appropriate end point to be used is given very careful consideration especially in view of the fact that the studies are more specifically designed for the measurement of EC50s. So we will need to know whether we are to use a NOEC for yield, any phytotoxic effect etc.
Board for the Authorisation of Pesticides	2.4.1 Species for algae tests (Annex II point 8.2.6)	This paragraph should be adjusted based on the new proposals for Annex II and III data requirements. Regarding tests with algae still discussion is going on if the endpoint should be based on only growth or that also biomass should be taken into account. Clarity is needed.
BASF SE	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	The comments with respect to the endpoint growth rate / biomass given in the previous chapter equally apply to this chapter. P19, 2nd para: The test should be preferably conducted according to the new OECD guideline 221 (no draft anymore). P 19, last para: A test protocol for Myriophyllum is under development, reference could be made to the recent AMRAP workshop.
UBA	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	Available Guideline: We assume that a future guidance document refers now only to the OECD-Guideline 221 (Lemna sp.Growth Inhibition Test; finalized in 2006) instead of the ASTM guideline and EPA guideline.
UBA	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	Recovery: We suggest addressing the current statement on the use of recovery studies for the risk assessment for aquatic macrophytes in more detail, considering following points: It should be stated that if recovery of individuals or populations is tested, the observed recovery has to be representative for the expected environmental and ecological situation in the field. At least, the observed recovery should allow an extrapolation to the corresponding field scenario. Hence, the results of single-species recovery tests – reflecting a rather artificial environment without interspecific competition etc. – should be used in the risk assessment only in a qualitative or semi-quantitative way. For instance, by differentiating between phytotoxic, non-reversible effects and reversible effects on the shoot growth, the remaining level of uncertainty can be reduced – this could justify lowering of the assessment factor. If recovery is considered in the risk assessment, the ecological implications of retarded growth (e.g., 50 % reduction of plant biomass for several months) should always be discussed.

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UBA	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	Criteria for an additional macrophyte test Possible criteria for an additional macrophyte test have lately been under discussion in the AMRAP workshop. Partly based on the contributions from that meeting, but also considering available experimental data on macrophyte toxicity of some herbicidal compounds, an approach was developed in DE for instant use in the authorization procedure. This approach uses a set of criteria that would either alone or in combination trigger an additional macrophyte test. 1. The active substance is an auxin or a respective precursor (cf. Sanco/3268/2001). 2. Ecotoxicological tests with terrestrial plants (Tier 1 and/or 2) show a consistently higher sensitivity of dicot species as compared to monocots (i.e. no overlap of the sensitivity spans). Limitation: It can be demonstrated by suitable data that the observed selectivity is due to morphological or physiological specifics of terrestrial plants and thus not to be expected for aquatic plants. 3. Efficacy trials or other source of data indicate that the MoA would not affect the morphologically reduced monocot species Lemna sp (e.g., the active substance affects biochemical processes that only occur in roots). 4. Available data for Lemna indicate an unexpectedly low sensitivity to a herbicidal compound. Criteria 1–2 both are sufficient alone to trigger an additional macrophyte test. In contrast,criteria 3 and 4 are used as supportive information; i.e. the necessity of an additional test is considered taking into account the available information in its entirety (case-by-case decision). We suggest considering this approach in a future guidance document.
Pesticides Safety Directorate	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	2.4.2 It should be noted that the draft OECD protocol has now been finalised (OECD 221 (March 2006)). Again we have the same comment as for algae so we will need clear guidance as to what parameter the NOEC is to be based on. Additionally if an additional species is tested then again the NOEC to be used should be clearly defined and it needs to be clarified if any phytotoxic effects are also to be considered. This should be considered in relation to the protocol for such studies e.g. ASTM E 1913-04 for Myriophyllum sibiricum.
Pesticides Safety Directorate	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	2.4.2 It is considered that any output from Amrap should be critically evaluated and if suitable be incorporated in to the revised guidance document. This should include consideration of the need for the testing of other species.

Contributor	Section	Comment
Alterra WUR	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	Comments on Guidance Document on Aquatic Ecotoxicology Public consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR) on the existing Guidance Documents for Aquatic and Terrestrial Ecotoxicology under Council Directive 91/414/EEC. Comments to paragraph 2.4.2 (Aquatic macrophytes) and Annex 3 The Guidance Document on Aquatic Ecotoxicology mentions options for testing of other aquatic macrophytes than Lemna in specific cases and in higher tiers. However, these options are not specified in the document. Guidance on when and how to perform additional macrophyte testing and guidance on higher tier studies that focus on aquatic macrophytes have not been included in the guidance document and were not available until recently. Recently, the AMRAP Organizing Committee (Lorraine Maltby (The University of Sheffield, UK, chair), Dave Arnold (CEA, UK), Fred Heimbach (RIFCON GmbH, DE, treasurer), Jo Davies (Syngenta, UK), Véronique Poulsen (AFSSA, FR). Christina Pickl (UBA, DE), Gertie Arts (Alterra WUR, NL, co-chair) organized the SETAC Europe Workshop "Aquatic Macrophyte Risk Assessment for Pesticides" on 14-16 January 2008 in Wageningen (NL) with 41 macrophyte experts from academia, authorities and business from all over Europe and the United States and Canada. The workshop aims were: • presenting an overview of the current European regulatory framework for the risk assessment of aquatic macrophytes; • identifying uncertainties and areas for improvement within the regulatory framework; • presenting and discussing the current state of the science of aquatic macrophyte testing in single species laboratory studies and mesocosm studies; • evaluating the extent to which currently available methods and understanding can address the uncertainties in the risk assessment of aquatic macrophytes; • making recommendations for improving aquatic macrophyte testing methodologies and risk assessment; From this workshop, four work groups evolved, which currently work on questions and guidance requirements that evolved from the workshop. The discussions and conclusions of the AMRAP Workshop will be published soon as a SETAC Guidance Document. The draft version is available now. Workshop participants received the draft version and sent their comments recently. The outcome of the workshop and work groups include: - A draft protocol for a laboratory toxicity test with Myriophyllum. The protocol will be ring-tested in 2009; - An overview of laboratory toxicity methods for testing aquatic macrophytes other than Lemna; - Criteria when an additional macrophyte has to be tested are proposed in the workshop report, but have to be validated; - Guidance on Species Sensitivity Distributions with aquatic macrophytes is being developed; - A Risk Assessment scheme for aquatic macrophytes is provided in the workshop report; The AMRAP Organizing Committee recommends to consider the outcome of the AMRAP Workshop for further updates of the Guidance Document on Aquatic Ecotoxicology and the Council Directive 91/414/EEC in order to better reflect the current status quo on aquatic macrophyte testing and aquatic macrophyte risk assessment for pesticides. The draft version of the AMRAP report is available via communities.setac.net. It is under "Technical Areas > Aquatic Toxicology and Ecology > Aquatic Macrophyte Risk Assessment Workshop". You can log in with a SETAC name and membership number.

Contributor	Section	Comment
Board for the Authorisation of Pesticides	2.4.2 Aquatic macrophytes (Annex II point 8.2.8)	This paragraph should be adjusted based on the new proposals for Annex II and III data requirements. For aquatic plants it is also recommended to take the proposals from the workshop AMRAP into account.
INIA	2.5 Study requirements for formulations (Annex III point 10.2)	2.5.1. Study requirements for formulations Formulated contains two or more active substances Not clear guidance are available for the risk assessment of the products containg two or more active ingredients. The evaluation of a product should reflect the toxicity of the product as a whole taking into account all the interactions among components. But, in the case of product containing more than one active substance it is difficult to determine the contribution of the two active substances. In many cases, the proposal of the notifier is to use toxicity of the product and compare with the PEC product. For this approach it is assumed that the two substances contribute to the toxicity of the mixture in proportion to their respective concentration. Also, it is assumed that spray drift is the only entry of the product in water bodies. However, not always the toxicity is proportional to the concentration and/or spray drift is not the relevant via entry in surface waters (e.g. runoff and drainage can be important). Clear guidance is needed. Extrapolations of toxicity data between similar formulations Another area of concern is how to extrapolate toxicity data between similar formulations. This is the special relevance for national registration.
BASF SE	2.5.1 Acute toxicity tests with the formulated product (Annex III point 10.2.1)	P 20, 2nd para: "If the active substance is more acutely toxic when it is formulated, TERs should be calculated on the basis of the data for the product..." add: "if drift is the major entry pathway"... (as stated in Annex III Introduction to Section 10 (vii)).
Pesticides Safety Directorate	2.5.1 Acute toxicity tests with the formulated product (Annex III point 10.2.1)	2.5.1It should be considered whether or not the principle of needing formulation data where one group is >100 times more sensitive than the next most sensitive groups is appropriate or not and holds true for more complex formulations. This could be done on the basis of information from Member States who will hopefully have some data to feed in to this. Some guidance on when formulations toxicity studies can be extrapolated would be useful. Also guidance where formulations data are not considered necessary would also be useful e.g. where the product is only to be used as a seed treatment.

Contributor	Section	Comment
Pesticides Safety Directorate	2.5.3 Chronic toxicity tests with the formulated product (Annex III Point 10.2.4)	2.5.3 The need for long term studies with formulation should be considered. For instance is the persistence of formulations worthy of further consideration? Can this parameter actually be determined?, do the ratios of coformulants to active substance remain the same over chronic timescales and following mixing/spraying? It seems that this is unlikely. In most cases chronic studies with the active substance will now be required (due to FOCUS exposure profiles). Hence the need for additional chronic formulation studies is arguably diminished unless there is a strong scientific reason for believing that chronic exposure to co-formulants is an issue - in which case a study with the co formulants of concern might be a better way to go. It should also be remembered that it is not possible to derive chronic formulation PECs.
Austrian Agency for Health and Food Safety	3. EXPOSURE ASSESSMENT	More and clear guidance on the exposure assessment for formulations is needed, especially for formulations with tow or more active substances. Generally a clear risk assessment for formulations should be developed (e.g. are there cases in which a chronic risk assessment for formulations is demanded, how should it be conducted?). This would help a lot in mutual recognition procedures and avoid a lot of discussions in expert meetings.
PAN-Europe	3. EXPOSURE ASSESSMENT	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request, and are happy to supply more scientific articles or background information on our position here if necessary. The points are: 4. Risk assessment should be focussed on the sensitive organisms, vulnerable life phases and cover all doses. In many instances in the past we observed that not the most sensitive organisms are tested, even though it was well known from open literature that other organisms were more sensitive. So we propose to check the scientific literature of the last ten years and use (international) databases like RTECS, CCOHS and PAN to find the most sensitive organisms for risk assessment. We also urge you to deny any statistical methods giving average data or -worse- select 90 or 95% of them, but keep strict to NOEC of the most sensitive one. Given the poor approach risk assessment is and the many uncertainties, no compromising should be allowed here. Vulnerable life phases are also many times neglected in risk assessment. Pre- and postnatal exposure should always part of the testing procedure and a follow-up in later phases on development and behaviour a standard requirement. More and more scientific articles show that chemicals (like diazinon) have effects at very low exposure level. We ask you to demand low-dose testing of every chemical.
Board for the Authorisation of Pesticides	3. EXPOSURE ASSESSMENT	It is important to take into account the results of the ELINK workshops with respect to the link between exposure and effects. In the report of ELINK also more precise guidance is given about the use of a PECtwa.
Swedish Chemicals Agency	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	The description of FOCUS surface water scenarios and other available guidance documents in the fate area may be replaced by relevant references. The guidance on selection of exposure time window for the risk assessment should be kept here, but needs to be updated in accordance with current practice. See PRAPeR discussions.

Contributor	Section	Comment
INIA	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	3.1 Exposure calculations and the implementation of FOCUS SW This section should be updated with the recommendations of FOCUS (2001) and FOCUS (2007)
Individual	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	The FOCUS exposure calculations should be validated by appropriate monitoring data to evaluate the protectiveness and reliability of the FOCUS surface water scenarios.
UBA	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	General comment: Considering the recent reports of the FOCUS working groups on landscape and mitigation (SANCO/10422/2005, version 2.0, September 2007) as well as on air we suggest that beyond this guidance document on aquatic ecotoxicology a new guidance on PEC calculation would be helpful. Such an exercise would comprise implementation of the results of the FOCUS reports in the PEC calculation as well as reconsideration of some calculation procedures of FOCUS surface water. For instance, more guidance is needed on the following points: - PEC surface water concentrations calculated by using the FOCUS scenarios are very much dependent on the selected simulation year. Furthermore, the year selected by FOCUS does not necessarily represent the desired 50th-percentile weather situation (see: M. Klein VIII Symposium Pesticide Chemistry - Environmental Fate and Human Health 2007) As a consequence, the results can vary between 'best case selection' and 'worst case selection'. No information is given to the user when calculation PEC values. - Implementation of results of the FOCUS Air working group (SANCO/10553/2006 Rev 2 June 2008) - When are FOCUS Step 2 calculations worst case calculations compared to FOCUS Step 3 as there are limited crop scenarios that give higher concentration in FOCUS Step 3 compared to FOCUS Step 2. - Acceptance of FOCUS Step 4 calculations in the context of the FOCUS Landscape and Mitigation (SANCO/10422/2005, version 2.0, September 2007) when mitigation measures for drift as well as for run off entries is considered.
UBA	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	General comment: It is a recognized approach for Annex I listing to use FOCUS surface water calculations as a basis for exposure assessment. However, on member state level for the authorization of a plant protection product other methodologies and scenarios may be used. For a new guidance document it would be helpful to focus mainly on the exposure assessment for Annex I listing. It should, nevertheless, be kept in mind that a FOCUS model result always reflects a specific climatic situation with a singular rainfall pattern. Hence, a single FOCUS model output can never be considered representative for all potential exposure patterns within a certain range of time.

Contributor	Section	Comment
Pesticides Safety Directorate	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	In Section 3, it would be worth developing guidance on how to deal with rapidly photolysising substances, particularly incorporating photolytic DT50 into FOCUSsw, although it is recognised that for these compounds at Step 3, the water phase degradation parameter can be relatively unimportant compared to the effects of water flow.
Pesticides Safety Directorate	3.1 Exposure calculations and the implementation of FOCUS Surface Waters	In Section 3.1, it would be worth mentioning that the principles of the FOCUS Degradation Kinetics Report should be used as the basis of all kinetic calculations for degradation parameters used in the FOCUSsw models.
INIA	3.1.1 Step 1 and 2 Calculations	3.1.1 FOCUS Steps 1 and 2 calculations Step 1 runpff/drainge loading is 10% instead of 15% Focus steps 1-3 cannot calculate accumulation in water and sediment layers
Individual	3.1.1 Step 1 and 2 Calculations	Small surface waters typically occurring in the agricultural landscape often are less than 30 cm in depth and therefore the FOCUS surface water calculations overestimate resulting water volume.
Individual	3.1.1 Step 1 and 2 Calculations	“At Step 1, the application rate is assumed to be the maximum season’s usage applied as a single dose, unless the DT50 in water for the compound is less than a third of the interval between treatments.” Intervals between treatments can be much smaller given there is more than one farmer in a catchment area applying the same pesticide simultaneously or without noticeable delay (see also 0. General comments).
Individual	3.1.1 Step 1 and 2 Calculations	“Four days after the last treatment, a percentage of the residue remaining on the treated field (determined using the soil degradation rate) is then added to the ditch as a run-off/erosion or drainage input and is added directly to the sediment layer of the ditch.“ As step 2 should represent worst-case loadings, I think it is necessary to shorten the time interval between pesticide application and runoff-induced pesticide entry into the ditch (current: 4 days) to create a more conservative scenario.
UBA	3.1.2 Use of Step 1 and 2 in the Risk Assessment Process	Comment to "Appropriate PECsw and PECsed values generated by Step1-2 in FOCUS can be used to compare to toxicity values to generate TER values." It would be helpful do define what is an appropriate PECvalue. That refers to the comments made to the use of PECtwa values.
Pesticides Safety Directorate	3.1.2 Use of Step 1 and 2 in the Risk Assessment Process	In section 3.1.2, it is worth noting that Step 3 can at times produce higher PEC values than at Step 2 (and exceptionally than at Step 1). It is recommended that a check be made that a more worst case risk assessment is not seen at Step 3 compared to Steps 1 and 2.

Contributor	Section	Comment
FURS	3.1.3 Step 3	Run-off is potentially important in Slovenia, but FOCUS run-off calculations are based on a single meteorological year and not protective. A multilateral project with Netherlands and Hungary demonstrated the PEC for run-off to be unpredictable and easy to manipulate. In many cases the model will not predict run-off no matter the properties of the substance. The R scenarios will need to be improved by doing calculations with meteorological data for at least 20 years (like with FOCUS groundwater) before FOCUSsw R scenario's can be relied upon. This should be indicated.
UBA	3.1.3 Step 3	When assessing the level of conservatism of STEP 3, it should also be taken into account that deposition due to volatilization is not considered in the model. As the Report of the FOCUS Air group is available (SANCO/10553/2006 Rev 2 June 2008) this exposure route can be addressed for risk assessment in the future.
INIA	3.1.4 Step 4	3.1.4 Step 4 Guidance for refinement options are given in FOCUS L&M (2007) Please update this section
Pesticides Safety Directorate	3.1.4 Step 4	In section 3.1.4, in relation to Step 4, it would be worth citing the FOCUS Landscape and Mitigation report in relation to potential mitigation measures that could be applied at Step 4.
INIA	3.2 Specific exposure scenarios	3.2. Specific exposure scenarios Rice: a summary of advances in modelling are welcome Volatilization and deposition: Reference to FOCUS (2008) should be included A summary on the Advances in watershed modelling are welcome For indoor uses clear guidance and rationale is needed whether the uses would lead to an exposure to aquatic organisms. Considerations of the new guidance under development are welcome
Pesticides Safety Directorate	3.2 Specific exposure scenarios	In section 3.2, it would be useful to give an update on MedRice. In addition, depending on timing of projects, it would be worth mentioning specific outcomes of the PPR work to develop a guidance document for protected crops. An update on the FOCUS Air report should also be given. 3.2 FOCUS air report has now been officially noted by the Standing Committee. I understand that whilst it makes some suggestion that deposition via air may need to be considered where volatilisation is an issue, it makes no proposals on how this can be done!
Austrian Agency for Health and Food Safety	3.3 Use of time weighted concentrations (PECtwa)	More and clearer guidance is needed for the use of time weighted concentrations for TER calculations. At the moment this issue is repeatedly a discussion point between authorities and notifiers as well as between MS and hence more and clearer guidance on this point is indicated.

Contributor	Section	Comment
Swedish Chemicals Agency	3.3 Use of time weighted concentrations (PECtwa)	Further guidance on the use of PEC TWA in relation to time to onset of effects is needed. It would be valuable if recommendations could be given regarding which end points that could be used together with a TWA-PEC, and the appropriate length of the TWA-period (if possible a list of different endpoint together with appropriate TWA-periods could be developed). A thorough discussion on which long term effects that can be caused by a single pulsed exposure is also needed.
UBA	3.3 Use of time weighted concentrations (PECtwa)	General comment: We see a need for a more detailed list of decision criteria for the use of a PECtwa or a PECini, since the question whether a PECtwa is justified or not has been a subject of discussion many times in the EU peer review of active substances. Among others, we suggest using the following criteria which are applied by default in DE: - If, in the case of potentially non-reversible effects, the time to onset of effects (TOE) in the ecotoxicological test cannot be determined, a PECini/max should be used instead of a PECtwa. - In the case of tests that span more than one life stage, the TWA time window should not be longer than the life stage of the highest ecotoxicological concern in the test. Rationale: If the time window is longer than the duration of a single life stage, the time to onset of effects in a later life stage in the test can be considerably over-estimated because the exposure time during earlier life stages might not be the cause of an effect on later life stages in the test. This could lead to an underestimation of the actual risk. Examples: - Fish early life stage test: Especially in the case of O. mykiss, many substances have a low bioavailability to the egg stage due to the impermeability of the eggshell. Hence, the effects becoming visible shortly after hatching will probably be due to the short exposure period in the post-egg-phase. Consequently, a TWA time basis from d0 to the date of onset of effects will considerably over-estimate the time needed to cause an effect on the most sensitive life stage. In this case, the time base for the calculation of the PECtwa should be the time from hatching to swim-up, provided that this life stage is thought to be the most sensitive in the test. - Daphnia reproduction test: If an effect on the reproductive success of the parent generation Daphnia occurs in the test, it is hardly possible to determine if it is caused by an effect on the parent Daphnia at the beginning of the test or by a direct effect on the F1 embryos at a later time. If, however, the TOA is defined as the time between t0 and the beginning of effects on the F1 generation, the „real" TOA might be considerably over-estimated. Consequently, test endpoints with regard to effects on the reproductive power of the F0 generation should generally not be used with a PECtwa in the risk assessment. - Algae population study: See specific comment to p. 27 of current GD. In addition, the according recommendations from the 2008 workshop ELINK (report not yet available) should be noted and critically reviewed.

Contributor	Section	Comment
UBA	3.3 Use of time weighted concentrations (PECtwa)	To p. 27 “However, the use of PECtwa values may be relevant for the algae risk assessment since the primary endpoint in the algae toxicity study is growth rate inhibition over the whole exposure period (i.e. a sublethal parameter), rather than percentage of dead or damaged cells at the end provided nominal concentrations are maintained throughout the test.”: The position of the UBA is that in the case of algae tests, the TWA-approach should generally not be used, especially if the tested algae species is meant to be a representative in the risk assessment for algae species as well as for higher aquatic plant species. Rationale: It should be noted that the effect level (effect on growth rate) will generally not be increased by a test duration longer than one cell division cycle. Thus, the time to onset of effects (TOE) will always be shorter than 24 h and can thus not be determined properly in the test. As a consequence, algae tests give practically no information on the ”real“ TOE in other species in the field, including higher aquatic plants. More to this it is normally not possible, in an algae test to differentiate between lethal (i.e., regarding the individual level, non-reversible effects) and sublethal effects (e.g., decelerated cell growth and division). Therefore, as a conservative assumption, effects in an algae test should always be considered to be non-reversible on an individual level as long as there is no reliable information proving the opposite. When, however, non-reversible effects occur, the determination of a TOE (not possible here, see above) would be a prerequisite to allow the use of a TWA. The fact that effects on algae are always reversible on the population level is not considered a valid argument, since the recovery potential of the test species population under lab conditions is not considered representative for species of concern in the field, especially not with respect to higher aquatic plants. Finally, the duration of an algae test is determined, on the one hand, by the minimum time needed to derive a proper population growth curve and, on the other hand, the maximum time in which exposure levels of the test substance can be kept constant and nutrients at a suitable level. It is clearly not determined by the exposure time deemed to be ecologically relevant for the tested algae or for any other species (including macrophytes) in the field, which the test has to represent in the risk assessment. Hence, the use of a 72 h default value is therefore rather arbitrary and seems to lack a sufficient scientific justification.
UBA	3.3 Use of time weighted concentrations (PECtwa)	To p. 27 “the use of PECtwa may not be appropriate for use with endocrine disrupting compounds […]”: Agreed that in the case of endocrine disrupting effects, a high level of caution should be assured. However, if in a specific case, there is enough evidence that a long-term exposure is needed to cause the endocrine disrupting effect, it might be considered case-by-case whether the use of a PECtwa is justified.

Contributor	Section	Comment
INIA	3.3 Use of time weighted concentrations (PECtwa)	3.3. Use of time weighted concentrations (PECtwa) A frequent risk assessment refinement step is using PECtwa, when measured concentrations show that test levels have been satisfactorily maintained over the exposure period. However it is not clear when is appropriate (or in what cases) to use PECtwa values. This approach is based on the results of the water sediment studies that are designed to study the route and rate of degradation of the active substance in aquatic systems and not for deriving PECTWA . This calculation is based on the guidance of FOCUS (2001) Some concerns are depicted below: 1) Pulse exposures: It is known that toxic effects of plant protection products on aquatic organisms depend of the dose and time. In many cases, similar effects are observed when exposed for a short time to a greater concentration or for a longer time to a smaller concentration, this is defined as reciprocity. However, reciprocity is not clear for acute exposure or when multiple applications of the plant protection product are intended. Thus, in field situations pulses of short duration are observed. How to approach this situation? 2) 21d-PECtwa or 7d-PECtwa: In the past, for pragmatic approaches the use of 21d-PECtwa or 7d-PECtwa have been used for risk assessment refinement without any justification. More advice is needed. 3) Algae and aquatic plants toxicity tests: It is always relevant to use PECtwa for algae or Lemna toxicity test since the primary endpoint in the algae toxicity test is growth rate? Please consider new proposals and discussions from ELINK workshop.
Pesticides Safety Directorate	3.3 Use of time weighted concentrations (PECtwa)	3.3 Clear guidance on the use of time weighted averages is required. Some guidance was drafted at ELINK and it should be considered whether or not this can be used as a basis for the discussions. A section needs to be drafted that allows a consistent approach based on good science that is supported by all Member States.
Board for the Authorisation of Pesticides	3.3 Use of time weighted concentrations (PECtwa)	It is important to take into account the results of the ELINK workshops with respect to the link between exposure and effects. In the report of ELINK also more precise guidance is given about the use of a PECtwa.
UBA	4. STANDARD RISK ASSESSMENT	The risk to the aquatic stages of amphibians is not explicitly addressed in the GD. At least some general remarks should be included with regard to the question to what extent the potential risks to this group might be covered by the existing assessment scheme.
FURS	4. STANDARD RISK ASSESSMENT	Exposure might be underestimated for substances that potentially accumulate in sediment. In general, this is not satisfactory covered in the guidance. It is proposed that in this situations a PECplateau is calculcated with the same formula used to calculate PECplateau in soil.

Contributor	Section	Comment
Pesticides Safety Directorate	4. STANDARD RISK ASSESSMENT	4 We believe consideration should be given to the need to cover active substances which partition to sediment where they may accumulate. The use of standard FOCUS surface water PECs may underestimate the risk from exposure when this is compared to the end point from a water spiked study. Instead we believe that the sediment PEC should be converted back to a water concentration and then compared with the water spiked study end point. Guidance should be given to allow a consistent European approach.
Swedish Chemicals Agency	5. HIGHER-TIER RISK ASSESSMENT	We agree with the PPR panel (Opinion on revision of annex II and III) that the current guidelines on field testing is unsatisfactory since many of the existing field tests are designed in such a way that less than 50 % effect will not be detected. Overruling the first tier assessment with uncertain field experiment is not justified. This needs to be considered during the revision of the guidance document.
Swedish Chemicals Agency	5. HIGHER-TIER RISK ASSESSMENT	When developing refinment procedures it should be recognised that the use of plant protection products will result in multiple exposure of pesticides which may cause synergistic and cumulative adverse effects. Hence we should not develop too sofisticated refinement methods which mainly serves to reduce the risk (modelling population/community level effects, including recovery etc.), without taking multiple exposure also into account. However, we believe that it is not feasible to include multiple exposure in a regulatory risk assessment under 91/414. This should be considerd when developing refinemnt methods, and may be the assessment should remain fairly “crude” in order to balance this lack of realism.
INIA	5. HIGHER-TIER RISK ASSESSMENT	5. Higher Tier acute risk assessment A summary of limitations and challenges of the current approach are welcome
PAN-Europe	5. HIGHER-TIER RISK ASSESSMENT	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request and are happy to supply more scientific articles or background information on our positions here if necessary. The points are: 3. Higher-tier risk assessment is on the moment an unwanted loophole in the decision-making. Higher-tier assessments can be done in many way and also in many unwanted and unscientific ways. We remember very well that a representative of DG SANCO on a stakeholder meeting confirmed that because of the "unless" clause in the Uniform Principles and the higer-tier tests done by industry no pesticide can be stopped if industry really tries. So we propose to completely start again with the higher-tier approach and deny all existent assessment varieties. We also know very well that HARAP and CLASSIC meetings were organised by industry, that industry "scientists" were the majority of the attendants and that access of PAN-Europe was denied. Still this "scientific" approaches were adopted by Member States and the Commission. We know very well that the micro/mesocosms were developped by consultancies (Alterra) which have industry as their clients. Micro/mesocosms have many weak points. Sediment, plants and other organisms like fish present in these mesocosms are many times not present in ditches and canals in the agricultural areas. Water in cosms is clean while in practice it is polluted by agriculture, air and fi. sewers. So a critical approach to this cosms studies would be appropiate, still this way is working and decision-making is decided by consultants and hardly by independant decision-makers. The higher-tier lacks an open approach, lacks a good debate on strenghts and weakenesses, excludes stakeholders, and gives power to a small group of experts with binding to specific interest groups.

