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

Presented by: Samuel Bishop
Date: 23rd November 2015

NAPPO Workshop June 2015

- 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?

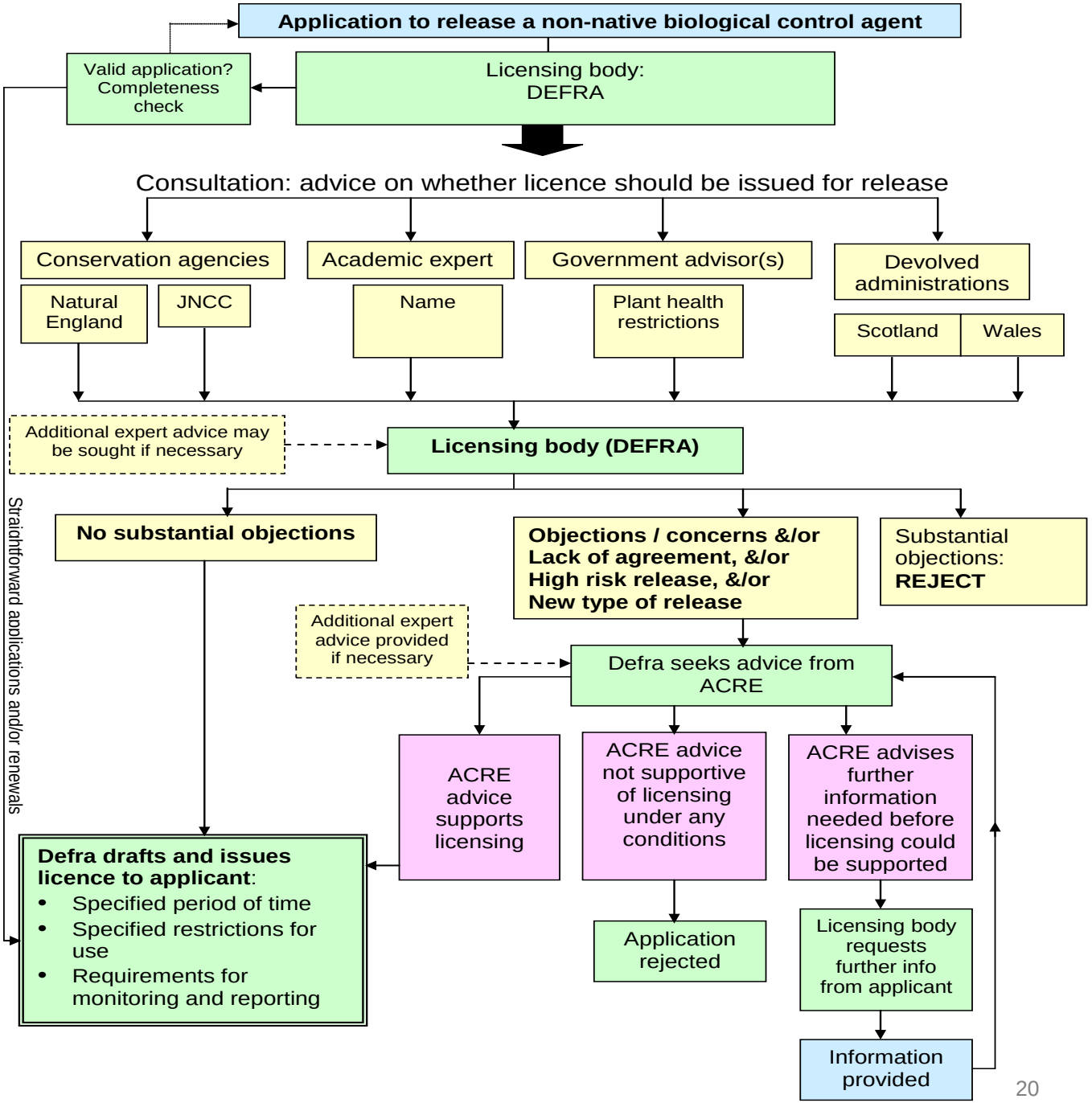
- Does the whole approvals/risk assessment process need to be followed?
  - Glasshouse - if agent cannot establish in the wider environment do you need to consider host range?
  - Outdoor releases – if agent is host specific do you need to consider establishment potential?

