Regulation of the release of Biocontrol agents in Switzerland

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A short view back…

- CH 1st country to make registration of macroorganisms compulsory in 1986
- 1st form for registration >10 years ago
- **Application form** for a licence to commercialise a plant protection product containing (beneficial) macroorganisms
  -> adapted 2014 to the form “PM 6/2 (3) Import and release of non-indigenous biological control agents”
Involved authorities

Federal Office for the Environment FOEN
Regulates: release/handling of organisms (esp. non-native, pathogen or genetically modified organisms) except organisms as plant protection products

Federal Office for Agriculture FOAG
Regulates: release of organisms as plant protection products (native and non-native)
Guideline: EPPO PM 6/2

(Federal Office of Public Health FOPH
Involved in regulation of microorganisms)
Ordinance on the Handling of Organisms in the Environment (Release Ordinance):

- All organisms to be released into the environment have to be self-assessed for safety
- All non-native invertebrate animals, all pathogen and genetically modified organisms require permit from corresponding authority to be released
- E.g. classical biological control outside of agriculture
Federal Office for Agriculture

Ordinance on Plant Protection Products PPPO

- All organisms (native and non-native) used for biological control in agriculture require permission to be released
- E.g. classical biological control in agriculture
- E.g. plant protection products (native and non-native)
- E.g. field/greenhouse trials with not (yet) approved plant protection products with organisms
Registration as plant protection products

First use of a BCA in Switzerland

Dossier and standardized application form handed in by applicant → Evaluation by experts of FOAG under consideration of EPPO PM 6/3 → Evaluation report sent to FOEN for statement → Decision of FOAG on acceptance of organism for Annex 1 of PPPO (approved agents) → Decision of FOAG on authorization of product

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Registration as plant protection products

BCA already on Annex 1 of PPPO

Dossier and standardized application form handed in by applicant

Evaluation by experts of FOAG under consideration of EPPO PM 6/3

Decision of FOAG on authorization of product

Organisms present on Annex 1 have to be (re-)evaluated:
• for each product
• for product changes
• after 10 years
Information required during the process

Based on EPPO PM 6/2 (as defined in PPPO)

Standardized form for macroorganisms:

- Information on the applicant
- Information on application (incl. EPPO list PM 6/3)
- Information on organism:
  - Identity
  - Characteristics
  - Origin
  - Natural distribution
  - Prior risk assessments and experiences
  - Efficacy
- Information on product
Our experience

- In practice CH is rarely the first country for release
- Form has been well received by the companies
- Continuous improvements from both sides
- Lead to better organization in general (dossier structure, information concentrated => easier/faster access, better/clearer communication,…)
- 10 year reevaluation hit us last year -> welcome update of (not yet) existing information…
- Improves the quality/survey of whole process -> unwanted side-effects (e.g. invasives, pathogens) may be prevented
Pro’s

- Few involved people -> easy communication speeds up the process
- Network tool for communication
- Expert network also due to the EPPO-IOBC panel
- Second set of eyes (FOEN/FOAG)
- In the long run: Process of authorization will speed up

and

Con’s

- Finding agreements with experts from FOEN
- In the short run: Process of authorization slowed down
Thank you for your attention

Agroscope  good food, healthy environment