Contributor	Section	Comment
Board for the Authorisation of Pesticides	5. HIGHER-TIER RISK ASSESSMENT	General: In the actual guidance document nothing is mentioned about ecological modelling. The workshop LEMTOX was organised to discuss this topic. The results from this workshop should be taken into account. Also relevant (parts from) PPR-opinions should be taken into account.
Danish EPA	5.2 Higher-tier acute risk assessment	The intention of the second paragraph was to make it possible to lower or disregard the acute TER for daphnids if the longterm TER for daphnids did not show any risk. We do not agree to this approach, because daphnids are not the target of the risk assessment aquatic invertebrates are and there might very well be other aquatic invertebrates that are at acute risk even though the chronic risk for daphnids have shown that they are not.
Swedish Chemicals Agency	5.2 Higher-tier acute risk assessment	Please reconsider the two last sentences in section 5.2. A discussion on the scientific background is needed.
Pesticides Safety Directorate	5.2 Higher-tier acute risk assessment	5.2 Use of an uncertainty factor of <100 where acute:chronic ratio is low requires further consideration. Data that support should an approach should be presented and considered during the discussions. If such data were collated during ELINK this could be examined too.
Board for the Authorisation of Pesticides	5.2 Higher-tier acute risk assessment	In paragraph 5.2 the acute/chronic (A/C) ratio is mentioned. According to NL the A/C ratio is the acute L(E)C50 compared with the chronic NOEC. But there are also other opinions. Therefore it is recommended to state explicitly in the guidance document what is meant with the A/C ratio.
Centre for watermanagement	5.2 Higher-tier acute risk assessment	Chapter 5.4.2.1 It is concluded in this chapter that risk assessment based on studies with constant exposure concentrations may overestimate the potential risk. This is not correct. It may overestimate the actual risk in the field. This is precisely the function of estimating potential risks (realistic worse case).
BASF SE	5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	P 30: …It therefore permits a reduction of the uncertainty factor that is applied to the lower-tier data." Add: "Unless there is evidence that the chronic sensitivity of a species may not be compared to the chronic sensitivity of another species, the information on species sensitivity from acute testing may also be applied to chronic testing (e.g. by using a relevant factor for the HC and the standard species)." ... If a considerable number of additional species...

Contributor	Section	Comment
Swedish Chemicals Agency	5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	Methods for dealing with uncertainty factors when additional data are available should refer to the EFSA opinion on this matter. From our understanding, however, so far only the simple approach in chapter 5.1 of this opinion has been practically used. The relevant sections could be implemented in the GD.
UBA	5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	P. 30, comment to: "If a considerable number of additional species was tested in valid studies, then it is possible that the uncertainty factors that are applied to the lowest toxicity value could be lowered by up to an order of magnitude. However, the full order of magnitude reduction is likely only to apply to acute risk assessments, e.g., Annex VI TER trigger for acute risk to fish and aquatic invertebrates.": The term "lowered by up to an order of magnitude" has been misinterpreted many times in terms of "lowered from 100 to 10 by default if enough data for a SSD are available." Thus, a list of criteria to be applied in the decision on the appropriate uncertainty factor should be reported in order to pay more attention to this critical issue. Proposals for criteria: - LC50-to-NOEC ratio within the same endpoint (RAC should never be higher than effect threshold value!) - specific (according to the mode-of-action) risk from effects other than those tested in acute tests (where they are caused by short-term exposure), i.e. delayed effects or ecologically relevant endpoints which are not tested - range of species tested, i.e. the remaining level of uncertainty regarding the variability in species sensitivity. - etc.
Pesticides Safety Directorate	5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	5.3 Additional species. Section should be updated to take into account PPR opinion (EFSA Journal 92005) 301, 1-45 and other latest thinking such as EFSA-Q-2005-112A+ B which includes information on the use of hazard concentration 5 values (HC5s). Our understanding is that the approach currently indicated based on HARAP has fallen out of favour as a result of the above opinions.
Board for the Authorisation of Pesticides	5.3 Reduction of the relevant uncertainty factor if data from additional single species tests are available	The PPR-opinion on this subject should be taken into account. Also more guidance should be given about the SSD-approach. NL have quite some experience with this approach and there is a lot of guidance available. Also validation exercises have been done by Alterra and DEFRA.

Contributor	Section	Comment
Austrian Agency for Health and Food Safety	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point 10.2.2)	We are aware that it is not easy to provide clear guidance on the evaluation of micro- and mesocosm studies and on the use of such studies for the risk assessment of a substance. However, it should be tried to more precisely define the relevant endpoints from such studies (NOEC, NOAEC, EAC?), which can be accepted for a refined risk assessment. If a NOAEC or an EAC are regarded acceptable it has to be defined, when e.g. an observed effect is not regarded adverse and when an effect is regarded as ecologically acceptable. Such definitions are still too vague in the current guidance document (including the Classic Workshop). Additionally guidance on the reduction of an assessment factor with such endpoints is needed. Currently it seems that there is no harmonised approach between MS.
Swedish Chemicals Agency	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point 10.2.2)	The guidance on how to evaluate higher tier studies need to be updated. A more detailed guidance is needed on how to judge if the community in a micro/mesocosm study is representative and protective for the proposed use(which taxonomic groups should be present in which numbers, physical design of experimental system), possibly developed as a checklist. Guidance on how to judge the quality of a study is needed (e.g. number of replicates, power of test, variation of data, verification of exposure, sampling frequency), possibly this can also be developed as a checklist.
Individual	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies)	The representativeness of the organisms tested in higher-test studies (micro- and mesocosms) must be proven to represent a realistic worst-case for all different species potentially affected by the active ingredient evaluated. It is questionable, if toxicity data derived from test with e.g. crustaceans, fish and aquatic insects are sufficiently representative for the extrapolation of the effects to other aquatic organism groups like - for example – amphibians. For further details see comment to 2.
Pesticides Safety Directorate	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point 10.2.2)	5.4 This should be updated in the light of the latest information and it should be checked whether the older references e.g. harap, classic are still useful.
Board for the Authorisation of Pesticides	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point	Regarding the higher tier effect studies for macrophytes the results from the workshop AMRAP should be taken into account.

Contributor	Section	Comment
	10.2.2)	
RIVM	5.4 Design and conduct of higher-tier effects studies including microcosm and mesocosm studies (Annex III point 10.2.2)	5.4 Design and conduct of higher-tier effects studies .... Chapter 5.4 gives guidance for the design and conduct of higher-tier effects studies. Hardly any guidance is however given for the summarising an evaluating of aquatic micro- and mesocosm studies. Since these types of higher tier studies are rather complex, the result in quite lengthy and complecated study reports. Therefore, at least in the Netherlands, a need was present for guidance how to summarise and evaluate these type of studies in a uniform way, and the Dutch Platform for the Assessment of Higher Tier Studies published a guidance document for this aim: Jong, F.M.W. de, Brock, T.C.M., Foekema, E.M., Leeuwangh, P., 2008. Guidance for summarizing aquatic micro- and mesocosmsstudies. A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies. RIVM report 601506009/2008. The Dutch Platform recommends to take this guidance document intoaccount as a useful tool for summarising and evaluating of aquatic micro- and mesocosmstudies. The guidance document is available at: http://www.rivm.nl/bibliotheek/rapporten/601506009.html
Danish EPA	5.4.1 Introduction	Re. definening endpoints: As mentioned we do not agree to the EAC concept -and the NOEAEC suffers from the some shortcommings. We perfer to use the following endpoints and definitions: NOAEC: 'No Observed Adverse Effect Concentration' the concentration for which there are only limited effects and recovery has occurred within an acceptable period of time for the most sensitive species/parameter. Recovery: recovery from a disturbed state to a state that is comparable with the control (i.e. there is no longer a difference for a species/parameter between the relevant exposure concentration and the control). Determination of the period that recovery covers is limited by the number of measurements that are taken. In any case the guidance document should provide clearly defined endpoints.

Contributor	Section	Comment
Danish EPA	5.4.1 Introduction	EAC is in our opinion a misnomer. From Natures point of view anything is acceptable. There is nothing in Ecology as such that says that a certain state of affairs is unacceptable. For instance a water body consisting of anaerobic sediment and tubificid larvae is a perfectly good ecosystem and Nature or Ecology does not pass judgement on its acceptability. On the other hand we – human beings – do pass judgement and we may decide that some state or effect is unacceptable. The point is that this concept is more what we believe is acceptable and therefore it is subjective. Being subjective it is influenced by all sorts of perceptions that are very much coloured by national considerations. It is thus not a strict scientific endpoint and should not be used as such in e.g. endpoint sheets. In our view the EAC should not be used as an endpoint. Furthermore we find that only study specific endpoints should be provided and that the assessment factors should not be included in the endpoints. Rather appropriate assessment fgactors should be considered for the final risk assessment based on all information available and considering the representativeness of the information for the particular risk assessment.
UBA	5.4.1 Introduction	Note that in practice, the term "EAC" has largely been replaced by the more accurate “regulatory acceptable concentration” (RAC).
UBA	5.4.1 Introduction	Comment to 5.4.1.2, p 31: The discussion results reported in recent SETAC workshop reports (AMPERE, LEMTOX, ELINK) with regard to the interpretation of the results of mesocosm tests should be critically reviewed in this chapter. In particular, the state-of-the-art in dealing with uncertainty regarding the representativeness of recovery observed in mesocosm tests should be reported. Some aspects: - Recovery fully representative for populations of organisms of concern in natural water bodies => Use of NOEAECmesocosm with uncertainty factor; - Recovery not considered fully representative of organisms of concern (e.g., semivoltine invertebrate species => Use of NOECmesocosm with lower uncertainty factor; - In addition, possible indirect effects beyond the scope of the mesocosm study (e.g., starvation in fish breed due to significant reduction of zooplankton observed in the study) should be considered in any case.
UBA	5.4.1 Introduction	Benthic invertebrates are frequently determinant for the overall level of risk to aquatic communities. The statistical power with regard to this group of organisms being unsatisfyingly low in many studies, it should be discussed how to deal with such data when deriving endpoints from mesocosms (weight-of-evidence approaches; “biological significance” versus statistical significance). The same applies to the problem of declining abundances in the control ponds after the date of the application of the test substance. It should be clearly stated in the revised guidance document that emphasis should be placed on this phenomenon ("pseudo-recovery") and that the disappearance of a statistically significant difference between control and treated pond after an initially observed effect does not automatically mean that full recovery (potential) has occurred.

Contributor	Section	Comment
UBA	5.4.1 Introduction	Comment to 5.4.1.2, p. 31: "The NOEAEC may be used for a direct comparison with the relevant PEC if uncertainty has been reduced considerably and the result from the study is relevant for overall decision making.": This proposal should be reviewed as it does not reflect the common practice in the EU risk assessment where uncertainty factors are applied to NOEC and NOEAEC values in the clear majority of cases. In this context, it should be considered that in general, more than one pesticide of the same group (insecticides, herbicides, fungicides) will be applied on one field. Thus, when deciding on the appropriate study endpoint and the uncertainty factor, it should be considered that effects to the same group of organisms might occur several times within a year. If this scenario is considered relevant, the "acceptable" time to full recovery should not be longer than the time between the applications of two different pesticides with a potential risk to the same group of organisms. Also applies to chapter 5.5.2, p 39.
FURS	5.4.1 Introduction	More guidance is needed for cases that the exposure pattern in the higher tier study (usually simulating a drift exposure) does not adequately cover the exposure pattern from other exposure routes (drainage, run-off).
Centre for watermanagement	5.4.1 Introduction	Chapter 5.4.1.1. The conclusion is drawn in this chapter that a general relationship is derived for herbicides and insecticides, from Brock et al.. It should be noted that the studies of Brock et al deals with a limited number of pesticides. Whether a general approach can be derived from these studies is questionable, or at least matter for debate. Chapter 5.4.1.2. The term Ecologically Acceptable Concentration creates a picture that it is the ecology that decides whether an effect is acceptable. In fact the acceptance of effects is a risk managers decision! It is OK to derive effect levels from these studies but the level to choose for risk assessment purposes is again a risk management decision. The height of assessment factors, in relation to the number of available data is also a risk management discussion.

Contributor	Section	Comment
UBA	5.4.2 Microcosm	We would like to point out that effect values derived from modified-exposure studies (e.g. peak exposure due to presence of sediment, in order to simulate the environmental fate of a substance in the test system) must always be related to the most sensitive life stage or stages and biological endpoints. This is particularly important in test systems (like fish ELS) spanning several life stages. As a prerequisite for assessing such modified-exposure tests, substance concentrations during the test must be analytically monitored using enough sampling points to perform a kinetic analysis of residue dynamics in the test system. At least, the concentrations at crucial biological transition points (like hatch and swim-up in a fish ELS) must be available. Provided that such data are available, it will be in principle possible to assign biological effects to actual exposure concentrations, e.g. the concentration prevailing at the beginning of the swim-up phase in a fish ELS if the most pronounced effects are observed during swim-up. (NB: Contrary to what has been stated in the PPR opinion on dimoxystrobin, we deem it not necessary that the concentrations at the end of the test must always be used as a very conservative estimate. Selection of the appropriate exposure concentration for deriving a NOEC depends on the type of effects observed as well as on the availability and quality of analytical measurements.) When planning modified-exposure tests, it might, however, prove more appropriate to use a test design in which all relevant life stages are exposed in parallel to the same concentrations (e.g., a fish ELS with simultaneous exposure of eggs, fry and juveniles). If the worst-case character of exposure in the modified-exposure test system is doubtful, e.g. there are indications for faster dissipation than expected under field conditions, the risk assessment should be based on results obtained under constant exposure conditions (flow-trough). Additional comment: Studies with realistic exposure conditions are no higher-tier studies in a biological sense. Thus, the standard assessment factors are to be applied when using their results in a risk assessment.
Board for the Authorisation of Pesticides	5.4.2 Microcosm	More guidance is needed with regard to modified exposure studies. At this moment it is not really clear how to judge these kind of studies (e.g. sediment/water ratio, suitable organic carbon content of the sediment etc.).
Danish EPA	5.4.3 Mesocosm - outdoor multispecies tests	In our view the issue of recovery is very complex and needs very careful consideration– both with regard to interpretation of the study itself and with regard to its use in extrapolating to the field/other systems/other regions. E.g. species that have several reproductive cycles under southern conditions may be univoltine under nordic conditions.
BASF SE	5.4.3 Mesocosm - outdoor multispecies tests	P 37, last para: The relevance of the pre-exposure period may be more important for systems which have been set up artificially. However, if mesocosms are started with a natural sediment and natural water, this will not be of much importance and a precise history of the system may be short, but should include information on the source of the water and sediment.

Contributor	Section	Comment
UBA	5.4.3 Mesocosm - outdoor multispecies tests	Comment to 5.4.3.3, p. 37: "Effects may be considered of low ecological significance if recovery takes place in a given time period like 8 weeks,": We do not agree to this general criterion of acceptability. As stated several times by the author T. Brock, the duration of 8 weeks was not meant as a criterion of acceptability but rather as a non-judgemental tool for effect classification. If a certain duration of effects is proposed in the revised guidance document, it should be backed up by a transparent scientific justification, including considerations like the use of more than one pesticides within one season and potential indirect effects beyond the scope of the study (e.g. in growth and survival of juvenile fish)
UBA	5.4.3 Mesocosm - outdoor multispecies tests	Comment to 5.4.3.2, p. 35: "[...] multivariate methods are recommended for describing community-level effects. The Principal Response Curve (PRC) method is a suitable multivariate technique designed to analyse microcosm and mesocosm tests (VAN DEN BRINK & TERBRAAK, 1999).": It should be critically reviewed (i) to what extent the PRC does reflect "the community level" in terms of "more-than-the-sum-of-effects-on-the-individual-populations" and (ii) how, in view of the Annex VI decision-making criteria, an effect on the community level is more relevant than an effect on a single population. Our position is that an absence of effects on the multivariate (PRC) level should not be used to overrule effects observed on the population level, as the populations are defined as an independent protection goal. Accordingly, an insufficient level of statistical power on the population level cannot be ironed out by multivariate statistical methods.
Pesticides Safety Directorate	5.4.3 Mesocosm - outdoor multispecies tests	5.4.3 Reference could be made to the recent OECD Environmental Health and Safety Publications Series on Testing and Assessment. No 53. Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms). OECD Paris April 2006. as this provides a good review of the key issues to consider. Guidance should be given on the importance of clarify making the mesocosm study end points completely transparent. So it should be clear what the end point was based on and if it is a recovery end point the time period required for this. Guidance on how best to present the results of a mesocosm would aid harmonisation. It would be useful to have guidance on the sort of uncertainty values to be used with micro and mesocosm studies and with NOECs and NOEAEC. It may be possible to draw on information from the Ampere workshop. 5.4.3.3 - Recovery can be specific to life cycle and it would be helpful if reference to life cycle databases could be included. It would also be helpful if further guidance could be given on the acceptable periods for recovery.
Board for the Authorisation of Pesticides	5.4.3 Mesocosm - outdoor multispecies tests	Regarding the summarising and evaluation of micro-/mesocosm studies guidance is available now: "De Jong et al., Guidance for summarizing and evaluation aquatic micro- and mesocoms studies, RIVM Report 601506009/2008." This guidance document should be taken into account. In the guidance document of De Jong et al., also a proposal for an adapted classification of effects from micro-/mesocosm studies is presented. This was agreed upon during the Ampere-workshop and should be taken into account.
Centre for watermanagement	5.4.3 Mesocosm - outdoor multispecies tests	Chapter 5.4.3 In general there is a lack of consistency is this chapter. Under the microcosm studies chapter clear disadvantages of the test system is given. For mesocosm studies also clear disadvantages can be addressed. These are not reported. Moreover, when using these studies in the risk assessment it is important to keep in mind that the study describes in fact the actual risk at the study location. In many cases knowledge on environmental variation, in relation to pesticides, lacks. Therefore precautionary assessment factors should be applied, that are underpinned by knowledge on inter and intra environmental variation. If not

Contributor	Section	Comment
		available precautionary principles must be applied.
Swedish Chemicals Agency	5.5 Risk assessment on the basis of higher tier data	It should be recommended to calculate the power of the studies. Guidance on methods for calculating power should be given in the guidance document. A discussion on which levels of power that is acceptable and how to treat studies with low power is also needed. It is also recognised by the PPR panel (Opinion on revision of data requirement) that many field tests are designed in such a way that les than 50 % effect will be detected and that overruling first tier assessment with uncertain field experiment is not justified.
Swedish Chemicals Agency	5.5 Risk assessment on the basis of higher tier data	A discussion of the scientific robustness of the generally accepted time to recovery of 8 weeks for all organism groups (independent of life history) is needed.
Swedish Chemicals Agency	5.5 Risk assessment on the basis of higher tier data	A discussion is also needed on which aspects (i.e. representativeness and quality) to take into account when selecting the safety factors to be used together with the results from the higher tier study (could be developed as a check list).
Board for the Authorisation of Pesticides	5.5 Risk assessment on the basis of higher tier data	Regarding the higher tier risk assessment for macrophytes the results from the workshop AMRAP should be taken into account.
Austrian Agency for Health and Food Safety	5.5.1 Single species tests	Clear guidance on the incorporation of additional single species tests into the risk assessment is urgently needed. E.g.: How to deal with SSDs and HC5 values. When is an SSD acceptable (acceptability criteria are needed, e.g. how to deal with multiple values for one species or with greater than values in the calculation of an SSD, is it acceptable to transform the data? etc.). What magnitude of reduction of an assessment factor is appropriate with a TER-value derived from and HC5? Is such an approach generally acceptable? How is the approach of the Scientific Panel Paper to be applied in practice (e.g. should a geometric mean of toxicity values for groups of invertebrates (crustacean, insects etc.) be used or should all data for invertebrates be pooled? What are the limitations of this approach?
UBA	5.5.1 Single species tests	To p. 39, “Single species tests are usually not designed to address the potential for recovery.”: Irrespective of this sentence, so-called “recovery studies” using single-species test systems with standard test species like algae and Daphnia have been submitted many times by applicants. Thus, it should be stated more clearly in the revised guidance document that such tests are generally not appropriate for the risk assessment, as the life-cycle characteristics of the standard test species do not reflect a realistic worst case. In natural water bodies, typically many species with longer life cycles occur. In addition, a recovery process observed under ecologically isolated conditions is not considered to be of high predictive power for conditions in the field (especially with regard to the lack of inter-species competition in the test).

Contributor	Section	Comment
Danish EPA	5.5.2 Semi-realistic microcosm and mesocosm	This section seems to suggest that from indoor microcosm studies NOEAEC values may be dirived that can be used in the risk assessment without an assessment factor - we do not agree to this. Such studies can not be used to define an overall ecosystem effect level - at least not that is relevant for a variety of natureal systems. In fact we do not find that a single mesocosm study can be used without an assessment factor. As the point of departure a minimum safety factor of 5 should be used for a mesocosm study as individual tests cannot be expected to be representative of all of the organisms or biotopes. The safety factor can be reduced if several studies of high quality are submitted that shed light on the difference between different natural systems. Studies that differ in terms of both time and space can be used to lower the safety factor if they represent different population mixes or biotopes.
Austrian Agency for Health and Food Safety	5.5.2 Semi-realistic microcosm and mesocosm	Information from the ELINK workshop should be taken on board. Guidance on linking the exposure estimates derived with FOCUS modelling and the modified exposure situation in the test systems should be provided.
UBA	5.5.2 Semi-realistic microcosm and mesocosm	Comment to 5.5.2, p. 39 “It is proposed that the use of ecological models for extrapolation is developed further in the future. NOEAECs from reliable static mesocosm studies should be regarded as generally representative or possibly conservative for surface waters in most agricultural landscapes.“: This statement should definitely be removed from the new guidance document, as it does not reflect the current state of science. For technical reasons, mesocosm systems contain predominantly species with a short lifecycle and high dispersal ability. Recovery processes observed in mesocosms can therefore not be considered to be generally representative for the populations of ecologically vulnerable species in the field. Moreover, often more than one pesticide with a potential hazard to a certain group of organisms is applied within on year in reality. Against this background, it appears rather questionable if the use of a NOEAEC without an uncertainty factor can assure an appropriate level of protection.
UBA	5.5.2 Semi-realistic microcosm and mesocosm	To 5.5.2, p. 39, “It may be appropriate to compare an NOEAEC directly with the PEC, provided all the uncertainty has been satisfactorily accounted for. Otherwise, some uncertainty factor has to be applied to define the EAC (see section 5.4.1.2).”: -> See our comment to 5.4.2.1, p. 31.
Board for the Authorisation of Pesticides	5.5.2 Semi-realistic microcosm and mesocosm	Regarding the interpretation of micro-/mesocosm studies the results from the workshop Ampere should be taken into account. Relevant parts from the guidance document Landscape and Mitigation should be taken into account.
UBA	5.6 Probabilistic Risk Assessment	One particular aspect should be added to the discussion of probabilistic methods, i.e. the risk of overlooking cumulations of unacceptable effects in a certain region or in a certain type of water body, when probabilistic approaches are applied. For further details, see Schulz et al. (in press in IEAM: "Probabilistic Landscape Level Risk Assessment for Pesticides in Germany, a Conceptual Framework").

Contributor	Section	Comment
UBA	5.6 Probabilistic Risk Assessment	The necessity for careful analysis of input data with regard to the existence of aggregations/cumulations is basically the same as also required for the effect side where species data for SSD is analyzed to reveal whether the data can be classified in certain species subgroups (e.g. different sensitivity due to phylogenetic constraints) that should not be combined in one SSD curve (see also Aquatic GD, page 40 "assumption that the organisms selected for testing are an unbiased sample"). On the exposure side, spatial aggregations of high exposure situations ("end of tail"-combinations in the PEC distribution function) might exist due to spatial autocorrelation of such exposure situations in the landscape. This means that scenario-based probabilistic approaches for exposure assessment have to consider this aspect in the derivation of approapriately protective scenarios. (Are the FOCUS scenario sufficiently protective with respect to this matter, e.g. standard assumption on depth of water bodies?) In contrast, geo-referenced probabilistic approaches explicitly address the spatial variability of exposure situations in field and therefore actually enable a direct comparison between local exposure situation and the relevant endpoint on the effect side (or more sophisticated geo-referenced modelling approaches).
Swedish Chemicals Agency	5.6 Probabilistic Risk Assessment	From what we have seen of the EUFRAM document it seems as if several of the approaches are too complicated to be generally recommended for risk assessment. At present, we consider that SSD approaches can be generally recommended for regulatory aquatic risk assessment. If other PRA approaches (e.g. combining distributions of exposure and effect) should be recommended in the guidance document generic scenarios and associated software needs to be developed. Hence, in the guidance document recommendations on how to perform and evaluate an SSD is needed. In addition a discussion on which endpoint (which HCx), grouping gof organisms, confidence level and safety factor that are appropriate is needed before it is possible to implement this method in regulatory risk assessment.
INIA	5.6 Probabilistic Risk Assessment	5.6. Probabilistic risk assessment Probabilistic risk assessment (PRA) is an emerging approach for environmental risk assessment, and an excellent toll to be used as higher-tier- risk assessment. This approach has been the subject of several workshops (HART, 2001; EUPRA, ECOFRAM) and recently has been discussed in ELINK. In aquatic risk assessment, PRA can be applied in different ways, at various levels of complexity, covering both the effects and exposure of risk assessment. It is a promising tool. Please update the section according to state of art.
Pesticides Safety Directorate	5.6 Probabilistic Risk Assessment	5.6 Guidance on how to evaluate and interpret population modelling is needed. It would be useful if this could include a consideration of what aspects of a model can be manipulated and therefore should be scientifically justified. It may be possible to use some of the information from ELINK to support this. Other Member States may be interested to see the UK based system (WEBFRAM) which uses some probabilistic elements and a UK based scheme for aquatic organisms (as well as birds and mammals). This can be viewed at www.webfram.com
Board for the Authorisation of Pesticides	5.6 Probabilistic Risk Assessment	The paragraph about probabilistic risk assessment should be updated based on the results of the EUFRAM workshop.

