REBECA Regulation of Biological Control Agents

Review of potential risks of botanicals and semiochemicals

Minutes of a workshop held on 13 – 14 June 2006 in Brussels

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Review of potential risks of botanicals and semiochemicals – Minutes of a workshop held on 13 – 14 June 2006 in Brussels.

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Agenda

Tuesday, 13 June 2006

Time	subject	speaker
12.00	*Arrival, registration, sandwiches*	
13.30	Welcome; administrative matters; introduction to the workshop	B. Speiser
13.40	Introduction to the REBECA project	R.U. Ehlers
13.50	Participants introduce themselves	Facilitator: B. Speiser
14.10	DG SANCO's point of view (presentation & questions)	W. Reinert
14.45	Experience with the UK pilot scheme and consequences for the biopesticide scheme	L. Moakes
Risk assessment for botanicals		
15.00	Example for a botanical: neem	H. Kleeberg
15.10	Examples for low-risk substances which are not plant-derived	L. Tamm
15.20	Data requirements for botanicals according to Sanco/10472/2003 – rev. 5	T. Mercier
15.50	Regulation of botanicals & semiochemicals in Switzerland	F. Fraga
16.00	Regulation of botanicals & semiochemicals outside Europe	B. Speiser, J. Hauschild
16.10	*Coffee break*	
16.30	Risk assessment for plant strengtheners in Germany	A. Makulla
16.45	*Discussion:* prioritize and comment on risks and risk assessment procedures for botanicals	Facilitator: R.U. Ehlers
17.45	*End of first day*	
18.45	*Meeting at the bar of Hotel Astrid*	
19.15	*Dinner at Restaurant «Scheltema», 7 rue des Dominicains*	

Wednesday, 14 June 2006

Risk assessment for semiochemicals		
9.00	Newly arrived participants introduce themselves	Facilitator: B. Speiser
9.05	Examples of semiochemicals	V. Veronelli
9.15	Data requirements for semiochemicals according to OECD Guideline 12	W. Sexsmith
9.45	New guidelines of the UK PSD concerning semiochemicals	S. Mattock
10.00	*Discussion:* prioritize and comment on risks and risk assessment procedures for semiochemicals	Facilitator: R.U. Ehlers
10.30	*Coffee break*	
Suggestions for improvements		
10.45	Introduction to group work	B. Speiser
10.50	Group work: (i) improvements for botanicals & other low-risk substances; (ii) improvements for semiochemicals; (iii) administrative improvements	
12.00	Plenum: Presentation of results of group work	Fac.: R.U. Ehlers
12.45	*Sandwich lunch*	
13.15	Group work, continued	
14.00	Final discussion, concluding remarks	Fac.: R.U. Ehlers
14.25	Next steps	B. Speiser
14.30	*End of workshop*	

Participants

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Introduction to the REBECA project

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Ehlers.pdf

DG SANCO's point of view

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20Assessment%20Botanicals%20Reinert_Sanco.pdf

Experience with the UK pilot scheme and consequences for the biopesticide scheme

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Moakes.pdf

Example for a botanical: neem

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Examples for low-risk substances which are not plant-derived

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Data requirements for botanicals according to Sanco/10472/2003 – rev. 5

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Mercier.pdf

Regulation of botanicals & semiochemicals in Switzerland

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Fraga.pdf

Regulation of plant extracts and semiochemicals in Australia

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Hauschild.pdf

Regulation of Biological Control Agents in Australia is laid down in the "Guidelines for the Registration of Biological Agricultural Products". The Australian Pesticides and Veterinary Medicines Authority (APVMA) is responsible for the assessment and registration of agricultural and veterinary chemical products. Actual data requirements depend on the product and its use pattern, so that actual requirements are decided with flexibility and case-by-case.

According to the Australian regulation, Biological Agricultural Products are defined as products, where "...the active constituent comprises or is derived from a living organism (...) with or without modification...". These active constituents comprise four major groups:

1. biological chemicals (e.g. pheromones, hormones, growth regulators, enzymes and vitamins)
2. extracts (e.g. plant extracts, oils)
3. microbial agents (e.g. bacteria, fungi, viruses, protozoa)
4. other living organisms (e.g. microscopic insects, plants and animals plus some genetically modified organisms)

Not included in this definition are plant growth promoting products that are not based on hormones or fertilisers, and invertebrate biocontrol agents like predatory insects, mites, and macroscopic parasites. It is important to note that biologically derived chemicals that have direct toxicity to the target species are exempted from the regulation presented here. Another group exempted from this regulation are biologically derived chemicals where purification and full identification is possible, e.g. nicotine, strychnine, rotenone and ivermectin.