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

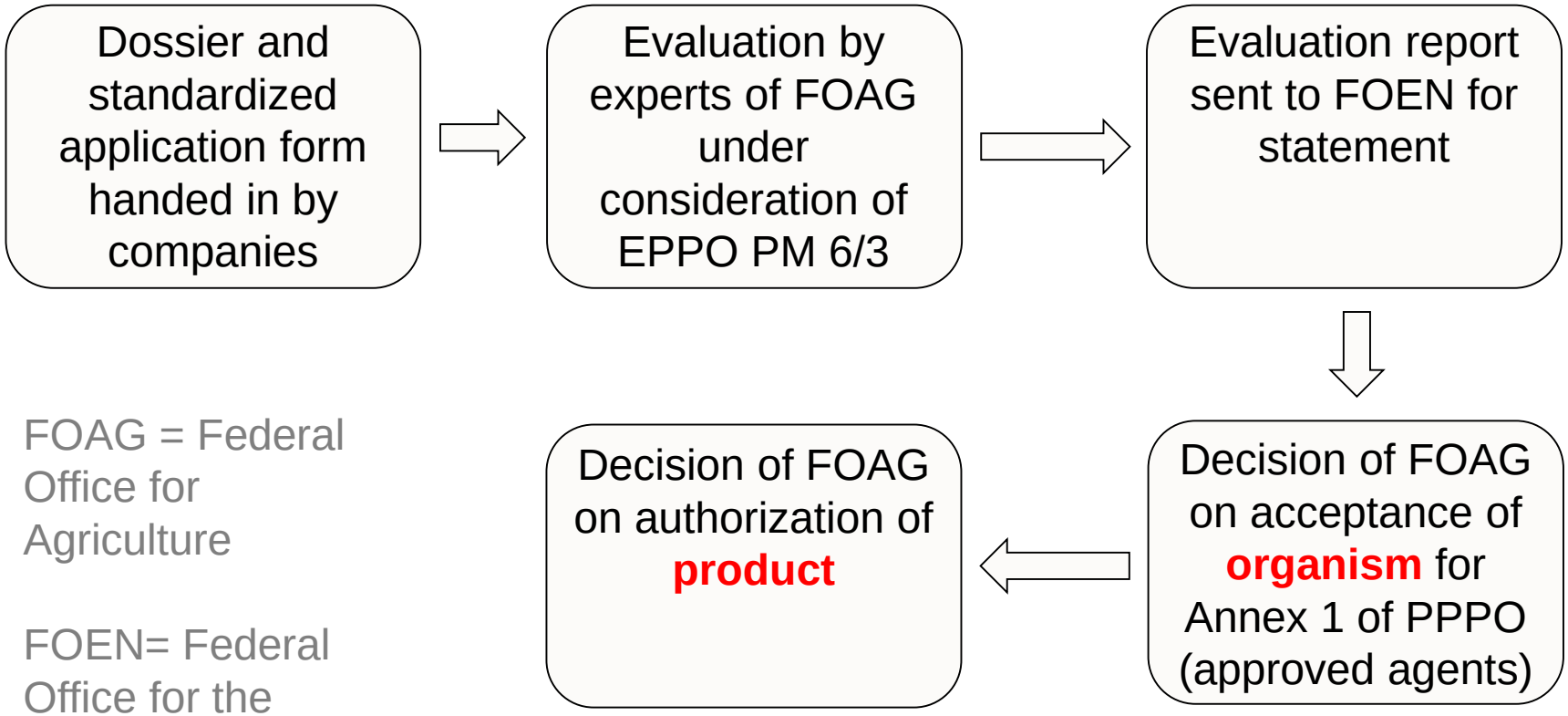
Example Assessment Processes

Process in the UK



Process in Switzerland

First use in Switzerland

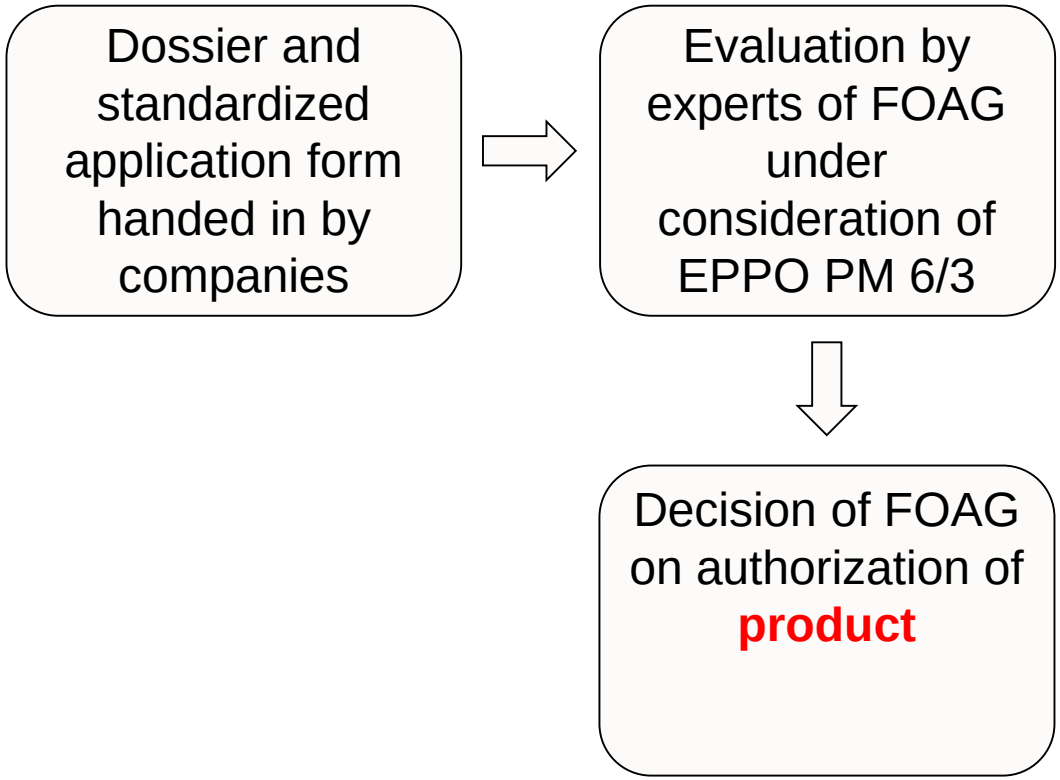


FOAG = Federal Office for Agriculture