Contributor	Section	Comment
Austrian Agency for Health and Food Safety	5.7 Higher-tier risk assessment for compounds which have a considerable potential to bioaccumulate	The assessment of substances with a clear tendency to bioaccumulate (e.g. high BCF and incomplete excretion) and which are additionally persistent is still a very open field in risk assessment. We also see the difficulty to provide a clear guidance for the risk assessment of such substances. On the other hand, only few substances have these characteristics and hence especially small MS have problems to build up enough expertise to assess the risk from the bioaccumulation of such substances. It might be an option to build up some sort of Panel from the EFSA expert data base who could perform an elaborate risk assessment for such substances.
Swedish Chemicals Agency	5.7 Higher-tier risk assessment for compounds which have a considerable potential to bioaccumulate	The current triggers for requirement of long term tests on fish are based on bioaccumulation, persistence and acute toxicity. It was agreed in the draft revised Annex II that the long term toxicity is not always related to the acute toxicity and therefore this trigger should be deleted. Further, we agree with the PPR opinion on Annex II: "Even if there is only acute exposure, long term toxicity studies (e.g. fish, aquatic invertebrates, earthworms) should still be provided unless it can be clearly demonstrated that no adverse delayed effects (of a short term exposure) are to be expected." This, in addition to the fact that based on the FOCUSsw scenarios, long term or repeated exposure may occur also for non-persistent compounds makes long term tests more or less a standard requirement.
Pesticides Safety Directorate	5.7 Higher-tier risk assessment for compounds which have a considerable potential to bioaccumulate	5.7 Bioaccumulation and food chain behaviour It should be ensured that the risk of bioaccumulation and secondary poisoning ties in with the new draft bird and mammal guidance document. Further consideration needs to be given as to the appropriateness of the methodologies / equations included in this section –both in relation to the assessment of secondary poisoning in terrestrial vertebrates and of the potential for biomagnification in aquatic food chains. The same basic methodology should be used in both Aquatic the 'Bird and Mammal' guidance documents, with the same symbols used for the various parameters involved. Bioaccumulating compounds often do not persist in the water phase but move rapidly into living organisms and /or sediment. Significant levels of bioaccumulation may occur within a few days of exposure and sometimes within hours. For such compounds use of a 21 day twa PEC is may therefore be inappropriate. In the absence of information on the relationship between the duration of exposure and potential bioaccumulation, initial PECsw levels should be used instead. For compounds that rapidly dissipate from the water phase, use of the results of a standard flow-through exposure BCF study is likely to over-estimate potential bioconcentration. This is best addressed by conducted a BAF study, using a water sediment test system with 'static' exposure. Potential residues in fish can then be estimated by multiplying the initial PECsw by the (maximum) BAF value. Currently no mention of the possible use of such studies is included.
UBA	5.7.1 Introduction	Please consider in a revised section on bioconcentration the current status of the revision of Directive 91/414/EEC, namely the newly introduced cut-off and substitution criteria. According to current drafting, a BCF > 5000 would be a criterion for substitution of the compound (in accordance with PBT assessment), hence no further higher tier risk assessment would be necessary or useful.

Contributor	Section	Comment
Swedish Chemicals Agency	5.7.3 Secondary poisoning for birds and mammals	The section on secondary poisoning of fish-eating birds and mammals should be updated in accordance with the revised Birds and Mammals document, alternatively referred to this document.
FURS	5.7.3 Secondary poisoning for birds and mammals	There is a need to further consider exposure via sediment. Substances with a potential to bioaccumulate are likely to partition to sediment. The highest risk then exists for the route: benthic invertebrates -> benthic fish -> fish eating bird/mammal. It also needs to be taken into account that such substances can accumulate in sediment. Where relevant, assessment should be based on a plateau concentration. Depending on the availability of appropriate protocols, a bioaccumulation study in a water-sediment system might also be an option or a study in microcosms/mesocosms as mentioned in 5.7.4.
UBA	5.7.4 Biomagnification in aquatic food chains	Page 42, General explanatory notes: There is a need for guidance on how to perform the risk assessment of biomagnifications in aquatic food chains. - Which requirements exist for modeling of the aquatic food chain (i.e. trophic level)? - How to cope with existing problems regarding experimental modeling with fish in mesocosm? - Which criteria exist for acceptability of modeled results? - Which criteria exist for evaluating the validity of models? For deriving meaningful decision criteria, it will be necessary to have such a discussion on aspects to consider. This would also comprise issues to consider for determination of appropriate safety factors.
Swedish Chemicals Agency	5.7.4 Biomagnification in aquatic food chains	We suggest that this section should be expanded to explain why risk assessments for substances that are bioaccumulated and persistent are specifically problematic. By contrast, we suggest reference to specific models for food-chain modelling should be deleted unless the models are validated, and in the latter case the conditions for such validation needs to be carefully mentioned and discussed. The current version of the Aquatic Guidance Doc. (SANCO/3268/2001) adds that "For extremely bioaccumulating and persistent substances it should be considered whether modelling and microcosm/mesocosm testing is appropriate at all because even the best test methods currently available may not be sufficient to fully investigate problems which are linked to these properties of a substance." This view corresponds to guidance recently developed under the REACH legislation. To the extent possible, we believe that guidance for risk assessment of chemicals should not be developed in fundamentally diverging ways under different legislation within the EU. We therefore find it important that the text quoted above from the current version of the Aquatic guid. Doc. be retained also in revised version. Discussions on trigger values for these issues are highly appreciated.

Contributor	Section	Comment
US EPA/OPP/EFED	5.7.4 Biomagnification in aquatic food chains	Section 5.7.4; p. 43 (Biomagnification). Assessment of bioaccumulation and biomagnification should also consider appropriately validated food web bioaccumulation models (e.g., Arnot and Gobas, 2004). Such models have been applied in a variety of regulatory and research programs within the USEPA. Furthermore, we recommend that evaluation of bioaccumulation consider multiple lines of evidence from laboratory, field, and model-based approaches, as different methods can different strengths and limitations (e.g., USEPA 2003; 2008). References: Arnot, J.A. and F.A.P.C. Gobas. 2004. A food web bioaccumulation model for organic chemicals in aquatic ecosystems. Environmental Toxicology and Chemistry 23(10):2343-2355. USEPA. 2003. Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000). Technical Support Document Volume 2: Development of National Bioaccumulation Factors. EPA-822-R-03-030. Office of Science and Technology, Office of Water, U.S. Environmental Protection Agency, Washington, DC 20460. December, 2003. USEPA. 2008. White Paper on Methods for Assessing Ecological Risks of Pesticides with Persistent, Bioaccumulative and Toxic Characteristics. Submitted to the FIFRA Scientific Advisory Panel For Review and Comment. Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide Programs, Environmental Fate and Effects Division Washington, D.C. October 7, 2008
FURS	5.7.4 Biomagnification in aquatic food chains	Guidance is needed on the interpretation of POP criteria. What kind of studies, how to evaluate, etcetera. Consistency with the guidance on interpretating POP criteria developed under REACH needs to be warranted
Board for the Authorisation of Pesticides	5.7.4 Biomagnification in aquatic food chains	It is recommended to give more guidance on biomagnification in aquatic food chains.
Austrian Agency for Health and Food Safety	6. METABOLITES	Are QSARs as a first estimate of the log Kow of metabolites acceptable?

Contributor	Section	Comment
UBA	6. METABOLITES	It should be discussed whether metabolites clearly >5% at two consecutive samplings and/or above 5% and increasing towards the end of the study have also to be considered as major metabolites in cases where there is a concern that toxicity is not covered by the active substance toxicity profile (see respective criteria in the GD on relevance of metabolites for groundwater). For some substances, metabolite fractions are formed with each single metabolite <5% but total amount of all metabolites in the sediment far above 10%, because of the large number of minor metabolites. For minor metabolites, ecotoxicological data is not necessarily available, and therefore the cumulative occurrence of structurally similar minor metabolites with ecotoxicological relevance cannot be excluded. We propose that risk from high fractions of co-occurring minor sediment metabolites should be assessed case-by-case, depending for instance on information on probable toxicity profiles, times of formation, time trends of occurrence etc.
INIA	6. METABOLITES	6. Metabolites 6.5 Calculation of Metabolites PECsw When a DT50 is not available, FOCUS SW proposes to use a Default DT50 of 1000 d instead of 300 d. Please update this value.
Pesticides Safety Directorate	6. METABOLITES	6 it should be recognised that the proposed revision of Annexes II and III of the fate data requirements indicate that the metabolite triggers applied for selection of metabolites for groundwater assessment should also apply to aquatic assessment. This is suggested for the sake of consistency. However, current practice is that ecotoxicologists rarely require exposure assessments for metabolites occurring at <10% even though the current GD indicates that metabolites <10% may need consideration. It would be useful if this process could further clarify (for practical purposes) the levels of metabolites in both soil and water that would trigger the need for an aquatic risk assessment. This would allow greater certainty for both competent authorities and applicants/notifiers.
Swedish Chemicals Agency	6.2 Definitions	The current definition of major metabolites in water “and/or” sediment is a bit confusing. It is not clear whether >10% refer to each compartment separately or to the total system. It should be clarified what the percent relate to – amount or mass. It is neither not clear how to evaluate data from a study in which the substance has been 14C- labelled. This should be clarified. Some guidance on how to deal with metabolites formed under anaerobic conditions and in studies on photochemical transformation would be useful.
Pesticides Safety Directorate	6.3 Potential routes of entry	In section 6.3, it would be helpful if it recognised that the current version of FOCUSsw has difficulties in simulating formation of metabolites.
Pesticides Safety Directorate	6.4 Data Requirements	6.4 It should be ensured that this section ties in with the latest fate guidance documents
FURS	6.4.2 Triggering of Aquatic Risk Assessments with Metabolites	The text should reflect that aquatic photodegradation metabolites can be considered not relevant in case hydrolysis or biodegradation half-lives of the active substance are much shorter.

Contributor	Section	Comment
Swedish Chemicals Agency	6.6 Requirements for Aquatic Organism Testing with Metabolites	The guidance provided in the current Aquatic Guid. Doc. is somewhat contradictory. It says (5th para) that "assessing metabolites should in essence be the same" as for parent compounds, and that testing with fish, daphnia and algae should be done, and also additional taxa in case these were the most sensitive to the a.s. But then (6th-7th para) it appears that assuming the metabolite is 10 times more toxic than the parent compound in the risk assessment, may replace use of endpoints from testing. We believe actual testing with metabolites is not always necessary but would welcome some more coherent guidance. We do not fully agree with the wording in the third para on page 44: "If it can be demonstrated that certain taxonomic groups are clearly less sensitive to the active substance (by a factor of 100) than other groups, testing (of metabolites) can be limited to those which are the most sensitive ones." For metabolites that are not structurally similar to the active ingredient, we do not think that the need for data should depend on the toxicity of the parent compound. We believe that the toxicity to 3 trophic levels should be addressed for these metabolites, not necessarily experimentally, but also eg. QSAR may be used. With regard to (Q)SAR data (6th para) it would be useful to include at least some basic guiding principles for the generation and use of such data. Again, there might be reasons to make use of guidance agreed elsewhere. There is guidance on this issue developed within OECD, and also REACH legislation, the latter in "Guidance on information requirements and chemical safety assessment. Chapter R.6: QSARs and grouping of chemicals" (ECHA, 2008).
Swedish Chemicals Agency	6.6 Requirements for Aquatic Organism Testing with Metabolites	Triggers for long term tests on metabolites should not be based on acute toxicity of the metabolite or acute/long term toxicity of parent, but only on persistence and potential for long term exposure.
Board for the Authorisation of Pesticides	6.8 Defining ecotoxicological relevance	The paragraph about "defining ecotoxicological relevance" is somewhat different in the aquatic guidance document compared with the terrestrial guidance document. This should be brought in line with each other.
Individual	7. RISK MANAGEMENT	„A standard risk assessment or even a higher-tier risk assessment (as referred to above) may indicate that the risk to aquatic life may only be acceptable providing that risk management measures are used.“ A surveillance of the risk management measures compliancy by the farming community should be mandatory, if the environmental risk of an active substance is only acceptable providing the use of such appropriate risk management measures. The lack of such surveillances may lead to an unacceptable environmental risk due to the possible neglect of risk-reducing management measures (e.g. buffer zones) during pesticide application.
Pesticides Safety Directorate	7. RISK MANAGEMENT	Section 7 should recognise recommendations made in the FOCUS Landscape and Mitigation report. The risk management section should be updated in light of the FOCUS landscape and mitigation report.

Contributor	Section	Comment
Centre for watermanagement	7. RISK MANAGEMENT	Chapter 7 The risk management chapter is focussing on mitigation measures. Actually it should be focussed on applying assessment factors in cases that only one mesocosm study is available. Also it should be discussed whether or not recovery is a criterion that can be used in the risk assessment. The Water framework directive (2000/60/EG) for example does not apply the recovery criteria in the environmental criteria. Applying recovery under 91/414/EG might lead to problems with the environmental criteria under 2000/60/EG. No clear vision is presented on combination toxicology. In the Netherlands water bodies are polluted with many pesticides in the same time window. This means that a risk assessment based on a single mesocosm with only one compound and recovery as end point, might not protect the environment due to combination toxicology. Compounds with equal mechanisms may add in toxicology, whereas compounds with different mechanism may elaborate multi stress effects. The save use of a pesticide should deal with these other factors in representative field trials (eg. for admission of a insecticide it may be important to subject the system to exposure to herbicides end fungicides in the time frame of the study in question).
Austrian Agency for Health and Food Safety	8.1 Definition of ecotoxicologically significant residues - aquatic life (Annex VI, 2.6.2)	The text should be made clearer, now it is hard to understand.
BASF SE	8.3 Endocrine Effects	Endocrine effects. This section should be updated (as already indicated in the present text) and should take into account all efforts at the OECD and EPA level to avoid duplication in vertebrate testing. Important is the emphasis on the appropriateness of normal risk assessment methodology and avoid cut-off criteria associated with ED. A listing of possible indications for ED from mammalian studies should be presented, so that the notifier and the authority may come to an agreement regarding the appropriate studies if any, based on a weight-of-evidence approach.
Austrian Agency for Health and Food Safety	8.3 Endocrine Effects	The development of a standardised risk assessment for potentially endocrine disruptors is still under development. The guidance document should provide as much guidance as currently possible in reference to the OECD "Endocrine Disrupters Testing and Assessment (EDTA) Task Force".
Swedish Chemicals Agency	8.3 Endocrine Effects	We would suggest that this section needs to be expanded significantly. It should be updated with current state-of-the-art knowledge from the OECD EDTA Task Force, also with regard to specific groups of organisms. Parameters/effects which are typical for disturbance of hormonal systems, and which are not covered by current standard toxicity tests, should preferably be listed. The implications on the uncertainty of standard risk assessment in case these particular parameters/effects have not been investigated needs to be discussed. If endocrine effects are suspected based on available data but adequate testing is not available for aquatic organisms (observations of the specific parameters for ED compounds), we propose that an extra assessment factor is needed. We suggest the whole section on Endocrine Effects should be moved and placed either early in the current section 2.1 General issues in toxicity test design - or in individual sections 2.2 Toxicity testing with fish, 2.3 Studies with aquatic invertebrates etc.

Contributor	Section	Comment
Pesticides Safety Directorate	8.3 Endocrine Effects	8.3 The endocrine effects section should be updated with the latest scientific knowledge on how to assess the risk from pesticides which are potentially endocrine disrupters.
Board for the Authorisation of Pesticides	8.3 Endocrine Effects	More guidance on endocrine effects will be available now and should be taken into account.
Pesticides Safety Directorate	9. REFERENCES	9 References to be updated in the light of new information.
Pesticides Safety Directorate	10. ANNEX	10 It would be very useful to have some new updated examples e.g. reflecting the need to think about exposure duration compared with the effects study. It could be seen if any from ELINK were suitable.
Pesticides Safety Directorate	10.1 Annex 1 - Worked examples regards sediment-dwelling organisms	10.1It would be useful to have some new examples e.g. covering actives which persist and accumulate in sediment.
Pesticides Safety Directorate	10.3 Annex 3: Testing requirements for active substances	Annex 3 of the document is very useful but it does not appear to be referred to in the text.
Alterra WUR	10.3 Annex 3: Testing requirements for active substances	Comments on Guidance Document on Aquatic Ecotoxicology Public consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR) on the existing Guidance Documents for Aquatic and Terrestrial Ecotoxicology under Council Directive 91/414/EEC. Comments Annex 3 The Guidance Document on Aquatic Ecotoxicology mentions options for testing of other aquatic macrophytes than Lemna in specific cases and in higher tiers. However, these options are not specified in the document. Guidance on when and how to perform additional macrophyte testing and guidance on higher tier studies that focus on aquatic macrophytes have not been included in the guidance document and were not available until recently. Recently, the AMRAP Organizing Committee (Lorraine Maltby (The University of Sheffield, UK, chair), Dave Arnold (CEA, UK), Fred Heimbach (RIFCON GmbH, DE, treasurer), Jo Davies (Syngenta, UK), Véronique Poulsen (AFSSA, FR). Christina Pickl (UBA, DE), Gertie Arts (Alterra WUR, NL, co-chair) organized the SETAC Europe Workshop “Aquatic Macrophyte Risk Assessment for Pesticides” on 14-16 January 2008 in Wageningen (NL) with 41 macrophyte experts from academia, authorities and business from all over Europe and the United States and Canada. The workshop aims were: • presenting an overview of the current European regulatory framework for the risk assessment of aquatic macrophytes;

Contributor	Section	Comment
		• identifying uncertainties and areas for improvement within the regulatory framework; • presenting and discussing the current state of the science of aquatic macrophyte testing in single species laboratory studies and mesocosm studies; • evaluating the extent to which currently available methods and understanding can address the uncertainties in the risk assessment of aquatic macrophytes; • making recommendations for improving aquatic macrophyte testing methodologies and risk assessment; From this workshop, four work groups evolved, which currently work on questions and guidance requirements that evolved from the workshop. The discussions and conclusions of the AMRAP Workshop will be published soon as a SETAC Guidance Document. The draft version is available now. Workshop participants received the draft version and sent their comments recently. The outcome of the workshop and work groups include: - A draft protocol for a laboratory toxicity test with Myriophyllum. The protocol will be ring-tested in 2009; - An overview of laboratory toxicity methods for testing aquatic macrophytes other than Lemna; - Criteria when an additional macrophyte has to be tested are proposed in the workshop report, but have to be validated; - Guidance on Species Sensitivity Distributions with aquatic macrophytes is being developed; - A Risk Assessment scheme for aquatic macrophytes is provided in the workshop report; The AMRAP Organizing Committee recommends to consider the outcome of the AMRAP Workshop for further updates of the Guidance Document on Aquatic Ecotoxicology and the Council Directive 91/414/EEC in order to better reflect the current status quo on aquatic macrophyte testing and aquatic macrophyte risk assessment for pesticides. The draft version of the AMRAP report is available via communities.setac.net. It is under "Technical Areas > Aquatic Toxicology and Ecology > Aquatic Macrophyte Risk Assessment Workshop". You can log in with a SETAC name and membership number.

APPENDIX B – COMMENTS ON THE EXISTING GUIDANCE DOCUMENT ON TERRESTRIAL ECOTOXICOLOGY

This compilation contains the comments received via the electronic form after the public consultation which closed at December 15th, 2008. This compilation contains all comments received regarding the existing Guidance Document on Terrestrial Ecotoxicology. Duplicated comments received from the same contributor appear only once and comments submitted by individuals on personal capacity are published anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization.

Table 8: Comments received on the existing Guidance Document on Terrestrial Ecotoxicology

Contributor	Section	Comment
FURS	0. GENERAL COMMENTS	Please take notice of guidance used in the assessment of other chemicals such as biocides. It often concerns the same active substances and consistency should be achieved whenever possible. Also the POP criteria should be covered. The Technical Guidance Document on Risk Assessment better reflects the current scientific views on terrrestrial hazard and risk assessment in a number of areas.
ICPS	0. GENERAL COMMENTS	Update Semi-field Methods for the Environmental Risk Assessment of Pesticides in Soil taking into consideration the outcome of PERAS workshop
individual	0. GENERAL COMMENTS	It seems difficult to make long-term ecological risk assessments based on short individual-based studies. Mesocosms and field studies are comparatively rare in the testing approach. Multiple applications are also rarely tested. We suggest that the exposure of populations towards mixtures or / and multiple applications (the real application schemes of crops) is mentioned in the GD since this justifies the incorporation of safety factors in the RA of single products. Due to uncertainties in long-term risk towards many groups (amphibians, reptiles, mosses,…) or animals with different strategies (r versus k- strategy species, herbivorous insects versus predatory insects, see below) we propose the formation of an independent funding body for scientific research that results in open publication and transparent data evaluation. So far data are mostly provided by industry and discussion is hampered by confidentiality agreements between industry and research institutions. Therefore only a minute fraction of the available information can be discussed openly. We think ecotoxicological RA would benefit from more transparency since this could also attract scientists from other fields (e.g. soil biology, ecology, …). Consider the paper by Newman, Crane and Holloway and the literature therein (Newman, M.C., M. Crane and G. Holloway. 2006. Does pesticide risk assessment in the European Union assess long-term effects?. Rev. Environ. Toxicol. 187: 1-65.). Monitoring schemes for groups at high risk should be discussed.

Contributor	Section	Comment
Inter-Environnement Wallonie	0. GENERAL COMMENTS	The current rules don't include any study about synergic effects: 1. Synergic properties have been described in treatments where different substances (e.g. insecticides and fungicides) are mixed, which is common practice (for instance, about the risk for bees, see Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60). This risk should be investigated as soon as suspected, for any non-target species. 2. Some insecticide have synergic effects with pathogenic fungi; Premise 200SC for instance is a PPP used against termites; this product disorientate the termites and make the soil fungi 10 000 times more dangerous, the Premise's advert explains. What about non target arthropods like ants? What about bees: fungi are present in the hives (Nosema, Beauveria)… For scientific peer-reviewed literature see e.g.: Santos, A.V., Lorenz de Oliveira, B., Samuels, R.I., 2007: Selection of entomopathogenic fungi for use in combination with sub-lethal doses of imidacloprid: perspectives for the control of the leaf-cutting ant Atta sexdens rubropilosa Forel (Hymenoptera: Formicidae), Mycopathologia 163:233–240. EFSA should investigate this issue.
PAN-Europe	0. GENERAL COMMENTS	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request, and are happy to supply more scientific articles or background information on our position here if necessary. The points are: 1. Risk is a poor approach to protect the environment. Risk assessment is a very poor approach in understanding biodiversity and the complex relations of ecosystems. Testing a few organisms gives some indication of toxicity of a chemical but no good picture at all of the effects on water ecosystem and biodiversity. Further to that testing only lets you find what you are looking at, and what is looked at is very limited. Risk assessments never showed the endocrine disrupting effects on water organisms like alligators or fish and risk assessment never preventing the massive dying of amphibians and bees we are witnessing now. So risk assessment should be done only with those chemicals having no very hazardous inherent properties because risk assessment is too "blind" for the many unexpected effects, unknown exposure routes in the environment and organisms. Additionally to risk assessment we need a hazard approach for the most hazardous chemicals and focus only on banning and substituting those ones. For the rest risk assessment might be the least worse approach on the moment but only if safety factors (never less than 10x10xNOEC) are taken into account. 2. Risk assessment of one chemical at a time is totally unscientific. Doing risk assessment of one chemical and pretending organisms and the environment are completely clean and unstressed is a fundamentally flawed way of working. In horticulture areas for instance dozens of pesticides are used and emitted in the soil at the same time as well as other chemicals and stress factors. Establishing maximum toxicity levels for chemicals for every chemicals and applying these in agriculture dominated areas is a shame. In a risk assessment other chemicals and stress factors have to be taken into account. Neglecting the many pesticides being neurotoxic and having cumulative effects won"t be defended by any professional. Doing risk assessment and "forgetting" about cumulative, synergistic effects and not taken into account other stress factors (low oxygen, fertilizers, etc.) gives a false signal of safety to society.

Contributor	Section	Comment
PAN-Europe	0. GENERAL COMMENTS	The comment of PAN-Europe on the moment touches the main points. We are available to give more detailed arguments for the comments we have on request, and are happy to supply more scientific articles or background information on our position here if necessary. The points are: 4. Risk assessment should be focussed on the sensitive organisms, vulnerable life phases and cover all doses. In many instances in the past we observed that not the most sensitive organisms are tested, even though it was well known from open literature that other organisms were more sensitive. So we propose to check the scientific literature of the last ten years and use (international) databases like RTECS, CCOHS and PAN to find the most sensitive organisms for risk assessment. We also urge you to deny any statistical methods giving average data or -worse- select 90 or 95% of them, but keep strict to NOEC of the most sensitive one. Given the poor approach risk assessment is and the many uncertainties, no compromising should be allowed here. Vulnerable life phases are also many times neglected in risk assessment. Pre- and postnatal exposure should always part of the testing procedure and a follow-up in later phases on development and behaviour a standard requirement. More and more scientific articles show that chemicals (like diazinon) have effects at very low exposure level. We ask you to demand low-dose testing of every chemical.
private	0. GENERAL COMMENTS	General comments The current rules don't include any study about synergic effects: 1. Synergic properties have been described in treatments where different substances (e.g. insecticides and fungicides) are mixed, which is common practice (for instance, about the risk for bees, see Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60). This risk should be investigated as soon as suspected, for any non-target species. 2. Some insecticide have synergic effects with pathogenic fungi; Premise 200SC for instance is a PPP used against termites; this product disorientate the termites and make the soil fungi 10 000 times more dangerous, the Premise's advert explains. What about non target arthropods like ants? What about bees: fungi are present in the hives (Nosema, Beauveria)… For scientific peer-reviewed literature see e.g.: Santos, A.V., Lorenz de Oliveira, B., Samuels, R.I., 2007: Selection of entomopathogenic fungi for use in combination with sub-lethal doses of imidacloprid: perspectives for the control of the leaf-cutting ant Atta sexdens rubropilosa Forel (Hymenoptera: Formicidae), Mycopathologia 163:233–240. EFSA should investigate this issue.
PSD	0. GENERAL COMMENTS	General comments: The guidance document contains much valuable advice which should be retained in any revised document. However, some updating is required, including: i) revisions due to proposed changes in Annex II and III data requirements and the overarching regulation (covering new areas such as impacts on biodiversity) ii) inclusion of additional advice - based on for example relevant PPR opinions and discussions at PRAPeR meetings. iii) further information on possible refinements of the risk assessment, with (where useful) worked examples placed in an Appendix. It is suggested that consideration be given to compiling the document in such a way to enable sections to be updated independently of each other - as and when significant developments in each area occur.