The active constituents considered in this presentation, semiochemicals and plant extracts, belong to groups 1 and 2, respectively. Products containing semiochemicals are characterized by low exposure of humans or non-target organisms to the active substances. This low exposure is due to very low application rates, high volatility, and the application in bait, trap or encapsulated formulation. Furthermore, semiochemicals have a potential for low toxicity.

Plant extracts may be used in unpurified or purified form. However, purification has to be incomplete and the composition not fully characterised. Examples are "pyrethrum", consisting of a mixture of related pyrethrins, or neem oil and neem extract, consisting of a mixture of characterised and uncharacterised components. If the composition of a plant extract can be fully characterized, full data requirements as for chemicals are applicable for the corresponding product.

Data required for semiochemicals and plant extracts firstly concern the biological properties of the active constituent:

- natural occurrence and distribution in Australia of the source organism
- natural occurrence of the chemical or relationship to the form occurring in an organism
- mode of action and specificity
- likely biological effects arising from use

Information concerning chemistry and manufacture (with emphasis on product composition and contaminants), and toxicology and occupational health and exposure is similar to that required for chemicals. Reduced data requirements compared to chemical plant protection products are applicable for residues (where studies are not normally required), for environmental fate and for ecotoxicology. Data requirements on efficacy are basically the same as for chemical products, "but a reduced level of efficacy may be accepted for a product that has advantages in reduced hazards to humans or the environment".

The following tables give an overview on plant extracts registered in Australia (table 1) and on those extracts that are exempted from approval by APVMA (table 2).

Table 1: Botanicals as active ingredients in agricultural products

Azadirachtin
Bitter orange extract
Extract of lemon eucalyptus
Neem seed extract powder
Rosemary oil
Spinosad

Table 2: Active constituents excluded from the requirements of APVMA approval

Cabbage extract
Canola oil
Capsicum oleoresin
Chilli extract
Citronella oil
Cypress wood oil
Derris dust
Eucalyptus oil
Garlic extract
Garlic oil
Lanolin oil
Lavender fragrance
Lime oil
Orange oil
Pine oil
Pyrethrins, Pyrethrin I, Pyrethrin II
Quassia
Rotenone
Salicylic acid
Sesame
Tea tree oil
Thymol

Risk Assessment for Plant Strengtheners in Germany

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Makulla.pdf

Plant strengtheners or plant resistance improvers make their own category of products in Germany. They are regulated by the German Plant Protection Act (PPA), so are also plant protection products. Plant strengtheners are defined in Article 2 no. 10 as substances that are (a) solely intended to enhance the resistance of plants to harmful organisms, (b) intended to protect plants against non-parasitic impairments, or (c) intended for use on cut flowers. This means that plant strengtheners may not have any biocidal effects nor effects that are covered by the definition of a plant protection product (PPP; e. g. as growth regulators or repellents).

The risk assessment in the course of the listing procedure is based on material safety data sheets for all the ingredients and additional data given by the applicant, and follows the pathway of answering the questions: is there any risk inherent in one of the substances or in the product?

(1) The environmental risk assessment furthermore gives special interest to the predicted concentration of the substances in the environment. If certain applications are too risky to the environment, they might be excluded. But, unlike for PPPs, no sophisticated risk management is accepted for plant strengtheners, i. e. the use has to be safe without risk mitigation. Otherwise a listing of such a product is not feasable.

(2) For the risk assessment in toxicology, the criteria are similar to those for home and amateur gardening, i. e. toxic substances are not allowed in plant strengtheners. The use of irritant products is restricted to professional users (only very few, exceptional cases). For products containing micro-organisms, the criteria of the directive 91/414/EEC are adopted.

(3) The assessment in efficacy covers mainly the question whether any of the ingredients acts as an active substance in the sense of a PPP with the exception of products for use on cut ornamental flowers: they may contain plant hormones. Only the plausibility of the mode of action is checked, but studies on efficacy are not required.

To conclude, plant strengtheners are products of low risk, but they are not congruent with the planned low risk category of the Directive 91/414/EEC. Because plant strengtheners must not act directly on harmful organisms, they most likely do not have effects on non-target organisms.

