



Evaluation and Regulation of Biological Control Agents

Workshop

Budapest

2015-11-23/24





Landmarks in the Regulatory Landscape and Objectives for the Workshop

Workshop on Evaluation and Regulation of
Biological Control Agents

2015-11-23/24

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Background and history ...



Biological Control Agents

- An organism [used] to reduce the population density of another organism (IOBC)
- A BCA may also be, potentially:
 - an invasive alien species
 - a plant pest
 - a quarantine plant pest
 - a harmful organism
 - a plant protection product
- Import, release and use are subject to a complex mixture of regulations
- This landscape has to be navigated so that biological control options can be adopted widely, quickly and safely
- Do we need better maps or an agreed route?



Biological Control Agents

- an invasive alien species (“an alien species whose introduction or spread has been found to threaten or **adversely impact** upon biodiversity and related ecosystem services” (EU Regulation))
- a plant pest (“Any species, strain or biotype of plant, animal or pathogenic agent **injurious to plants** or plant products” (IPPC))
- a quarantine plant pest (“A pest of potential economic importance to the area endangered thereby and **not yet present there**, or present but **not widely distributed** and being officially controlled” (IPPC))
- a harmful organism (“any species, strain or biotype of plant, animal or pathogenic agent **injurious to plants** or plant products” (EU Plant Health Directive))
- a plant protection product (“chemical or biological products used in agriculture to protect plants” (OECD))

Problems of terminology and distinctions

- macrobial / microbial
- classical / augmentative
- released / marketed
- non-indigenous / indigenous
- likely to establish / not likely to establish
- non-commercial / commercial



History

- 1996 EPPO/CABI Workshop
Safety and Efficacy of Biological Control in Europe
- 1999 - EPPO Standard PM 6/1
first import of exotic BCAs for research in containment
- 2000 - EPPO Standard PM 6/2
import and release of exotic BCAs
- 2001 - EPPO Standard PM 6/3
list of BCAs widely used in the EPPO region



Streatley 1996 – EPPO / CABI Workshop

Conclusions

- “The introduction of BCAs into Europe is necessary for research purposes, for classical control programmes and for commercial purposes. In considering the value and risks of establishing exotic BCAs in Europe, an eco-regional approach should be taken.”
- “... practices for the import of macrobiological agents at present vary greatly between European countries. These practices should be harmonized, with appropriate conditions recommended for different purposes.”
- “The workshop suggested that an EPPO Panel should be established, and promote the adoption of harmonized recommendations on good practice for the import of macrobiological agents.”

Streatley 1996 – EPPO / CABI Workshop

- “Enormous **variation exists today in regulatory procedures** for biological control introductions. Some ... countries ... have developed protocols for safety testing and quarantine most European countries have not.” (Waage)
- “Sensible regulatory procedures which apply fairly **to both classical biological control and commercial introductions** will be of enormous value to the development of biological control in Europe ...” (Waage)
- “Registration procedures for biological control agents are very diverse in Europe ... Standardization of registration in Europe **may take about a decade.**” (Van Lenteren)
- “Similar problems exist for importation of natural enemies. Establishment of a **‘positive list’** of natural enemies would help in speeding up implementation of biological control.” (Van Lenteren)

Globally ...



International Plant Protection Convention

“With the aim of preventing the introduction and/or spread of regulated pests into their territories, contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may: ...

- d) prohibit or restrict the movement of **biological control agents and other organisms of phytosanitary concern claimed to be beneficial** into their territories”

FAO Code of Conduct / ISPM3

- 1997 *FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents* 1997
- 2005 *ISPM3 Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*
 - “The standard addresses biological control agents capable of self-replication as well as sterile insects and other beneficial organisms and includes those packaged or formulated as commercial products”
 - “The scope of this standard **does not include** living modified organisms, **issues related to registration of biopesticides**, or microbial agents intended for vertebrate pest control.”
 - “In some cases, the scope of these guidelines may be deemed to extend **beyond the scope and provisions of the IPPC** as described above. For example, although the primary context of this standard relates to phytosanitary concerns, ‘safe’ usage as mentioned in the standard is intended to be interpreted in a broader sense, i.e. minimizing other non-phytosanitary negative effects.”

