



Department
for Environment
Food & Rural Affairs

Biological Control

A comparison of European and North American Approaches

EPPO/COST-SMARTER/IOBC/IBMA/CABI Workshop on Evaluation and Regulation of Biological Control agents

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- Preparation of petitions for first release of non-indigenous entomophagous Biological Control agents
- NAPPO RSPM 12: Guidelines for Petition for First Release of Non-Indigenous Entomophagous Biological Control Agents
- I attended to present a European perspective

Initial conclusions

- Processes in both Europe and North America are remarkably similar
- Information requirements are generally the same
- Same concerns over the quality of data provided in applications/petitions
- Similar questions over how far risk assessment needs to go
- Processes are generally quite complex and time consuming

Legislation and Harmonisation



Regulation/legislation

- There is no overarching regulatory framework across Europe or even within the European Union
 - Range from countries with well developed regulatory procedures to those with none at all
 - Recognition that the lack of regulations has contributed to the success of the use of biological control
 - Is this in fact desirable?
- There is no overarching regulatory framework in North America

Harmonisation

- Voluntary harmonisation of requirements is one way of dealing with a lack of regulation
- Most easily be done via standard setting by recognised bodies/organisations
 - e.g. EPPO, NAPPO, IPPC
- Particularly important for countries sharing land borders
 - Transboundary movement



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))

NAPPO Standards

- RSPM 7: Guidelines for Petitions for first release of Non-indigenous Phytophagous BCAs
- RSPM 12: Guidelines for Petition for First Release of non-indigenous Entomophagous BCAs
- RSPM 22: Guidelines for the construction and operation of a containment facility for insects and mites used as BCAs



NAPPO Standards

- **RSPM 26: Certification of Commercial Arthropod BCAs moving into NAPPO Member Counties**
- RSPM 39 Packaging for the International Shipment of Live Invertebrates Used as BCAs
- Like EPPO, drafting groups include industry representatives
- USA and Canada publish lists of approved BCAs

Key Information Requirements in both EPPO and NAPPO Standards



The agent

- What is it the proposed agent
 - Taxonomy
 - Is it really what you think it is
 - How do you cope with species complexes
 - Source of initial population
 - May have implications for completing an application
 - Location of voucher specimens
- Purity/integrity of cultures
 - How easy to maintain purity
 - How easy to monitor and audit

Host Range Testing

- One of the most important (& contentious) issues
- How much can you learn from existing information
 - From its native range
 - From its introduced range
- How do you develop a list of test subjects
 - Various methods have been developed
 - How do you pick the most appropriate method



Establishment potential

- Another key and often difficult factor
- Experimental design can be difficult
 - How much involvement should regulators have in developing this
- Does the origin of the initial population have an influence?
 - Should releases be restricted to populations from the same origin?

A Key Question

- How much trust can be placed in the results of laboratory tests transferring to the receiving environment?
 - More reliable for host testing?
 - More reliable for assessing establishment potential?



Cost benefit analysis

- Should cost/benefit analysis be part of the assessment process
- Does it depend on the end use?
 - e.g. commercial use on ornamentals for retail
 - e.g. classical weed control



Post release monitoring

- Is it always needed?
- What is being monitored?
- Who does the monitoring?
 - Applicant
 - Regulator
- Contingency plans if negative non-target effects are observed?



For consideration.....

- Does efficacy need to be considered as part of the approval process?
- Does the whole approvals/risk assessment process need to be followed?
 - Glasshouse - if agent cannot establish in the wider environment do you need to consider host range?
 - Outdoor releases – if agent is host specific do you need to consider establishment potential?