Contributor	Section	Comment
Royal Beekeepers Federation of Flanders	0. GENERAL COMMENTS	The current rules don't include any study about synergic effects and they exist as explaned even on the Bayer website: "Premise (imidacloprid) has a double action. Premise kills termites on contact. In areas of lesser concentration of spray, termites coming in contact with Premise stop grooming and feeding and die of fungal infection from soil." What about bees: fungi are present in the hives (Nosema, Beauveria)… For scientific peer-reviewed literature see e.g.: Santos, A.V., Lorenz de Oliveira, B., Samuels, R.I., 2007: Selection of entomopathogenic fungi for use in combination with sub-lethal doses of imidacloprid: perspectives for the control of the leaf-cutting ant Atta sexdens rubropilosa Forel (Hymenoptera: Formicidae), Mycopathologia 163:233–240. EFSA should investigate this issue.
Swedish Chemicals Agency	0. GENERAL COMMENTS	1. Alter title of this Guidance document to what it embraces, i.e. Guidance Document on Terrestrial Ecotoxicology including pollinators, arthropods, soil organisms and non-target plants. Note this suggestion of a new title is valid only if this GD will be altered according to our proposed changes below, where we suggest that terrestrial vertebrates are excluded in this GD since it will be covered by the GD on Birds & Mammals, and that bees will be replaced by pollinators. 2. We welcome inclusion of guidance on non-agricultural use (e.g. home gardens, public gardens, non-commercial use). 3. Preferably, the guidance document should not repeat information and guidance from the test guidelines. A reference to the relevant TG would be sufficient. This would allow for future revisions of the TG without the need to update the guidance document. 4. Over the last years we have found the current Guidance Document helpful in many ways (interpretation of data requirements, how to proceed from tier one risk assessments etc.). It is important that any revised guidance document provides clear guidance. In this context it is of importance to note that a substantial part of the current Guidance Document reflects policy and guidance on various decisions by risk managers. It is desirable that guidance on these matters is not excluded from the revised guidance document. It is recognised that such matters are out of the scope of the EFSA"s activity. A task for the Commission and for the Member States can therefore already at this stage be identified; to take the outcome of the EFSA"s revision on board for development of a new guidance document. It may be helpful for the further work and the division of work (scientific vs policy and risk management related) if EFSA during their revision clearly identifies those issues (included in the current guidance document) that are put aside and not addressed or developed further during the revision because they are not purely scientific in nature. 5. For the various groups of organisms discussed in the current guidance document, we lack clear guidance on how to assess the risk from formulations containing more than one active ingredient. 6. Throughout the document, reference is being made to current Annex II and III to the Directive 91/414/EEC. The content and any future recommendations need to be checked with revised version (rev. 8) of the data requirements. 7. Throughout the document text which make reference to other documents needs to be updated (e.g. to OECD guidelines/guidance documents, EPPO schemes etc.). 8. Any revision of the guidance document should make use of experience gained in the discussions in PRAPeR meetings as well as in PPR Opinions, to discuss and where appropriate include as general guidance in the document. 9. The PPR panel (Opinion on revision of annex II and III) acknowledges that the current guidelines on field testing is unsatisfactory since many of the existing field tests are designed in such a way that less than 50 % effect will not be detected. Overruling the first tier assessment with uncertain field experiment is not justified. This needs to be considered during the revision of the guidance document.

Contributor	Section	Comment
		10. When developing refinement procedures it should be recognised that the use of plant protection products will result in multiple exposure of pesticides which may cause synergistic and cumulative adverse effects. Hence we should not develop too sophisticated refinement methods which mainly serves to reduce the risk (i.e. modelling population/community level effects, including recovery), without taking multiple exposure into account. We therefore trust that it is not feasible to include multiple exposure in a regulatory risk assessment under 91/414 EEG. This should be considered when developing refinement methods; and the assessment should perhaps remain fairly "crude" in order to balance this lack of realism.
UBA	0. GENERAL COMMENTS	COMMENT ON THE PROCEDURE/WEB INTERFACE: Entering a larger number of comments in consecutive order of chapters is tedious, because the highlighting under "Chapter/Section" always jumps back to "0. GENERAL COMMENTS" after sending of each comment. Could this be improved for future commenting exercises?
UBA	0. GENERAL COMMENTS	Currently, the risk assessment strategies proposed for the terrestrial and aquatic environment are deemed to lack congruency in several aspects. Apart from the unavoidable differences caused by media properties, there are also issues like the use of assessment/safety factors, the realisation of the tiered approach, the selection of risk descriptors, the consideration of population recovery etc., which are considered differently in the two main areas of environmental risk assessment. It is thus unclear whether the same level of protection is afforded by the standard risk assessment for the terrestrial and aquatic environment. Consequently, some doubts remain whether the general protection goal as defined by Directive 91/414/EEC can actually be achieved for all taxa in all compartments of the environment. We would like to suggest that the current revision of the GDs for Aquatic and Terrestrial Ecotoxicology is used to achieve better congruency between those sections in terms of risk assessment.
UBA	0. GENERAL COMMENTS	The current GD aims to provide guidance for assessing the risk to all groups of organisms somehow related to the terrestrial environment, although already the possible exposure routes of these organisms are much more diverse than in the aquatic environment. In our opinion, simple continuation of this current approach would be problematic, since increased levels of complexity and extended demands regarding the presentation of data, arguments and conclusions might lead to a document of unmanageable size. Hence, a new system for structuring information might be worth considering, proceeding stepwise from highly generic to highly specific issues. The first step or tier could include an introduction to the overall assessment approach, discussion of factors which would be relevant to estimate protection levels, cross-references to E-fate issues etc. The second tier would then address still more generic issues, but relevant primarily for certain groups of organisms; such grouping could either be done according to relevant exposure routes (which would result in one top-chapter for arthropods and plants and one top-chapter for all organisms dwelling in the field soils) or according to trophic levels (which would result in separate top-chapters for invertebrates above and below the soil surface, for plants and for micro-organisms). Finally, the specific issues with regard to testing and assessing the risk for certain taxa/communities would be dealt with in a third tier. We think that such approach could provide the necessary balance between congruency over all areas of assessment on the one hand and flexibility in considering the diverse available information on specific taxa/communities .
UBA	0. GENERAL COMMENTS	For several issues addressed in the comments, DE has meanwhile developed interim approaches or position papers for performing the risk assessment. If the EFSA work group is interested in considering these during the GD revision process, we will be glad to provide all required information on request and we will also be available for discussions.

Contributor	Section	Comment
UBA	0. GENERAL COMMENTS	Over the last months, it has turned out that seed treatments pose a much higher risk to non-target life than expected (e.g., due to abrasion of active substances before or during sowing). There is a need to address this type of risks in the new GD.
US EPA/OPP/EFED	0. GENERAL COMMENTS	I am sending these comments on behalf of the terrestrial biology technology team (TBTT) of EPA/OPP/EFED who reviewed the draft working document titled "Document on Terrestrial Ecotoxicology" Under Council Directive 91/414/EEC (hereafter referred to as the working draft). It is the understanding of the TBTT that this document provides an overview of the data requirements and risk assessment methods used by member states of the European Union to conduct ecological risk assessments. The TBTT is not commenting on the risk assessment methodology or the data requirements per se, but on differences in methods and data outlined in the working document and those used by EPA/OPP/EFED to conduct ecological risk assessments that could be problematic if data requirements and risk assessment methods were to be harmonized. Also, neither data requirements nor risk assessment methods are fully described or even summarized in this document. Therefore, it is difficult to comment on potential issues. However, apparent differences, when noted, are included in the following sections.
US EPA/OPP/EFED	0. GENERAL COMMENTS	Section 2.4 of the document indicates that toxicity tests are typically conducted using the TGAI (as opposed to formulations) with noted exceptions including arthropod and earthworm tests. This is apparently consistent with data requirements under FIFRA; however, terrestrial plant tests submitted to EPA/OPP/EFED are also typically conducted using a representative formulated product. The document also indicates that a suite of standard studies on birds, bees, arthropods, earthworms, and soil microorganisms may also be required on a representative formulation. These data are not typically required under FIFRA, but could be useful to risk assessment.
INIA	1 Introduction	2.1. Introduction It would be welcome to define the protection aims.
COPA-COGECA WP on Honey	2 General issues	To our knowledge, the current assessment rules do not take into account existing studies about synergic effects of active substances contained in a mix of plant protection products. However, this is a quite common agricultural practice (e.g. spreading mixture of insecticides and fungicides). The toxicological risk of such mixtures should be assessed for any non-target organisms likely to get in contact with treatment mixtures of different plant protection products, at least as soon as the use of a plant protection product in mixture is authorised. The assessment should be standardised as much as possible. As example, the following study can be referred to: Vandame, R., Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neurosci. Lett. 251 (1998) 57-60. On top of that, certain insecticides have been proved to have synergic effects with pathogenic fungi and increase thus the efficiency of action. See for example the following study: Santos, A.V., Lorenz de Oliveira, B., Samuels, R.I., 2007: Selection of entomopathogenic fungi for use in combination with sub-lethal doses of imidacloprid: perspectives for the control of the leaf-cutting ant Atta sexdens rubropilosa Forel (Hymenoptera: Formicidae). Mycopathologia 163:233–240. Honey bees are in permanent contact with certain fungi. Any risk assessment of an active substance should therefore include also the evaluation of a possible synergic effect of major fungi present in bee colonies (e.g. Ascosphaera, Beauveria) and the active substance.

Contributor	Section	Comment
Swedish Chemicals Agency	2 General issues	2 General issues 1. We generally agree with the outline of this chapter and suggest that the topics covered in the current guidance document should be included in a revised guidance document, though in amended and updated form. See also comments on individual sub-chapters below. 2. Companies are obliged to do a literature search and submit information which may be of relevance to the risk assessment. However, we regularly find important information, available in the "open literature" that is not submitted. Today, studies are often discarded since it is not a GLP study or does not follow a guideline. Nonetheless, the information may be of importance and this decision should not be subjected to the notifier. We therefore propose that the notifier should make a very short summary of the study and thereby the authority can decide whether it may be of importance. Guidance on how to make this summary is needed in the guidance document; this is a general point which should be considered during revisions of guidance document in all sections.
EPBA & DBIB	2.1 Introduction to the assessment of chemicals in the terrestrial environment	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible. In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive.

Contributor	Section	Comment
		• All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide "incorporated" inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
FURS	2.1 Introduction to the assessment of chemicals in the terrestrial environment	"There is a common understanding that the ecological risk assessment aims not at individuals but at the protection of populations." For birds and mammals this remains an open question!
individual	2.1 Introduction to the assessment of chemicals in the terrestrial environment	The protection goal is unclear and needs a stronger definition. Should all species (populations) be protected? Is a loss of 5% of the species in an area acceptable? If we want to protect local populations does that mean that we want to protect the local gene pool? How should this be assessed? How is e.g. the local population of an earthworm species defined? If the wider concept of biodiversity (interaction / functions, ecosystem level, species level and genetic level)should be included as a protection goal ideas for measurement and implementation in RA should be provided. Another point in the protection goal discussion is the value of in-crop populations. Are we generally interested in the protection of off-crop or also in-crop populations? For contrast: Do we want the farmer to manage his land similar to a nature conservation area (minimal impact) or do we allow maximum impact in-crop. (e.g. no weeds and no arthropods due to total control with PPPs). The terrestrial off-crop habitat also needs a clear definition. Are buffer strips in the agricultural landscape considered off-crop habitat (these buffer strips are usually not very wide). A frequently encountered question is: where is the off-crop habitat in agricultural landscapes?
Swedish Chemicals Agency	2.1 Introduction to the assessment of chemicals in the terrestrial environment	2.1 Introduction to the assessment of chemicals in the terrestrial environment 1. P5–6, 2nd to last paragraph. There is a need for a broad description of what effects are considered as adverse (or, one may say of the protection goal). We therefore suggest to either keep the citation from CSTEE 2000 and the following text or to develop another but in essence similar framework for the terrestrial ecotoxicological assessments.

Contributor	Section	Comment
EPBA & DBIB	2.2 Animal experimentation	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
EPBA & DBIB	2.3 NOEC-values as summary parameters	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And

Contributor	Section	Comment
		this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
INIA	2.3 NOEC-values as summary parameters	2.3. NOEC-values as summary parameters Please update this section including the references of OECD guidance document on statistical analysis of ecotoxicity tests (2003).
PSD	2.3 NOEC-values as summary parameters	Use of NOEC test is referred to as “still acceptable” when in reality the NOEC is currently the preferred regulatory endpoint for chronic studies – should this be given more emphasis? It is suggested that consideration is given to mention of the ‘benchmark’ dose method, with (if accepted) details included as to the confidence intervals required and what the benchmark response should be.

Contributor	Section	Comment
Swedish Chemicals Agency	2.3 NOEC-values as summary parameters	2.3 NOEC-values as summary parameters 1. This paragraph needs to be revised in the light of OECD Guidance Document on Statistical Analysis of Ecotoxicity Data (OECD Series on Testing and Assessment No 54). Where appropriate we would welcome more clear guidance on statistics, without repeating what is already included in test guidelines. 2. We would prefer if ECx (the value of x needs to be agreed on) could be used as a starting point for the risk assessment instead of the NOEC. NOEC depends on the choice of test concentrations and number of replications and rewards poor experiments, i.e., high variability, with high NOEC values. The PPR panel suggests in the opinion on the data requirements to open up the text in the annex II and II for this possibility by using the wording "reference point" instead of NOEC. Thus guidance on how to calculate ECx or similar reference points is needed in this guidance document. 3. We would also appreciate a discussion of the possibility to include the information in the confidence intervals around an ECx into the risk assessment. This would further encourage the development of better data since more narrow confidence intervals would result in a higher "reference point".
UBA	2.3 NOEC-values as summary parameters	We propose to highlight much more explicitly the drawbacks of the NOEC approach in (eco)toxicity testing, both from a general scientific/statistical perspective as well as regards the restricted use and lower informative value of NOEC design studies in the risk assessment. Please provide more guidance on how to evaluate the statistical power of a given test (design), at least by appropriate references such as: OECD, (2006) Current approaches in the statistical analysis of ecotoxicity data: a guidance to application. OECD series on testing and assessment Number 54. OECD Paris ENV/JM/MONO(2006)18
COPA-COGECA WP on Honey	2.4 Test substance, formulation testing	The lead for standard toxicity tests on the lead formulation: Given that some formulations might have synergic effects when being blend to other formulations, we consider that studies with the formulations should be made systematically.

Contributor	Section	Comment
EPBA & DBIB	2.4 Test substance, formulation testing	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.**Error! Hyperlink reference not valid.**
INIA	2.4 Test substance, formulation testing	2.4. The need for standard toxicity tests on the lead formulation Some formulation products contain more than one active substance. Guidance on how to conduct the risk assessment should be welcome

Contributor	Section	Comment
Inter-Environnement Wallonie	2.4 Test substance, formulation testing	p. 6, line n°17) ""If the risk indicators are well above the TER trigger or below the HQ trigger then studies with the formulation could be dispensable"": some formulation substances can have synergic effects with the active substance; formulation products should always be tested.
Swedish Chemicals Agency	2.4 Test substance, formulation testing	2.4 Test substance, formulation testing 1. Considering tank mixing of several products, we would appreciate discussions of these gaps in our risk assessments. Today only one product at a time is risk assessed, not the entire tank content in a worst-case situation.
UBA	2.4 Test substance, formulation testing	We propose to either strictly provide guidance for formulations containing one active substance only (what is considered to be the reasonable option for lead formulations in the EU review programme) or to provide more and explicit guidance on how to deal with formulations containing more than one active substance - throughout all areas and organisms to be considered, respectively. For example, guidance is needed, if and under which circumstances bridging from studies with formulations with one active substance to formulations with more than one active substance (and vice versa) is scientifically justifiable. More guidance on formulation testing would be appreciated in view of the common tasks in national authorisation procedures, where a relevant number of formulations contain more than one active substance (in DE 24% of all registered products). This concept for the risk assessment of formulations should be consistent within the assessment schemes for the different groups of organisms.
AGES	2.5 Endocrine effects	This chapter should be updated if new knowledge / OECD reports or other is available.
EPBA & DBIB	2.5 Endocrine effects	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL.

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		2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide "incorporated" inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
INIA	2.5 Endocrine effects	2.5. Endocrine effects For birds and mammals refer to new guidance document to assess the risk on birds and mammals, or EFSA opinion already published (The EFSA Journal (2008) 734: 1-181).
PSD	2.5 Endocrine effects	Endocrine effects: This section should be updated, with clearer guidance given about how to deal with potential endocrine disrupters.
Swedish Chemicals Agency	2.5 Endocrine effects	2.5 Endocrine effects 1. P6. The section on endocrine disruptors needs to be updated according to the current state of the art. If endocrine effects are suspected based on available data but adequate testing is not available for terrestrial organisms (observations of the specific parameters for ED compounds), we propose that an extra assessment factor is added. 2. This section needs to be updated with current state-of-the-art knowledge from the OECD EDTA Task Force, also with regard to specific groups of organisms (birds/insects etc.). Parameters/effects which are typical for disturbance of hormonal systems, and which are not covered by current standard toxicity tests, should preferably be listed. The implications on the uncertainty of standard risk assessment in case these particular parameters/effects have not been investigated and needs to be discussed. 3. Guidance on birds & mammals are available in a separate GD; hence, guidance of endocrine effects is needed for organisms covered in this GD only.
UBA	2.5 Endocrine effects	Endocrine specific data requirements are not explicitly laid down in Directive 91/414/EEG. At present, internationally agreed endocrine specific testing and assessment strategies are lacking for all relevant groups of non-target organisms. Such strategies need to be developed in order (i) to systematically identify potential endocrine disrupters, (ii) to mechanistically characterize endocrine mediated effects and (iii) to reliably derive thresholds of no-concern and regulatory acceptable concentrations, respectively for endocrine mediated adverse effects of ecological relevance. The development and international validation of endocrine specific testing procedures for the derivation of qualitative and mechanistic information (screening assays) as well as testing protocols for a quantitative assessment of endocrine mediated effects on apical endpoints (e.g. growth, reproduction, sexual development) are just underway (cf. OECD EDTA activities). We therefore strongly propose to include the latest developments on the OECD level and provide at least some general guidance how to address this issue case-by-case and based on a weight-of-evidence approach. Moreover it should be mentioned that endocrine specific study protocols not finally validated by

Contributor	Section	Comment
COPA-COGECA WP on Honey	2.6 Higher tier tests	Please refer to our comments on point 4.3
Ctgb	2.6 Higher tier tests	2.6 Higher tier tests: First bullet: avian repellency tests are generally not recommended anymore (interpretation problems), thus this is not a very good example.
EPBA & DBIB	2.6 Higher tier tests	General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.

Contributor	Section	Comment
Inter-Environnement Wallonie	2.6 Higher tier tests	2.6. Higher tier tests, last § (p. 7, line n° 18: """with regards to methods some tests…""": when the substance is available for pollinators through the foraged matrices, the reliability of field tests is not sufficiently established. Please refer to our comments about point 4.1, higher tier tests.
PSD	2.6 Higher tier tests	Higher tier Tests (Page 7, first point -lines 4-7): Mention is made of the use of the results of an 'avian acceptance test' to refine the 'food consumption rate' - whereas such information would usually be submitted to support the use of an 'avoidance factor' in a refined exposure assessment (FIR not being affected). Also, given that use of acceptance / palatability tests in refining the exposure assessment is frequently not appropriate (due to such studies not reflecting 'field' conditions), it is suggested that a better example is included.
Swedish Chemicals Agency	2.6 Higher tier tests	2.6 Higher tier tests 1. Last paragraph. The text on what should be considered when planning higher tier studies is appreciated - but brief. We would welcome more elaborated guidance. 2. Guidance on how to judge the quality of a study is needed (e.g. number of replicates, power of test, variation of data, verification of exposure, sampling frequency), possibly this can also be developed as a checklist. 3. It should always be recommended to calculate the power, in particular of field studies. Guidance on methods for calculating power should be given in the guidance document. A discussion on which levels of power that is acceptable and how to treat studies with low power is also needed. 4. Furthermore, we need to agree on the multivariate statistics that should be used for evaluating higher tier studies (i.e. PRC) and clear guidance on these methods is needed. 5. When developing refinement procedures it should be recognised that the use of plant protection products will result in multiple exposure of pesticides which may cause synergistic and cumulative adverse effects. Hence we should not develop too sophisticated refinement methods which mainly serves to reduce the risk (i.e. modelling population/community level effects, including recovery), without taking multiple exposure into account. We therefore trust that it is not feasible to include multiple exposure in a regulatory risk assessment under 91/414. This should be considered when developing refinement methods; and the assessment should perhaps remain fairly "crude" in order to balance this lack of realism.
Ctgb	2.7 Persistence	2.7 Persistence: The current 'spreading' of the guidance for the persistence risk assessment over two separate guidance documents is a bit untransparent. An option could be a new, integral guidance document on the Risk Assessment on Persistence in Soil in which both fate and ecotox guidance is included and combined. Another option is a clear and separate chapter in the Guidance Document on Terrestrial Ecotoxicology with the ecotox part of the persistency risk assessment.
FURS	2.7 Persistence	Reference to POP criteria is needed
individual	2.7 Persistence	Are the models by Romijn et al. 1994 validated?
INIA	2.7 Persistence	2.7. Persistence Please refer to the output of the current Guidance Document persistence in Soil (9188/VI/97 rev. 8) revision. This guidance document is under revision. Please update this section with the state of the art.

Contributor	Section	Comment
PSD	2.7 Persistence	Persistence (this paragraph of section, p7): It is stated that not all the terrestrial organism food chain models used have been validated. Is this still the case and is it possible to mention which models have been validated?
Swedish Chemicals Agency	2.7 Persistence	2.7 Persistence 1. Guidance on birds & mammals are available in a separate GD; hence, guidance of persistence and bioaccumulation are needed for organisms covered in this GD only. 2. We suggest that this section should be expanded to explain why risk assessments for substances that are bioaccumulated and persistent are specifically problematic. By contrast, we suggest reference to specific models for food-chain modelling should be deleted unless the models are validated, and in the latter case the conditions for such validation needs to be carefully mentioned and discussed. The current version of the Aquatic Guidance Doc. (SANCO/3268/2001) adds that "For extremely bioaccumulating and persistent substances it should be considered whether modelling and microcosm/mesocosm testing is appropriate at all because even the best test methods currently available may not be sufficient to fully investigate problems which are linked to these properties of a substance." This view corresponds to guidance recently developed under the REACH legislation. To the extent possible, we believe that guidance for risk assessment of chemicals should not be developed in fundamentally diverging ways under different legislation within the EU. We therefore find it important that the text quoted above from the current version of the Aquatic guidance document be retained also in revised version. 3. Discussions on trigger values for these issues are highly appreciated.
UBA	2.7 Persistence	We strongly recommend striving for consistency to the GD "Persistence in Soil" already under development (or already drafted?); i.e. questions of an appropriate exposure assessment have to be announced from both a chemical`s and (relevant non-target) organism`s perspective. If during this exercise any relevant inconsistencies are identified, it may become necessary to even update the "Persistence in Soil" GD. (Note: The redrafting of these GDs should not have been planned independently.)
UBA	2.7 Persistence	page 7, last sentence: Please check the state of the science regarding the proposed bioaccumulation and biomagnification models. Are these validated meanwhile?
UBA	2.7 Persistence	page 8, 1st para: What about metal compounds? These clearly do not fit into the common risk assessment scheme proposed in the GD (for organic chemicals). Please provide detailed guidance to the extent possible or at least an explanatory note on how to cope with such compounds.
Ctgb	2.8 Metabolites	2.9 Metabolites - Relevant compartments: Soil metabolites are also relevant for birds and mammals, via secondary poisoning (earthworms). - Requirements for assessment and testing: The 10% trigger is mentioned, however, in today risk assessment practice the triggers for groundwater metabolites are more or less used for all aspects (i.e. >10%, 2x5 at consecutive time points and maximum not reached). - Defining ecotoxicological relevance: metabolites are considered ‘ecotoxicologically relevant’ when they pose a similar or higher risk than its parent compound and therefore risk mitigation measures are needed. The remark on risk mitigation measures is confusing and needs further clarification: what if the metabolite is more toxic than the parent, but no risk mitigation is needed? In practice the metabolite will still be considered ecotoxicologically relevant.

Contributor	Section	Comment
Dansih EPA	2.8 Metabolites	2.9 Metabolites The distiction between minor and major metabolites should be reconsidered. If a substance is applied at a rate of 100 kg/ha 5 % formation of a metabolite may be quite problematic. Also the focus on whether the metabolite contains the "active moiety" should be reconsidered. Effects on non-target (being realy non-target) may not be related to the active moiety
FURS	2.8 Metabolites	"By definition the PEC for a minor metabolite is lower than the PEC for the parent compound by more than a factor of 10; accordingly minor metabolites even if 10 times as toxic as their parent compound can be considered as safe, provided that the parent compound is safe and also provided that no new concern with regard to persistence is brought in" The argumentation relies on the assumption that sampling was done during the actual peak of occurence of a metabolite. Given the limit number of sampling times in experimental studies, this will not be the case in many occasions.
individual	2.8 Metabolites	It is unclear how to transfer the µg/bee data to an application rate. No citation for the calibration is given (Candolfi et al 2001 is not treating the honey bee calibration).
PSD	2.8 Metabolites	Metabolites (Section 2.9 in current doc, pp10-14): Given that certain potential plant protection product active substances have shown a degree of food chain biomagnification, the statement (Page 11, first paragraph under 'Vertebrates) that 'It is not considered likely that modern plant protection products magnify in vertebrate food chains' is not considered accurate and would be best deleted in the revised document (with mentioned retained that this possible route of exposure 'should not be ignored'). Also, it should be recognised that the proposed revision of Annexes II and III of the fate data requirements indicate that the metabolite triggers applied for selection of metabolites for groundwater assessment should also apply to terrestrial assessment of soil dwelling organisms. Further clarification as to the levels of metabolites in both soil and water that would trigger the need for an aquatic risk assessment would be useful.
Swedish Chemicals Agency	2.8 Metabolites	2.9 Metabolites 1. P10-11. More guidance on how to deal with photolytic metabolites or metabolites formed under anaerobic conditions would be useful. 2. P13. Definition of ecotoxicologically significant residues. The proposed definition implies that only metabolites that pose a higher or comparable risk as the active substance. From our point of view, the definition should include all metabolites that pose a risk following the intended use of the parent compound.
AGES	2.9 Risk assessment	ad PRA: This section should be updated according to the EUFRAM report if the use of PRA is intended.
COPA-COGECA WP on Honey	2.9 Risk assessment	Validation, rationale for critical TER and HQ: to our knowledge, the critical hazard quotient of 50 for bees has been established according to a validation procedure that does not take into account systemic active substances used in seed coating. Therefore, the validation procedure should be amended accordingly.

