Invertebrate Biological Control Agents

Regulation In Europe

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Regulation in Europe

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History

- Biological control using invertebrate predators has been used successfully in Europe for a long time

- There is no overarching regulatory framework across Europe, nor within the European Union
  - Range from countries with well developed regulatory procedures to those with none at all
  - Recognition that the lack of regulations in many countries has contributed to the success of the use of biological control
  - Growing concern about negative environmental impacts

EPPO standards

- 1996: Establishment of a Joint EPPO/IOBC panel on the safe use of biological control agents

- Developed several standards
  - First import of exotic BCAs for research under contained conditions (PM6/1(1))
  - Import and release of BCAs (PM6/2(3))
  - List of IBCAs widely used in the EPPO region(PM 6/3(4))

REBECA project

- EU funded project: Regulation of Biological Control Agents (2006-2008)
- Reviewed biological control regulations across
  - EU, Australia, Canada, New Zealand and USA
- Identified EPPO standards were not routinely used
- Made recommendations, including on applications and information requirements for first releases.

EPPO and REBECA

- EPPO standards amended based on some of the REBECA recommendations.

- Significant changes to PM 6/2(3)
  - Guidelines for an application form for import, shipment, rearing and release of IBCA's
  - Guidelines for completion of an application
  - Guidelines for the assessment of an application