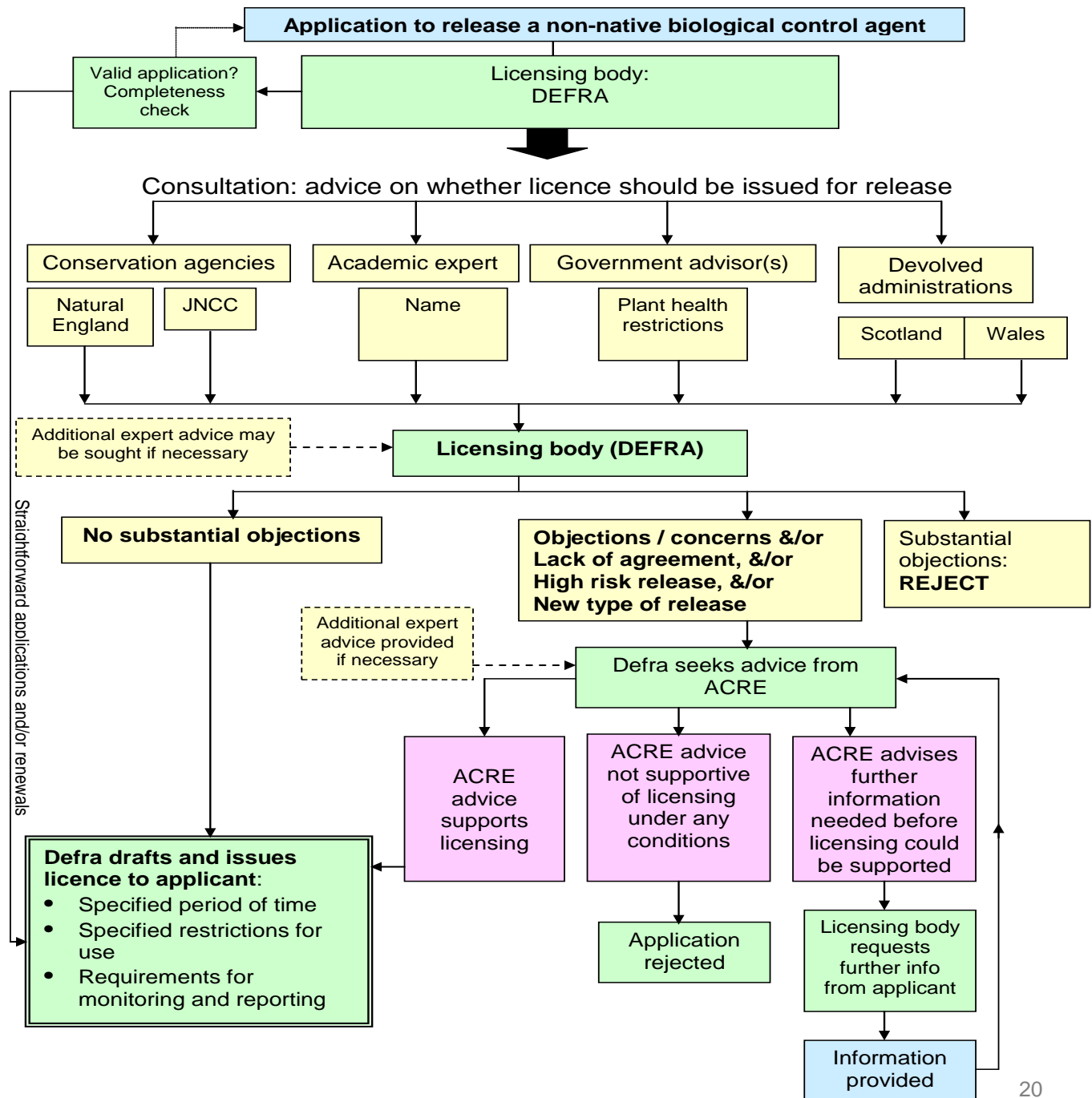
For consideration.....

