



## **Deliverable 14:**

### **Summary of risks and tools to determine risks for botanicals and semiochemicals**

#### **REBECA**

Regulation of Biological Control Agents

Specific Support Action

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### Document History

The document is based on the results of 2 workshops conducted in Brussels, Belgium, June 13-14, 2006 and in Salzau, Germany, September 18-22, 2006. Experts from science, regulatory authorities and industry attended the meetings and reviewed the minutes, which were used to produce this document.

### Document Abstract

The potential risks of «botanicals» & «semiochemicals» are reviewed in separate sections. The main focus is on human and environmental risks, testing methods, data requirements for registration and rationales for reduced data requirements. The document delivered the basis for subsequent workshops on 'improved regulatory procedures for botanicals and semiochemicals'. Therefore, proposals or recommendations on improved data requirements and test system in the present document are preliminary.

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## Botanicals

### ***Botanicals in plant protection***

Plants, and particularly plant extracts, have been used for plant protection since a long time<sup>1</sup>. Extracts can range from crude to highly purified. Quantitatively, the most important botanical is pyrethrum, followed by neem, rotenone and essential oils. Ryania, nicotine, sabadilla, garlic oil and *Capsicum* oleoresin have limited use<sup>2</sup>. Typical uses are:

- **insecticides** (e.g. pyrethrum, rotenone, rape seed oil, quassia extract, neem oil, nicotine),
- **repellents** (e.g. citronella),
- **fungicides** (e.g. laminarine, fennel oil, lecithine),
- **herbicides** (e.g. pine oil),
- **sprouting inhibitors** (e.g. caraway seed oil) and
- **adjuvants such as stickers and spreaders** (e.g. pine oil)

### ***Other use of botanicals***

Plant extracts and other materials of plant origin are also used for purposes not covered by Dir. 91/414, such as

- **fertilizers and soil conditioners** (e.g. green waste compost, seaweeds and seaweed extracts, sawdust, wood chips, composted bark, bark of hemlock pine [iron micronutrient fertilizer]),
- **biocides** (e.g. pyrethrum, neem),
- **foods and spices**. Some plant products which are mainly used as foods or spices also have a secondary use in plant protection, e.g. rape seed oil, lecithine, garlic, mustard powder, fennel and caraway. Use in plant protection is covered by Dir. 91/414, but is quantitatively minimal in comparison to use for human consumption.

### ***Environmental impact and human health risks of botanicals***

'Botanicals' covers an extremely heterogeneous group of substances, i.e. unprocessed and processed plant extracts. Furthermore, plant 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. Extracts of plants 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.

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<sup>1</sup> See B.J.R. Philogène, C. Regnault-Roger and C. Vincent (2005): Botanicals: Yesterday's and today's promises. In: Biopesticides of Plant Origin, C. Regnault-Roger, B.J.R. Philogène and C. Vincent (eds), Intercept Ltd, pp 1-15.

<sup>2</sup> M.B. Isman (2006): Botanical insecticides, deterrents and repellents in modern agriculture and an increasingly regulated world. Annual Review of Entomology 51, pp 45-66.

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 covered by the term botanicals***

The characterization of 'substance', as required by Dir. 91/414, poses major problems in plant extracts. In contrast to chemicals, plant extracts contain more than one compound /substance and variability of the presence of individual components is inevitable which poses substantial problems in current registration.

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.

### ***Assessment of chemical properties***

Plants contain a multitude of chemical substances, and the same is true for plant extracts (e.g. water and ethanol extracts), unless if they are highly purified. One or several substances may be active against the target pest, one or several substances may present a hazard to human or animal health or the environment, and many other substances have neither effect.

Often, the «active substance» is a cluster of very similar substances. For example, pyrethrum contains three esters of chrysanthemic acid and three esters of pyrethric acid. Of these, pyrethrin I and II are the most abundant and account for most of the insecticidal activity. Neem contains more than a dozen azadirachtin analogues, but the major form is azadirachtin, and the other analogues contribute little to overall efficacy. Neem also contains other triterpenoids such as salannin, nimbin, and derivatives thereof. Their role has been controversial, but seems to be minor in comparison to azadirachtin<sup>3</sup>. In conclusion, it is often not possible in botanicals to draw a clear line between active and inactive substances. However, it is usually possible to identify one or a few substances which are responsible for most of the activity of the extract.