Contributor	Section	Comment
FURS	2.9 Risk assessment	Interpretation of TER and HQ values In the context of the revsion of the guidance document on birds and mammals, it was proposed not to apply the same triggers in refined risk assessment. There are good arguments not to stick to the triggers set for first tier RA, but in regulatory practise a clear concept is needed how to decide in refined RA.
PSD	2.9 Risk assessment	Probabilistic risk assessment (p10): We suggest the following additional 'shortcoming' is added to those already stated: 'The acceptability criteria in relation to the outputs from a PRA are currently not well defined'. Where a PRA approach is suggested in the revised document, we recommend that advice (or reference to advice) is included as to how the outputs from such an approach should be used in the regulatory risk assessment. Is there more up-to-date and extensive information which could be referenced?
Swedish Chemicals Agency	2.9 Risk assessment	2.8 Risk assessment 1. P9–10, Interpretation of TER and HQ values. We lack a discussion and more elaborated guidance here on the main aspects of uncertainty in the risk assessment, and on ecological significance of effects.
Ctgb	3 Terrestrial vertebrates	3 Terrestrial vertebrates: No comment, we assume that this will be updated with the new guidance document.
individual	3 Terrestrial vertebrates	p.13 Refer to: Scientific Opinion of the Panel on Plant protection products and their residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. The EFSA Journal (2008) 734, 1-181). So far the risk for bats is not assessed. Bats are insectivorous species and therefore potentially exposed to insecticide residues. The smaller bats, such as the common pipistrelle, have a body weight of 3-8 g and are therefore blow that of the common shrew (10 g) that is proposed as an insecitivorous mammal. All 37 bat species are protected in Europe with a special European Agreement in place (Agreement on the Conservation of Populations of European Bats , EUROBATS, 1991). Under ARTICLE III (Fundamental Obligations) paragraph 8. reads: 'Each Party shall, wherever appropriate, consider the potential effects of pesticides on bats, when assessing pesticides for use, ….' The obligations of this agreement should be implemented in the GD. In terrestrial vertebrates we miss the adult stages of amphibians that spend a considerable proportion (in most European species the majority) of their life time in the terrestrial habitat. A permeable skin and migration to water bodies for spawning in spring when agricultural activity is high may lead to a high exposure of this group discussed in the amphibian decline literature (e.g. Blaustein et al. 2003 Ultraviolet radiation, toxic chemicals and amphibian population declines - Diversity & Distributions). This area is so far understudied. Another understudied group not mentioned in the GD are the reptiles, a group that also includes many protected species (45% of the European species are in danger of extinction). Their often high trophic position might lead to an increased risk (Hopkins 2000 Reptile toxicology: challenges and opportunities on the last frontier in vertebrate ecotoxicology - Environmental Toxicology and Chemistry). Both groups are treated in detail in Sparling, Bishop, & Linder - Ecotoxicology of Amphibians and Reptiles, 2000. It may be worth pointing out that both groups are not covered in the assessment schemes proposed for birds and mammals, due to lack of data and knowledge on the parameters affecting their specific risk.

Contributor	Section	Comment
INIA	3 Terrestrial vertebrates	3. Terrestrial vertebrates For birds and mammals refer to new guidance document to assess the risk on birds and mammals, or EFSA opinion already published (The EFSA Journal (2008) 734: 1-181).
Swedish Chemicals Agency	3 Terrestrial vertebrates	3 Terrestrial vertebrates 1. P14-16. This section should be deleted and referred to the revised guidance document for birds and mammals.
UBA	3 Terrestrial vertebrates	In principle, all relevant aspects for assessing the risks for birds and mammals are now considered in the EFSA proposal for a revised GD for birds and mammals (Scientific Opinion of the Panel on Plant protection products and their residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. The EFSA Journal (2008) 734, 1-181). Before this background, we suggest dropping this section from a revised Guidance Document. It may, nevertheless, be worth pointing out that reptiles or amphibians are not explicitly covered in the assessment schemes proposed for birds and mammals, irrespective of their high potential to get exposed due to their migration behaviour, their habitat preferences and, in the case of amphibians, a permeable skin. Even though we admit that this gap is due to lack of data and knowledge on the parameters affecting the specific risk, a total disregard of amphibians and reptiles in the risk assessment scheme is not deemed compliant to the general protection aims defined in Directive 91/414 EEC.
AGES	3.1 Data requirements and testing	The data requirement should be adapted according to what is being decided in the Annex II and III amendments of Directive 91/414/EEC (or the new Regulation) (this concerns e.g. dietary toxicity)
US EPA/OPP/EFED	3.1 Data requirements and testing	Birds • Some aspects of avian toxicity studies are briefly discussed in the guidance document. For example, the discussion of the avian LC50 study only includes a summary of a single issue regarding differences in measured verses nominal pesticide concentrations in the diet. No other discussion is included. Therefore, there is insufficient information to allow for a determination of whether or not there are discrepancies in data requirements and risk assessment methods outlined in the guidance document compared to those used by EPA/OPP/EFED. • The guidance document indicates that avian reproduction data are not required for chemicals with half-lives <14 days and are applied only in the fall. These data are required under FIFRA for all outdoor uses, and there is not a numeric criteria used to indicate when this study is not required. • No information on exposure assessments for terrestrial organisms is included in the guidance document. Therefore, exposure methods were not reviewed.
FURS	3.2 Exposure assessment	There is a need to further consider exposure via sediment. This is not satisfactory covered in the current GD for birds and mammals and the proposed revision. Substances with a potential to bioaccumulate are likely to partition to sediment. The highest risk then exists for the route: benthic invertebrates -> benthic fish -> fish eating bird/mammal. It also needs to be taken into account that such substances can accumulate in sediment over a number of years.

Contributor	Section	Comment
FURS	3.3 Risk assessment	The concept of estimating toxicity of a combination of two or more active sustance assuming additive effects should be mentioned
AGES	4 Bees	The whole section should be updated in the light of recent developments (new EPPO scheme, risk assessment for systemic seed dressings, (sub)chronic toxicity and risk assessment, larval toxicity and risk assessment, potential exposure to dust from seed dressings). The ICPBR guidance should be followed as mentioned in the Annex II and III amendments of Directive 91/414/EEC.
beekeeper	4 Bees	4 Bees EFSA Guidance document on Terrestrial Ecotoxicology, in chapter 4, does not yet contain any clear and imposed rules to measure the chronic toxicity of pesticides on the bees. However, it is proved that the bees are suffering e smog of pesticides (it is the case with the pesticides used for covered seeds). Also, nothing over the subletal effects as lose of orientation So, if the text is not profoundly reworked, we will stay to face the present difficulties: a lot of tests on field where the exposition of the bees stays uncertain. In the same time, no any test to evaluate the chronic DL50. It is however basic to investigate the chronic effects on the bees as soon it is possible. Otherwise, the benefit of the pesticides will be largely compensated with the great loses of health in the nature and in the human population …
COPA-COGECA WP on Honey	4 Bees	Chronic toxicity tests When the active substance is detected in nectar and pollen, its persistence in the plant should be assessed. We believe that if the substance is considered systemic and persistent, chronic toxicity should be assessed because, in realistic conditions, the bees will ingest the substance day after day during the crop flowering. Relation between acute and chronic toxicity cannot be considered as simple and constant; for instance, when a substance is persistent in the bee organism, accumulation leads to higher chronic effects. A TER should be calculated based on acute and chronic LD50. Chronic toxicity tests should be carrying out over a sufficiently long period of time (e.g. 10 days).
Ctgb	4 Bees	4 Bees: This section should be updated with the results from the ICP-BR workshop of October 2008 in Bukarest.
EPBA & DBIB	4 Bees	part 4 Higher tier risk assessment for bees Key parameters which may be considered in a field trial include: mortality (assessed via the use of dead bee traps) Dead Bee Traps just register those bees that “just made the hive, after the contact with the PPP or died inside the hive. Negative experiences with modern PPP suggest that larger parts of the “contaminated bees” never reach the hive after contact on the crop. Another aspect of the dead bee traps use, is the not always done: evaluation of the effectiveness of the existing constructions. If the results of dead bee traps are reported, the estimated effectiveness of the used construction should also be reported. For insect growth regulators and other active substances which may cause long-term adverse effects on hive health, evidence is required confirming a lack of effects on hive health over a long time period. The development of a group of honeybee colonies over longer time always shows a high variability, making it nearly impossible to conclude on some adverse effects in longer time experiences. Final Remarks

Contributor	Section	Comment
		For chronic sublethal effects, which influence bee behaviour (orientation, learning) tests are “under development”, but estimates for long term effects on honeybee-colony survival of those influences are still missing. Since the blooming season 1986 the need for adequate testing procedures insect growth regulators contaminating the honeybee colony was felt. But now-a-days OECD Environment, Health and Safety Publications Series on Testing and Assessment No. 75 Guidance Document on the Honeybee (Apis Mellifera L.) Brood Test under Semi-field Conditions (2007) is published together with the new lab-test (Aupinel). This might appear symptomatically for the actual situation for honeybee and other pollinator risk assessment procedures under the heading - “terrestrial eco toxicology and unacceptable influence on the environment”. We suggest to extend the Annex VI B 2.6.2 and C 2.6.2 . According to that Annex: analytical methods must be available for postregistration control and monitoring purposes among which there are methods for residue analysis of the active substance, metabolites, breakdown or reaction products. The methods must be able to determine and confirm residues of toxicological, ecotoxicological or environmental significance, must be developed before registration. After the introduction and registration of insect growth regulators and systemic insecticides, large efforts are undertaken to develop the necessary and adequate tests. In order to give the community the opportunity to judge the eco toxicological risks before the registration of a substance, why not add the “adequate methods for post registration control of pollinator eco toxicological effects “ to the rules. As soon as a new group of insecticidal substances with a new mode of action is developed this would give the community the needed tools from the beginning of the introduction and not years later.
EPBA & DBIB	4 Bees	part 3; remark, may be part1 came in as part 2 also, sorry 4 Bees For general background information sees the upcoming EPPO scheme (EPPO 2002b) There are new EPPO recommendations on their way and might become available during 2009. (See: ICPBR-Meeting Bucharest 2008) 4.1 Data requirements and testing Bee brood feeding test (Annex II 8.3.1.2) A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A new lab test being more accurate than semi-field or field test is published:Aupinel, Pierrick; Fortini, Dominique; Michaud, Bruno; Marolleau, Franck; Tasei, Jean-Noël; Odoux, Jean-François, 2007.Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094.It can be seen from the available reports: • Semi field tests sometimes lead to the absence of bee brood even in the control hives. • In field tests, a lack of bee brood can occur due to meteorological conditions. • Obviously the lack of bee brood in control and treated hives doesn’t allow drawing conclusions about a low risk because of the mask effect. Residue test (Annex III 10.4.2)

Contributor	Section	Comment
		Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop. As it is known, that pollen in the beehive (beebread) can rest their untouched for up to 10 months, it seems appropriate to have data on aged residues in that matrix as well. This holds also for the systemic plant protection products. Testing of systemic plant protection products For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed. Systemic plant protection products used as seed treatments are available to all plant-tissue. This means that the active substances are being “encapsulated” inside the pollen grains. Those PPP only come available to an individual bee in case the grain is digested. This can lead to chronic intoxication of those honeybees inside a colony. As this high pollen consumption is done to enable that bee to feed the younger larvae; the loss of that cohort of bees has influence on the survival value of the colony. Up till now validated detailed tests on those aspects of chronic and toxic effects on colony life fails.

Contributor	Section	Comment
EPBA & DBIB	4 Bees	part 2 General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee hermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible. In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
FUAL	4 Bees	Mixed treatments (e.g. insecticides and fungicides) are common practice. Risks of synergic effects must be investigated.

Contributor	Section	Comment
individual	4 Bees	Bees harvest honey and pollen from a large variety of plants. When there are many different plants producing food at the same time, bees will preferentially harvest on the most attractive plant(s). Presenting a field of treated crop to bee hives for testing purposes, does not imply that the bees will forage in this particular field. Furthermore, bees when able to harvest quantities of food which exceed their need will store the excess for consumption during a less favourable period when food is less readily available. The lag time between harvesting and consumption can last months (harvest in spring consumption the following winter) As a consequence of the combination of these two behaviours, presenting a field of treated plants to bee hives for testing purposes does not imply: - that the bees will forage in this particular field as there might be other more attractive food sources. - that the harvested food will be consumed and its effect(s) on the bee be measurable immediately. I therefore suggest that the guidance document on terrestrial ecotoxicology be modified by adding the following rules: - To be considered valid any field/tunnel/tent tests should prove that the bees have significantly harvested nectar or pollen from the treated plant and have consumed this nectar or pollen. In the absence of such proof, the test should be considered inconclusive. - Due to the lag time between harvesting and consumption, for field/tent/tunnel tests, conclusions should only be drawn after observing the test hives for a cycle of a full year starting when the hives are first exposed to the substance. - Field/tent/tunnel tests should not be used to evaluate the effect of the product on the brood. The results concerning the impact on the brood should be derived from tests demonstrating that the brood has been fed with pollen and honey which contains the substance. In case the substance is systemic and persistent (present in the pollen or the nectar) chronic toxicity is a possible exposure route and this route must be assessed independently of other routes. In real conditions, when the nectar or the pollen contains the substance even at lower levels than LD50, bees will ingest low doses repeatedly. Doses will accumulate in the bee organism and can lead to chronic effects which cannot be considered as identical to acute toxicity without conclusions derived from chronic toxicity tests. In case the product is a neurotoxic and its action mode disrupts the behaviours of the pests, behavioural tests need to be carried out on bees in order to assess if the product impact bee behaviours or not. To be conclusive such test need to be carried on a period of time that is representative of studied bee behaviours or the hive life cycle. Amongst other areas tests should cover the following: bee orientation ability during harvesting of pollen, nectar or water, queen egg production from January to October, brood development from January to October.
INIA	4 Bees	4. Bees Testing of systemic plant protection products Please update with the upcoming EPPO scheme for systemic plant protection products and the proposal of ICPBR meeting (systemic effect working group) for plant protection products that are proposed for soil or seed treatments. The persistence of the product in soil may result in an exposure of bees, in the case of the growth of an attractive plant in the rotation. Please clarify when additional residues involving crop rotation are needed.

Contributor	Section	Comment
individual	4 Bees	There is no comment about association of different products What about the effect of products on the bees who are not going out collecting nectar or pollen but on the ones who are working inside the hive concentrating the nectar...they might have a different metabolism than the older one. I think it could be interesting to have field studies because the bees tend to go on the same species until the "harvest"is complete so they are at even higher risk of concentrating toxic products. What about the secundary effects of chronic exposure to toxic products? The toxicity should not only be evaluated on term of mortality but also on term of morbidity :like the desorientation...
PSD	4 Bees	General comments on bee section (p16-18): Requirements for testing of systemic compounds have been clarified since the last draft of the GD and a risk assessment scheme is under development. The most up-to-date guidance available should be used in the revised document. ICPBR will be able to advise as at the moment this is still draft. More detailed guidance in relation to the evaluation of systemic pesticides (including seed treatments) and insect growth regulator pesticides would be useful.
SNA	4 Bees	Although it is acknowledged those systemic seed treatments are stressing bees due chronic effects, there is still no clear guidelines to assess the chronic toxicity on honeybees in this document. Those guidelines which need to become mandatory. No change from the old hazard quotient which is mainly oral or contact when we should assess persistence and chronic effects. Nothing is mentioned for assessing sublethal effects on honeybees" behaviour either. Using field and semi-field tests the bees exposure is doubtful, there is a lack of guidelines to assess the chronic lethal 50 dose. I hope this will help. Thanks for your comments by anticipation.
Swedish Chemicals Agency	4 Bees	4 Bees 1. P17-19. It should be clarified whether pollinators or exclusively honeybees are meant to be covered by the risk assessment. We would be in favour of changing the heading to "Effects on pollinators" and open the possibility to require a test also on a second species, e.g., bumblebees, in addition to the honeybees. 2. The section should be updated with more detailed guidance for estimating the exposure of bees from systemically acting compounds which may end up in pollen and nectar, and also a method for estimating the exposure via dust from treated seeds or granular products. Since the HQ approach is only validated for sprayed products, alternative risk assessment methods should be proposed for other compounds. 3. Guidance on repeated applications is needed.
University of Liège, Belgium	4 Bees	It has now been commonly accepted among honeybee experts and scientists that, along with acute intoxication, pesticides are highly toxic towards bees because of their long term effects: chronic toxicity must be deeply investigated, over months, as toxic pollen is stored in the hives and its toxic effect is more than probably acting on the bee colony during months (for instance: storaging during summer and use at the end of the winter).

Contributor	Section	Comment
Bee Computing sprl	4.1 Data requirements and testing	1. You assume "Where there is only one relevant route of exposure (e.g. oral exposure in the case of soil application),..." This is completely wrong and you know perfectly well that more than 11500 hives were killed in Bade-Würtemberg in spring 2008 just because of soil dust containing Chlothianidin. Seed coating can be absorbed by bees just by contact as well as by polluted nectar, pollen or water. 2. You refer to "EPPO guideline 170" for higher tier tests. That guideline does not apply to seed coating treatments. So why do you refer in many places to a guideline that doesn"t give any information about the test to perform ? 3. "Standard lab tests are normally not required for metabolites". This is not acceptable for most seed systemic insecticides, as their metabolites are known to be extremely toxic to bees. Moreover, these product remain in the environment for a very long period of time. 4. No chronic test appears in your document. Many scientific papers have clearly demonstrated the risk due to long term exposure. It is not acceptable to skip these tests and a chronic toxicity lab test must absolutely be integrated.
COPA-COGECA WP on Honey	4.1 Data requirements and testing	Bee brood feeding test The toxicity of an active substance for bee larvae cannot be inferred from the toxicity for adult bees. Certain active substances are more toxic for larvae than for adults and the other way round (e.g. “Alix, A., and Vergnet, Chr., 2007: Risk assessment to honey bees: a scheme developed in France for non-sprayed systemic compounds, Pest Manag Sci.63”, point 4.2). A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. The following evaluation method can be used: Aupinel, P., Fortini, D., Michaud, B., Marolleau, F., Tasei, J_N. and Odoux, J-F. : Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094). This laboratory test is more accurate than semi-field or field trials. Semi- field trails may lead to the absence of bee brood even in the control hives. In field tests, a lack of bee brood can occur due to meteorological conditions. Such a lack of bee brood in control and treated hives can misinterpret the trial conclusions. Higher tier tests These tests are based entirely on recommendations of EPPO which has some gaps. For instance cage tests as currently performed have no relevance when the product is applied in seed coating. Tunnel tests are unable to detect delayed effects (through consumption by bees of pollen and honey stock). Field tests are not sufficiently accurate for assessing effects on the bee behaviour. For active substances used in seed coating, no toxic standard is available and the bee exposure cannot be proved. Thus tunnel and field tests cannot be considered as highest tier tests when the bees are possibly exposed to residues of the active substance through the foraged matrices; PEC/PNEC ratios based on sub-lethal toxicity trials would be more relevant.
COPA-COGECA WP on Honey	4.1 Data requirements and testing	Long-term effects (see Annex II of 91/414/EEC, point 8, part Introduction) should be evaluated. We consider this should be done when there is a likelihood of chronic exposure of bees to the active substance. Guidelines (including those of EPPO) should distinguish two ways of risk assessment: -When the bee exposure is mainly acute and topical the current assessment scheme would be applied (HQ, higher tier tests = cage, tunnel, field trials) -When the bee exposure is mainly chronic and oral (substance detected in nectar and pollen at concentrations that are considered significant regarding the toxicity) a new assessment scheme of chronic toxicity should be developed and implemented. Residues measurement in nectar and pollen should be required when the active substance is deemed or suspected to be systemic and present during longer periods (based on Pow , Poa if relevant, and persistence). In this new assessment scheme, cage, tunnel or field trials

Contributor	Section	Comment
		would not be considered as highest tier tests; instead, PEC/PNEC trials should be performed as higher tier tests.
EPBA & DBIB	4.1 Data requirements and testing	part 3; remark, may be part1 came in as part 2 also, sorry 4 Bees For general background information sees the upcoming EPPO scheme (EPPO 2002b) There are new EPPO recommendations on their way and might become available during 2009. (See: ICPBR-Meeting Bucharest 2008) 4.1 Data requirements and testing Bee brood feeding test (Annex II 8.3.1.2) A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A new lab test being more accurate than semi-field or field test is published: Aupinel, Pierrick; Fortini, Dominique; Michaud, Bruno; Marolleau, Franck; Tasei, Jean-Noël; Odoux, Jean-François, 2007.Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094. It can be seen from the available reports: • Semi field tests sometimes lead to the absence of bee brood even in the control hives. • In field tests, a lack of bee brood can occur due to meteorological conditions. • Obviously the lack of bee brood in control and treated hives doesn't allow drawing conclusions about a low risk because of the mask effect. Residue test (Annex III 10.4.2) Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop. As it is known, that pollen in the beehive (beebread) can rest their untouched for up to 10 months, it seems appropriate to have data on aged residues in that matrix as well. This holds also for the systemic plant protection products. Testing of systemic plant protection products For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed. Systemic plant protection products used as seed treatments are available to all plant-tissue. This means that the active substances are being "encapsulated" inside the pollen grains. Those PPP only come available to an individual bee in case the grain is digested. This can lead to chronic intoxication of those honeybees inside a colony. As this high pollen consumption is done to enable that bee to feed the younger larvae; the loss of that cohort of bees has influence on the survival value of the colony. Up till now validated detailed tests on those aspects of chronic and toxic effects on colony life fails.

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EPBA & DBIB	4.1 Data requirements and testing	part 2 General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. (Werner.von.der.Ohe@LAVES.Niedersachsen.de) Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible. In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
FURS	4.1 Data requirements and testing	In view of incidents during seed drilling, the text needs to be revised.

Contributor	Section	Comment
individual	4.1 Data requirements and testing	Bees harvest honey and pollen from a large variety of plants. When there are many different plants producing food at the same time, bees will preferentially harvest on the most attractive plant(s). Presenting a field of treated crop to bee hives for testing purposes, does not imply that the bees will forage in this particular field. Furthermore, bees when able to harvest quantities of food which exceed their need will store the excess for consumption during a less favourable period when food is less readily available. The lag time between harvesting and consumption can last months (harvest in spring consumption the following winter) As a consequence of the combination of these two behaviours, presenting a field of treated plants to bee hives for testing purposes does not imply: - that the bees will forage in this particular field as there might be other more attractive food sources. - that the harvested food will be consumed and its effect(s) on the bee be measurable immediately. I therefore suggest that the guidance document on terrestrial ecotoxicology be modified by adding the following rules: - To be considered valid any field/tunnel/tent tests should prove that the bees have significantly harvested nectar or pollen from the treated plant and have consumed this nectar or pollen. In the absence of such proof, the test should be considered inconclusive. - Due to the lag time between harvesting and consumption, for field/tent/tunnel tests, conclusions should only be drawn after observing the test hives for a cycle of a full year starting when the hives are first exposed to the substance. - Field/tent/tunnel tests should not be used to evaluate the effect of the product on the brood. The results concerning the impact on the brood should be derived from tests demonstrating that the brood has been fed with pollen and honey which contains the substance. In case the substance is systemic and persistent (present in the pollen or the nectar) chronic toxicity is a possible exposure route and this route must be assessed independently of other routes. In real conditions, when the nectar or the pollen contains the substance even at lower levels than LD50, bees will ingest low doses repeatedly. Doses will accumulate in the bee organism and can lead to chronic effects which cannot be considered as identical to acute toxicity without conclusions derived from chronic toxicity tests. In case the product is a neurotoxic and its action mode disrupts the behaviours of the pests, behavioural tests need to be carried out on bees in order to assess if the product impact bee behaviours or not. To be conclusive such test need to be carried on a period of time that is representative of studied bee behaviours or the hive life cycle. Amongst other areas tests should cover the following: bee orientation ability during harvesting of pollen, nectar or water, queen egg production from January to October, brood development from January to October.
individual	4.1 Data requirements and testing	Development of bee larval test should be mentioned. Other bee species are not addressed. Many of the wild bee species are protected Europe. Some are important, specific pollinators. Since they are smaller than honey bees and often solitary with different behaviour they might be more susceptible to pesticide exposure (see for example: Helson, Barber & Kingsbury 2004 Laboratory toxicology of six forestry insecticides to four species of bee (Hymenoptera: Apoidea). Archives of Environmental Contamination and Toxicology; Devillers et al. 2003 Comparative toxicity and hazards of pesticides to Apis and non-Apis bees. A chemometrical study. SAR and QSAR in Environmental Research).
Inter-	4.1 Data	General comment

Contributor	Section	Comment
Environnement Wallonie	requirements and testing	The 91/414/EEC Directive (Annex II, point 8, Introduction) lays down : (ii) ""In particular, the information provided for the active substance, together with other relevant information (…) should be sufficient to (…) – permit an evaluation of short and long-term risks for non target species (population communities, and processes – as appropriate"". Thus the long-term effects on bees should be investigated as soon as a chronic exposure is suspected. Guidelines should distinguish two assessment ways: - When the bees exposure is mainly acute and topical the current assessment scheme is applied (HQ, higher tier tests = cage, tunnel, field tests) - When the bees exposure is mainly chronic and oral (substance detected in nectar and pollen at concentrations that are considered significant regarding the toxicity) a new assessment scheme should be performed. Residues measurement in nectar and pollen should be needed as soon as the substances are suspected to be systemic and available during long periods (based on Pow , Poa if relevant, and persistence). In this new assessment scheme, cage, tunnel or field tests are not considered as highest tier tests; PEC/PNEC trials should be performed as higher tier tests. Chronic toxicity tests When the substance is detected in nectar and pollen, persistence in the plant should be assessed. As soon as the substance is considered systemic and persistent, chronic toxicity should be assessed because, in realistic conditions, the bees will ingest the substance day after day during the crop flowering. Relation between acute and chronic toxicity cannot be considered as simple and constant; for instance, when a substance is persistent in the bee organism, accumulation leads to higher chronic effects. Thus chronic toxicity assessment must be performed since the chronic bees exposure is suspected to implement the 91/414/EEC Directive (article 4) and above mentioned point 8 of Annex II; a TER should be calculated based on acute and chronic LD50. Chronic toxicity tests should be performed on 10 days; Bee brood feeding test The substance toxicity for larvae cannot be inferred from the toxicity for adult bees. Some substances are more toxic for larvae than for adults and some others are more toxic for adults than for bee brood (see Alix, A., and Vergnet, Chr., 2007: Risk assessment to honey bees: a scheme developed in France for non-sprayed systemic compounds, Pest Manag Sci.63, point 4.2). A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A method is validated by the French “Commission des toxiques” and is now published (Aupinel, P., Fortini, D., Michaud, B., Marolleau, F., Tasei, J_N. and Odoux, J-F. : Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094). This lab test is more accurate than semi-field or field tests. Semi field tests sometimes lead to the absence of bee brood even in the control hives. In field tests, a lack of bee brood can occur due to meteorological conditions. Obviously the lack of bee brood in control and treated hives doesn’t allow drawing conclusions about a low risk because of the mask effect. Higher tier tests Cage tests are designed for sprayed products; as currently performed they have no relevance when the product is applied in seed dressing. Tunnel tests are unable to detect delayed effects (through pollen or honey stocks consumption). Field tests are not sufficiently accurate for assessing effects on the bee behaviour. For such substances, no toxic standard is available and the bee exposure cannot be proved. Thus tunnel and field tests cannot be considered as highest tier tests when the bees are exposed through the foraged matrices; PEC/PNEC ratios based on sublethal toxicity trials are more relevant.