- How much involvement/consultation should there be between neighbouring countries?
- Should dossiers be reviewed after a certain period of time?
 - If yes then how often?
 - What happens if a different conclusion is reached
- How/where does cost/benefit fit

Example Assessment Processes

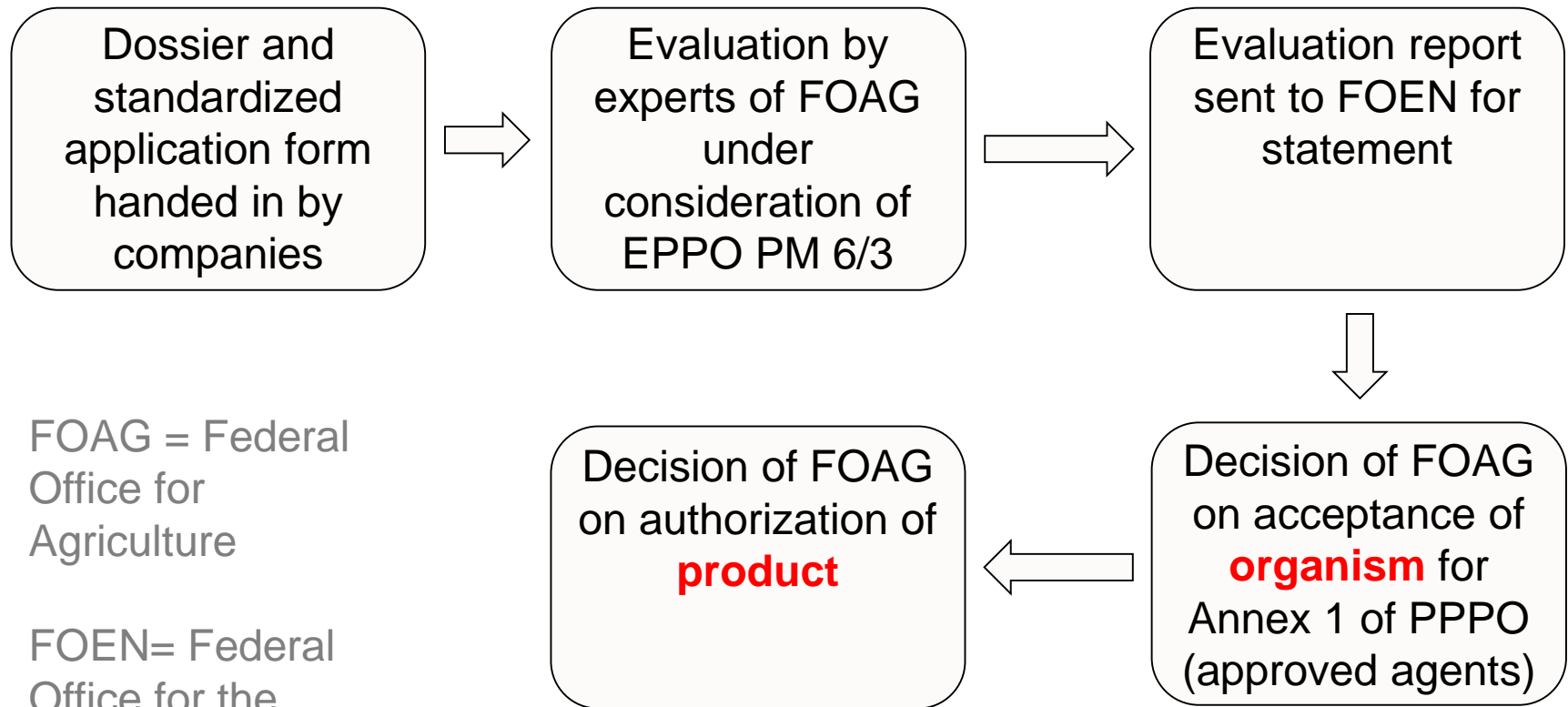


Process in the UK



Process in Switzerland

First use in Switzerland



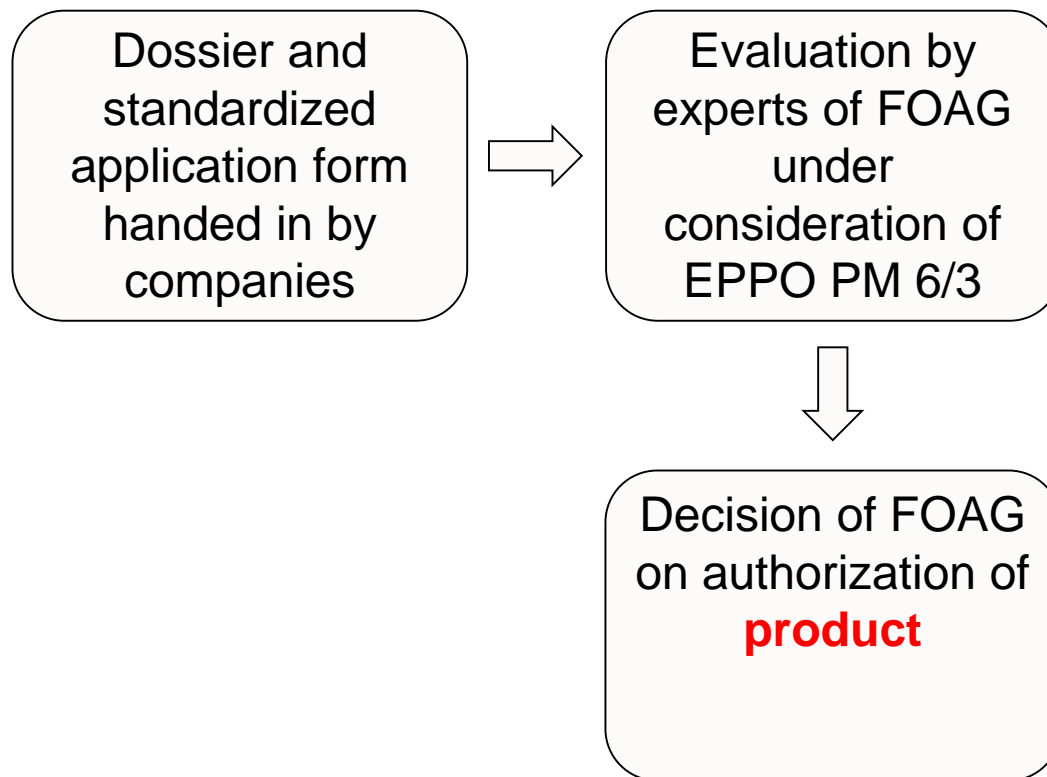
FOAG = Federal Office for Agriculture

FOEN= Federal Office for the Environment



Process 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

Process 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

Process in Mexico

SAGARPA
SECRETARÍA DE AGRICULTURA,
GANADERÍA, DESARROLLO RURAL,
PESCA Y ALIMENTACIÓN



SENASICA
SERVICIO NACIONAL DE SANIDAD,
INDICIDAD Y CALIDAD
AGRICOLMENTARIA

Importer application to the Plant Health General Directorate

↓ 1

The NBCRC (National Biological Control Reference Centre) receives a copy of the import application, addressing the requirements set out in Articles 101 and 102 of the Plant Health Act, and additional supporting technical information based on the RSPM 12

↙ 2

Issue authorization and recommendations together with an official letter signed by the Plant Health General Director.

↘ 2

Issue rejection of import and recommendations together with an official letter signed by the Plant Health General Director, including detailed reasons for rejection

↘ 2'

Recommendation

↖ 4

If in doubt, consultation with the NCPAG (National Consultative Phytosanitary Advisory Group) Biological Control Committee takes place. The group consist of:

- ✓ Academic Professionals
- ✓ Research Professionals
- ✓ Government Officials

↑ 3

5

6

Decision is sent to the interested parties

Note:

1. In order to be able to import, the applicant is responsible to send copies of the certificates of origin and biological purity to the NCBCR, as well as information about the actual activities after the importation.
2. If the applicant fail to send the information indicated above, the next application to import biological control agents will be refused until all requirements are fulfilled.
3. **Permits are valid for one year and are renewable.**

Process in Canada

Process for Biological Control Agent Petitions