In contrast to synthetic pesticides, plant extracts almost inevitably contain a large array of highly diverse substances which are hardly or not at all responsible for the effect on the target pest. In terms of Dir. 91/414, they are considered as «by-products» or «impurities». If they are present in quantities  $\geq 1$  g/kg in the active substance as manufactured, they are considered as «significant impurities». If they are of toxicological and/or ecotoxicological or environmental concern, they are considered as «relevant impurities» (see Annex IIA, Point 4.).

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<sup>3</sup> M.B. Isman (2006): Botanical insecticides, deterrents and repellents in modern agriculture and an increasingly regulated world. Annual Review of Entomology 51, pp 45-66.

Two groups of substances may present a hazard to human or animal health or the environment: (i) certain plant metabolites with high toxicity<sup>4</sup>, and (ii) microbial metabolites or decay products which may be formed during manufacture<sup>5</sup>. The presence of other plant metabolites is unavoidable (except if they can be eliminated by purification), while microbial decay products can be avoided with appropriate quality management.

## ***Rationales for reduced data requirements regarding risk assessment***

### **Draft working document SANCO/10472**

Reduced data requirements are described in the SANCO draft working document 10472<sup>6</sup>. However, this document is not legally binding and has been used rarely until now, so there is only little experience with its practical application.

The data requirements in SANCO/10472 apply to plant protection products made from all edible parts of plants used for animal or human feed, and in addition to other parts of plants which are listed explicitly<sup>7</sup>. It also applies to parts of plants currently authorised as herbal drugs in European pharmacopoeia and known traditionally for plant protection properties, which are listed explicitly<sup>8</sup>. Further, the data requirements apply only to plant extracts made with water and/or ethanol. For plant protection products made from other plants or plant parts or with other solvents, data requirements will be established case-by-case in a pre-submission meeting, based on the available information. It is not exceptional that plant extracts are used as such. For registration purposes, the extract is therefore to be considered as the active ingredient and also as the plant protection product. Therefore, the guidance has not been separated in requirements for Annex II (active substance) and Annex III (plant protection product), but has to be interpreted on a case-by-case basis.

The document identifies two categories: Category 1: PPP made from one or several *plants*; category 2: PPP made from one or several *plant extracts*. A tiered approach is taken, where the tier 1 data requirements are explicitly described and tier 2 data can be requested on a case-by-case basis.

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<sup>4</sup> E.g. alkaloids, terpenes, glycosides

<sup>5</sup> E.g. mycotoxins

<sup>6</sup> SANCO/10472/2003 – rev. 5 (6.7.2004). Draft working document concerning the data requirements for active substances of plant protection products made from plants or plant extracts.

<sup>7</sup> artichoke (edible parts), basil (whole plant), black pepper (fruit), carvi (fruit), chives (clove), coriander (fruit), elder (bark, flower, fruit), garden sage (whole plant), garlic (clove), horse tail (leaf), laurel (leaf), mint (whole plant), olive (oil), onion (bulb), oil seed-rape (oil), sesame (seed), soybean (oil), squash (seed), sunflower (oil), tomato (fruit)

<sup>8</sup> bladder wrack (thallus), feverfew (whole plant), lavender (whole plant), nettle (whole plant), rhubarb (rhizome only), sweet chamomille (whole plant)

## Low-risk and basic substances

The proposed new Regulation<sup>9</sup> on plant protection products contains special requirements for «low risk active substances» and for «basic substances». These are relevant for a number of botanicals. The proposal does not specify how a low risk substance is identified. Low risk active substances are approved for longer periods than other substances (Art. 22), and products based on low risk active substances are authorized within short periods (Art. 46).

Basic substances are defined as active substances which (i) are not predominantly used as a plant protection product but (ii) nevertheless have some use as a plant protection product, either directly or in a product consisting of the substance and a simple diluent, (iii) are not substances of concern, and (iv) are not directly marketed for use as plant protection products. Examples could be rape seed oil, garlic oil, fennel oil, caraway seed oil, lecithine or essential oils.