For further information on listed products, the listing procedure and the application form please see: www.bvl.bund.de

Examples of semiochemicals

Vittorio Veronelli
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and Shin-Etsu Representative for the IBMA EU Task Force on pheromones

Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Veronelli.pdf

Semiochemicals are chemicals mediating interactions between organisms; insects make a wide use of them to exchange communications for their survival. Pheromones are used to transport stimuli among individuals of the same species and Lepidoptera use them specifically for mating.

The sexual pheromones of Lepidoptera are among the most investigated since decades. Chemically, they resemble fatty acids such as many oleic compounds, and are based on linear carbon chains with some oxygen and hydrogen groups. They are well known as'SCLP' (Straight Chained Lepidopteran Pheromones) and are widely used to establish the activity of insects pest (Monitoring) or to control them directly or indirectly (Mass Tapping, Lure & Kill, Mating Disruption etc.).

Synthetic mimics of SCLP applied to disrupt mating through various methods of release have gradually gained popularity as PPP and Mating Disruption is now regularly applied on more than 600 000 ha of crops and forests worldwide.

Their indirect mode of action (not killing even the target, just disturbing the male flight orientation), the extremely low amount released in the field both on short and long time, the extremely small amount persisting in air and the specific low toxicity and extremely rapid environmental degradation combined with their preventive activity to reduce pest populations are the basis of their success.

The application of synthetic pheromones to control indirectly those insect pest, the larvae of which spend most of their lives inside the crop (such as in viticulture and fruit production) have contributed to reduce the total chemical input and the residues considerably.

Data requirements for semiochemicals according to OECD Guideline 12

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Download of slides: http://www.rebeca-net.de/downloads/Risk%20assessment%20botanicals%20semiochemicals%20Sexsmith.pdf

An overview of the background leading up to the development of OECD Series on Pesticides Number 12, 'Guidance for Registration requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control', as well as the key issues and results was presented. The impetus for the work under the OECD Pesticide Programme came out of the harmonization activity related to arthropod pheromone data requirements between the United States and Canada. In addition, there was interest within the OECD Pesticide Programme to facilitate access to reduced risk pesticides. A process was initiated with Canada as lead, to compare current data requirements among countries, review areas of similarity and of differences and to build consensus towards common data requirements. This included an OECD workshop hosted by Canada in Ottawa, in 1999.

A key focus for discussion was the fact that data requirements should be reduced, particularly for Straight-Chain Lepidopteran Pheromones (SCLP) because pheromones are different from conventional chemical pesticides, being non-toxic, target specific and naturally occurring chemicals that have low application rates, dissipate rapidly and for SCLPs are very well characterized. This rationale, building on the US White Paper on this topic, was developed as a critical part of the OECD Guidance document. With this as a rationale, substantial reduction of data requirements was agreed, particularly for the SCLPs, with minimal toxicity data required, no residue chemistry and metabolism data required, no exposure data required, no environmental toxicity and fata data required, and reduced information for efficacy required, as compared to conventional chemicals. This was considered appropriate to the risk, with substantial harmonization achieved in the 2001 OECD Guidance document, with some key differences remaining.

UK evaluation of a mating disruption pheromone

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The UK pesticide regulatory authority used the OECD guidance on semiochemicals to evaluate a mating disruption product (codlemone). The pheromone was considered as a new active substance in the UK. It was evaluated under UK national requirements because codlemone is on the 4th list of the 91/414/EEC review programme. The application was considered by the independent UK Advisory Committee on Pesticides (ACP), who accepted the risk assessment approach as outlined in the OECD guidance.

The risk assessment was based on the series of reduced data requirements and/or waivers specified for straight chain Lepidopteran pheromones (SCLP). It made use of the information and published data provided in the guidance document. Although using this as the basis, the evaluation also identified any specific issues relating to the product formulation and use which required further consideration. These were addressed by reasoned cases and the submission of further information. In addition, UK legislation required information to classify and label the active and formulated product.

The efficacy requirements were addressed by a series of reasoned cases, trials and other information. Exceptionally a limited literature search was also undertaken to gain a better understanding of the technique and assist in interpreting the data provided. The UK operates a flexible system to address efficacy, which allows the use of relevant non-UK data, will approve varying levels in performance provided a measurable benefit is demonstrated, and the submission of relevant published information to support a data requirement.

