



Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Economic Affairs DEA
Federal Office for Agriculture FOAG

Regulation of beneficial insects and bio-control in Switzerland

23rd October 2006



Regulation of plant protection products

European Union EU:

Legislation in accordance with Council Directive **91/414/EEC** of 15th July 1991 concerning the placing of plant protection products on the market.

Switzerland CH:

Entry into force of the currently valid ordinance concerning the placing of plant protection products on the market (**SR 916.161**) on 1st August 2005.

The two legislations are in principle almost the same but ...



but ...

EU: Council Directive 91/414/EEC

Active substances: substances or micro-organisms including viruses, having general or specific action ...

CH: SR 916.161

Active substances: substances, **macro-organisms** and micro-organisms including viruses, having general or specific action ...

Macro-organisms: insects, mites, nematodes.



But ...

EU: Council Directive 91/414/EEC

Annex II: Requirements for the dossier to be submitted for the inclusion of an active substance in Annex I

- Part A: Chemical substances
- Part B: Micro-organisms, including viruses.

Switzerland:SR 916.161

Annex II: Requirements for the dossier to be submitted for the inclusion of an active substance in Annex I

- Part A: Chemical substances
- Part B: Micro-organisms, including viruses
- **No specific requirements defined for macro-organisms.**



But ...

EU: Council Directive 91/414/EEC

Annex III: Requirements for the dossier to be submitted for the authorization of a plant protection product

- Part A: Chemical preparations
- Part B: Plant protection products based on preparations of micro-organisms including viruses.

Switzerland: SR 916.161

Annex III: Requirements for the dossier to be submitted for the authorization of a plant protection product

- Part A: Chemical preparations
- Part B: Plant protection products based on preparations of micro-organisms including viruses.
- **No specific requirements defined for plant protection products based on macro-organisms.**



But ...

EU: Council Directive 91/414/EEC

Annex VI: Uniform principles for evaluation and authorization of plant protection products

- can be applied on chemical preparations
- and on plant protection products based on preparations of micro-organisms.

Switzerland:SR 916.161

Annex VI: Uniform principles for evaluation and authorization of plant protection products

- can be applied on chemical preparations
- can **not** be applied on plant protection products based on preparations of micro-organisms
- **and can not be applied on plant protection products based on macro-organisms.**



Conclusions on the actual legislation in Switzerland in relation to Macro-Organisms

- Macro-organisms are considered in Switzerland as active substances of plant protection products when used for that purpose.
- Plant protection products may not be placed on the market in Switzerland unless they have been authorized.
- The Swiss legislation does **not** provide
 - criteria for the submission of a demand concerning macro-organisms as active substance (Annex II)
 - criteria for the submission of a demand concerning macro-organisms as product (Annex III)
 - and principles for their evaluation and authorization (Annex VI).



Actual practice: general

Checklist to macro organisms has to be delivered for authorization

- 1st Version '90
- 2nd Version since 2001
- 3rd Version not applied because we wait results from project REBECA .



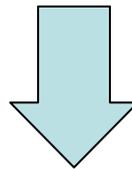
Actual practice: Checklist

- Identity of macro-organism
- Geographical distribution
- Range/potential of hosts/preys
- Climatic Requirements
- In EPPO List?
- Biological effectiveness and application
- Methods of product quality control
- Evaluation/recording by FAO, WHO or third countries including refusals
- Compatibility with the environment
- Potential/known damages.



Actual practice: general

- Check list
- The authority may require the submission of additional studies.
- The submission of parts of the dossier can be claimed as unnecessary but that claim must be justified (waiver).



flexible, pragmatic approach



Actual practice: results

- From the Swiss point of view, the application of appropriate regulatory procedures is important in order to maintain public confidence in biological control and to facilitate the introduction and use of macro-organisms.
- Switzerland will continue to require authorization of macro-organisms as plant protection products.
- Practical case: Authorization of the Harlequin Ladybird *Harmonia axyridis* refused in 1997.
- The case of *Harmonia axyridis* also shows that the success of a national approach is limited.



Needs

- Need for harmonized criteria covering Annex II:
Dossier requirements for the inclusion of an active substance in Annex I
Basis: Bigler F. *et al* (CAB Reviews, 2005).
- Need for harmonized criteria covering Annex III:
Dossier requirements for the authorization of a plant protection product
Standards on efficacy: Needs to develop protocols for trials and criteria for evaluation (f.ex. by EPPO).
- Need for harmonized principles covering Annex VI:
Uniform principles for evaluation and authorization of plant protection products
Industry needs transparency, accountability, consistency, proportionality and targeting as statede by IBMA (White paper, 2005).



... and these also
are our expectations
to REBECA