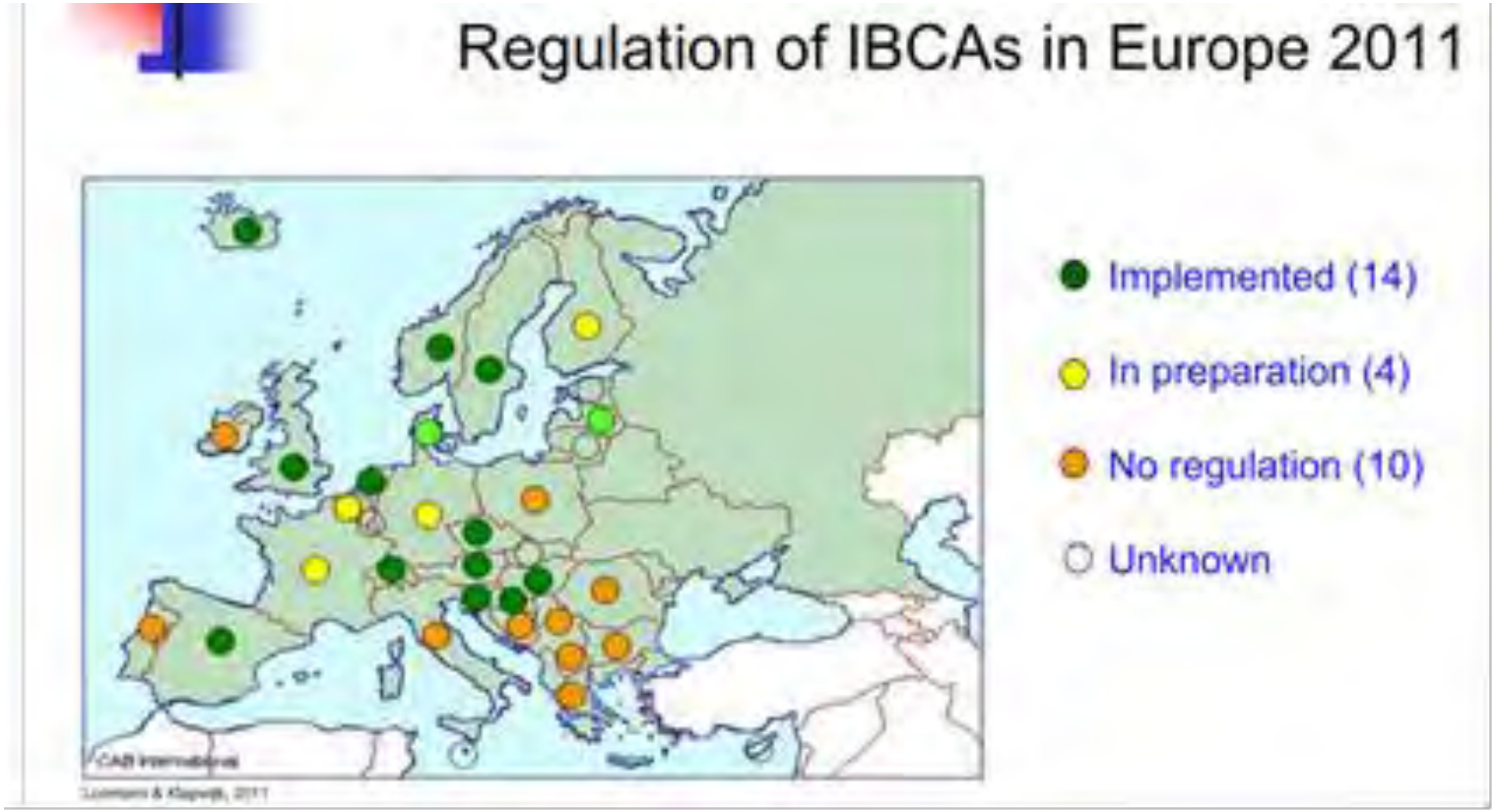
IBCAs widely used in the EPPO region

- Standard PM6/3(4)
- IBCAs which may be considered safe to use across the EPPO region:
  - Includes indigenous, introduced or established IBCAs
  - Used in more than 5 EPPO countries for at least 5 years with no reports of negative non-target effects.
- 3 categories
  - Commercially used
  - Successfully introduced classical IBCAs
  - IBCAs formerly recommend by EPPO

IBCAs widely used in the EPPO region

- EPPO countries may use this standard to aid regulation
- Presence on the list may mean that countries simplify/dispense with their usual regulatory processes
- Not all countries choose to do this though