The mating disruption product was evaluated under the auspices of a UK pilot scheme for biological products, which has now been replaced by the ‘Biopesticides Scheme’. Its aim is to assist the approval of biological products through reduced fees and, where appropriate, reduced data requirements. Part of the scheme is to provide guidance. The UK therefore has produced a draft guideline – ‘Efficacy guideline 220: Data requirements and trials design for mating disruption product’. This is available on the PSD website and comments are welcome (www.pesticides.gov.uk). Many of the issues discussed will also apply to other semiochemical techniques.

The guideline firstly discusses addressing the 91/414/EEC efficacy data requirements. It emphasizes the importance of preliminary data and published information on the target pest and semiochemical. This can be used as the basis of reasoned cases either to replace or reduce the amount of data required. It also greatly assists the evaluator in interpreting the data provided. The second part of the guideline highlights the key factors for mating disruption pheromones which affect trials design. It discusses issues relating to the choice of site, plot size and replication, monitoring, and assessments. This information on trials design has been drafted into a proposed EPPO guideline which will be taken forward to the next EPPO fungicide/insecticide working panel.

Report of the working group «botanicals»

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Participants

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Review of potential risks

'Botanicals' covers an extremely heterogeneous group of substances, i.e. unprocessed and processed plant extracts. In addition, this working group also dealt with simple chemicals and microbial metabolites. Furthermore, plant extracts and microbial extracts may be highly refined (i.e. 1 active substance) or represent a 'cluster' of substances present in an extract. Characteristics of substances may be very well known (edible, traditional use, e.g. fennel oil, garlic oil, rape seed oil) or virtually unknown a priori (e.g. spinosin A). Extracts of plants (and microbials) may vary due to variability in the composition of the raw material (e.g. neem extracts) and/or due to processing/storage conditions.

In conclusion, risks associated with the use of 'botanicals' may vary between very low and very high. Risks should therefore be assessed case-by-case. The discrimination of low risk substances from other substances should be the result of an assessment.

Characterization of substances

Plant extract-based PPP may be highly refined or may consist of clusters of substances. The definition of components of the 'substance', the concentrations as well as the quality (e.g. absence of contaminants) of the extract need to be specified. The definition should (i) specify the main active components (either a.i. itself or a suitable lead substance), and (ii) allow for feasible analytics. Risk assessments should be done with defined (standardised) clusters of substances if an assessment with the individual compounds is not feasible or not practical.

Proposed actions: prepare guidelines for specification of substance clusters (and potential contaminants)

Review of current registration and risk assessment practices

As the risk may vary substantially between individual substances or groups of substances, the current scheme of risk assessment established for new active substances applies in principle also to botanicals. However, pre-existing knowledge of risks ("history of safe use") is sometimes not sufficiently used in evaluation processes (e.g. to allow for waivers). A strategy to overcome this bottleneck consists in applying a tiered evaluation approach which includes the rules to allow for waivers. In the USA, a catalogue of waivers has been prepared which mirrors the current practice in data requirements.

For PPP made from plant extracts, the SANCO draft guidance document (SANCO/10472 rev. 5) specifies a tiered evaluation process. The draft guidance document is presently used by some MS in the 4th stage evaluation process. Regulators and industry currently gain experience with the use of the guidance document. A review of the experiences will facilitate further improvements of the guidance

document. Improvements of the guidance document may include grouping of substances, addition of substances/plants to the 'reference list' etc. Further improvements may be achieved by adding experience from OECD member countries.

For certain chemical substances, the SANCO draft guidance document (SANCO/10473 rev. 4) specifies an evaluation process restricted on tier 1.

Data requirements may vary substantially between MS and therefore hamper the predictability of the registration process. Strategies to overcome this important bottleneck include (i) mutual recognition of registration between MS, and (ii) the use of guidance documents to harmonize data requirements between MS. However, a prerequisite for harmonization between MS is information exchange between regulators. Additional efficacy has been achieved by inviting the industry to 'pre-submission consultation meetings in order to specify data requirements.

Proposed actions

- prepare catalogue of accepted waivers (sorted by substances).
- All stakeholders to review their experiences with the application of the guidance documents.
- encourage information exchange between regulators (e.g. e-mail group of experts, training opportunities for experts).
- encourage pre-submission consultation meetings between regulators and industry (already successfully implemented in several MS).