ISPM3: “NPPOs or other ... authorities should:

- carry out pest risk analysis of biological control agents and other beneficial organisms prior to import or prior to release;
- ensure, when certifying exports, that the phytosanitary import requirements of importing contracting parties are complied with;
- obtain, provide and assess documentation as appropriate, relevant to the export, shipment, import or release ...;
- ensure [they] are taken either directly to designated quarantine facilities or mass-rearing facilities or, if appropriate, passed directly for release into the environment;
- encourage monitoring of release ... in order to assess impact on target and non target organisms.
- Prior to release, NPPOs or other responsible authorities are encouraged to communicate details of the intended release that **may affect neighbouring countries**.... details ... may also be communicated to relevant **RPPOs**.”

Convention on Biodiversity

Article 8

- “Each Contracting Party shall, as far as possible and as appropriate:
 - (h) Prevent the introduction of, control or eradicate those alien species which **threaten** ecosystems, habitats or species”



Within the EU ...



EU Regulation on invasive alien species (1143/2014)

“This Regulation does not apply to:

- (d) harmful organisms listed in [the Plant Health Directive 2000/29] and harmful organisms for which measures have been adopted in accordance with Article 16(3) of that Directive;
- (f) micro-organisms manufactured or imported for use in plant protection products already authorised or for which an assessment is ongoing under [the Plant Protection Products Regulation 1107/2009];”



EU Regulation on invasive alien species (1143/2014)

Article 22 paragraph 3

- “Member States may also apply provisions ... to ensure coordination and cooperation with other relevant Member States as regards **invasive alien species of Member State concern** identified in national lists

Article 23

- **Member States may maintain or lay down more stringent national rules** with the aim of preventing the introduction, establishment and spread of invasive alien species. Those measures shall be compatible with the TFEU and be notified to the Commission in accordance with Union law.”

EU Habitats Directive (92/43)

[slide added following the workshop]

Article 22

- "In implementing the provisions of this Directive, Member States shall ... (b) ensure that the deliberate introduction into the wild of any species which is not native to their territory is regulated so as not to prejudice natural habitats within their natural range or the wild native fauna and flora and, if they consider it necessary, prohibit such introduction."



EU Regulation on the placing of plant protection products on the market (1107/2009)

- “... lays down rules for the authorisation of plant protection products **in commercial form and for their placing on the market, use and control** within the Community.
- ‘micro-organisms’ means any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material;
- ... shall apply to **substances, including micro-organisms** having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as ‘active substances’
- ‘**substances**’ means **chemical elements and their compounds**, as they occur naturally or by manufacture ...”

EU Regulation on the placing of plant protection products on the market (1107/2009)

- “‘placing on the market’ means the **holding for the purpose of sale within the Community**, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves, but not the return to the previous seller. **Release for free circulation** into the territory of the Community shall constitute placing on the market for the purposes of this Regulation;
- A plant protection product shall not be placed on the market or used unless it has been authorised in the Member State concerned in accordance with this Regulation.”

Data requirements (284/2013)

- “A summary and **evaluation of all data relevant to the environmental impact** shall be carried out ... It shall include a detailed and critical assessment of those data in the context of relevant evaluative and decision making criteria and guidelines, with particular reference to **the risks for the environment and non-target species** that may or do arise, and the extent, quality and reliability of the database. In particular the following issues shall be addressed:
 - **prediction of distribution** and fate in the environment, and the time courses involved,
 - identification of non-target species and populations at risk, and prediction of the extent of potential exposure,
 - identification of precautions necessary to avoid or minimise contamination of the environment, and for the
 - protection of non-target species.”
- This is not a Pest Risk Analysis under plant health rules!

