



## **Deliverable 18:**

### **Positive list of «low risk» candidate botanicals and semiochemicals**

## **REBECA**

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### Document History

This document is based on the results of 4 workshops (Brussels, Belgium, June 13-14, 2006; Salzau, Germany, September 18-22, 2006; Brussels, Belgium, June 18-19, 2007; Brussels, Belgium, September 21, 2007) and of e-mail consultations in-between these workshops. Experts from science, regulatory authorities and industry attended the meetings and reviewed the minutes, which were used to produce this document.

### Document Abstract

This document briefly reviews discussions in the REBECA project and guidance documents and regulatory issues relating to «low risk» and «low concern» status of botanicals and semiochemicals. There are two tables with low risk candidate botanicals and semiochemicals which were identified in the REBECA project.

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## Introduction

### ***Risk in botanicals***

The REBECA proposals for adapted data requirements and regulatory procedures for «botanicals» and for «semiochemicals» (see deliverable no 16) state that «'Botanicals' covers an extremely heterogeneous group of substances [...] In conclusion, risks associated with the use of 'botanicals' may vary between very low and very high».

The REBECA project recommends «a system in which botanicals of low risk/concern are identified *early* in the process, and are subject to reduced data requirements» (see deliverable no 16). Perhaps, the term «low risk candidates» would be more appropriate, as long as the evaluation is not completed.

Regulators have pointed out that according to the precautionary principle, an assessment is needed to determine whether a substance is «low risk». For botanicals, the normal data requirements would therefore apply.

The REBECA project recommends that substances with a history of safe use in plant protection or for other purposes shall be considered as «low concern» substances. Safe use in human nutrition, animal feeding, cosmetics, agriculture (e.g. fertilizers), occurrence in nature (e.g. nettle), pharmacopoeia, biocide or technical use may provide justifications to replace some or all studies in certain areas.

Document SANCO/10472<sup>1</sup> contains a list of plants and plant extracts to which reduced data requirements should apply.

Under the proposed new Regulation on plant protection products<sup>2</sup>, «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).

A number of botanicals are currently being evaluated in the framework of the 4<sup>th</sup> stage re-evaluation. An up-to-date assessment of their risks will be available as soon as these evaluations are completed.

### ***Risk in semiochemicals***

The REBECA proposals for adapted data requirements and regulatory procedures for «botanicals» and for «semiochemicals» (see deliverable no 16) state that «Semiochemicals are generally effective at very low rates, comparable to levels that

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<sup>1</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>2</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.

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. Furthermore, they are usually not directly applied to the crop. In this case, exposure is limited to localised areas where the dispensers are placed (note: exposure may be higher in the case of direct application). All these factors minimise the risk of adverse effects from the use of semiochemicals».

OECD consensus document no 12<sup>3</sup> concludes that straight-chained lepidopteran pheromones (SCLPs) in particular have a low toxicity, and that arthropod semiochemicals in general have a low exposure potential. (i) SCLPs are of low toxicity to mammals. (ii) The application rate is typically low and probably comparable to natural emissions over the course of a season. (iii) Volatility and rapid environmental transformation minimise residues in crops and exposure of non-target organisms.

The general legal considerations described above for botanicals also apply for semiochemicals.

### **«Low risk» candidate botanicals**

For the reasons given above, the REBECA project cannot establish the low risk/concern status of a substance, but can only indicate candidate substances. The «REBECA proposals for adapted data requirements and regulatory procedures for botanicals and for semiochemicals» (deliverable no 16) propose to establish a list of plants and/or combinations of plants and extraction methods which are recognized as of low risk/concern. This should be an open list which can be amended when new botanicals have been evaluated. As a starting point, all substances which are currently listed in SANCO/10472, all substances on the «25b list» of the US EPA and all substances with GRAS status should be considered for such a list. Some of these substances are given in Table 1.

### **«Low risk» candidate semiochemicals**

As described above for botanicals, the REBECA project cannot establish the low risk/concern status of a substance, but can only indicate candidate substances. The «REBECA proposals for adapted data requirements and regulatory procedures for botanicals and for semiochemicals» (deliverable no 16) propose that all SCLPs are treated as low risk substances. Some examples of SCLPs are given in Table 2.

The REBECA project assumes that many non-lepidopteran pheromones have similar safety profiles as the SCLPs, and suggests similar, relaxed registration requirements, as soon as this assumption is confirmed. At the moment, however, these phero-

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<sup>3</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

mones are not well known from a regulatory point of view, and have to be evaluated on a case-by-case basis.

**Table 1:** Examples of «low risk» candidate botanicals.

<p><b>1 A) Edible parts of plants used for human nutrition or animal feed (as listed in SANCO/10472)</b></p> <p>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).</p>
<p><b>1 B) Parts of plants authorized as herbal drugs (as listed in SANCO/10472)</b></p> <p>bladder wrack (thallus), feverfew (whole plant), lavender (whole plant), nettle (whole plant), rhubarb (rhizome only), sweet chamomille (whole plant).</p>
<p><b>1 C) Plant extracts classified as Minimal risk pesticides («25b list» of the US EPA)</b></p> <p>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 sulfates, 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.</p>
<p><b>1 D) Example of a plant extract classified as GRAS (21 CFR 184.1400)</b></p> <p>lecithine.</p>

**Table 2:** Examples of «low risk» candidate semiochemicals: list of selected SCLPs.

<p><b>2 A) SCLP acetates</b></p> <p>5-decen-1-yl acetate            (E)-8-dodecenyl acetate            (E/Z)-8-dodecenyl acetate            (Z)-8-dodecenyl acetate            (Z)-9-dodecenyl acetate            (7E, 9Z)-dodecadien-1-yl acetate            (E)-11-tetradecenyl acetate            (Z)-9-tetradecenyl acetate            (Z)-11-tetradecenyl acetate            (9Z, 12E)-tetradecadien-1-yl acetate            (Z)-11-hexadecen-1-yl acetate            (Z)-13-hexadecen-11-ynyl acetate            (7Z, 11E)-hexadecadien-1-yl acetate            (2E, 13Z)-octadecadien-1-yl acetate            (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate</p>
<p><b>2 B) SCLP alcohols</b></p> <p>5-decenol            (Z)-8-dodecenol            (E, E)-8,10-dodecadien-1-ol            1-tetradecanol            (Z)-11-hexadecen-1-ol</p>
<p><b>2 C) SCLP aldehydes</b></p> <p>(Z)-7-tetradecenal            (Z)-9-hexadecenal            (Z)-11-hexadecenal            (Z)-13-octadecenal</p>
<p><b>2 D) Blends of SCLP acetates</b></p> <p>(Z)-8-dodecenyl acetate &amp; dodecan-1-yl acetate            (Z)-9-dodecenyl acetate &amp; dodecan-1-yl acetate            (7E, 9Z)-dodecadienyl acetate &amp; (7E, 9E)-dodecadienyl acetate            (7Z, 11Z)-hexadecadien-1-yl acetate &amp; (7Z, 11E)-hexadecadien-1-yl acetate</p>
<p><b>2 E) Blends of SCLP aldehydes</b></p> <p>(Z)-9-hexadecenal; (Z)-11-hexadecenal &amp; (Z)-13-octadecenal</p>
<p><b>2 F) Blends of different SCLPs</b></p> <p>5-decen-1-yl acetate &amp; 5-decen-1-ol            (E/Z)-8-dodecenyl acetate &amp; (Z)-8-dodecenol            (Z)-11-hexadecenal &amp; (Z)-11-hexadecen-1-yl acetate</p>