The situation in 2011

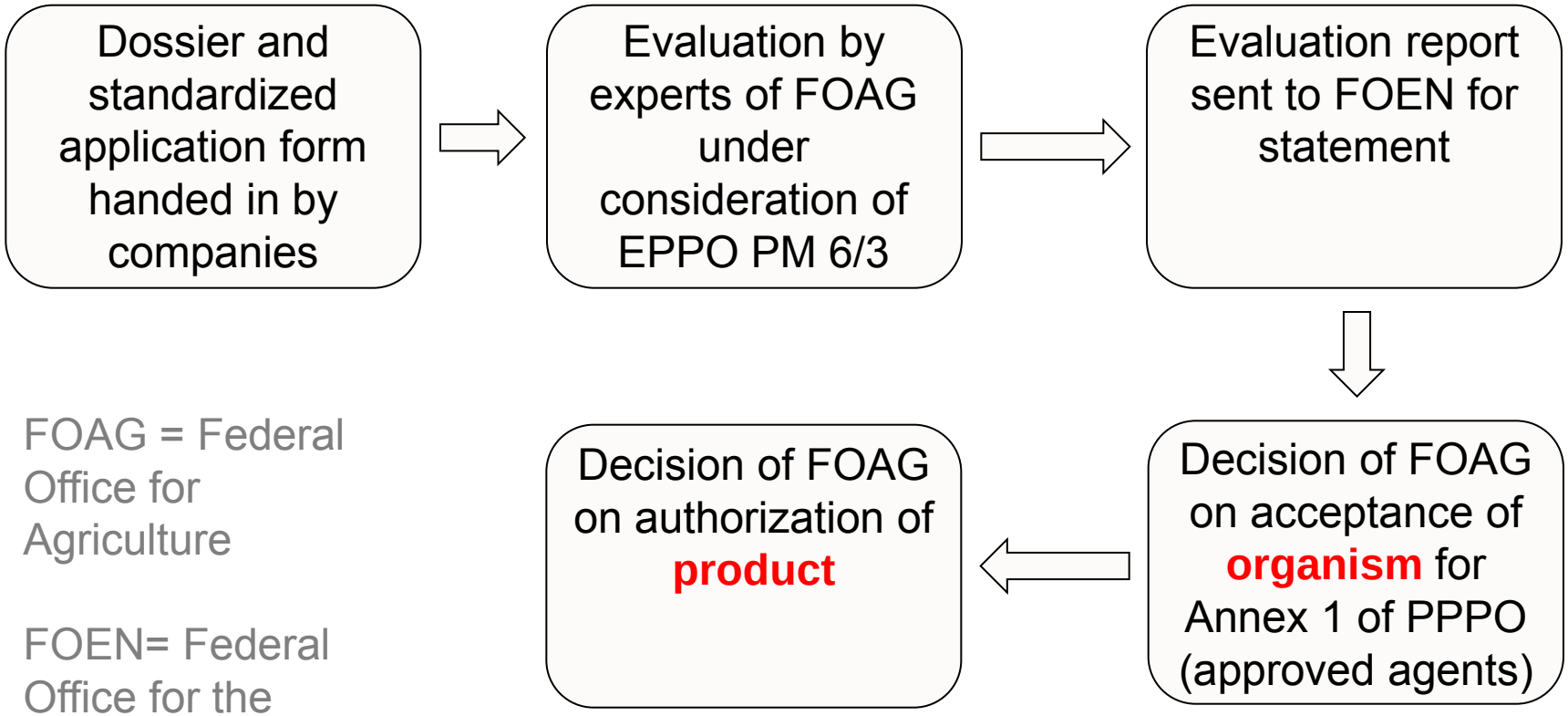


Regulation in the Netherlands

- Collection of data from literature
- Undertake any testing required
- Compile dossier following EPPO standard 6/2(3)
- Risk assessment primarily based on cold tolerance
- Submission of dossier to regulator
  - Will check and confirm all required data is included
  - Evaluation by regulator
- Answer within 8 weeks
- Permit for release valid for 5 years