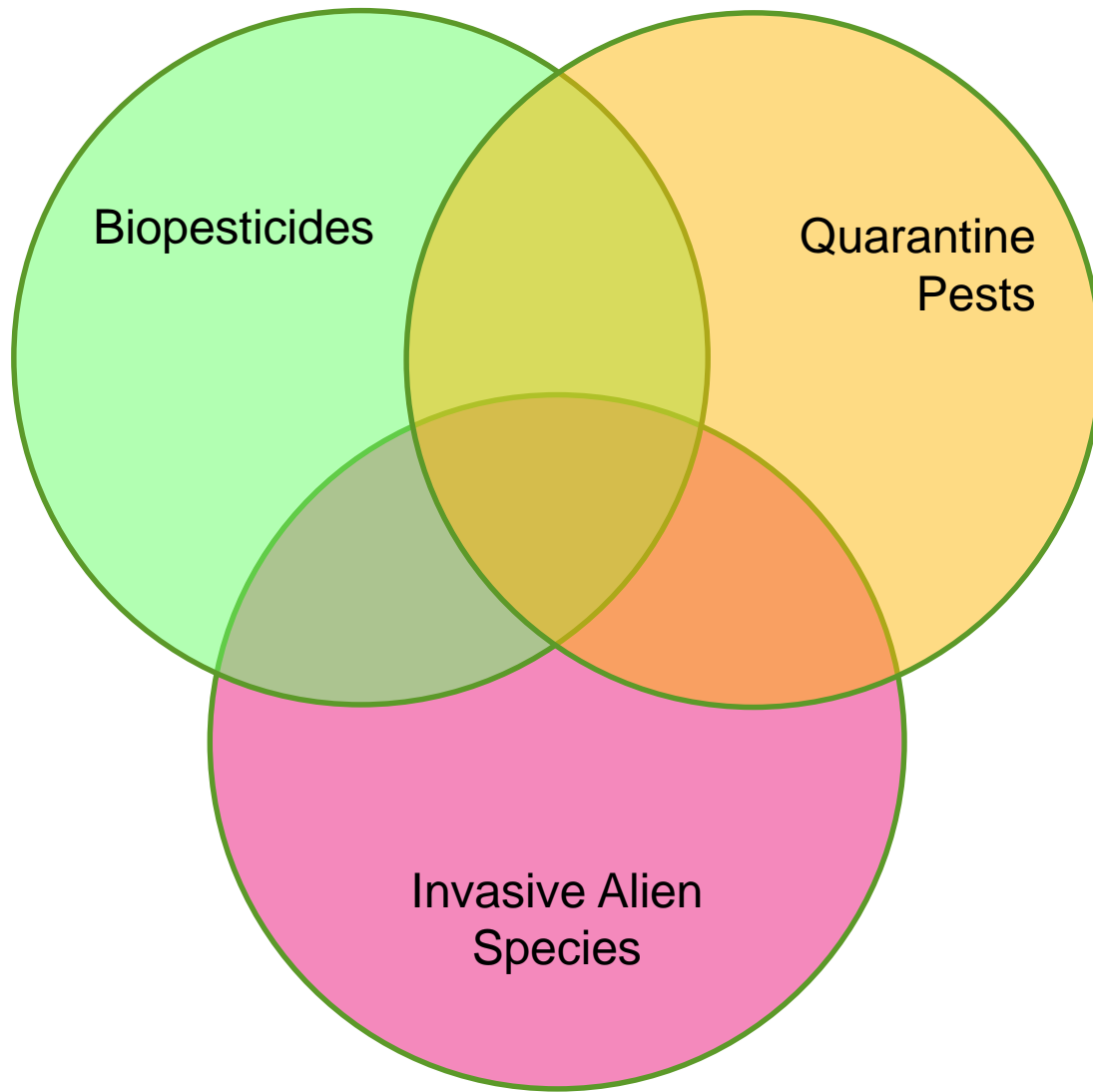
Proposed EU Regulation on pests of plants

“A pest shall be referred to as a 'quarantine pest', with respect to a defined territory, if it fulfils all of the following conditions:

- (a) its identity is established ...;
- (b) it is not present in that territory ... or, if present, only distributed to a limited extent within that territory ...;
- (c) it is capable of entering into that territory, of perpetuating its presence ... for the foreseeable future ... (hereinafter: 'to establish') and of spreading within that territory, or, if present, those parts of it where it is distributed to a limited extent ...;
- (d) its entry, establishment and spread would ... have an **unacceptable ... impact** for that territory, or, if present, those parts of it where it is distributed to a limited extent; and
- (e) feasible and effective measures are available to prevent the entry into, establishment or spread of that pest within that territory, and mitigate its phytosanitary risks and impacts.”

An attempt to visualise this ...



