



Minutes of REBECA workshop 9 (**semiochemicals**): Brussels, June 18th 2007

Participants: David Cary, Jérémy Denis, Anita Fjelsted, Adolf Heintze, Heikki Hokkanen, Owen Jones, Hubertus Kleeberg, Kiki Machera, Ingeborg Menzler-Hokkanen, Götz Neurath, Patricia Pitton, Catherine Regnault-Roger, Robin Sheppard, Bernhard Speiser (chair), Bernd Stein, Olaf Strauch, Lucius Tamm (minutes)

Welcome, aims of workshop, amendments to agenda

BS **welcomes** all participants to the workshop and gives an introduction to the aims of the workshop. The **aims of the workshop** are to (i) discuss & evaluate REBECA proposals for the improvement of the registration process of semiochemicals which have been developed so far, to (ii) identify proposals with a high degree of consensus between regulators, industry and academia, to (iii) identify proposals which are controversial including reasons for controversy, (iv) to improve current and add new proposals if necessary, and to (v) evaluate the proposals for feasibility of implementation and their impact on cost and duration of the registration process. It is emphasized that the 'semiochemicals proposals' are specially adapted to the needs of registration of semiochemicals whereas more general proposals to improve the registration process are listed in a separate document ('Proposals for improvements of the EU regulation and registration process of BCAs', discussed (but not yet finalized) at the REBECA Porvoo meeting May, 2007). The finalized consolidated REBECA proposals will be presented at the final conference (Brussels, September 2007) to a wider audience of stakeholders.

The working document upon which the discussion during the workshop is based has been developed based on two earlier REBECA workshops (Brussels, Salzac; held in 2006) and it has been circulated to all invited experts. Written comments have been submitted to BS prior to the meeting by AGES (AT), PSD (UK), CTB (NL), and Ulf Heilig (IBMA representative, FR). These comments have been integrated into the current working document.

BS presents the **agenda** which is unanimously accepted by the participants. The **minutes** of the meeting are integrated wherever suitable into the working document 'REBECA proposal on facilitations in the registration requirements for semiochemicals'. Issues raised during the meeting which do not fit into the working document are listed below.

Current state of 4th stage evaluation and new pesticide regulation

PP informs on the current state of development. The 4th stage evaluation process encounters delays since 93 DARs are expected but only 10 DARs have been received by the Commission so far. The Commission is currently working on a proposal that would simplify the procedure permitting to respect the deadline of end 2008. It is expected to be voted on July 2007. The new regulation on placing on the market of plant protection products that will repeal Directive 91/414s currently discussed in co-decision procedure at Parliament and Council level. It is expected that the first reading in Parliament will be finalized in September/October 2007. The definition of 'substances of low concern' is one of the issues discussed (Note H. Köpp: The draft regulation does not foresee an a priori definition of 'low risk substances'. Rather, the 'low risk' would be the result of an assessment).



Results of discussion of the REBECA proposals on semiochemicals:

All proposals are discussed and partly revised in detail. The outcome of the discussion is directly implemented into the revised proposals document (see annex I). Further issues raised in the discussion:

Collective listing of SCLPs: some concern has been raised which is not directly related to SCLPs: The collective listing of a group of substance might be a prejudice for other groups and therefore pose some problems.

Collective listing AND listing as a group of 'low risk substances' might pose a problem due to the discrepancy of expiry date of the first and last substance to be registered. The definition of 'low risk substance' is still pending. (Note H.Köpp: At the Rebeca workshop in Salzau, the EU Commission had already clarified that the draft regulation does not foresee an a priori definition of 'low risk substances'. Rather, the 'low risk' would be the result of an assessment. The current wording of the minutes implies that somebody is working on such a priori definition. It therefore gives a wrong impression and raises wrong expectations.)

Results of stakeholder meetings:

Stakeholder meetings: the stakeholders are asked (i) to assess the impact if all proposals are implemented in the future, (ii) to assess the list of proposals for completeness and suggest further amendments if necessary.

Industry:

The industry stakeholders state that the proposed improvements will greatly facilitate the registration of the next series of applications and/or new semiochemicals which are currently in the pipeline. This will specifically apply for minor uses. The industry expects that major disadvantages (as compared to other OECD countries) will be removed. In general, predictability of registration is expected to be improved, costs reduced and the registration process will be shortened. The industry stakeholders therefore fully support the implementation of the proposals.

If the registration process for PPP can be improved, this should also have an impact on new applications which fall under the biocide regulation or veterinary medicine (ectoparasite control). It is therefore recommended to the authorities to take REBECA results also into account in e.g. biocide registration processes.

The 'Swedish proposal' is regarded with great interest. However, detailed information is necessary to give a well-founded assessment from the industry's point of view.

The industry stakeholders emphasize that publicly funded research in the field has become less fashionable and that there is substantial lack of funding of e.g. identification of additional semiochemicals and their function.

Regulators:

The present regulators assessed each proposals for the effort it takes for implementation. It was stated that the proposals with three-stars can be implemented with a reasonable effort. Proposals with two stars will need a more detailed analysis. The proposals will facilitate the process without compromises to safety issues.