## Plant strengtheners

Plant strengtheners are not regulated at EU level. There have been attempts to define data requirements for plant strengtheners with low risk profile (SANCO/1003/2000 rev. 3). However, these activities have been discontinued.

## Minimal Risk Pesticides

In the USA, there is a list of substances that can be used as pesticides without any registration. These substances are called Minimal Risk Pesticides, the list is known as «25b list». The list contains many essential oils. All inerts must be on EPA's 4A inert list, all ingredients must be identified on the label, and the label may not contain false or misleading claims. Currently, the 25b list includes, among others, the following botanicals: castor oil, cedar oil, cinnamon and cinnamon oil, citric acid, citronella and citronella oil, cloves and clove oil, corn gluten meal, corn oil, cottonseed oil, eugenol, garlic and garlic oil, geraniol, gernanium oil, lauryl sulfate, lemongrass oil, linseed oil, malic acid, mint and mint oil, peppermint and peppermint oil, rosemary and rosemary oil, sesame (includes ground sesame plant) and sesame oil, sodium lauryl sulfate, soybean oil, thyme and thyme oil and white pepper.

In Australia, the following plant extracts are excluded from the requirements of APVMA approval as constituents in plant protection products: 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 and Thymol.

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<sup>9</sup> Proposal for a Regulation of the European parliament and of the Council concerning the placing of plant protection products on the market. 2006/0136 (COD), 12.7.2006.

## **Substances of low concern**

The Commission (DG SANCO) is currently working on a new regulation which will contain criteria for identifying active substances of 'low concern'. These criteria are not specifically made for botanicals, but it is likely that some botanicals will fulfil them. Particularly for substances which are used as food or feed, it can be assumed that certain criteria are met.

## **Semiochemicals**

### ***Semiochemicals in plant protection***

Semiochemicals are chemicals emitted by plants, animals, and other organisms – and synthetic analogues of such substances – that evoke a behavioural or physiological response in individuals of the same or other species. They include pheromones and allelochemicals. Pheromones modify the behaviour of other individuals of the same species, while allelochemicals act on different species.

Most semiochemicals used in plant protection products are «straight-chained lepidopteran pheromones» (SCLPs). They have their natural function as sexual pheromones. They are produced and released by female Lepidoptera to attract («call») males for mating. Males are able to find females over relatively long distances, using the concentration gradient of the pheromone in the air. In the «mating disruption» technique, the pheromone is artificially applied in excess, so that no gradient from a calling female can be built up. Therefore, males are no longer able to find females, resulting in unfertilized females and a reduction in offspring. Besides mating disruption, semiochemicals can also be used for mass trapping, monitoring and «attract & kill». In mating disruption and mass trapping, semiochemicals are considered as pesticides. In monitoring and attract & kill, they are not considered as pesticides, and are therefore exempt from registration.

Semiochemicals present a particular case among active ingredients used in plant protection products, as they are the only pesticides not intended to kill the pest organism. Semiochemicals have a high specificity for the target species.

### ***Environmental impact and human health risks of semiochemicals***

The OECD 12 consensus document<sup>10</sup> provides the following rationale for reduced data requirements: Semiochemicals are generally effective at very low rates,

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<sup>10</sup> Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control. OECD Environment, Health and Safety Publications Series on Pesticides No. 12. ENV/JM/MONO(2001)12.

comparable to levels that occur naturally. They are generally volatile and usually dissipate rapidly in the environment. In addition, many end use products are formulated in passive dispensers (hollow fibres, tapes) that present little direct exposure to humans and non-target organisms. All these factors minimise the risk of adverse effects from the use of semiochemicals. OECD no 12 concludes that SCLPs in particular have a low toxicity, and that arthropod semiochemicals in general have a low exposure potential.

- SCLPs are of low toxicity to mammals.
- The application rate is typically low and probably comparable to natural emissions.
- Volatility and rapid environmental transformation minimise residues in crops and exposure of non-target organisms.