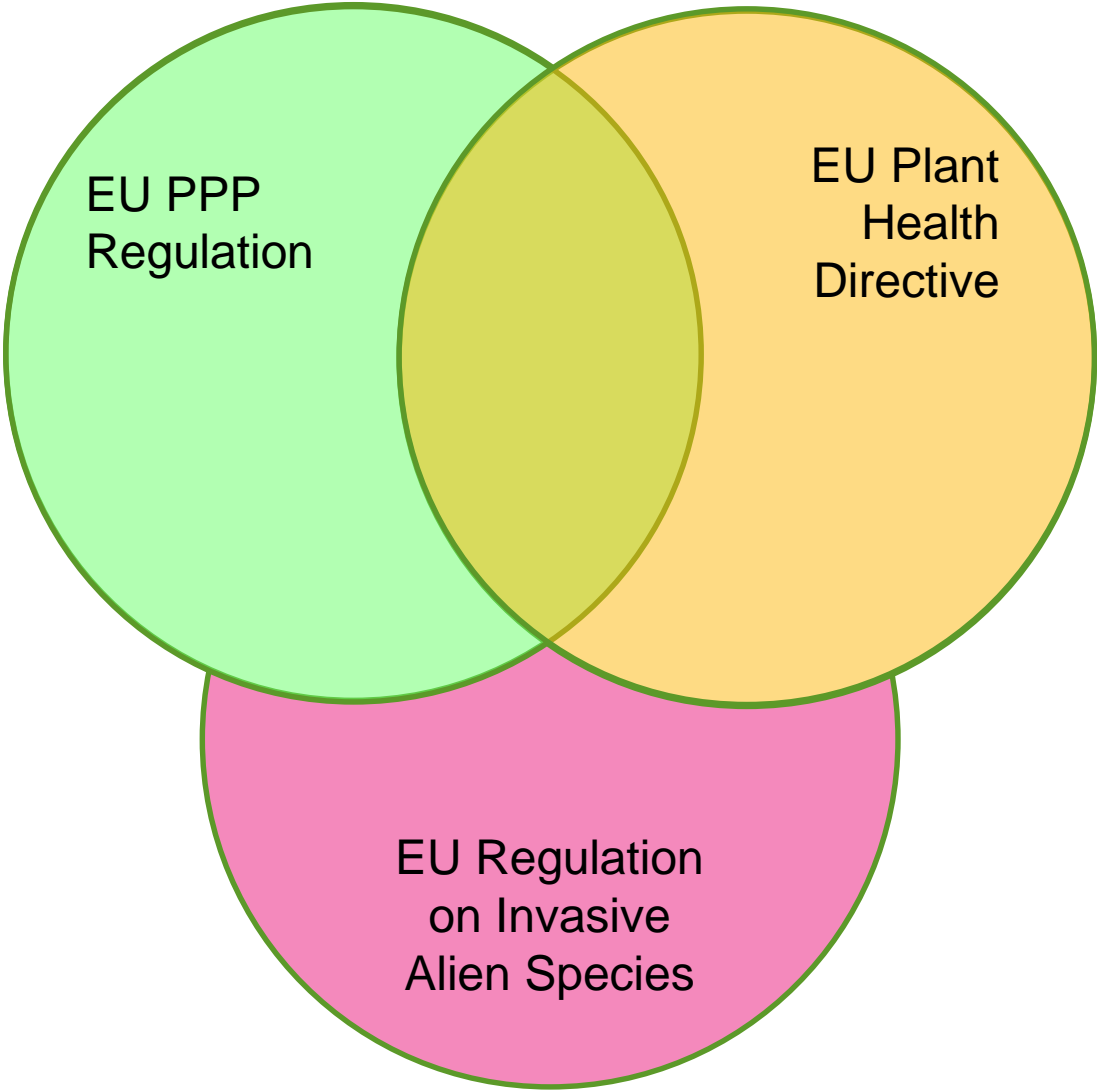


Biopesticides

Quarantine
Pests

Invasive Alien
Species



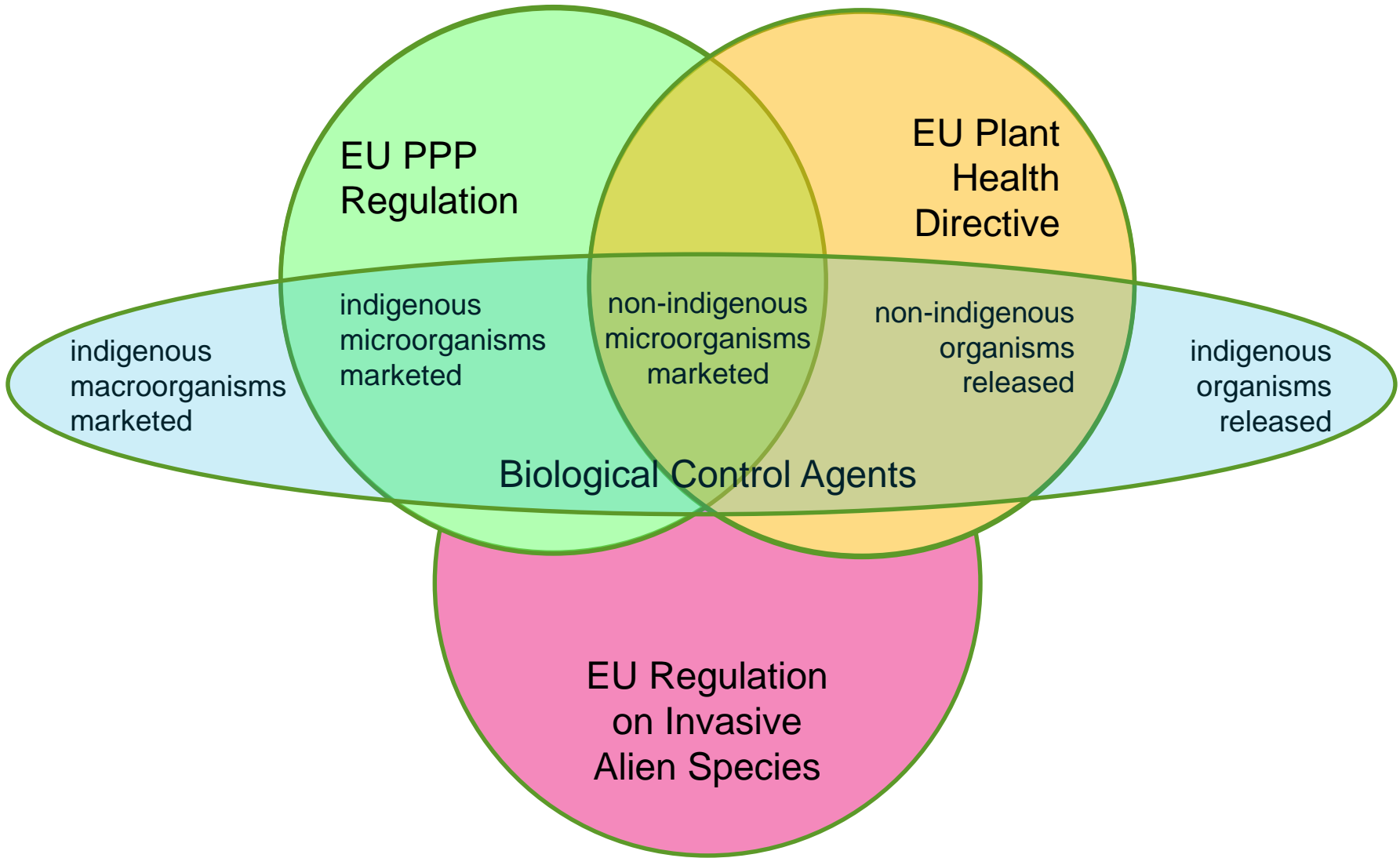


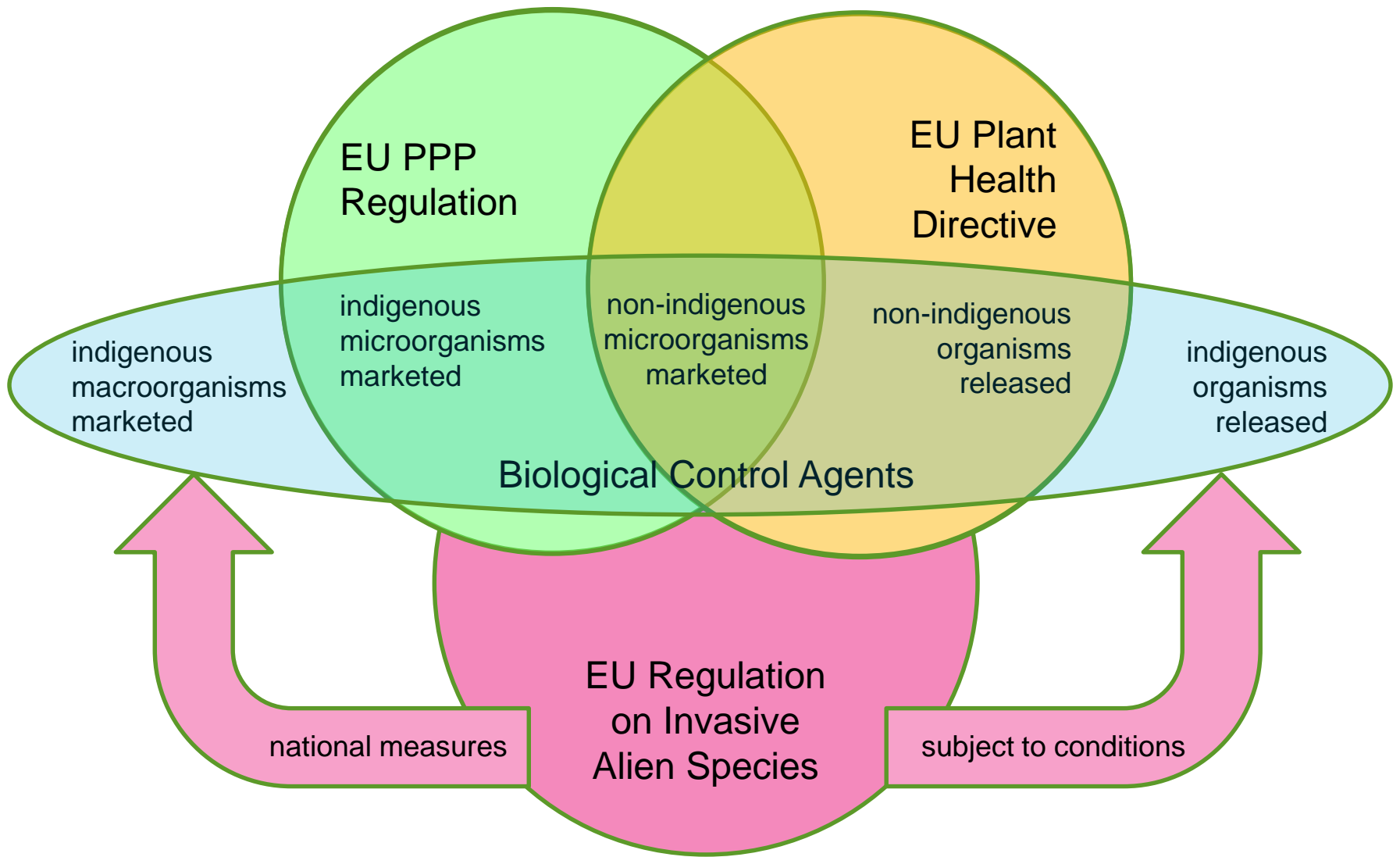
EU PPP
Regulation

EU Plant
Health
Directive

EU Regulation
on Invasive
Alien Species







Summary and objectives ...



Summary of problem

- Three new pieces of EU regulation address different risks
- but not, explicitly, biological control agents
- New separate legislation is unlikely for the EU
- Similar situation in some non-EU member countries?
- Use of biological control may be unnecessarily restricted
- Therefore we need agreed guidance to ensure harmonisation of interpretation and implementation?
 - Agreed between whom?
 - What sort of guidance, addressed to whom?
 - How harmonised?
 - In what direction to harmonise?
 - How to build on what has already been achieved?

EPPO Role

- PM6 Standards developed and in use
- New EPPO Strategy for 2015-2020
 - Plant Protection Products - focus on efficacy
 - Biological Control Agents - focus on ???
- Aim to do what member countries want within resource limits!
- New Decision Support Scheme for Environmental Risk Assessment under consideration by Panel
- EPPO / IOBC Panel needs agreed Terms of Reference

Objectives of Workshop

- Common understanding of which rules apply to which scenarios
- Knowledge of how rules are currently applied in different countries
- Analysis of resulting problems and of knowledge gaps
- Recommendations to regulators
- Recommendations to industry
- Recommendations to researchers
- Recommendations to EPPO
 - Input to strategy in relation to work on biological control agents
 - Input to decision-support scheme for import and release of non-indigenous invertebrate biological control agents of plant pests'
 - Input to terms of reference for the IOBC / EPPO Panel



Thank you!