Regulation in Switzerland

First use in Switzerland

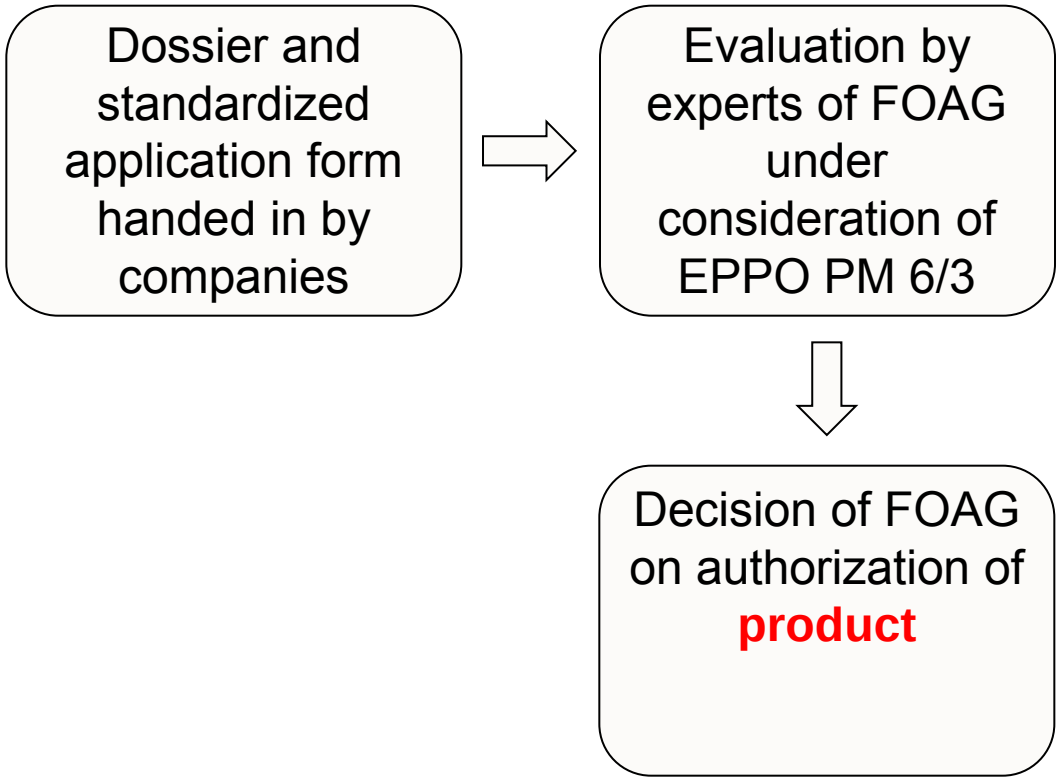


FOAG = Federal Office for Agriculture

FOEN= Federal Office for the Environment

Regulation in Switzerland

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

Regulation in Italy

- Release of IBCAs into natural and semi natural environments is prohibited
- Release indoors is permitted
  - Can be difficult to discriminate between indoors and semi-natural environments
  - Release into glasshouses is permitted.
- Import of organisms to be used for plant health purposes is regulated
  - Specific authorisation needed
  - Based on an environmental risk assessment

Regulation in the UK - Legislation

- The release of all non-native animals (and some plants) into the wild is prohibited.
  - Include semi confined situations such as glasshouses and poly-tunnels.
  - Non-native = of a kind not ordinary resident in and is not a regular visitor to Great Britain in a wild state.
- Secretary of State can grant licences to allow the release of NN species
  - Control of pests on crops
  - Control of invasive organisms

Regulation in the UK - Licences

- England, Scotland, Wales and Northern Ireland issue own licences.
  - All use a similar model template
- Licence holders have a legal responsibility to comply with the statutory conditions in licences
- Inspection and enforcement mechanism via Defra inspectorates and the police

Regulation in the UK - Licences

- Two types of licence
  - Releaser's licence, for experimental or species (re-) establishment purposes
  - Supplier's and grower's licences for commercial release (sale and distribution)
- Licences can valid for different time periods
- Less onerous re-assessment for renewals
  - Have conditions in licence been met by licence holder
  - Check to confirm that no new relevant information has become available.

Regulation in the UK - Application

- Defra has developed a comprehensive application form and a guide to completing it
- Based on EPPO standards and recommendations from REBECA
- Available to stakeholders on-line
- Regulator happy to be consulted about applications as they are being written

Regulation in the UK - Assessment

- Non-Classical purposes

Demonstration that potential benefits outweigh any risks; what are the potential impacts of the release

