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Agroscope

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)

Federal Office for the Environment

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

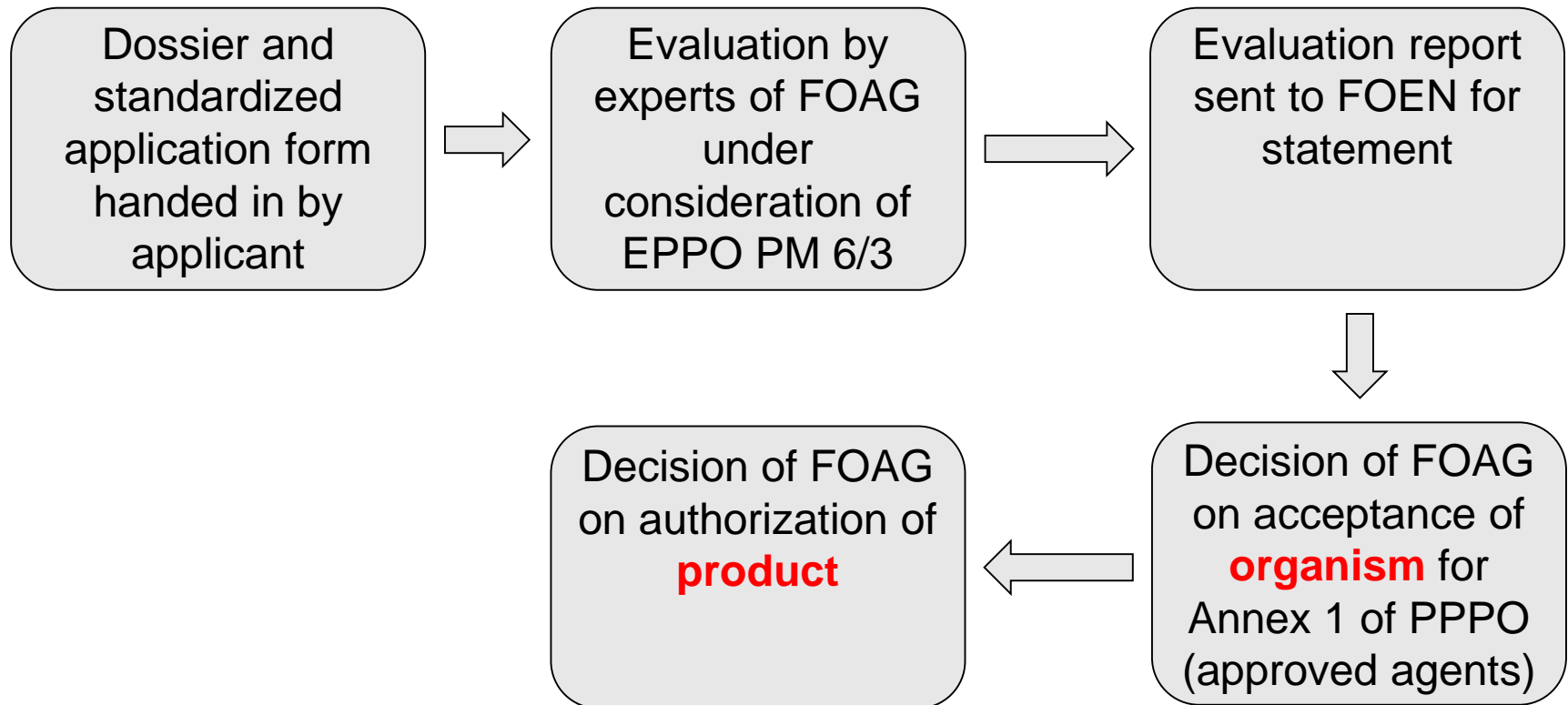
Federal Office for Agriculture

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

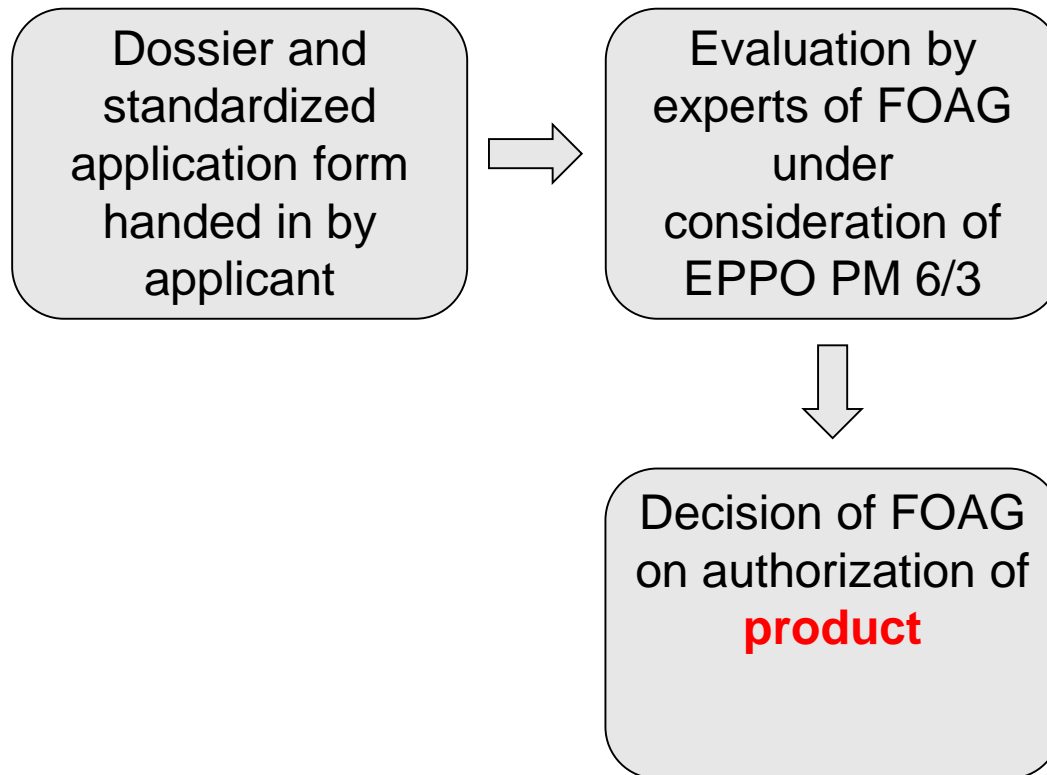
Registration as plant protection products

First use of a BCA in Switzerland



Registration as plant protection products

BCA already on Annex 1 of PPPO



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

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Eidgenössisches Volkswirtschaftsdepartement EVD
Bundesamt für Landwirtschaft BLW
Fachbereich Pflanzenschutzmittel

Gesuch um Erteilung einer Bewilligung für das Inverkehrbringen eines Pflanzenschutzmittels mit Makroorganismen (Nützlingen)

gestützt auf:

- Art. 160 des Bundesgesetzes vom 29. April 1998 über die Landwirtschaft (Landwirtschaftsgesetz, LWG, SR 910.1);
- Verordnung vom 12. Mai 2010 über das Inverkehrbringen von Pflanzenschutzmitteln¹

Eingang Gesuch:

Durch Zulassungsstelle PSM auszufüllen