Draft action plan for botanicals

Objective	Instrument	who	When
Inventory of current registration practice	Part of REBECA	WP 2	2006
List of permitted waivers (data requirements, substances)	Inventory of waivers		
SANCO guidance document improvement			
Extensions of positive list	Conference 1		2006
Revision of guidance document based on recent experiences use OECD framework.	Conference 1	European Commission	start: 2006
Initiate e-mail group of experts	List of contact points	A. Fjelsted	Done
Exchange of experience and training of regulators and applicants			
Pre-submission consultation		Member State authorities	
Evaluate existing alternative approaches (positive lists of low-risk substances, plant strengtheners)			
Close gap between annex 1 inclusion and plant strengtheners (data requirement)			

Report of the working group «semiochemicals»

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Participants

Wendy Sexsmith (leader), Susan Mattock (notetaker), David Cary, Robin Sheppard, Bernhard Speiser, Olaf Strauch, Vittorio Veronelli, Gillian Walters

Risks

The participants agreed with the view expressed in OECD guidance document No 12 («Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control». OECD Series on Pesticides, Number 12, 26-Feb-2002; thereafter called «OECD 12») that semiochemicals have low inherent toxicity and present a low risk. (note from the editor: some keywords on the rationale are given in the introduction to OECD 12: semiochemicals modify behaviour of the pest species rather than killing them, they are more target specific than conventional insecticides, are used at concentrations close to those in nature and dissipate rapidly)

OECD guidance

OECD 12 proposes a reduced data set for semiochemicals. Further reductions in data requirements are proposed for straight-chained lepidopteran pheromones (SCLPs). Note: The US EPA are proposing further reductions in data requirements, compared with OECD 12. OECD 12 is a guidance document, and registration authorities are not obliged to adopt it. However, OECD 12 reflects a clear and broad consensus among regulators, and all EU member states have had the opportunity to feed their views into this document. The UK have used the OECD guidance in approving a pheromone product and are content to continue to use it for future applications. However, some member states require additional data, for example during the 91/414 re-registration process. There was a discussion in this working group whether this would set a precedent, with additional data being requested regularly in the future. Because the OECD 12 data requirements were considered sufficient, such a development would be considered undesirable and retrograde. Suggestions:

- **The EU should formally adopt OECD 12, or an improved version of it (see second bullet-point), to ensure a consistent approach between Member States. Such an adoption is possible within Directive 91/414. In the meantime, national registration authorities are encouraged to adopt OECD 12.**
- **Straight-chained pheromones of non-lepidopteran (e.g. coleopteran) origin should have the same, reduced data requirements as SCLPs. For other semiochemicals, it should be decided on a case-by-case basis whether they have to meet the data requirements for SCLPs or for other semiochemicals.**

Build-up of expertise

One major problem with the registration of semiochemicals is that many regulators have very little expertise with this special type of products. This may cause delays and uncertainties, e.g. regarding the acceptance of waivers. Better communication should lead to a consistent interpretation of OECD 12 (e.g. acceptance of waivers). Suggestions:

- **REBECA should look at different mechanisms to improve communication and harmonization between member states** (e.g. meetings, e-mail groups etc.). Note: as a first step, the UK PSD will consider to disclose risk assessment documents, to illustrate how UK applied the OECD guidance (note from the editor: it was asked whether the proposed “Network of Excellence” will help in providing expertise for regulators).

Registration under the biocides directive

Some semiochemicals are used both as Plant Protection Products (PPPs or pesticides) and as biocides. Applicants experience considerable differences in data requirements and in registration costs in the two procedures. Suggestions:

- **Data requirements for registration of semiochemicals as PPPs and as biocides should be harmonized.**
- **OECD 12 should also be adopted within biocides directive (98/8).** Note: this might be difficult because they already adopted guidance (note from the editor: it was later commented that this guidance is in effect OECD 12 reworked to remove many of the waivers).
- **Costs of evaluations and discrepancies between biocides and PPPs need to be addressed.**

Flexibility

Requirements concerning efficacy data must be flexible and need to recognise that mode of action and effect are specialized. The effect will not be population related, but usually yield benefits (marketability) and/or mating reduction. Suggestions:

- **A flexible approach can be based around a combination of cases, published information, development work and field trials.** Note: there is a UK draft guidance on addressing data requirements and trials design based on these ideas. The latter part is now being taken forward as an EPPO guideline.

Test methods for risk and efficacy are currently the same as for conventional pesticides. Some of these may not be applicable.