These findings have been supported by experience of the US EPA, resulting in a recent proposal for relaxed registration requirements for semiochemicals<sup>11</sup>. The REBECA project anticipates that these findings will also be supported by the 4<sup>th</sup> stage re-evaluation.

SCLPs have been intensively studied and are widely used in plant protection. The currently available knowledge shows that the lepidoptera have pheromones with very similar structure and function, and with very similar safety profiles.

The pheromones of other arthropods are much less studied. Nevertheless, several other taxonomic groups of arthropods also have pheromones which are structurally very similar within one taxonomic group, e.g.:

- beetles (coleoptera): pheromones based on terpenoids,
- midges (a group of flies; diptera): pheromones based on diacetoxo alkanes,
- pentatomides (a group of bugs; heteroptera): pheromones based on alkene esters.

At the moment, these pheromones are not well known from a regulatory point of view, and have to be evaluated on a case-by-case basis. With increasing experience, however, these pheromones could be regulated in a more generic way, comparable to that suggested above for SCLPs.

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<sup>11</sup> Federal Register, Part III, Environmental Protection Agency, 40 CFR Parts 158 and 172, Pesticides; Data Requirements for Biochemical and Microbial Pesticides; Proposed Rule, March 8, 2006

## ***Risk and efficacy assessment of semiochemicals***

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 test toxicity of a pheromone by spraying it directly onto bees, even though this kind of exposure 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 interpret 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 ought to be accepted in pheromones than in other pesticides. In particular, for impurities which are SCLPs or structurally similar substances, validated analytical methods shall only be required if they are present in quantities  $\geq 20$  g/kg.

### **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.

Requirements for analysis of impurities should be reduced for pheromones/semiochemicals. 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).

## **Annex 1: List of participants Brussels meeting**

Claude Alabouvette, INRA, France  
David Cary, Exosect Limited, United Kingdom  
Miriam Döring, University of Kiel, Germany  
Ralf-Udo Ehlers, University of Kiel, Germany  
Anita Fjelsted, Danish EPA, Denmark  
Anne Laure Fondeur, Ministry of Agriculture, France  
Felix Fraga, Swiss Federal Office for Agriculture, Switzerland  
Rüdiger Hauschild, GAB Consulting GmbH, Germany  
Jean-Marie Joubert, Laboratoires Goëmar, France  
Hubertus Kleeberg, Trifolio-M GmbH, Germany  
Rogier Kolnaar, Koppert Biological Systems, The Netherlands  
Alexandra Makulla, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Germany  
Susan Mattock, Pesticide Safety Directorate, United Kingdom  
Thierry Mercier, INRA, France  
Lisa Moakes, Pesticide Safety Directorate, United Kingdom  
Lars Niemann, Bundesinstitut für Risikobewertung (BfR), Germany  
Wolfgang Reinert, European Commission, Brussels  
David Sadler-Bridge, ECOspray Ltd, United Kingdom  
Wendy Sexsmith, Health Canada, Canada  
Robin Sheppard, IBMA, United Kingdom  
Bernhard Speiser, Research Institute of Organic Agriculture (FiBL), Switzerland  
Olaf Strauch, University of Kiel, Germany  
Lucius Tamm, Research Institute of Organic Agriculture (FiBL), Switzerland  
Vittorio Veronelli, CBC (EUROPE) Ltd., Italy  
Gillian Walters, United Kingdom  
Hermann Wilhelmy, W. Neudorff GmbH KG, Germany

## Annex 2: List of presentations Brussels

All presentations are available on the REBECA webpage ([www.rebeca-net.de](http://www.rebeca-net.de)).

### Introduction to the REBECA project

*Ralf-Udo Ehlers, University of Kiel, Institute for Phytopathology, Hermann-Rodewald-Strasse 9, D-24118 Kiel, Germany*

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

### DG SANCO's point of view

*Wolfgang Reinert, European Commission, Health and Consumer Protection Directorate General, Rue Froissart 101 F101 04/80, Brussels, Belgium*

Download of slides: [http://www.rebeca-net.de/downloads/Risk%20Assessment%20Botanicals%20Reinert\\_Sanco.pdf](http://www.rebeca-net.de/downloads/Risk%20Assessment%20Botanicals%20Reinert_Sanco.pdf)