Contributor	Section	Comment
private	4.1 Data requirements and testing	The 91/414/EEC Directive (Annex II, point 8, Introduction) lays down : (ii) In particular, the information provided for the active substance, together with other relevant information (…) should be sufficient to (…) – permit an evaluation of short and long-term risks for non target species (population communities, and processes – as appropriate Thus the long-term effects should be investigated as soon as chronic exposure is suspected. Guidelines should distinguish two assessment ways: - When the bees exposure is mainly acute and topical the current assessment scheme is applied (HQ, higher tier tests = cage, tunnel, field tests) - When the bees exposure is mainly chronic and oral (substance detected in nectar and pollen at concentrations that are considered significant regarding the toxicity) a new assessment scheme should be performed. Residues measurement in nectar and pollen should be needed as soon as the substances are suspected to be systemic and available during long periods (based on Pow , Poa if relevant, and persistence). In this new assessment scheme, cage, tunnel or field tests are not considered as highest tier tests; PEC/PNEC trials should be performed as higher tier tests. Chronic toxicity tests When the substance is detected in nectar and pollen, persistence in the plant should be assessed. As soon as the substance is considered systemic and persistent, chronic toxicity should be assessed because, in realistic conditions, the bees will ingest the substance day after day during the crop flowering. Relation between acute and chronic toxicity cannot be considered as simple and constant; for instance, when a substance is persistent in the bee organism, accumulation leads to higher chronic effects. Thus chronic toxicity assessment must be performed since the chronic bees exposure is suspected to implement the 91/414/EEC Directive (article 4) and above mentioned point 8 of Annex II; a TER should be calculated based on acute and chronic LD50. Chronic toxicity tests should be performed on 10 days; Bee brood feeding test The substance toxicity for larvae cannot be inferred from the toxicity for adult bees. Some substances are more toxic for larvae than for adults and some others are more toxic for adults than for bee brood (see Alix, A., and Vergnet, Chr., 2007: Risk assessment to honey bees: a scheme developed in France for non-sprayed systemic compounds, Pest Manag Sci.63, point 4.2). A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A method is validated by the French “Commission des toxiques” and is now published (Aupinel, P., Fortini, D., Michaud, B., Marolleau, F., Tasei, J_N. and Odoux, J-F. : Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094). This lab test is more accurate than semi-field or field tests. Semi field tests sometimes lead to the absence of bee brood even in the control hives. In field tests, a lack of bee brood can occur due to meteorological conditions. Obviously the lack of bee brood in control and treated hives doesn’t allow drawing conclusions about a low risk because of the mask effect. Higher tier tests Cage tests are designed for sprayed products; as currently performed they have no relevance when the product is applied in seed dressing. Tunnel tests are unable to detect delayed effects (through pollen or honey stocks consumption). Field tests are not sufficiently accurate for assessing effects on the bee behaviour. For such substances, no toxic standard is available and the bee exposure cannot be proved. Thus tunnel and field tests cannot be considered as highest tier tests when the bees are exposed through the

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		foraged matrices; PEC/PNEC ratios based on sublethal toxicity trials are more relevant.
Royal Federation of Flamish Beekeepers	4.1 Data requirements and testing	91/414/EEC Directive stipulates that the information provided for the active substance should be sufficient to permit an evaluation of short and long-term risks for non target species (population communities, and processes – as appropriate. This means that the long-term effects has to be investigated each time a chronic exposure is expected. Guidelines has tot taken in account: 1. When the bees exposure is mainly acute and topical the current assessment scheme is applied (HQ, higher tier tests = cage, tunnel, field tests). 2. When the bees exposure is mainly chronic and oral (substance detected in nectar and pollen at concentrations that are considered significant regarding the toxicity) a new assessment scheme should be performed. Residues measurement in nectar and pollen should be needed as soon as the substances are suspected to be systemic and available during long periods (based on Pow , Poa if relevant, and persistence). In this new assessment scheme, cage, tunnel or field tests are not considered as highest tier tests; PEC/PNEC trials should be performed as higher tier tests. Bee brood feeding test The substance toxicity for larvae cannot be deduced from the toxicity for adult bees. Therefore a bee brood feeding test is necesary in the cases that the bee brood exposure is suspected. Problem with semi field tests. This kind of test sometimes masks the reality and leads to untrue conclusions as they can lead to the absence of beebrood, even in the control hives. In field tests, a lack of bee brood can easily occur due to meteorological conditions. Chronic toxicity tests Persistence in the plant should be assessed if the systemic and persistent substance is detected in nectar and pollen as well as the chronic toxicity because, in real, the bees will ingest the substance day after day during the crop flowering. One has to consider that the relation between acute and chronic toxicity is very complex and constant. Thus chronic toxicity assessment is to be measured since the chronic bees exposure is suspected to implement article 4 of the 91/414/EEC Directive.
US EPA/OPP/EFED	4.1 Data requirements and testing	Bees • The guidance document indicated that acute oral studies and acute contact studies in bees are routinely required. EPA/OPP/EFED requires only an acute contact toxicity study; additional tests are conditionally required based on the results from the acute contact study. The acute oral study is no longer a data requirement. • Critical HQs (comparable to EPA's LOCs) are 50 for honey bees and 2 for arthropods. This value is considerably greater than EPA's LOCs of 0.05. These values are 1000-fold and 40-fold, respectively, higher than EPA's LOC used for endangered terrestrial invertebrates. Differences in LOCs for other taxonomic groups are noted, but are less dramatic.
Bee Computing sprl	4.2 Exposure assessment	You claim: "For systemic plant protection products, exposure considerations and calculations should be based on the a.s. (or metabolite) present in the respective plant parts (e.g. nectar, pollen) to which honeybees could be exposed. However, it should be noted that estimates of these concentrations are rarely available." This is not correct, the toxicity document given by the manufacturer often give the a.s. concentration found in the treated plant (sap at least). This is a major problem, as even on treated plant the concentration is so low that it cannot be measured. So why do you define a computation that is nearly impossible in most cases? In that chapter you recognize that unknown or unmeasurable concentrations can be found in bee food! Such products should be brought to market only if analytical methods are sensitive enough to detect the a.s. in both sap, nectar

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		and pollen on all treated plants.
EPBA & DBIB	4.2 Exposure assessment	part 3; remark, may be part1 came in as part 2 also, sorry 4 Bees For general background information sees the upcoming EPPO scheme (EPPO 2002b) There are new EPPO recommendations on their way and might become available during 2009. (See: ICPBR-Meeting Bucharest 2008) 4.1 Data requirements and testing Bee brood feeding test (Annex II 8.3.1.2) A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A new lab test being more accurate than semi-field or field test is published: Aupinel, Pierrick; Fortini, Dominique; Michaud, Bruno; Marolleau, Franck; Tasei, Jean-Noël; Odoux, Jean-François, 2007.Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094. It can be seen from the available reports: • Semi field tests sometimes lead to the absence of bee brood even in the control hives. • In field tests, a lack of bee brood can occur due to meteorological conditions. • Obviously the lack of bee brood in control and treated hives doesn't allow drawing conclusions about a low risk because of the mask effect. Residue test (Annex III 10.4.2) Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop. As it is known, that pollen in the beehive (beebread) can rest their untouched for up to 10 months, it seems appropriate to have data on aged residues in that matrix as well. This holds also for the systemic plant protection products. Testing of systemic plant protection products For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed. Systemic plant protection products used as seed treatments are available to all plant-tissue. This means that the active substances are being "encapsulated" inside the pollen grains. Those PPP only come available to an individual bee in case the grain is digested. This can lead to chronic intoxication of those honeybees inside a colony. As this high pollen consumption is done to enable that bee to feed the younger larvae; the loss of that cohort of bees has influence on the survival value of the colony. Up till now validated detailed tests on those aspects of chronic and toxic effects on colony life fails.

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EPBA & DBIB	4.2 Exposure assessment	part 2 General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible. In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.

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individual	4.2 Exposure assessment	Bees harvest honey and pollen from a large variety of plants. When there are many different plants producing food at the same time, bees will preferentially harvest on the most attractive plant(s). Presenting a field of treated crop to bee hives for testing purposes, does not imply that the bees will forage in this particular field. Furthermore, bees when able to harvest quantities of food which exceed their need will store the excess for consumption during a less favourable period when food is less readily available. The lag time between harvesting and consumption can last months (harvest in spring consumption the following winter) As a consequence of the combination of these two behaviours, presenting a field of treated plants to bee hives for testing purposes does not imply: - that the bees will forage in this particular field as there might be other more attractive food sources. - that the harvested food will be consumed and its effect(s) on the bee be measurable immediately. I therefore suggest that the guidance document on terrestrial ecotoxicology be modified by adding the following rules: - To be considered valid any field/tunnel/tent tests should prove that the bees have significantly harvested nectar or pollen from the treated plant and have consumed this nectar or pollen. In the absence of such proof, the test should be considered inconclusive. - Due to the lag time between harvesting and consumption, for field/tent/tunnel tests, conclusions should only be drawn after observing the test hives for a cycle of a full year starting when the hives are first exposed to the substance. - Field/tent/tunnel tests should not be used to evaluate the effect of the product on the brood. The results concerning the impact on the brood should be derived from tests demonstrating that the brood has been fed with pollen and honey which contains the substance. In case the substance is systemic and persistent (present in the pollen or the nectar) chronic toxicity is a possible exposure route and this route must be assessed independently of other routes. In real conditions, when the nectar or the pollen contains the substance even at lower levels than LD50, bees will ingest low doses repeatedly. Doses will accumulate in the bee organism and can lead to chronic effects which cannot be considered as identical to acute toxicity without conclusions derived from chronic toxicity tests. In case the product is a neurotoxic and its action mode disrupts the behaviours of the pests, behavioural tests need to be carried out on bees in order to assess if the product impact bee behaviours or not. To be conclusive such test need to be carried on a period of time that is representative of studied bee behaviours or the hive life cycle. Amongst other areas tests should cover the following: bee orientation ability during harvesting of pollen, nectar or water, queen egg production from January to October, brood development from January to October.
PSD	4.2 Exposure assessment	Bee exposure assessment (p 17): Information about crops known to be not attractive to bees and also those known to be very attractive to bees could usefully be added here.
Bee Computing sprl	4.3 Risk assessment	You claim: "The critical HQ of 50 was validated against incidents (EPPO 2002b); it is only applicable to spray products." If you consider that the HQ cannot be applied to non-sprayed products, you must give another similar test replacing it ! There is not a single scientific document that can be found justifying the elimination of the HQ concept for seed coatings. Moreover, many studies have been using the PEC / PNEC approach which give very accurate results in that case. Why do you

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		still refuse to integrate this approach ?
COPA-COGECA WP on Honey	4.3 Risk assessment	Concerning semi-field and field trials the following items should be reflected in the guidelines. The EPPO guidelines should be also amended accordingly if appropriate: 1.In all semi-field and field trials, key parameters should be always compared to control levels (negative non-pesticide or positive pretreatment) based on a validated toxic standard. In case no positive control is technically possible, the number of trial hives in negative control should be increased in order to overcome natural variations between the bee colonies. 2.Field tests should be performed in realistic conditions (e.g. the use of irrigation should not be allowed if this is not a common agricultural practice). In case of trials evaluating sub-lethal effects, the trial conditions should be described (e.g. range of temperature, luminosity, material used for tunnels). 3.Semi-field and field trials should include a statistical validation and reliability evaluation. When a trial aims at observing a given parameter (e.g. foraging activity), the natural variability in that given parameter should be evaluated and taken into account, particularly if no positive control is used. In case a high natural variability is observed the test should be considered not conclusive. 4.Each trial description should contain information about the parameters it is able to assess and the ones it cannot assess. 5.Referring to our general comment under point 2, any presence of relevant bee pathogens (not only fungi but also spores of bacteria such as Paenibacillus sp.) should be taken into account. Systematic pathogen monitoring will provide additional data to evaluate possible synergic effects between the active substance and those relevant be pathogens.
EPBA & DBIB	4.3 Risk assessment	part 3; remark, may be part1 came in as part 2 also, sorry 4 Bees For general background information sees the upcoming EPPO scheme (EPPO 2002b) There are new EPPO recommendations on their way and might become available during 2009. (See: ICPBR-Meeting Bucharest 2008) 4.1 Data requirements and testing Bee brood feeding test (Annex II 8.3.1.2) A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A new lab test being more accurate than semi-field or field test is published: Aupinel, Pierrick; Fortini, Dominique; Michaud, Bruno; Marolleau, Franck; Tasei, Jean-Noël; Odoux, Jean-François, 2007.Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094. It can be seen from the available reports: • Semi field tests sometimes lead to the absence of bee brood even in the control hives. • In field tests, a lack of bee brood can occur due to meteorological conditions. • Obviously the lack of bee brood in control and treated hives doesn't allow drawing conclusions about a low risk because of the mask effect. Residue test (Annex III 10.4.2) Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop.

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		As it is known, that pollen in the beehive (beebread) can rest their untouched for up to 10 months, it seems appropriate to have data on aged residues in that matrix as well. This holds also for the systemic plant protection products. Testing of systemic plant protection products For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed. Systemic plant protection products used as seed treatments are available to all plant-tissue. This means that the active substances are being “encapsulated” inside the pollen grains. Those PPP only come available to an individual bee in case the grain is digested. This can lead to chronic intoxication of those honeybees inside a colony. As this high pollen consumption is done to enable that bee to feed the younger larvae; the loss of that cohort of bees has influence on the survival value of the colony. Up till now validated detailed tests on those aspects of chronic and toxic effects on colony life fails.

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FURS	4.3 Risk assessment	The HQ>50 might be applied to require further testing/risk mitigation with other possible routes of exposure such as dust during seed drilling, sysutemic pesticides.
FURS	4.3 Risk assessment	Concerns about the effects of pesticides on bees are widespread in Slovenia (and many other countries). A procedure to assess the off-crop risk to bees is needed to support risk characterization and risk management. The procedure to assess off-crop risk to other non-target arthropods is not adequate for certain substances that are highly toxic to pollinators.

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Inter-Environnement Wallonie	4.3 Risk assessment	4.3. Risk assessment, higher tier tests. Higher tier tests for bees (p. 18, last §), general comment About field and tunnel tests the guidelines should include the following rules: 1. Any tunnel or field tests should include a negative control and a positive control based on a validated toxic standard. If no positive control is technically possible, tested and negative control hives should be more numerous in order to overcome natural variations between the colonies. 2. An observation pattern is used for sublethal effects observation. The test conditions (temperature, luminosity, spectral absorbance of the tunnel material.…) should be described. 3. Tunnel and field test should include a statistic validation. 4. The test reliability should be evaluated. a. When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When a high natural variability is observed the test should be considered not conclusive. b. The test conclusions should include a short comment about the parameters the tests is able to assess and the ones it cannot assess (for example delayed effects for pollen consumption when relevant for the tested substance or product). 5. The pathogen presence, even at non-pathological level (spores are found in disordered and healthy colonies), should be taken into account. Pathogen follow-up is extremely important to detect synergic effects between the active substance and common diseases (Nosema sp., foulbrood, etc.). 6. Field tests should be performed in realistic conditions (for instance: if the concerned crop is not usually irrigated, irrigation should not be allowed).
private	4.3 Risk assessment	About field and tunnel tests the guidelines should include the following rules: 1. Any tunnel or field tests should include a negative control and a positive control based on a validated toxic standard. If no positive control is technically possible, tested and negative control hives should be more numerous in order to overcome natural variations between the colonies. 2. An observation pattern is used for sublethal effects observation. The test conditions (temperature, luminosity, spectral absorbance of the tunnel material.…) should be described. 3. Tunnel and field test should include a statistic validation. 4. The test reliability should be evaluated. a. When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When a high natural variability is observed the test should be considered not conclusive. b. The test conclusions should include a short comment about the parameters the tests is able to assess and the ones it cannot assess (for example delayed effects for pollen consumption when relevant for the tested substance or product). 5. The pathogen presence, even at non-pathological level (spores are found in disordered and healthy colonies), should be taken into account. Pathogen follow-up is extremely important to detect synergic effects between the active substance and common diseases (Nosema sp., foulbrood, etc.). 6. Field tests should be performed in realistic conditions (for instance: if the concerned crop is not usually irrigated, irrigation

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		should not be allowed).
Royal Federation of Flamish Beekeepers	4.3 Risk assessment	Note in advance: Field tests should always be performed in realistic conditions! About field and tunnel tests the guidelines should include the following rules: 1. Any tunnel or field tests should include a negative control and a positive control based on a validated toxic standard. If no positive control is technically possible, tested and negative control hives should be more numerous in order to overcome natural variations between the colonies. 2. An observation pattern is used for sublethal effects observation. The test conditions (temperature, luminosity, spectral absorbance of the tunnel material.…) should be described. 3. At present, tunnel and field test don"t have a statistic validation and there is not foreseen in an evaluation of the test reliability. 4. A test which would observe a given parameter (foraging activity for instance), has to include an estimation of the natural variability in certain circumstances, to avoid mask effects. In the case of high natural variability, the test can not be conclusive. 5.The test conclusions have to explain the parameters the test is able to aprise or not (for example delayed effects of pollen consumption by larvae). 6.Presence of pathogens, even if a colony seems healthy, must be taken in account (spores are found in both ill and healthy colonies). Pathogen follow-up is absolutely necessary to detect synergic effects between the active substance and diseases (nosema sp., stonebrood, foulbrood, etc.).
EPBA & DBIB	4.4 Risk mitigation options	part 3; remark, may be part1 came in as part 2 also, sorry 4 Bees For general background information sees the upcoming EPPO scheme (EPPO 2002b) There are new EPPO recommendations on their way and might become available during 2009. (See: ICPBR-Meeting Bucharest 2008) 4.1 Data requirements and testing Bee brood feeding test (Annex II 8.3.1.2) A bee brood feeding test should be performed as soon as the bee brood exposure is suspected. A new lab test being more accurate than semi-field or field test is published: Aupinel, Pierrick; Fortini, Dominique; Michaud, Bruno; Marolleau, Franck; Tasei, Jean-Noël; Odoux, Jean-François, 2007.Toxicity of dimethoate and fenoxycarb to honey bee brood (Apis Mellifera) using a new in vitro standarized feeding method, Pest Manag Sci 63: 1090 – 1094. It can be seen from the available reports: • Semi field tests sometimes lead to the absence of bee brood even in the control hives. • In field tests, a lack of bee brood can occur due to meteorological conditions. • Obviously the lack of bee brood in control and treated hives doesn’t allow drawing conclusions about a low risk because of the mask effect. Residue test (Annex III 10.4.2) Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop.

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		As it is known, that pollen in the beehive (beebread) can rest their untouched for up to 10 months, it seems appropriate to have data on aged residues in that matrix as well. This holds also for the systemic plant protection products. Testing of systemic plant protection products For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed. Systemic plant protection products used as seed treatments are available to all plant-tissue. This means that the active substances are being “encapsulated” inside the pollen grains. Those PPP only come available to an individual bee in case the grain is digested. This can lead to chronic intoxication of those honeybees inside a colony. As this high pollen consumption is done to enable that bee to feed the younger larvae; the loss of that cohort of bees has influence on the survival value of the colony. Up till now validated detailed tests on those aspects of chronic and toxic effects on colony life fails.

Contributor	Section	Comment
EPBA & DBIB	4.4 Risk mitigation options	part 2 General comments The current rules aim at a single substance evaluation. It is very well known that the use of PPP in practice means mixing of eg. Fungicides and insecticides. Synergistic properties are well known: Edward D. Pilling, Paul C. Jepson, 1993 Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pesticide Science 39(4),293 - 297. ; Vandame, R., et Belzunces, L.P., 1998: Joint actions of deltamethrin and azole fungicides on honey bee thermoregulation, Neuroscience Letters 251 (issue1): 57-60 This means, that at the national level implementation (GAP) those aspects must be part of the formulation risk-assessments. And this risk should be investigated as soon as suspected, for any non-target species. 2.1 Introduction to the assessment of chemicals in the terrestrial environment. There should be introduced a reference to the actual accepted general needs for the conservation of pollinators (including honeybees) under the scope of the actual bio diversity programme in line of the Convention on Biological Diversity - THE SÃO PAULO DECLARATION ON POLLINATORS. 2.3 NOEC-values as summary parameters It is known for adult honeybees, that the outcome of tests with adult honeybees in order to find the no-observed-effect concentration (NOEC) even as a regression-based parameter, the values are extremely biassed by the physiological background (Protein-content of the diet preceding the tests). Actual Data by LAVES, Celle: Pers. Comm. Dr W. von der Ohe. Or Lit.: Mühlen W., R. Hintzen, R. Forster.1993. Arguments for the Necessity of Multiple Testing to Evaluate the Toxicity of Pesticides to Honeybees. Proceedings 5th ICPBR Symposium on the Hasards of Pesticides to Bees, Wageningen, NL. 2.6 Higher tier tests It is said: Higher tier tests generally provide information on exposure and effects under more realistic conditions compared with standard laboratory tests. Therefore many uncertainties are reduced, however, as some of the variables are not under the control of the experimenter, the results tend to be less reproducible. In the case of honeybee colonies tests the test re liabilities should be evaluated. • When a test aims to observe a given parameter (foraging activity for instance), the natural variability should be estimated to avoid mask effects, particularly if no positive control test is used. When high variability is observed, the test should be considered not conclusive. • All test conclusions should include a short comment about the parameters the test is able to assess and the ones it cannot assess. • (For example delayed pollen consumption when relevant for the tested substance or product) A systemic insecticide “incorporated” inside the pollen grains can only become toxic for honeybees digesting pollen and/or the larvae those bees feed.
FURS	4.4 Risk mitigation options	The current text only highlights the risk of foraging in the crop. In less intensive agricultural areas in Europe it is common practise to have bee hives directly adjacent to crop fields and mitigation measures to protect the hives from contamination can be just as relevant.
individual	4.4 Risk mitigation options	Early morning / evening application: Although this mitigation might lead to lower effects on honey bees other arthropods might be at high risk (e.g. bumble bees that forage earlier and later in the day than honey bees and during colder weather). It therefore seems a doubtful mitigation method and should only be accepted if substantial evidence for low risk towards all NTAs is provided.

Contributor	Section	Comment
UBA	4.4 Risk mitigation options	In view of a potential extension of the honeybee risk assessment to other mobile arthropod species (see comments to chapter 5), the effectiveness of the proposed risk mitigation options for the protection of other nectar-, pollen- and honeydew-feeding insect species should be critically reviewed. For instance, insects foraging at night (e.g., moths and some beetle species) would not be protected by restricting applications to the late evening after sunset.
AGES	5 Other arthropods	We think that a revision / amendment of the ESCORT 2 document parallel to the revision of SANCO/10329/2002 would be desirable (e.g. ESCORT 3).
Ctgb	5 Other arthropods	5 Other arthropods: This section clearly needs updating, or rather ESCORT 2 needs updating. Firstly there are some generic issues that are currently being used by several / all(?) MS but which are not included in Sanco/10329/2002 or ESCORT 2: - Trigger to be used for laboratory tests (glassplate) for other species than T. pyri and A. rhopalosiphi: in general a trigger of 50% is used (i.e. not 30%, but the same value as for extended laboratory tests, which is justified since the use of a stricter trigger value for glassplate tests than for extended lab tests makes no sense). The triggering of additional species is also not jeopardised, since the use of 50% effect as trigger is more strict than HQ 2 as trigger. - The use of aged residue tests: it seems to be generally agreed amongst MS that aged residue tests are not acceptable for the off-field risk assessment, because for the off-field actual (instead of potential) recovery has to be demonstrated. However, what type of study should be submitted instead is not so clear (see also below). - In-crop single species field studies are not acceptable to adress the off-crop risk, because in-crop species are not representative for the off-crop and population specific parameters must be taken into account. Further there are several issues that could use more guidance/clarification: - Definition of ecologically relevant period. - If a risk is found in the first tier and a field study is considered necessary, should this field study include the first tier species, or is it more important to conduct the field study in a representative (agro-)ecosystem in which the firts tier standard species maybe are not present? There seems to be a tendency amongst MS to the latter, however this is not consequently used in EU-risk assessments. - If a field study is needed because of an off-field risk, should this field study be conducted in an off-field ecosystem? - Seed dressings and granular formulations: In ESCORT 2 it is recommended to conduct tests with e.g. spiders and ground dwelling beetles, whereas in Sanco/10329/2002 Hypoaspis & Folsomia are recommended as a first step and studies with e.g. Aleochara sp. as tier 2 if deemed appropriate. In this way it is unclear which species are to be preferred. NL uses the working agreement that for formulations that will be incorporated in the soil, studies with either Hypoaspis aculeifer, Folsomia candida or Aleochara bilineata (provided that the test substance is mixed into the soil) are all acceptable since these contain in-soil stages during the test. Studies with Poecilus and Pardosa are not acceptable. The latter species are acceptable for formulations sprayed on bare soil. - Trigger for the Hypoaspis aculeifer and Folsomia candida risk assessment. In The EPPO scheme for soil organisms, an AF of 5 is proposed.

Contributor	Section	Comment
Dansih EPA	5 Other arthropods	In principle we find that the risk assessment should be harmonised with other terrestrial risk assessment and use a TER based approach For bees there are specieal circumstances which have resulted in the HQ approach - but this does not make sence for arthropods. The use of a number of different factors (Hq > 2 - uncertainty default value 10
individual	5 Other arthropods	What about other terrestrial invertebrates? Is it for example safe to assume that molluscs are protected by a RA based on data for arthropods? Molluscs are herbivorous and potentially exposed to PPP residues and highly sensitive towards metals. PPP effects in aquatic molluscs can be detected in mesocosm studies and are then addressed in aquatic RA. This section is based on the ESCORT 2 workshop. The decision making process and results from this workshop are not transparent and some of the data remain unpublished (e.g. variation in sensitivity in different T. pyri strains).For following workshops we suggest a transparent policy and open publication of the process and data behind the decision making process. The document from the ESCORT 2 workshop considers only predatory species or parasitoids historically derived from so called 'beneficials' used in IPM. These species might have a robust body since they need to overcome prey and therefore their exposure might be reduced. Other arthropods also feed directly on residues of PPPs on plants. These herbivorous insects include butterflies/moths but also grasshoppers and true bugs and are typically found 'off- field'. Typical, sensitive 'off-field' species need to be identified and included in the testing scheme that currently only works with 'in-field' 'beneficial' species. The current species are all r-strategy species. Long-term effects might be different in k-strategy species. Since insects form the basis of the terrestrial food chain where plant biomass is converted into animal biomass it seems especially important to understand exposure patterns and long-term effects on this group. Decreases in arthropod biomass due to direct or indirect effects (e.g. food plant loss for insects due to herbicide treatments) might affect vertebrate species. The concept of population recovery of arhropods needs evaluation (and clear definition!) since biomass of arthropods might be crucialfor vertebrates during specific periods in the year (e.g. during bird breeding period of birds, amphibian emergence,…). Food availability at these times is fundamental and recovery of arthropod populations late in the year has no relevance. Herbicide effects on insect populations and arthropod communities could potetially be higher than efects of insecticides due to elimination / reduction of important food plants (in- and off-crop). Since herbicides can show no direct effect in A. rhopalosiphi or T pyri tests no higher tier study is necessary in the current scheme. This approach underestimates the effects of herbicides and needs re-evaluation.
PSD	5 Other arthropods	Other arthropods - background details (pp18-19): Given that the use of 'ESCORT 2' is now well established, the introductory section could be made briefer, with this including a succinct explanation as to the different trigger values used compared with that stated in Annex VI C of the Directive. Given the uncertainty regarding some of the ESCORT 2 assumptions, further consideration of the appropriateness of the scheme and ways in which it may be improved would be desirable. The revised guidance should include any recent developments in this area.
Swedish Chemicals Agency	5 Other arthropods	5 Other arthropods 1. During the revision of the data requirement the PPR panel had several important comments regarding testing and risk assessment of non-target arthropods. These should be taken into account also during the revision of the guidance document.