No further gaps are detected and no further proposals are identified. The table below reflects the state of the discussion at the workshop.



page	proposal	Implementation easy / fast: *** difficult / slow: *	Potential impact great: *** / small: *	
			on duration	on costs
4	Collective listing of SCLPs in Annex I	**	***	***
5	'Low risk' status of SCLPs	(***)	(**)	*
5	Analysis of impurities	***?	*	***
5	Number of samples to be analyzed	*	***	***
5	Risk assessment of SCLPs (1)	?	***	**
5	Risk assessment of SCLPs (2)	?	*	*
6	Risk assessment of other semiochemicals	??	***	***
7	Efficacy evaluation (1)	***	*	***
7	Efficacy evaluation (2)	**	**	**
7	Efficacy evaluation (3)	***	***	***

LT, 6th July 2007 (minor editorial corrections on 31st August, BS)



Minutes of REBECA workshop 9 (botanicals): Brussels, June 19th 2007

Participants: Mark Briggs, David Cary, Jérémy Denis, Anita Fjelsted, Adolf Heintze, Heikki Hokkanen, Hubertus Kleeberg, Jean-Marie Joubert, Herbert Köpp, Kiki Machera, Ingeborg Menzler-Hokkanen, Thierry Mercier, Götz Neurath, Wolfgang Reinert, Catherine Regnault-Roger, Bernhard Speiser (chair), Bernd Stein, Olaf Strauch, Lucius Tamm (minutes), Hermann Wilhelmy

Welcome, aims of workshop, amendments to agenda

BS **welcomes** all participants to the workshop and gives an introduction to the aims of the workshop. The **aims** of the workshop are to (i) discuss & evaluate REBECA proposals for the improvement of the registration process of botanicals which have been developed so far, to (ii) identify proposals with a high degree of consensus between regulators, industry and academia, to (iii) identify proposals which are controversial including reasons for controversy, (iv) to improve current and add new proposals if necessary, and to (v) evaluate the proposals for feasibility of implementation and their impact on cost and duration of the registration process. It is emphasized that the 'botanicals proposals' are specially adapted to the needs of registration of botanicals whereas more general proposals to improve the registration process are listed in a separate document ('Proposals for improvements of the EU regulation and registration process of BCAs', discussed (but not yet finalized) at the Porvoo meeting May, 2007). The finalized consolidated REBECA proposals will be presented at the final conference (Brussels, September 2007) to a wider audience of stakeholders.

The working document upon which the discussion during the workshop is based has been developed based on two earlier REBECA workshops (Brussels and Salzau; held in 2006) and it has been circulated among all invited experts. Written comments have been submitted to BS prior to the meeting by PSD (UK), CTB (NL), David Sadler-Bridge (Ecospray, UK), and Ulf Heilig (IBMA representative, FR). These comments have been integrated into the working document.

BS presents the **agenda** which is unanimously accepted by the participants. The **minutes** of the meeting are integrated wherever suitable into the working document 'REBECA proposal on facilitations in the registration requirements for botanicals'. Issues raised during the meeting which do not fit into the working document are listed below.

Discussion of the REBECA proposals on botanicals:

All proposals are discussed and partly revised in detail. The outcome of the discussion is directly implemented into the revised proposals document (see annex II). However, issues raised in the discussion which are not implemented in the revised proposals document are listed here:

It was suggested to widen the scope of REBECA to other groups of substances as botanicals, e.g. stone preparations or simple substances such as bicarbonates. It is pointed out that this is not feasible within the context of REBECA (as discussed at the Salzau meeting 2006) because of the complexity and heterogeneity of the groups of substances as well as because of contractual restrictions of the REBECA project. However, it is agreed that proposals developed for the improved evaluation of botani-



cals should be introduced when developing e.g. guideline documents for other substances than covered by REBECA.

The question is raised whether RMS are already applying the draft guidance document in the 4th stage evaluation and what the experience has been obtained so far. MB states that the guidance document, in order to be effective, has to be applied by both, applicant and regulator (not only be the RMS). Not all notifiers made use of it. In conclusion it is stated that the draft guidance document needs amendments (suggested by lessons learned documents and REBECA proposals) and that it has a good chance to become a working document to be widely used in the future.

Major bottlenecks in the current evaluation include (i) requirements for identification of substances in plant extracts (addressed in proposal), (ii) requirements for analysis for identification of components and during quality assurance (need for too many validated analysis methods) (addressed in proposal), and (iii) the need to identify substances of low concern before a full risk assessment.

The industry-scale use of botanicals may lead to extinction of rare species if no proper precaution is applied. It is therefore encouraged to ensure sustainable and durable production systems and to include 'fair trade' schemes in order to take intellectual property rights (e.g. traditional use) into account.

Results of stakeholder meetings

Stakeholder meetings: the stakeholders are asked (i) to assess the impact if all proposals are implemented in the future, and (ii) to assess the list of proposals for completeness and suggest further amendments if necessary.

Industry:

The industry stakeholders state that the proposed improvements will facilitate the registration process of the next series of plant extracts. In general, predictability of registration is expected to be improved, costs will be reduced and the registration process will be shortened. The industry stakeholders therefore fully support the implementation of the proposals.

The 'Swedish proposal' (the proposal was not available in written form during the workshop) is regarded with great interest. However, detailed information is necessary to give a well-founded assessment from the industry's point of view.

The industry stakeholders emphasize that publicly funded research in the field has recently become less fashionable and that there is substantial lack of funding of e.g. identification of additional botanicals.

Regulators:

The present regulators assessed each proposal for the effort it takes for implementation. It was stated that the proposals with three stars can be implemented with a reasonable effort. Proposals with two stars will need a more detailed analysis. The proposals will facilitate the process without compromises to safety issues.

No further gaps are detected and no further proposals are identified. The table below reflects the state of the discussion at the workshop.



page	proposal	Implementation easy / fast: *** difficult / slow: *	Potential impact great: *** / small: *	
			on duration	on costs
6	Amendments of SANCO/10472			
7	Identification	***	***	**
8	Manufacturing methods (1)	***	**	**
8	Manufacturing methods (2)	***	*?	*
9	Risk assessment	***	**?	**
	Efficacy 1	**	**	*
	Efficacy 2	**	**	*
	Selectivity			

LT, 6th July 2007 (minor editorial corrections on 31st August, BS)