Example 1: bee test

In the past, a company has been asked to spray pheromone directly onto bees, even though this is not relevant to product use. **Suggestion: Where test methods for risk and efficacy are not applicable, a reasoned case as to non-relevance should be sufficient.** Note: currently, the UK interprete Dir. 91/414 in this way. EPPO also acknowledge that alternative methods, or deviations from standards, may be justified (PP 1/223(1) Introduction to the efficacy evaluation of plant protection products).

Example 2: analysis of impurities

Dir. 91/414 requires analysis down to 0.1% for impurities. In view of (a) the mode of application which prevents direct contact with crops, and (b) the low application rates, higher levels of impurities in pheromones/semiochemicals? than in other pesticides ought to be accepted. **Suggestion: Requirements for analysis of impurities should be reduced for pheromones/ semiochemicals.**

Example 3: 5 batch analysis

Dir. 91/414 also requires GLP 5 batch analysis. For some pheromones not produced every year, this would be pseudo-replicated analysis of same sample. Not all OECD members have GLP requirement. **Suggestion: Where not applicable, it should be possible to waive the requirement for GLP analysis of 5 batches** (note from the editor: it was later suggested that it should also be possible to waive the requirement for GLP analysis of 5 batches including where there is no benefit resulting from this information).

Crop destruction

Costs of crop destruction after experimental use are prohibitive for efficacy trials. Suggestions:

- **For trials with pheromones, crop destruction should not be required.** Note: in some member states, there is a waiver and destruction is not required based on the fact that they are not applied directly to the crop.

Harmonization and work sharing

For most pheromones, data required are mainly pest specific and little dependent on country or geographic zone. Conclusion:

- **Semiochemicals represent a good opportunity for international sharing of evaluations and disclosure of risk assessments**, e.g between the EU and North America and other regions.

Official recognition
Costs of official recognition (GEP) in different member states can be prohibitive for small companies. The working group did not propose a solution for this problem.

Definition of active ingredient
Semiochemicals are often applied as blends, either of different substances or of different isomers of the same substance. The precise wording of the listing in Annex 1 of Dir. 91/414 decides what is the active ingredient and has an impact on defining what is a new active. The listing in Annex 1 is a responsibility of the Commission (DG SANCO). Suggestions:

- **The impact of different modes for listings of semiochemical actives should be studied.**
- **The Commission and the REBECA project should jointly organise a meeting to discuss this with interested parties.**

Role of EFSA
The participants were uncertain of the procedural workings of EFSA in reviewing guidance and commenting on them, e.g. what are timelines? (note from the editor: prior to the workshop, REBECA has obtained contact with Christopher Lythgo from the EFSA. He expressed his regret for not being able to participate in the workshop and wished to stay informed about the progress.

Priorities
The working group considered the following issues to be the highest priority:

1) EU-wide, formal adoption of OECD 12 and more harmonized interpretation.
2) Harmonization of data requirements under the biocides directive 98/8 with those under the pesticides directive 91/414. Ideally, formal adoption of OECD 12 also under 98/8.
3) Flexibility in data requirements, e.g. for efficacy and analytical data.

Actions for the REBECA project
The working group suggests that the REBECA project should …

- work towards adoption of the OECD 12 criteria in the EU (note from the editor: The working group did not specify whether (a) the Commission (DG SANCO, contact person: Wolfgang Reinert) should prepare an EU guidance document based on OECD 12, or (b) data requirements for semiochemicals should be implemented into the directive. In case (b), they would be legally binding, but it would probably take longer time to obtain consensus for such a directive).
- suggest to all EU member states to use OECD 12 as a guidance document during the transitory phase until it has been finalised as an EU guidance document and until member states have formally taken note of the document. (contact person: Anita Fjelsted).
- work towards harmonization of the registration practice for semiochemicals under the biocides directive 98/8 with that under the plant protection products directive 91/414, and towards adoption of the OECD 12 criteria under the biocides directive 98/8 (DG Environment, contact person: Jürgen Helbig (juergen.helbig@ec.europa.eu) (note from the editor: it was not discussed how this should be achieved. Once an EU guidance document with data requirements for semiochemicals is in place, DG SANCO and DG environment ought to obtain harmonization of these data requirements of plant protection products and biocides).
- suggest to the OECD Biopestides Steering Group to amend OECD 12, e.g. in the light of the further reductions in data requirements for pheromones proposed by the US EPA (contact person: Anita Fjelsted).
- look into mechanisms which might build up expertise and improve international exchange of experience with semiochemicals among regulators.
- reflect on the impact of different modes for listings of semiochemical actives, and discuss this with interested parties together with the DG SANCO.