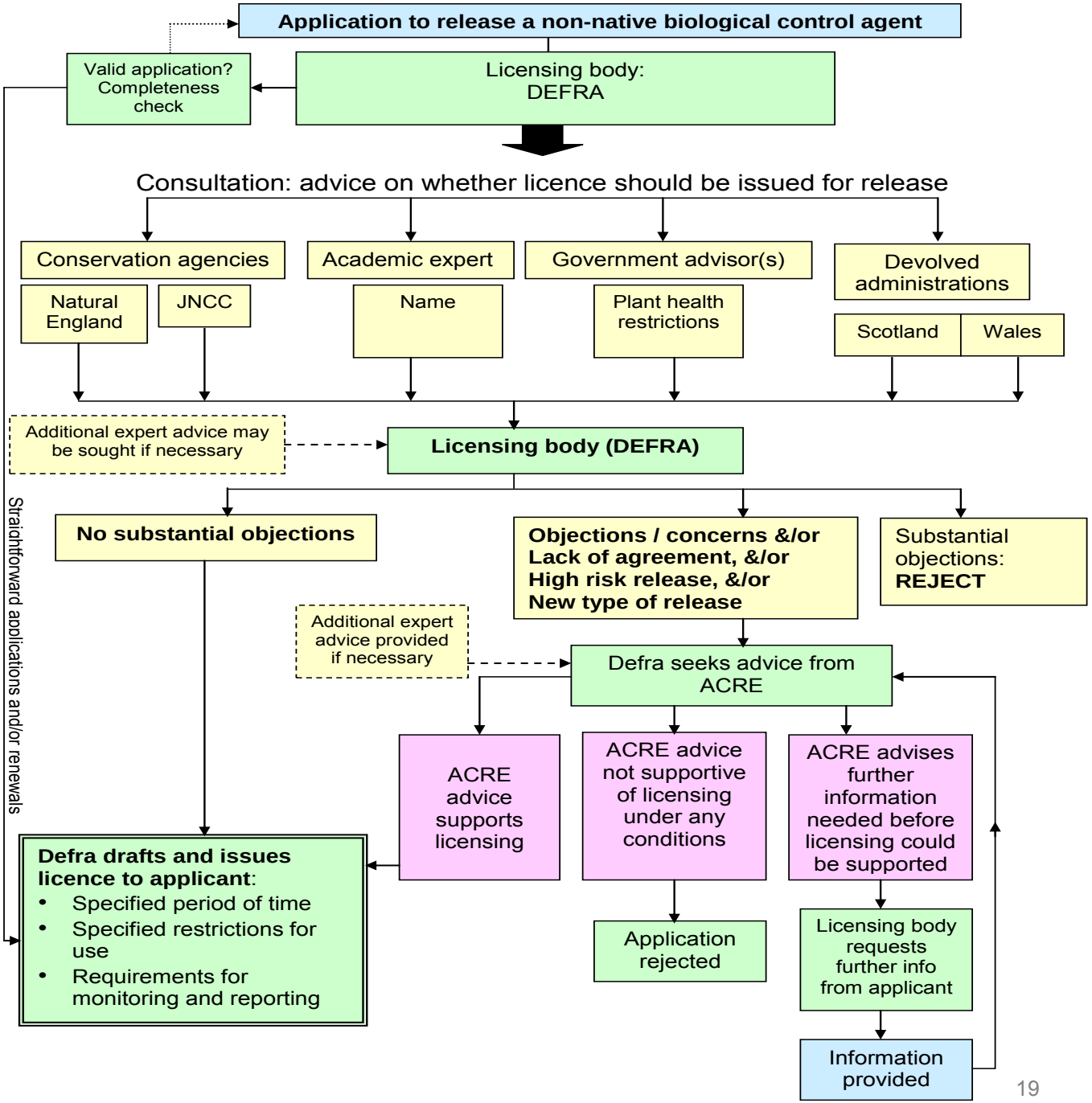
Evidence:

- quality and integrity of the organism to be released
- that the organism will not persist or establish in the wild in GB
- consideration of the organism's specificity and potential interactions with or impact on non-target species
- applicants for renewal: expected to have met all reporting and monitoring requirements

Evidence provided in:

- description of production QA measures
- studies of ability to overwinter outdoors and in protected environments
- results of host range testing on native species, if appropriate
- demonstration of understanding of organism's behaviour *in situ*
- reports on use in comparable climates may be provided as supporting evidence

Consultation process



Points to note:

- Most assessors work on the presumption in favour of using native species where they exist:
  - Some assessors would not recommend licensing a non-native BCA if a suitable native species exists
  - Want to see evidence for the need for the release and the availability of native species to address the problem
  - Want to see discussion of potential alternatives to the non-native agent and why the non-native offers the optimum solution
- Efficacy is **not** taken into consideration
- To date no classical release of an invertebrate predator has been permitted in the UK.