FOEN= Federal Office for the Environment

Process in Switzerland

BCA already on Annex 1 of PPPO



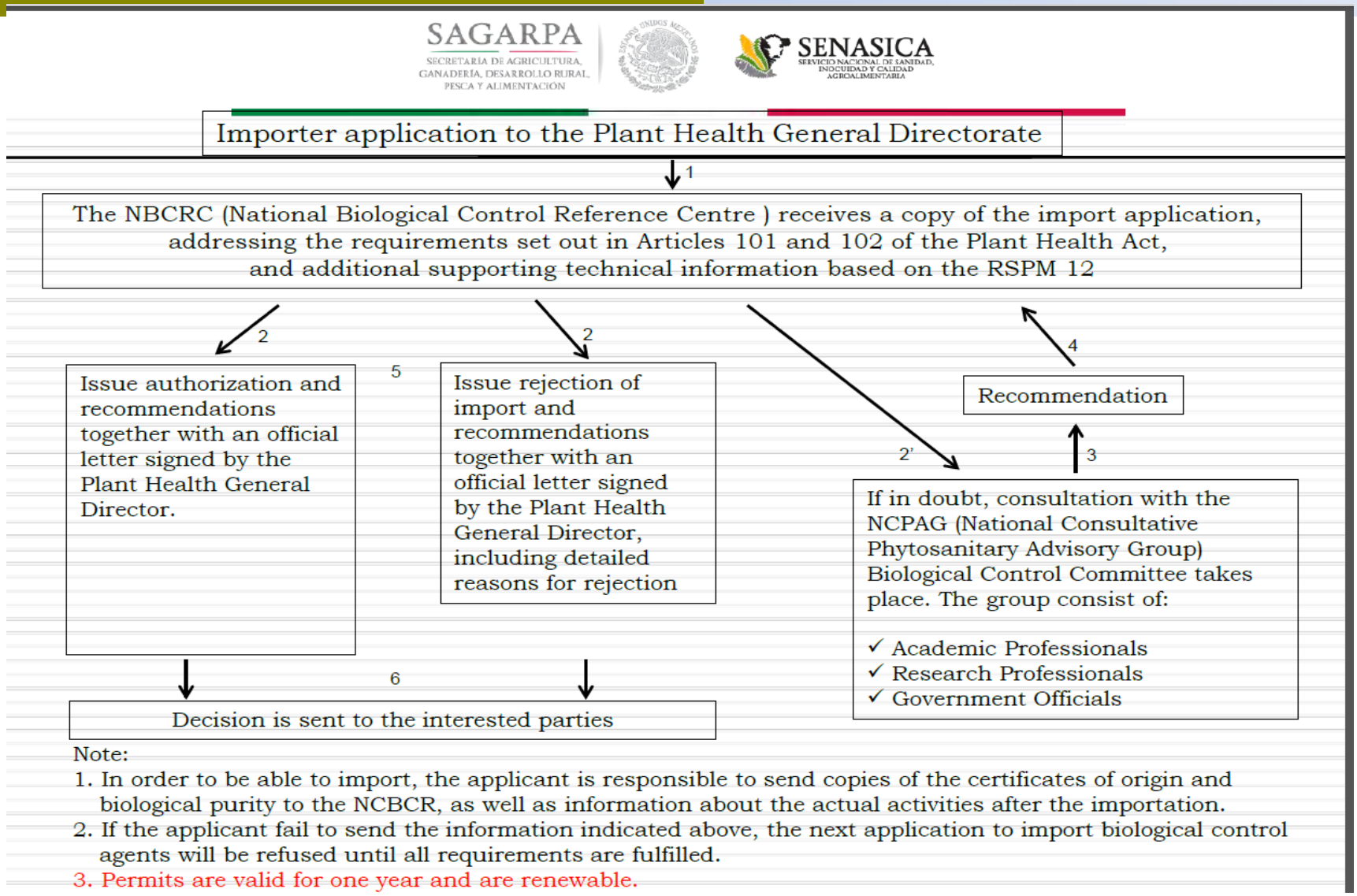
Organisms present on Annex 1 have to be (re-) evaluated:

- 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



Process in Canada