Contributor	Section	Comment
UBA	5 Other arthropods	This chapter in the current GD in principle constitutes an extended reference to the report of the ESCORT 2 Workshop (Candolfi et al., 2001). This is not deemed a transparent approach, because neither the underlying data and information nor any remaining controversial points between workshop participants are visible. Although we appreciate very much the input and advice provided by SETAC and other scientific organisations, we still think that the new GD should not directly depend on any workshop report. Conclusions should be documented together with all relevant arguments and references to original data where necessary.
UBA	5 Other arthropods	The current approach for assessing the risk to non-target arthropods is strictly divided into an in-field assessment, which focuses on species considered as beneficial in agriculture, and an off-field assessment, which is intended to cover the risk for the whole arthropod fauna. This approach implies different protection goals for both areas. However, no clear protection goals are defined for in-field biota in Directive 91/414 EEC. One option to overcome this problem might be to conduct assessments for different levels of protection in parallel. Furthermore, it appears to be the underlying assumption in the current concept that in-field and off-field arthropod populations can be considered fully separate in terms of risk. However, this distinction is at the end of the day artificial. While sessile species in the off-crop area would probably be covered by an assessment based on exposure at drift rates, this would obviously not be the case for mobile species visiting the in-crop area in search for food/prey. Examples include flying insects (mainly Hymenoptera, Diptera and Lepidoptera) as well as ground dwellers (like some carabid beetles with a home range comprising hiding places in off-crop structures and hunting grounds in agricultural fields). The current in-field risk assessment strongly relies on the capacity of affected populations for quick recovery, either by fast reproduction or by recolonisation (from not affected populations elsewhere or from protected life stages). Thus, the time needed for residues to drop below a hazardous level is a core parameter of this assessment. While this approach might indeed work for species dwelling exclusively in crops (and thus being accustomed to regular and drastic impacts), it will probably underestimate the risk for mobile species. It is suggested to explore whether the current risk assessment approach can be extended to facilitate also an estimation of risk for species not exclusively bound to the off-crop area, but also not belonging to the typical in-crop fauna. It might be helpful to analyse tools used in honey bee risk assessment whether they could be used also for other arthropod species. It is acknowledged, that current legislation does not provide clear cut criteria for deciding on the acceptability of risk to mobile species, since also pest species to be controlled could belong to this group. Also, actual exposure levels will strongly depend on landscape structures, e.g. the ratio of cropped and non-cropped areas as well as their distribution in the landscape. Nevertheless, attempts to provide guidance for quantifying exposure and risk for this group would be highly appreciated.
UBA	5 Other arthropods	The overall testing and assessment strategy currently proposed is to some extent not congruent. At the tier-1 level, high physiological sensitivity is brought forward as an argument for selecting T. pyri and A. rhopalosiphi as standard test organisms. But as soon as modified-exposure studies (on natural substrate) come into the play, the selection of test organisms is mainly driven by habitat (soil dwellers versus foliar dwellers). Experience has shown that the test organisms used as representatives for soil dwellers are in most cases much less sensitive than the foliar dwellers. It is not clear whether this difference in sensitivity between soil and foliar dwellers is "real" or might be an artifact due to selection of relatively insensitive test species to represent soil-dwelling arthropods.

Contributor	Section	Comment
UBA	5 Other arthropods	The subject of the risk assessment is restricted to arthropods. Assumed that other groups of invertebrates are intended to be part of the protection aim as well, it should be critically reviewed to what extent other groups of arthropods, especially snails, are sufficiently protected by a risk assessment performed with arthropods only.
US EPA/OPP/EFED	5 Other arthropods	Other Arthropods • The guidance document included a lengthy discussion of toxicity, exposure, and risk assessment methods for arthropods other than honey bees. EPA/OPP/EFED does not routinely receive or require toxicity data on arthropods, and no established risk assessment methods have been established within EPA/OPP/EFED. However, if these data are available, EPA/OPP/EFED may use such data to inform the risk assessment.
individual	5.1 Data requirements and testing	Apart from the above mentioned consideration because of their IPM background it is noteworthy that existing standard tests with T. pyri and A. rhopalosiphi are costly since the test organisms are not easily handled. It seems odd that to date not many ecotoxicoloical standard test were carried out with Drosophila, an established laboratory species that comes in many strains with an genome studied in great detail. Since it is the organism with many (maybe the most) insights in its development, Drosophila would also be an ideal candidate to assess endocrine effects. Results on efficacy testing (e.g. Lepidoptera and Diptera pest species) could be helpful in ecotoxicological RA and should be included in the data set. Spiders should be tested separately, preferably a small species such as Erigone atra. p.21 Field test should also include a relevant number of replicates of off-crop buffer strips close to control and full rate plots to evaluate drift effects on the off-crop arthropod community and understand recolonisation patterns.
PSD	5.1 Data requirements and testing	Other arthropods – Standard tests (pp19-20): Additional information on NTA tests required for substances with a 'special mode of action' (e.g. insect growth regulators, substance acting via oral ingestion) would be helpful.
RIVM	5.1 Data requirements and testing	Page 21, higher tier tests. Chapter 5.1 gives some guidance for the design and conduct of field studies with non-target arthropods. Hardly any guidance is however given for the summarising an evaluating of non-target arthropod field studies. Since these type of higher tier studies can be rather complex, they might result in quite lengthy and complicated study reports. And since the guidance for conducting these studies is only general, the studies and the study reports are very diverse. Therefore, at least in the Netherlands, a need was present for guidance how to summarise and evaluate these type of studies in a uniform way, and the Dutch Platform for the Assessment of Higher Tier Studies is drafting a guidance document for this aim: Jong, F.M.W. de, Bakker, F.M., Brown, K., Jilesen, C.J.T.J., Posthuma-Doodeman, C.J.A.M., Smit, C.E., van der Steen, J.J.M. van der, in prep. Guidance for summarising and evaluating field studies with non-target arthropods. The Dutch Platform recommends to take this guidance document intoaccount as a useful tool for summarising and evaluating of non-target arthorpod field studies. The guidance document is foreseen to be finalised before summer 2009, after a external consultation of international experts. A draft version can be obtained from frank.de.jong@rivm.nl

Contributor	Section	Comment
UBA	5.1 Data requirements and testing	The selection of test species was originally driven by IPM considerations, i.e., they represent groups of arthropods considered as beneficial for agriculture (parasitoids, predators). Important taxonomic groups like Lepidoptera are not tested, although many insecticides are specifically designed for controlling lepidopteran pests. Also, the group of hemimetabolous insects as well as phytophagous arthropods appear underrepresented. Hence, it should be investigated to which extent testing with the current standard species is sufficient to ensure appropriate protection of the whole arthropod fauna, including e.g. pollinators, phloem succers, saprophagous or phytophagous arthropods etc. If available data suggest consistently higher sensitivity of hitherto not tested species, recommendations for extended testing schemes would be helpful.
UBA	5.1 Data requirements and testing	It is mentioned that "… limit tests can be conducted …". We would appreciate if clearer guidance was provided in which cases limit test are acceptable and under which circumstances dose/response studies should be compulsory.
UBA	5.1 Data requirements and testing	In our opinion, the results from efficacy testing with insecticides/acaricides should be considered to a greater extent also in the NTA risk assessment. This would include selection of appropriate test species as well as of specific endpoints corresponding to the mode-of-action of the compound.
UBA	5.1 Data requirements and testing	Contact exposure to dried residues on treated substrate is the predominant route considered in NTA testing, while actual exposure in the field could also occur via overspray (in-field), contact with spray droplets (off-field) or ingestion. The available data should be checked whether the focus on contact toxicity is sufficient to ensure appropriate protection also for other exposure routes. It may be worthwhile considering whether bridging is possible to results from efficacy testing obtained by, e.g., dipping infested leaves in insecticide solutions. (Whilst it should be kept in mind that the intention of efficacy testing is different from NTA testing, e.g. the focus will probably be on more resistant strains of pest organisms rather than on highly sensitive species.)
UBA	5.1 Data requirements and testing	In principle, there are two options for conducting extended laboratory tests, either whole plants could be sprayed and the leaves/plants directly used in testing or testing could be conducted using cut leaves, which are sprayed on one surface only in the testing laboratory. From the perspective of risk assessment, no application of a "vegetation distribution factor" (vdf) is required in the first case, while in the second case the actual test exposure is reduced by a vdf of currently 10 (but it should be lower - see our respective comment). Hence, testing on leaves from whole sprayed plants is closer to reality, but the variability within the replicates might be too high to confirm statistically possible treatment effects. On the other hand, application of a generic vdf might introduce an artificial bias into the risk assessment. It may be useful to analyse available data if there are indications that one test design would be more appropriate for the risk assessment than the other.
UBA	5.1 Data requirements and testing	Some evidence lately compiled in DE suggests that standard arthropod effect values (NOER, ER50; here for T. pyri and A. rhopalosiphi) obtained in certain laboratories are consistently lower (up to a factor of one order of magnitude) than those from other studies/laboratories. All of these studies were conducted according to the IOBC guideline. One possible explanation could be that the guideline does not account for parameters like nozzle type or spraying pressure. Another explanation could be different sensitivity of the T. pyri strains used for testing. It should be investigated if such observations can be confirmed also on a larger scale and whether potential shortcomings of the test guideline could be compensated by additional guidance. If the above-mentioned inter-lab variability cannot be reduced by those attempts, the level of protection assured by the standard risk assessment should be critically reviewed in the course of the revision of the GD.

Contributor	Section	Comment
UBA	5.1 Data requirements and testing	The ESCORT 2 approach explicitly excludes the data on sublethal effects from tests on inert substrate in tier 1. It is claimed that these figures are unreliable. We do not support this general statement. Most arthropod species addressed by the risk assessment will only have one reproductive phase during their whole lifespan; if this is disrupted, it will have the same effect on the population as the death of the individual would have had. Hence, information on reproductive parameters should always be considered (quantitatively or qualitatively, depending on the reliability of derived effect values) in the risk assessment from tier 1 onwards. The statement from the ESCORT 2 workshop that the risk arising from sub-lethal effects is fully covered by the HQ acceptability trigger of 2 for T. pyri and A. rhopalosiphi is not substantiated for other species. In addition, we see a discrepancy between the statement in the GD that the sublethal endpoints are unreliable and the fact that these endpoints are an integral part of standardised and validated IOBC test guidelines. In these guidelines, the only organism for which the reproductive endpoints are considered statistically not reliable is Coccinella septempunctata.
AGES	5.2 Exposure assessment	- The calculation of MAF values should be harmonised between ESCORT 2 and the section Birds & Mammals - Vegetation distribution factor: As the currently used figure of 10 is unreliable and has never been supported by data, a more appropriate value should be proposed in the new guidance document, and reasoning (background data) should be provided.
individual	5.2 Exposure assessment	The vegetation distribution factor is under discussion and should be addressed. We suggest an open public discussion of all aspects that is basd on access to publications to all stakeholders. Discussion is often only present in workshops with a restricted number of participants.
UBA	5.2 Exposure assessment	A vegetation distribution factor of 10 (relevant for two-dimensional study designs) was proposed by the ESCORT 2 Workshop (Candolfi et al., 2001) to be used in the off-field risk assessment and is referred to in the current GD. However, the GD also contains a remark that this value is considered not reliable. We agree to this conclusion. The German UBA has therefore assessed some experimental data in order to derive a more reliable vdf. A draft publication on this exercise was distributed among the participants of the PRAPeR Expert Meetings on Ecotoxicology in September 2006. We came to the conclusion that the vdf should not exceed 5. Our general remark with regard to a better congruency between the different sections especially applies to the exposure assessment, where fate experts should be consulted in order to aim at a consistent approach for all groups of organisms.
UBA	5.2 Exposure assessment	Authorities frequently encounter the argument in applicants" risk assessments that off-field exposure due to drift is patchy in nature and thus differs from the much more homogenous in-field and toxicity test exposure. It is argued that "patchy" exposure should result in a lower risk than predicted from tests with homogenous exposure. However, some few tests have meanwhile been conducted with variation of either substance concentration or water volume in spraying to simulate drift exposure. No significant differences in effect levels could be detected. It would be much appreciated if this issue could be explored further during the revision process of the GD. If at the end of the scenarios could be identified where patchy exposure would indeed result in lower risk (this might perhaps depend on the density of droplets in relation to leaf sizes?), tools must be developed to quantitatively describe patchiness and its effect on exposed arthropod populations (e.g., in terms of “proportion of local population affected at a certain application/drift rate” = %Effect at drift rate x proportion of habitat exposed). Otherwise, this phenomenon cannot be considered as risk-mitigating effect.

Contributor	Section	Comment
AGES	5.3 Risk assessment	risk for solid formulations: Studies with Poecilus cupreus larvae and with Pardosa sp. should be added to the recommended species.
Dansih EPA	5.3 Risk assessment	As mentioned we do not support the HQ approach for n.t. arthropods. In addition the use of a number of different factors (Hq > 2 - uncertainty default value 10, correction factor 5) makes the assessment non-transparent.
individual	5.3 Risk assessment	It would be helpful to harmonise RA and refer to a TER value also in NTAs.
PSD	5.3 Risk assessment	Non-target arthropod risk assessment (pp22-23): It would be helpful to include further guidance about how to assess the risk from pelleted formulations, seed treatments and insect growth regulators.
UBA	5.3 Risk assessment	The use of an HQ (for assessments based on glass-plate testing) or "modified exposure" term (for assessments based on extended laboratory testing) as proposed by ESCORT 2 for arthropods in general is deemed scientifically doubtful. Since the TER approach is well established in all other areas of environmental risk assessment, the necessity for using a different risk descriptor for arthropods is not understood. In particular, the approach is not considered sufficiently transparent, since all different types factors affecting the predicted risk are expressed as modifications of the exposure term. Whilst this is appropriate for the vdf, the so-called "correction factor" CF is actually an assessment factor for inter-species variability in sensitivity and has nothing to do with exposure. Worse than that, the level of uncertainty is not visible in the final HQ or "modified exposure" term. Consequently, we strongly suggest that the future risk assessment for NTAs should be based on a TER approach.
UBA	5.3 Risk assessment	The ESCORT 2 workshop report proposes applying an HQ acceptability trigger of 2 in the first tier for both in-field and off-field assessments. In our understanding, this proposal is based on comparisons between laboratory testing results and single-species field investigations – including population recovery – on the two standard test species A. rhopalosiphi and T. pyri. However, these species are both r-strategists with specific traits allowing them to quickly compensate even drastic losses of individuals on population levels (e.g., fast generation cycles, high reproduction rates, protected life-stages during development). Even if their physiological sensitivity (on the level of individuals) is high, their ecological sensitivity (on the level of populations) is rather low. It may be that the resulting "overall sensitivity" is sufficiently low to ensure protectiveness of a risk assessment for other typical in-crop organisms, as these are typically also r-strategists. However, from what is said, it should be obvious that any extrapolation of this approach to the off-crop biocoenoses as well as to mobile species (including also K-strategists) is so highly uncertain that it cannot be scientifically justified. Also from a principal point of view, the introduction of a factor considering recovery for organisms dwelling in non-target areas already at Tier I is definitely not in line with the general approach proposed in the GD on Aquatic Ecotoxicology, where the Tier I RAC is always much lower than the measured effect threshold level. Since such considerable difference in the level of protection between the different protection goals should be avoided, we suggest critically reviewing the criteria applied in the risk assessment for terrestrial arthropods.

Contributor	Section	Comment
UBA	5.3 Risk assessment	To safely avoid false negatives in the tier-1 risk assessment, the HQ approach with the acceptability trigger of 2 should not be used for assessing the off-field risk or the risk to mobile species. As regards in-crop biocoenoses, the justifications given for the protective character of the specific HQ values for A. rhopalosiphi and T. pyri also for other species should be critically re-evaluated.
UBA	5.3 Risk assessment	Aged-residue studies are not regarded to be suitable for refinement of the standard off-field risk assessment. These tests can only indicate what time is required for residues to drop below a hazardous level, which would enable recolonisation of the treated/affected area. This concept might be protective for typical in-crop organisms, as these are typically r-strategists with high dispersal ability or the potential to survive as protected life stages. However, any extrapolation of this approach to the off-crop biocoenoses (including also K-strategists) is highly uncertain. A higher-tiered approach considering recovery of populations of species in off-crop areas would require detailed analyses of real landscapes on the exposure side and new risk assessment and risk management concepts for deciding on the acceptability of population effects larger than zero.
UBA	5.3 Risk assessment	In the current assessment concept, a reduction of the so-called "correction factor" CF (actually an assessment factor for interspecies variability in sensitivity) from 10 to 5 is granted when the step is made from tier-1 testing on inert substrate to "higher-tier" testing on natural substrate. But the actual reason for the reduction of CF is not the step to using natural substrate, but the requirement to test additional species that comes with it in the ESCORT 2 scheme. This could lead to confusion, e.g. in a situation where tests with additional species on inert substrate are presented. If in such a scenario one species (e.g. T. pyri) was identified to be much more sensitive than all others and the extended laboratory test was conducted only with this species, reduction of CF would formally be not possible despite the added certainty regarding species sensitivity distribution. Even more, a comparison of sensitivity based on glass-plate testing could well be more reliable than a comparison based on extended laboratory testing, because no bias is introduced by different natural substrate properties or by 2-D vs. 3-D test designs. To clarify the concept, it might be beneficial to offer two distinct refinement options: 1) testing of additional species under highly standardised conditions to obtain information on species sensitivity distribution and/or 2) testing with modified exposure on natural substrate to obtain information on toxicity under more realistic exposure conditions. This would also be more in parallel with concepts well established in the aquatic risk assessment.
individual	6 Soil organisms	The section on soil organisms needs restructuring. Again a protection goal should be defined (focus on biodiversity and / or function?). The specific treatment of soil organisms and the separation from ‘terrestrial’ organisms seems arbitrary for many taxa that develop in the soil but live on the soil as adults (many insects). The sensitivity of the litter bag test needs evaluation. There should now enough submitted data be available. The test would give more information of potential effects if it was combined with the assessment of soil microfauna (mites, Collembola).

Contributor	Section	Comment
INIA	6 Soil organisms	6. Soil organisms The present risk assessment scheme follow for the compartment soil has a particular interest in the context of the revision of the section ecotoxicology of Annexes II and III of Directive 91/414/EEC. These sections have been revised by a working group on behalf of DG Sanco, and the revised versions have been commented by EFSA and other MS. The new of Annexes II and III are under revision for the commission. Please update the data requirements according to the approval of the new Annexes II and III. In the current version of Annex II and III of 91/414/EEC and the associated guidance documents, the risk assessment for soil organisms and processes are a combination of structural (earthworms and arthropods) and functional (breakdown organic matter, respiration, fixation of nitrogen) based risk assessment. However, the panel already recommends suppressing litter bag studies in the evaluation of the risk to terrestrial environments (EFSA-Q-2006-170) and to include instead data requirements related to the effects on soil micro-and macrofauna. The recommendations for the new Annex III package only require a litter bag study when the product is applied as sterilizing. The litter bag study assesses the capacity of the soil to breakdown organic matter. This endpoint has a high ecological relevance. If the test is not required a gap at the level of assessment of the functional capacity of the soil after pesticides application is identified. Further guidance is need in the case of persistent compounds. Some issues remain in Directive 91/414/EC that do not bring any help in risk assessment, such as: - level of assessment is unclear: interested in the potential effects on soil function or structure, or both? - In general low level of guidance for persistent substances - A summary of limitations and challenges on the ecotoxicology in soil is welcome. For example, in order to study the effects of pesticides on soil biodiversity, it is a need to identify appropriate indicators groups and in order to maintain the soil productivity the role of mycorhizas is essential. These aspects are not taken into account in the current approach. - Some guidance on how to evaluate the ecotoxicity of fumigants is welcome
PSD	6 Soil organisms	Soil organisms (pp23-29): This section needs to be amended to take account of the proposed revised Annex II and III data requirements (with mention of the need for litter bag tests being deleted). The risk assessment for 'other soil macro-organisms' should ideally take account of the proceedings of the PERAS Workshop held on this subject - which are due to be published shortly by SETAC.
Swedish Chemicals Agency	6 Soil organisms	6 Soil organisms 1. EFSA is currently revising the Guidance Document on Persistence in Soil under Council Directive 91/414/EEC (Working Document SANCO/VI/97 rev. 8 final 12 July 2000). It is proposed to include both soil persistence and effects on soil organisms in this GD. We therefore suggest that this section on soil organisms is inserted into that new GD or merge the new Soil GD into this Terrestrial GD. 2. P24-31. The section on soil organisms would benefit from a different disposition, with one subheading per organism group, each including data requirements, exposure assessment and risk assessment. 3. The section should be updated to reflect the outcome of the extensive discussions regarding soil organisms that took place during the work with revision of Annex II and III. For example, the requirement of an earthworm acute toxicity study was proposed to be replaced by a sublethal test for all compounds, and the risk assessment for other soil organisms is proposed to focus on structural rather than functional endpoints (e.g. it was proposed to omit the litterbag test).

Contributor	Section	Comment
		4. During risk assessments it should be highlighted and considered that only contact exposure is assessed in the test for sublethal effects on earthworms, since the worms are fed with uncontaminated food.
UBA	6 Soil organisms	We propose including an initial sub-chapter on general aspects (e.g. scope of the risk assessment for soil organisms, protection goals, bioavailability, see below) and to improve the overall structure of this chapter (individual subchapters on the three major groups of soil non-target organisms to be addressed here, i.e. earthworms, soil micro-arthropods and micro-organisms).
UBA	6 Soil organisms	Knowing that this is not in the remit of EFSA's PPR, we would nevertheless like to emphasise the urgent need for a clear and sufficiently detailed definition of the protection goals with regard to soil organisms. The final GD to be used by authorities and applicants should explicitly define whether the assessment scheme (i) should include structural and functional endpoints with the latter superseding the first (i.e. the current situation, except for earthworms), or (ii) should include structural and functional endpoints with specific focus on effects over one year and over several years, respectively and specific higher-tier options for both types of parameters, or (iii) should include structural endpoints only and dismiss functional testing and assessment. (Reference should be made also to draft revision 8 of Annexes II and III to Directive 91/414/EEC, Point 8.4.) In a second step, the relevant ecological receptors/studies (both on lower tier/standard soil toxicity testing and higher tier) should be defined, including detailed guidance on the relevant endpoints to be used in risk assessment and the relevant magnitude and ecological significance of observed effects. If recovery/recolonisation is to be considered, appropriate time windows are to be defined in addition. This should be done for the three major groups of soil non-target organisms separately (earthworms, soil micro-arthropods and micro-organisms).
UBA	6 Soil organisms	Bioavailability is the major issue and primary reason for complexity (and thus source of uncertainty) in the risk assessment for soil organisms. In order to sharpen the consciousness in this respect, we propose adding at least a sub-chapter aiming to define this term and to give references for further reading We would like to make the following proposal for a definition of "bioavailability" (taken from: REACH-TGD, Effects on Terrestrial Organisms): "By addressing bioavailability of substances in soil, a potential method to deal with the diversity and complexity of soils is provided. Bioavailability considers the processes of mass transfer and uptake of substances into soil-living organisms which are determined by substance properties (key parameter: water solubility, KOC, vapour pressure), soil properties (with key parameter: clay content, organic matter content, pH-value, cation exchange capacity) and the biology of soil organisms (key parameter: micro-habitat, morphology, physiology, life-span). The practical meaning for effect assessment of both organic substances and metals is the observation that not the total loading rate, but only the bioavailable fraction of a substance in soil is decisive for the observed toxicity. Although being subject to extensive research activities in the past decade, there is actually no general approach for assessing the bioavailability of substances in soils. Major difficulties are the differences and the restricted knowledge about exposure pathways relevant for soil organisms and the fact that bioavailability is time-dependent. The latter phenomenon is commonly described as a process of "ageing" of substances in soil: Due to increasing sorption, binding and incorporation into the soil matrix, bioavailability and consequently toxicity changes (mostly decreases) with time. Additional factors like climate conditions and land use may also influence bioavailability. Nonetheless, bioavailability should be critically considered when interpreting existing soil toxicity data as well as during the design of new studies."

Contributor	Section	Comment
AGES	6.1 Data requirements and testing	- The data requirements and the risk assessment should be adapted according to what is being decided in the Annex II and III amendments of Directive 91/414/EEC (or the new Regulation) - Earthworm field studies: Further guidance on the evaluation of effects and acceptability criteria (% effects based on total earthworm numbers, individual species numbers or biomass). The "Guidance for summarising earthworm field studies"of de Jong et al. (2006) should be cited.
AGES	6.1 Data requirements and testing	During the SETAC Europe Workshop PERAS, October 2007 in Coimbra PT, semi field test methods were discussed (http://www.gaiac.rwth-aachen.de/peras/) and in the near future a guidance from this workshop should be available (currently a draft is circulated). Therefore this point should be updated and adapted with regard to the output from the guidance.
Ctgb	6.1 Data requirements and testing	6.1 Data requirements and testing – sublethal effects on earthworms: The triggers for sublethal earthworm studies do not cover the situation where DT90f is between 100 and 365 d and frequency is 2 and where DT90 f < 100 d and frequency > 3. 6.1 Data requirements and testing – Other soil non-target macro-organisms: This section needs a thorough revision. See also our comment on 2.7: we would prefer a separate guidance (chapter) on the persistence risk assessment, to improve transparency. Further, the litterbag has been removed from the data requirements (with some exceptions, e.g. for soil fumigants), thus the flow-scheme on page 26 has lost its purpose. In general there seems to be agreement that structural endpoints are preferred above functional endpoints. We would agree to see this reflected in the guidance.
Danish EPA	6.1 Data requirements and testing	In our view the triggering for earthworm sublethal studies should be reconsidered. Such studies should generally be required, evidence to this account has been presented by DE and AU in connection with the revisions of the data requirements.
Danish EPA	6.1 Data requirements and testing	The triggering system - figure 1 - needs to be revised - discussions on this issues have been ongoing in connection to the revision of the data-requirements. We do not support that the litterbag test should be included in the triggering scheme to address risk identified for earthworms or other soil organisms. In fact the usefulness of a litterbag test - given its ability to detect effects- should be reconsidered.
PSD	6.1 Data requirements and testing	Sub-lethal effects on earthworms (p 24): Further guidance would be helpful on whether sub-lethal effects on earthworms need to be assessed when the 'DT90f is between 100 and 365 days and/or the number of applications is between 3 and 6'.
RIVM	6.1 Data requirements and testing	Page 25, earthworm field studies. Chapter 6.1 gives some guidance for the design and conduct of higher-tier effects studies with earthworms. Hardly any guidance is however given for the summarising an evaluating of field studies with earthworms. Since these type of higher tier studies can be rather complex, they might result in quite lengthy and complicated study reports. Therefore, at least in the Netherlands, a need was present for guidance how to summarise and evaluate these type of studies in a uniform way, and the Dutch Platform for the Assessment of Higher Tier Studies published a guidance document for this aim: Jong, F.M.W. de, Beelen, P. van, Smit, C.E., Montforts, M.H.M.M., 2006. Guidance for summa-rising earthworm field studies. A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies. RIVM report 601506006/2006. ISBN 90-6960-154-0. The Dutch Platform recommends to take this guidance document into account as a useful tool for summarising and evaluating of

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		earthworm field studies. The guidance document is available at: http://www.rivm.nl/bibliotheek/rapporten/601506006.html
RWTH Aachen University	6.1 Data requirements and testing	Comments on Terrestrial Guidance Document to EFSA: Public consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR) on the existing Guidance Documents for Aquatic and Terrestrial Ecotoxicology under Council Directive 91/414/EEC. Page 29 6 Soil organisms 6.1 Data requirements and testing Other soil non-target macro-organisms c) Higher tier tests The Terrestrial Guidance Documents mentions options for higher tier testing of PPPs on soil organisms. However, no guidance was available until recently on when and how to perform higher tier studies on soil organisms. Therefore, the PERAS Organizing Committee (Andreas Schaeffer (Technical University Aachen, DE, chair), Frank de Jong (RIVM, NL), Simon Hoy (PSD, UK), Joerg Roembke (ECT, DE), Fred Heimbach (Bayer CropScience, DE, treasurer), Paulo Sousa (University Coimbra, PT) and Martina Ross-Nickoll (Technical University Aachen, DE) organised the SETAC Europe Workshop "Semi-field Methods for the Environmental Risk Assessment of Pesticides in Soil" (PERAS) on 8-10 October 2007 in Coimbra, Portugal with 55 experts on soil ecotoxicology from academia, authorities (including EFSA) and business from all over Europe, including some non-European experts. The workshops aims were: • To highlight the current state of knowledge on semi-field methods to assess the impact of PPPs on soil community structure and function. • To identify suitable 'state-of-the-art' methods, from laboratory to field, which can be used to assess the impact of PPPs on soil communities. • To select the most appropriate testing methods to fit into a tiered testing and risk assessment approach for PPPs in soil (TME or any other suitable method), with a particular focus on higher tier laboratory and semi-field methods which may be employed between 1st tier laboratory tests and full scale field studies. • To discuss technical details of the TME method in order to agree on a standardised test method as far as feasible. • To discuss the use of TME and other higher tier semi-field studies in the regulatory framework of PPPs in Europe. • To identify key gaps in knowledge and areas for further research and development in soil testing and risk assessment. The discussions and conclusions of the PERAS Workshop will be published soon as a SETAC Guidance Document. The draft version is available now. Workshop participants received the draft version and are asked to review and comment the draft document to ensure the documents fairly reflects the outcome of the workshop. The outcome of the workshop provides specific and scientifically sound recommendations for the higher tier testing of PPPs on soil organisms and risk assessment as indicated in the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC. The Organizing Committee recommends to consider the outcome of the PERAS Workshop for further updates of the Guidance Document on Terrestrial Ecotoxicology and the Council Directive 91/414/EEC in order to better reflect the current status quo on higher tier testing and risk assessment of PPPs in soil ecotoxicology.