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

*Lisa Moakes, Pesticide Safety Directorate, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX, United Kingdom*

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

### Example for a botanical: neem

*Hubertus Kleeberg, Trifolio-M GmbH, Sonnenstrasse 22, DE-35633 Lahnu, Germany*

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

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

*Lucius Tamm, Research Institute of Organic Agriculture (FiBL), Ackerstrasse, CH-5070, Frick, Switzerland*

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

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

*Thierry Mercier, INRA, SSM, Centre de Versailles, route de saint cyr, FR-78026 Versailles Cedex, France*

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

### **Regulation of botanicals & semiochemicals in Switzerland**

*Felix Fraga, Swiss Federal Office for Agriculture, Mattenhofstrasse 5, CH-3003 Berne, Switzerland*

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

### **Regulation of plant extracts and semiochemicals in Australia**

*Rüdiger Hauschild*

*GAB Consulting GmbH, Hinter den Höfen 24, D-21769 Lamstedt, Germany*

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

### **Risk Assessment for Plant Strengtheners in Germany**

*Alexandra Makulla, Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL), Messeweg 11/12, 38104 Braunschweig, GERMANY*

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

### **Examples of semiochemicals**

*Vittorio Veronelli*

*Managing Director for the Italian branch of the Japanese company CBC Co. Ltd. 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>

### **Data requirements for semiochemicals according to OECD Guideline 12**

*Wendy Sexsmith*

*Health Canada, 1600 Scott Street, Tower B, suite 410, Holland Cross, P.L. 3104A, Ottawa, Ontario K1A 0K9, Canada*

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

### **UK evaluation of a mating disruption pheromone**

*Susan Mattock*

*Pesticide Safety Directorate, Mallard House, 3 Peasholme Green, York YO1 7PX, United Kingdom*

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

### **Annex 3: List of participants of botanical workshops Salzau**

Barker Sonia, Pesticides safety directorate, United Kingdom  
Fondeur Anne-Laure, Ministry of agriculture and fisheries,  
France Fraga Felix, Bundesamt für Landwirtschaft, Switzerland (part time)  
Heilig Ulf, Consultant, France  
Kleeberg Hubertus, TRIFOLIO-M GmbH, Germany  
Köpp Herbert, Federal office of consumer protection and food safety, Germany  
Lindqvist Isa, Plant protection MTT agrifood research, Finland  
Regnault-Roger Catherine, Université de Pau et des pays de l'Adour, France  
Reinert Wolfgang, European Commission, Belgium (part time)  
Sadler-Bridge David, ECOspray Ltd, United Kingdom  
Tamm Lucius, Research institute of organic agriculture (FiBL), Switzerland  
Wilhelmy Hermann, W. Neudorff GmbH, German

### **Annex 4: List of participants of semiochemical workshops Salzau**

Anna-Carin Bäckman (University of Agricultural Sciences, Sweden)  
Anja Bartels (AGES, Austria)  
David Cary (Exosect, United Kingdom)  
Susan Mattock (PSD, United Kingdom)  
Robin Sheppard (IBMA, United Kingdom)  
Bernhard Speiser (FiBL, Switzerland).

Wolfgang Reinert (European Commission, DG SANCO, Belgium),  
William E. Schneider (EPA, United States)  
Franz Streissl (EFSA, Italy).

## Annex 5: List of presentations Salzau

All presentations are available on the REBECA webpage ([www.rebeca-net.de](http://www.rebeca-net.de)).

### Potential of Botanicals and Semiochemicals

**Botanicals:** Catherine Regnault-Roger (University of Pau, France)

**Semiochemicals:** Anna-Catrin Bäckman (Swedish University of Agricultural Sciences)

### Comparison of Registration Requirements in Different Countries:

**Botanicals:** Rüdiger Hauschild (GAB Consulting GmbH, Germany)

**Semiochemicals:** Rüdiger Hauschild (GAB consulting, Germany)

### Summary of the Brussels Workshop (13.-14.06.2006)

**Botanicals:** Lucius Tamm (FIBL, Switzerland)

**Semiochemicals:** Susan Mattock (PSD, United Kingdom)