

# Regulation of Biological Control Agents: International and National Context

**Antoon Loomans**

Plant Protection Service  
Wageningen, The Netherlands

*Nieuwe paden,  
vitale natuur*



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## Overview

- International legislation
  - EU legislation
  - National legislation



National Geographic 2003

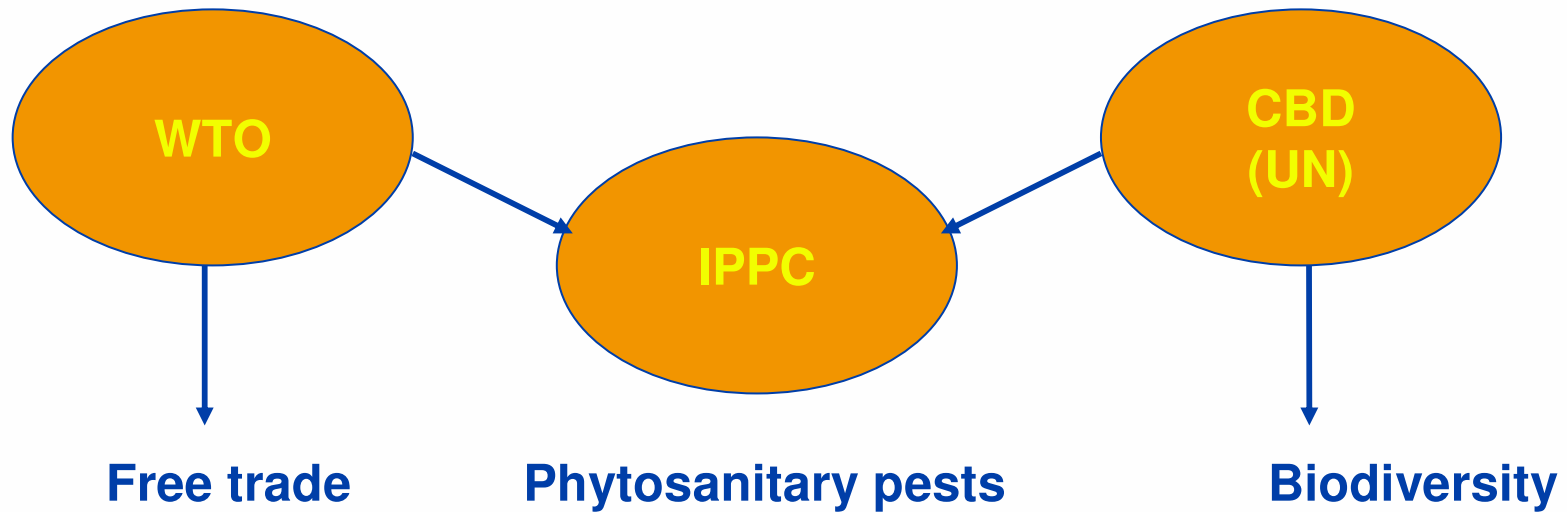


# Legislative Instruments Macrobials

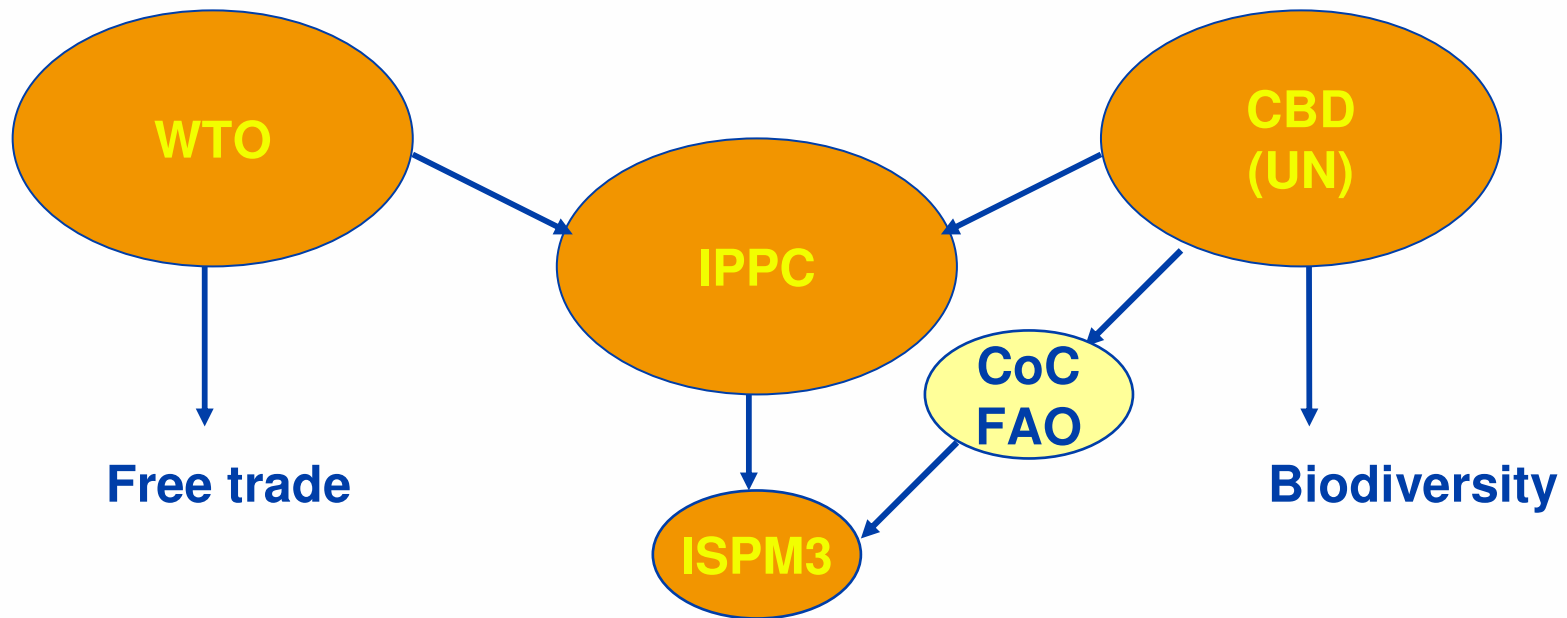
Two major **international legally binding** treaties:

