

REBECA project

Workshop 3

Review of potential risks of botanicals and semiochemicals

Brussels, 13-14 June 2006

DG SANCO's point of view

Annexes II, III and VI

- Revision of the 'A'-Annexes ongoing
- Discussion on Annex VI should be based on the revised Annexes II and III
- EFSA opinion (soon) available for phys-chem, analytics and residues
- Last EFSA opinion ready by mid 2007?
- Adoption per section or integral?

List 4 - substances

- Review ongoing
- Deadlines for submission of DARs June resp. November 2006
- Decision making by end of 2008
- Joint dossier for semiochemicals
- Wide range in quality of the dossier for plant extracts

Guidance documents (under progressive development)

- [Plant strengtheners](#) with low risk profile - Data requirements (doc. Sanco/1003/2000, rev. 3), 21 June 2001
- [Plant extracts](#) - data requirements (doc 10472, rev. 5), 6 July 2004
- [Chemical substances](#) - data requirements (doc 10473, rev. 4), 6 July 2004

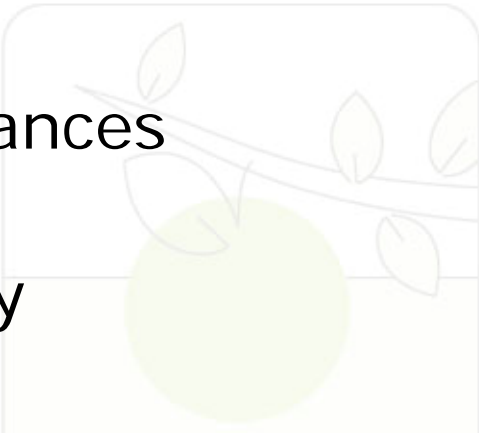
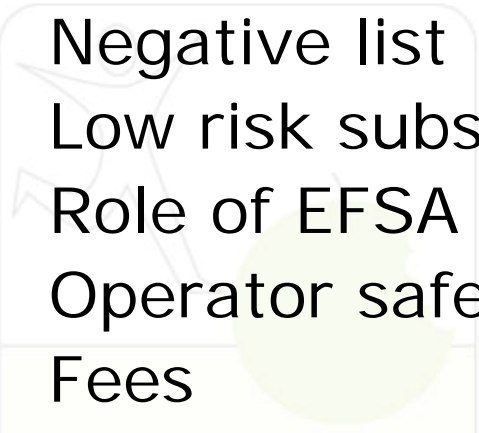
Main issues

- Regulation (legal quality)
- Zonal mutual recognition
- Comparative assessment
- Criteria for approval
- Data protection
- Information duty



Other issues

- Scope
- Negative list
- Low risk substances
- Role of EFSA
- Operator safety
- Fees
- Data access / confidentiality
- GMO's
- Minor Uses
- Monitoring and controls



"Backbone"

- Ensure high level of protection of human and animal health and the environment
- Particular attention to vulnerable groups
- Precautionary principle applies
- Ensure that industry demonstrates that substances or products do not adversely effect human health or the environment
- Only substances where it has been demonstrated that they present a clear benefit and where no harmful effect on human or animal health or any unacceptable influence on the environment should be included in plant protection products

Other purposes

- Strict deadlines should be applied in order to speed up the approval of active substances
- If the evaluation of a substance reveals that it presents considerably less of risk than other substances, it is appropriate to facilitate the placing on the market
- Specific provisions should ensure that substances of value for plant protection which are not predominantly used as a PPP and where the economic interest of applying is limited may also be approved as far as their risk is acceptable

...and what about REBECA?

- “Low risk substances”
 - “Basic substances”
 - Strict deadlines
 - Rules on renewal of approval
 - Comparative Risk Assessment
 - Zonal authorisation system with obligatory mutual recognition
- 