Contributor	Section	Comment
		The draft version of the PERAS Guidance Document is available via http://www.gaiac.rwth-aachen.de/peras/ under "follow up".
Swedish Chemicals Agency	6.1 Data requirements and testing	6.1 Data requirements and testing 1. P24. On page 5, sublethal effects on earthworms are proposed as an example for when a formulation study would fulfil also the Annex II data requirement. If this is still acceptable, it could be mentioned also in section 6.1. 2. There is in general little guidance on how to interpret effects on the soil microflora. Arable land is influenced by a lot of handling like addition of nutrients in different forms, addition of pesticides and mechanical treatment of the soil. The soil microflora is generally considered to be enough resilient to maintain the necessary functionality for a good crop production. At the time when we will consider changes in the soil microflora of importance to crop production then more in depth investigations are necessary. Further methods need to be developed other than the OECD test methods on soil nitrification and carbon mineralisation. By that time modern methods to study functional and structural diversity in soil microbial communities could be considered. Such methods are developed by different research groups and could be further developed to study potential impact of pesticides on soil communities and preferably be used during efficacy testing to get a whole growing season. Methods are used and developed by e.g.: Uppsala Microbiomics Center, Sweden. Contact person: Assoc. Prof. Sara Hallin Sara.Hallin@mikrob.slu.se ; Phone: +46-18-673209 http://www.microbiomics.se/ Widenfalk, A., Bertilsson, S., Sundh, I., Goedkoop, W. (2007). Effects of pesticides on community composition and activity of sediment microbes - responses at various levels of community organization. Environ. Pollut. 152(3):576-584 Professor Kornelia Smalla, BBA Institute for Plant Virology, Microbiology and Biosafety, Germany k.smalla@bba.de; Phone: +49 (531) 299-3814 Neumann, G. Kania, A. Weinert, N. Smalla, K. Meincke, R. Berg, G. Ros, B. Block, A. Mohler, V. Dong, X. Wenzel, G. Munch, J.C. Radl, V. Schloter, M. Impact of transgenic potatoes with overproduction of zeaxanthin on rhizosphere processes and soil quality in agricultural production. Poster presented at Rhizosphere 2, Montpellier, France 26-31 August, 2007. 3. P30–31, Refined risk assessment for earthworms. The section on the earthworm field studies need to be updated. In their opinion on the data requirement the PPR panel stated that the current guideline on the field testing is unsatisfactory since effects less than 30 % will not be detected. They further stated that the scientific robustness behind a recovery period of 1 year is not clear. These comment need to be considered during the revision.
UBA	6.1 Data requirements and testing	Earthworm toxicity testing issues to be updated and/or refined further: 1. According to the draft revised version of Annex II and III to Council Directive 91/414/EEC (draft revision 8 submitted to KOM on 20.09.2007), the acute testing (OECD 207) will supposedly be omitted in the future whereas a test on sub-lethal effects (OECD 222) will be mandatory. The testing and risk assessment scheme for earthworms thus should include this development, i.e. guidance is needed on if and how existing acute toxicity data are still to be used in risk assessment in relation to data from chronic testing data. This may be of special relevance with regard to metabolites (where waiving of chronic testing was possible based on the results of acute testing). However, if acute data will be of importance in the future assessment, the appropriateness of the acute critical TER values (i.e. 10) should be critically evaluated (as high acute-to-chronic ratios are generally observed for earthworms, which is actually the reason for omitting the "insensitive" acute test from the data requirements).

Contributor	Section	Comment
		2. Most important, clear guidance on the appropriate test design (for the most relevant chronic study) is needed. Today, several variations of key parameters in test design (artificial test soil with 5% peat versus artificial test soil with 10% peat versus natural test soil; mixing of the test substance into soil versus spray application; addition of feed (cow manure) before application of the test substance versus addition of feed (cow manure) following application) are deemed to have a major impact on the study results. Comparability of results from different studies is not warranted, which is considered highly unfortunate for a tier-1 standard toxicity test. Moreover, clarity is needed, whether options for refinement do exist at the stage of laboratory testing (e.g. refinement of the results obtained from a test where the test substance was mixed into the soil by the result from testing spray-application). 3. Regarding earthworm field testing, the latest developments in this area should be included or at least referenced. For the design of field studies reference should be given to: Kula et al. (2006): Technical recommendations for the update of the ISO earthworm field test guideline (ISO 11268-3). J Soils Sediments 6 (3) 182-186. For the interpretation of field studies refer to: De Jong et al. (2006): Guidance for summarising earthworm field studies. RIVM, Bilthoven, 46 pages. Not considered yet in the existing test guidelines, we strongly propose to include chemical analysis of the residues of the test substance (active substance(s) and/or major metabolite(s)) at least following application in order to confirm the validity of the exposure design. Inclusion of soil residue analysis will clearly increase the confidence in earthworm field study results and is essential if extrapolation of study results to other regions/soil conditions is to be undertaken. Most important, explicit guidance on the use of earthworm field test results in risk assessment are needed. This should address both the ecological relevance of different effect types (effects on overall abundance/biomass versus effects on populations of single species/ community effects) as well as the acceptable effect size and effect duration (recovery). For the latter, please refer also to De Jong et al. (2006).
UBA	6.1 Data requirements and testing	We support in general the proposals from the draft revised version of Annex II and III to council Directive 91/414/EEC to reduce data requirements for soil microorganisms. The soil nitrogen transformation study is considered more relevant and sensitive to evaluate the impacts of substances on soil microbial activity compared to the carbon mineralisation test. Hence, this expected change in legislation should also be reflected in the revised GD. As regards formulations containing more than one active substance, we are of the opinion that soil nitrification studies has to be submitted also in cases where the individual active substances did not cause effects greater than 25% after 28 days in tests on microbial activity. In cases where (major) metabolites cannot be expected to have been formed during the test duration with the parent compound, further testing of respective metabolites is considered necessary. It might be useful to recommend accompanying soil analyses for parent compound and known metabolites, however, this should not be mandatory.
UBA	6.1 Data requirements and testing	Other soil non-target macro-organisms (Annex III 10.6.2), page 26: The heading of a respective sub-chapter should be adapted: Soil micro-arthropods (collembolan reproduction and gamasid mites) are mainly in focus here - at least when starting with direct effects as proposed in the testing scheme below.

Contributor	Section	Comment
UBA	6.1 Data requirements and testing	In the current assessment approach, persistence of an active substance or metabolite in soil is primarily addressed as a fate issue, i.e. exposure plateaus after several years of consecutive use are estimated and form the basis for TER calculations. However, this would not cover effects caused only on a long-term time scale and thus not being captured in standard testing. It should be discussed whether there are indications for such type of additional effects and if so, whether they should be regarded relevant in the field and require adapted testing. In that case, recommendations for testing approaches and methodologies would be highly appreciated.
UBA	6.1 Data requirements and testing	Soil micro-arthropod data requirements: A concept to make use of the effect values from non-target arthropod (NTA) standard tests in a risk assessment for soil micro-arthropods (soil mesofauna) was suggested by DE in the expert group for revising the Annex II/III data requirements in 2007. Unfortunately, the concept could only be introduced late in the process, so there were some discussions, but no final conclusion with respect to the revised data requirements. Since we are still convinced that our approach would constitute a marked improvement as compared to the scheme in the current GD, we would like to invite the EFSA work group to consider it in the discussions on the revision of the GD. Basically, the approach is based on taxonomy rather than on habitat, following the working hypothesis that sensitivity to a pesticide is primarily driven by the physiology of an organism, whereas the habitat affects bioavailability and thus exposure levels. Consequently, we think that the physiological sensitivity of the soil-dwelling mite H. aculeifer can in principle be represented by the physiological sensitivity of another sensitive mite species, including the mite species T. pyri. This would hold similarly for the collembolan F. candida and the potential that its physiological sensitivity is represented by that of A. rhopalosiphi. To ensure that physiological sensitivity is assessed under worst-case conditions, only NTA tests on inert substrate should be considered. 1) calculate PECsoil in (mg as/kg soil) 2) recalculate glass plate L/ER50 for T. pyri or A. rhopalosiphi to (mg as/kg soil) using the same parameters and assumptions as for PECsoil calculation 3) calculate TER values (L/ER50)/(PECsoil) 4) if TER values are >10 (typically used for L/ER50 data, more conservative) or >5 (same trigger as currently used for soil organisms, would still be conservative according to UBA data analysis, see below), conclude on acceptable risk 5) if TER trigger is breached for T. pyri, perform test with H. aculeifer or if TER trigger is breached for A. rhopalosiphi, perform test with F. candida 6) redo TER calculations with new effect values An analysis has been made in the UBA comparing available toxicity figures and risk quotients for H. aculeifer and F. candida with TER values obtained as described above. This analysis comprised 18 compounds for collembolans/insects and 24 compounds for mites with a slight bias towards more persistent and insecticidal compounds (due to current triggering of soil mesofauna tests). The assessment using NTA glass-plate toxicity data was in all cases at least as protective as the assessment using soil mesofauna toxicity data. In 16 out of 18 (collembolans/insects) and 24 out of 26 (mites) cases, the increase in protection was higher than one order of magnitude. Hence, the approach can be considered scientifically justified as well as sufficiently protective. Moreover, refinement of this tier 1 where required is easily possible by using either specific toxicity data for soil mesofauna organisms or by directly proceeding to higher-tiered semi-field or field studies.

Contributor	Section	Comment
UBA	6.1 Data requirements and testing	Soil micro-arthropod data requirements: The litter-bag test as an option for a refined risk assessment if any risk is indicated on tier 1 (collembolan or mite study) is not supported by DE. The outcome of this kind of functional test is not considered appropriate to decide whether populations of non-target soil micro-arthropods are at risk or not. Suitable options for higher tier testing methods (e.g. Terrestrial Model Ecosystems, TME) should be described and proposed in a tiered testing scheme. As asked for earthworm field studies in another comment, explicit guidance on the use of higher tier test results in risk assessment is needed. Such guidance should address both the ecological relevance of different effect types (effects on overall abundance/biomass versus effects on populations of single species/ community effects) as well as acceptable effect levels and effect duration in view of potential recovery.
US EPA/OPP/EFED	6.1 Data requirements and testing	Soil Organisms • The guidance document indicates that an acute effects study on earthworms is required if contamination of soil is possible. There are also some additional conditional requirements for earthworms. These data are not typically required by EPA, but may be requested on a case-by-case basis. However, these data would be useful for risk assessment purposes. The guidance document also indicates that tests on effects to soil microbes and soil nitrification and carbon mineralization are also required when soil may be contaminated. These data are not typically required or submitted to EPA, but may be useful in risk assessment.
AGES	6.2 Exposure assessment	- The data requirements and the risk assessment should be adapted according to what is being decided in the Annex II and III amendments of Directive 91/414/EEC (or the new Regulation) - Earthworm field studies: Further guidance on the evaluation of effects and acceptability criteria (% effects based on total earthworm numbers, individual species numbers or biomass). The “Guidance for summarising earthworm field studies”of de Jong et al. (2006) should be cited.

Contributor	Section	Comment
INIA	6.2 Exposure assessment	6.2. Exposure assessment some concerns are identified with respect to relevant exposure levels in ecotox data package versus Exposure in risk Assessment Schemes and depicted below: Exposure in ecotoxicity tests for the soil compartment: - Monitoring exposure in ecotoxicity tests is often not properly addressed. According with many international protocols, it is recommended to monitor the exposure concentrations at least at the beginning and at the end of the test. When exposure is not properly monitored, the time at which the effect occurs in static systems is unknown, and therefore the time to base the calculations upon is unknown too. On the other hand, in the best cases, when the concentrations are available, they are expressed as total content of pesticides and not as pore water concentration. Thus, clear guidelines are needed on how to proceed when not appropriate measurements of the exposure concentrations are available. We realize that for controlled and closed test systems, relatively simple calculation approaches can be used to estimate these exposure concentrations. However, for higher tier (or uncontrolled systems), the calculation of the exposure should require more complicated procedures. Clear guidance should welcome. - PECinitial, PECplateau and/or PECtwa?. In the current version, PECinitial or PECplateau are relevant concentrations for risk assessment when the product is applied only one time. For multiple applications the PEC after the last application is relevant. We consider that the inclusion of PECtwa is a good proposal for refining risk assessment, however, the necessary parameters for estimating that concentrations are not frequently available. Please, clear guidelines and uncertainties associated to these estimations are required. Regarding to PECsoil in the plateau a refinement of exposition may be calculate the plateau at 20 cm, and add the initial PECsoil at 5 cm. This approach is based on the agricultural practice of ploughing up the soil before sowing Ecological relevance of the total content of pesticide in soil or as pore water In the current version, the exposure is expressed in terms of total content in soil and not as pore water concentration. Information about ecological relevance of both measures would be welcome. It is expected that the concentration on the pore water or the total (bio)-available content in soil should be different. How to choose the more appropriate value? Proposals and uncertainties associated are needed. Exposure levels at several soil depths: In the current version, the total pesticide content in the top 5 cm of soil has been used. For refinement will be welcome to explore pesticide content in the top 30 cm, this should be relevant for meso- and macrofauna soil communities.
PSD	6.2 Exposure assessment	6.2 Soil Exposure assessment (pp27-28): It is recommended that the results of the workgroup revising the ‘Persistence’ Guidance Document are cited with respect to methods and procedures for calculation of PECsoil.

Contributor	Section	Comment
UBA	6.2 Exposure assessment	There is serious uncertainty whether the present exposure estimates for soil organisms are appropriate or at least sufficiently protective if used in risk assessment. This stems from the fact that the proposed model assumptions (e.g. homogeneous distribution of the chemical of interest in the upper 5 cm soil layer) are simplistic in view of the actual complexity of exposure encountered by the diverse soil organisms. For example earthworms: There are three different major ecological groups of earthworms to be protected (namely anecic, endogeic and epigeic) with distinct differences in expected exposure. Epigeic species are potentially highly at risk from direct overspray and contaminated food sources (residues on litter), while the probably most relevant route of exposure for anecic species is contaminated food (residues on litter) and for endogeic species it is exposure from ingesting contaminated soil. Hence, a review exercise is deemed necessary in order to answer this question (at least for earthworms and soil micro-arthropods). This is even more important as the design of e.g. earthworm tier 1 testing is not sufficiently standardised (see comment on earthworm toxicity testing above). Additionally, tillage and no-tillage cropping systems complicate this issue. The overall aim is to achieve a LINK between the exposure in laboratory and field ecotox studies and the expected exposure under proposed application conditions of the respective plant protection product. Again we strongly recommend striving for consistency to the GD "Persistence in Soil" already under development (or already drafted?). Additional comment: The earthworm example also indicates that similar simplistic approaches proposed to account for bioavailability in different soils (e.g. pore-water being discussed as the most relevant exposure route for all soil organisms) have severe shortcomings and should not be implemented without in-depth review and a robust scientific justification.
Ctgb	6.3 Risk assessment	6.3 Refined risk assessment for earthworms – Higher tier studies: Guidance on the use of safety factors on earthworm field studies would be welcome.
PSD	6.3 Risk assessment	Standard risk assessment for earthworms (p28): The appropriateness of the use of an EPPO correction factor to the results of earthworm lab toxicity studies (where the log Kow > 2.0) would benefit from further validation – since this factor was based on work with heavy metals. Also, it is our understanding that this correction is only required where the artificial test soil contains 10% or more organic matter. Refined risk assessment for earthworms (pp28-29): The acceptability criteria for affects on earthworms in field studies is not defined and further guidance is required on this. PSD (UK) has previously considered a demonstration of full population recovery within a year of treatment to be acceptable.
UBA	6.3 Risk assessment	Page 30, para 6: Whether the re-calculation of the soil content from application rate is indeed an appropriate option for “refinement” should be critically discussed, also in view of our other comments on earthworm toxicity testing (appropriate design). The other proposed refinement option of using natural soils in laboratory testing is considered of limited value - at least if artificial soils are believed to represent a “realistic worst case” soil exposure scenario. Hence, we propose to check the suitability.

Contributor	Section	Comment
UBA	6.3 Risk assessment	Page 30, para 5: There is some uncertainty whether the proposed critical TER values (TER-acute = 10 and TER-long-term = 5) are sufficiently protective for the long-term sustainability of earthworm communities under field conditions of agricultural use. There are two reviews addressing this issue (Heimbach (1992): Effects of pesticides on earthworm populations: comparison of results from laboratory and field tests. In: Greig-Smith et al. (Eds.). Ecotoxicology of earthworms. and Jones & Hart (1998): Comparison of laboratory toxicity tests for pesticides with field effects on earthworm populations: a review. In: Sheppard et al. (Eds.): Advances in earthworm ecotoxicology. SETAC, Pensacola Fl.). However the underlying data are limited and do not reflect the state-of-the-art especially in earthworm field testing. Therefore, a critical re-evaluation whether the protection goal is assured by the existing critical TER values is proposed.
UBA	6.3 Risk assessment	Page 30, para 4: Consideration of a factor accounting for bioavailability in standard testing systems is in principle considered justified. However, the current approach of using a fixed factor of 2 depending on a lipophilicity trigger (Pow > 2) is deemed to be too simplistic and should be refined. First, the selection of the trigger is not appropriate. In most other circumstances, a high Pow is understood as a driver towards substance accumulation in fatty tissues. But what is actually needed here is a descriptor for the tendency of a compound to be bound to the organic soil fraction, i.e. mainly humic substances. A Pow may be used for estimating such tendencies when no other data are available for a compound, but this is clearly not the case for active substances in plant protection products. Here, we will always have a set of Koc factors as the relevant descriptors for the strength of compound sorption to soil. Hence, this Koc dataset should also be used for triggering bioavailability correction. Second, a “digital” (either no correction or correction by a factor of 2) approach is likely to underestimate bioavailabilty for compounds shortly below the trigger and overestimate bioavailabilty. In the end, since TER values are directly proportional to the corrected or non-corrected effect values, quite different levels of protection could occur for relatively similar compounds. It should therefore be explored whether it would be possible to define some mathematical correlation between Koc and bioavailability in the testing system. Such correlation could then be a part of the risk assessment procedure, rather than proposing “corrected LC50” or “corrected NOEC” values. As mentioned in another comment, the test design for an earthworm reproduction study is not sufficiently standardised today, meaning that several distinct exposure scenarios are realisable, e.g. high/low peat content, food contaminated or not, admixing of test item in the substrate or surface spray etc. All of those parameters, not only the peat content, will probably affect the actual exposure level for the worms in the test vessels, but for an unknown extent. In practice, available test results do not provide a consistent picture in this respect (although a detailed review of test results in this respect was not undertaken); hence it is quite often difficult to decide whether bioavailability actually depends most on foc (correction required according to current GD) or more on other parameters (correction factor may be dropped according to current GD). All in all, it would be helpful if a recommendation could be made which of the possible test designs is most likely to ensure realistic worst-case exposure and should be preferred. Such recommendation should also include suggestions, for which type of test designs bioavailability correction is appropriate and how that should look like.

Contributor	Section	Comment
Mellifica asbl	6.4 Risk management options	About BEES 1. Synergic properties have been described in treatments where different substances (e.g. insecticides and fungicides) are mixed, which is common practice . This risk should be investigated as soon as suspected, for any non-target species. 2. Some insecticide have synergic effects with pathogenic fungi; Premise 200SC for instance is a PPP used against termites; this product disorientate the termites and make the soil fungi 10 000 times more dangerous, the Premise's advert explains. What about bees: fungi are present in the hives (Nosema, Beauveria) 3. The long-term effects of pesticides should be investigated as soon as chronic exposure is suspected. 4. The substance toxicity for larvae cannot be inferred from the toxicity for adult bees.A bee brood feeding test should be performed as soon as the bee brood exposure is suspected Regards.
individual	7 Non-target plants	Non-target plants are non-crop plants located outside the treatment area….. So far only higher plants are included the RA. Mosses, ferns and lichens are not considered. We feel that 8 plant species that are often weed species (and therefore r-strategy species) are not represneting the flora of Europe that is potentially present in the agricultural landscape. We also would like to draw attention to the fact that fungi are not addressed.
INIA	7 Non-target plants	7. Non-target plants (NTP) Please consider the output of ecotoxicology of Annexes II and III of Directive 91/414/EEC. These sections have been revised and have been commented by EFSA and other MS. The new of Annexes II and III are under revision for the commission. Please update the data requirements according to the approval of the new Annexes II and III. Only drift via is considered in order to assess the risk in NTP. Other routes as runoff and erosion may be important especially for persistant a.s. Guidance in this aspects are welcome
US EPA/OPP/EFED	7 Non-target plants	Non-target Plants • The guidance document indicates that plant studies are conducted on 6 to 10 plant species. A study that evaluates 10 species of terrestrial plants is required for pesticides with outdoor uses for EPA. • The trigger for conducting a Tier II plant test included in the guidance document is different than EPA"s – the guidance document indicates that Tier II studies are required if a 50% effect level is observed in one species, or if multiple species are affected (no quantitative value that constitutes an effect was given) in Tier I studies. EPA requires Tier II studies when a 25% effect occurs in 1 or more species in Tier I studies. • The guidance document considers spray drift to be the primary exposure route for terrestrial plants. However, EPA considers both runoff and spray drift. Also, the default spray drift values appear different than those used by EPA. Different spray drift fractions are given for various crops. However, the method used to derive these values is not described.

Contributor	Section	Comment
PSD	7.3 Risk assessment	7.3 Non-target plant risk assessment (pp32-33) Tier 2 Deterministic approach: It is currently stated that the trigger can be reduced if more than 6 species have been tested. It would be helpful to include further details (e.g. how many species, how far to reduce?). Tier 2 Probabilistic approach: It is currently stated that if the ED50 for less than 5% of the species (i.e. the HC5) is below the highest predicted exposure level the risk to terrestrial plants is acceptable, with no mention of use of an uncertainty factor or confidence limits being made. This is not in line with other areas of risk assessment. It needs to be considered whether the currently stated methodology provides the appropriate level of protection Tier 3 Higher tier risk assessment based on field studies: Further guidance as to how information on the 'ecological relevance of the observed effects' and on 'potential for recovery' could be used in a non-target plant higher tier risk assessment (including 'acceptability' criteria) would be helpful. How does the currently stated 'consequences on soil functions' relate to the NTP risk assessment?
Swedish Chemicals Agency	7.3 Risk assessment	7.3 Risk assessment 1. P34. The sentence should read: "If the ED50 for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to not be acceptable."
UBA	7.3 Risk assessment	Knowing that risk management is not in the remit of EFSA's PPR, we would nevertheless like to state that the TER acceptability criteria for decision making should be reconsidered in the final revised GD. In the approach currently followed in DE, effects on non target plants are considered acceptable when a TER = 10 is reached in a deterministic assessment based on the standard dataset for terrestrial plants. A TER value of 5 can be accepted if at least 10 species have been tested, whereupon this dataset should comprise species known to be sufficiently sensitive (demonstrated by, e.g., screening data or also efficacy data in case of herbicidal compounds). The same approach should also be applied to a risk assessment based on effect values from field studies performed as mono species studies, because these cannot contribute to a reduction of the uncertainty about interspecies variability in sensitivity.
UBA	7.3 Risk assessment	Considering the richness and diversity of the plant realm, a number of 8 species should normally be considered the lower limit for performing a probabilistic risk assessment. The current GD suggests that a HC5 over E50 values may be used directly in a risk assessment, i.e. without a safety factor. However, this implies that by performing an SSD, all sources of uncertainty would be addressed and no considerable uncertainty would remain with respect to the overall risk for plant biocoenoses. This is obviously not the case, since (i) the margin between EC50 and NOEC values is not considered, (ii) the additional information obtained from an alternative calculation method (SSD) is minimal once the single test results are available, and (iii) standard toxicity tests with plants cannot address issues like reproduction, which are also decisive for the risk in the natural environment. Additionally, indirect effects like species shifts in the off-field vegetation due to interspecific competition cannot be captured in a risk assessment based on single species tests (see B. Strandberg, Poster SETAC Europe 2008 "Effects of herbicide drift on hedgerow biodiversity"). In DE, a TER acceptability criterion of 5 is generally used if enough appropriate species have been tested, irrespective whether a probabilistic effect assessment has been performed with these data.

Contributor	Section	Comment
UBA	7.3 Risk assessment	When re-writing the section on risk assessment for terrestrial non-target plants, it is suggested that the following issues are discussed. The currently proposed selection of test species is based on technical aspects, but not on parameters like ecological relevance of species, species life-cycle characteristics, region of natural occurrence etc. Thus, the ecological representativeness of these test species is low. it is therefore crucial that their representativeness in terms of sensitivity is high enough to afford a sufficient level of protection for all species. Is this assumption supported by the available data? What information is available on differences in sensitivity between crop and non-crop species? Many plant taxa did not bear crop species. Thus, they might not be represented sufficiently by common crop species. Effects on the community level are currently not covered in the assessment strategy. It may be worth noting that a new SETAC Work Group on NTTP Risk Assessment was founded with the intention to develop options for higher-tier testing and risk assessment for terrestrial plants.

ABBREVIATIONS

GD	Guidance Document
HQ	Hazard Quotient
MS	Member State
NTA	Non-Target Arthropods
PEC	Predicted Environmental Concentration
PPP	Plant Protection Product
RA	Risk Assessment
RM	Risk Management
TER	Toxicity Exposure Ratio
TWA	Time Weighted Average