- Für das Inverkehrbringen von Pflanzenschutzmitteln mit Makroorganismen² als Wirkstoff ist bei der Zulassungsstelle eine Bewilligung einzuholen.
- Entsprechende Gesuche sind mit diesem Formular der Zulassungsstelle unter folgender Adresse einzureichen:
Bundesamt für Landwirtschaft BLW
Fachbereich Pflanzenschutzmittel
Mattenhofstr. 5
3003 Bern
- Pro Wirkorganismus ist jeweils ein gesondertes Formular auszufüllen.
- Gemäss Art. 4 der Pflanzenschutzmittelverordnung ist mit dem Gesuch zu belegen, dass sich das Pflanzenschutzmittel zum vorgesehenen Gebrauch eignet und der vorschriftgemässe Gebrauch nicht wesentliche nachteilige Nebenwirkungen zur Folge hat.

¹ Verordnung über das Inverkehrbringen von Pflanzenschutzmitteln (Pflanzenschutzmittelverordnung, PSMV) vom 12. Mai 2010, SR 916.161

² Nematoden, Arthropoden (Insekten, Milben u. a.) gemäss Art. 3, PSMV vom 12. Mai 2010, SR 916.161

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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

and

Con'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

- Finding agreements with experts from FOEN
- In the short run: Process of authorization slowed down



Thank you for your attention



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