- 1. International Plant Protection Convention (IPPC – 1951)**
  - addresses economic impact exotic species
- 2. Convention on Biological Diversity (CBD – 1992)**
  - addresses ecological impact exotic species
- 3. World Trade Organisation (WTO)**

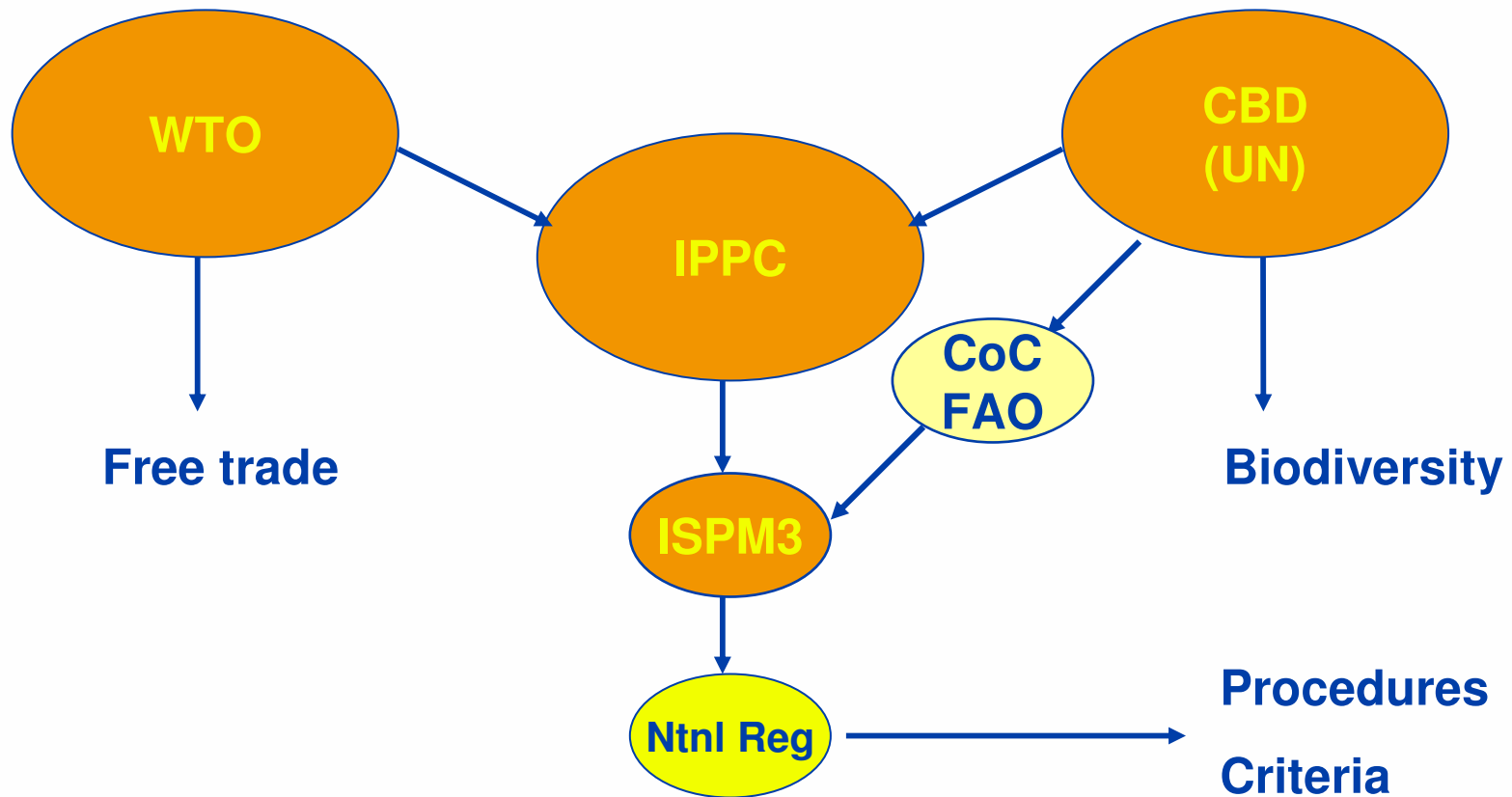
# Legislative Instruments



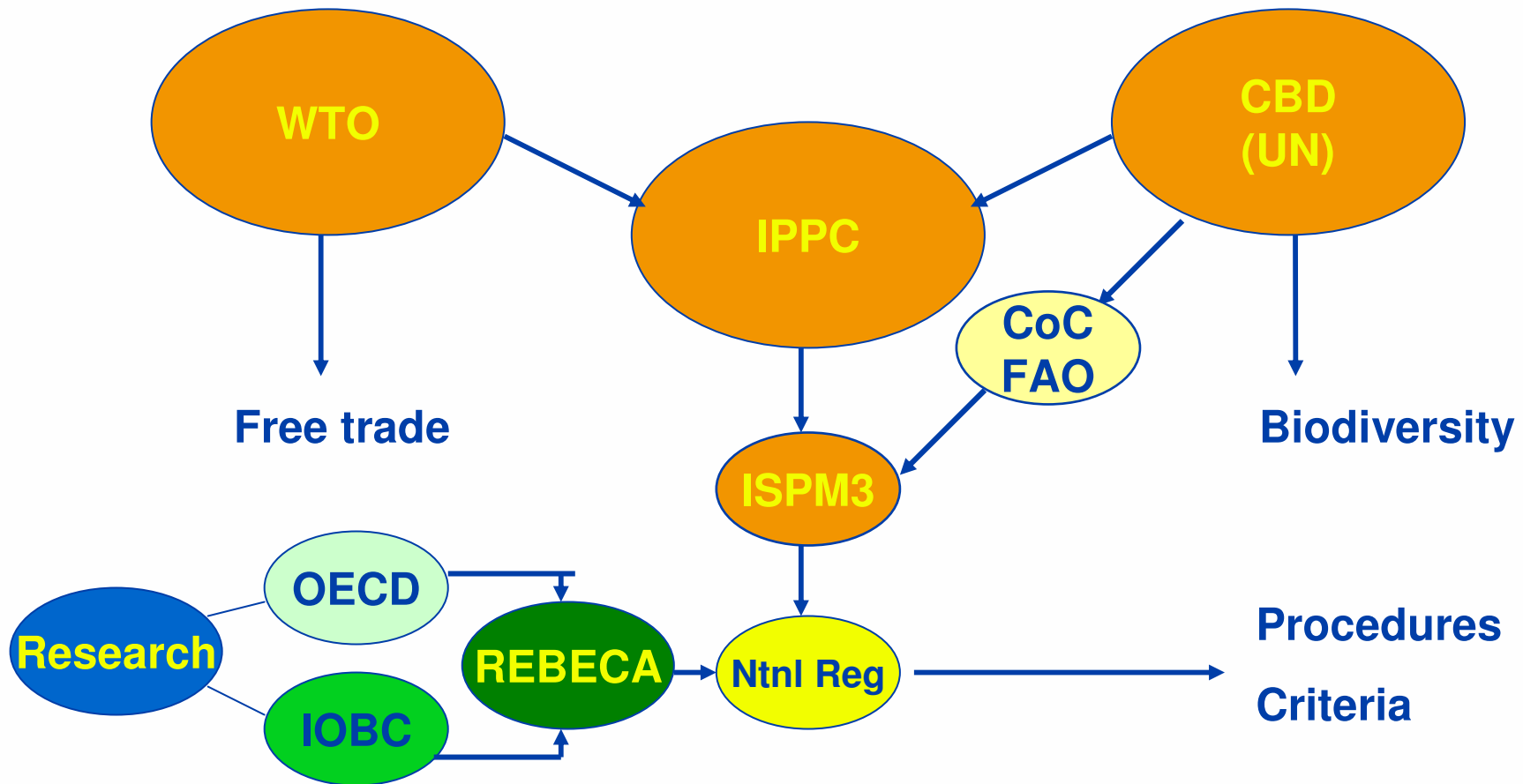
# Legislative Instruments



# Legislative Instruments



# Legislative Instruments





# Legislative Instruments

## Changes

### from Code of Conduct to ISPM3

- export, import, shipment and release
- exotic and native
- legally binding standard
- emphasis also on environmental risks
- implementation, documentation

[import, 1st introduction]



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# Legislative Instruments EU

## Micro-organisms:

Directive 91/414, Part B (micro-organisms and viruses including corresponding annexes)

## Macro-organisms:

No legislation / directive (national regulations)

➔ **REBECA**

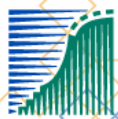


# Legislative Instruments EU

## Introduction exotic species

three types of national legislation:

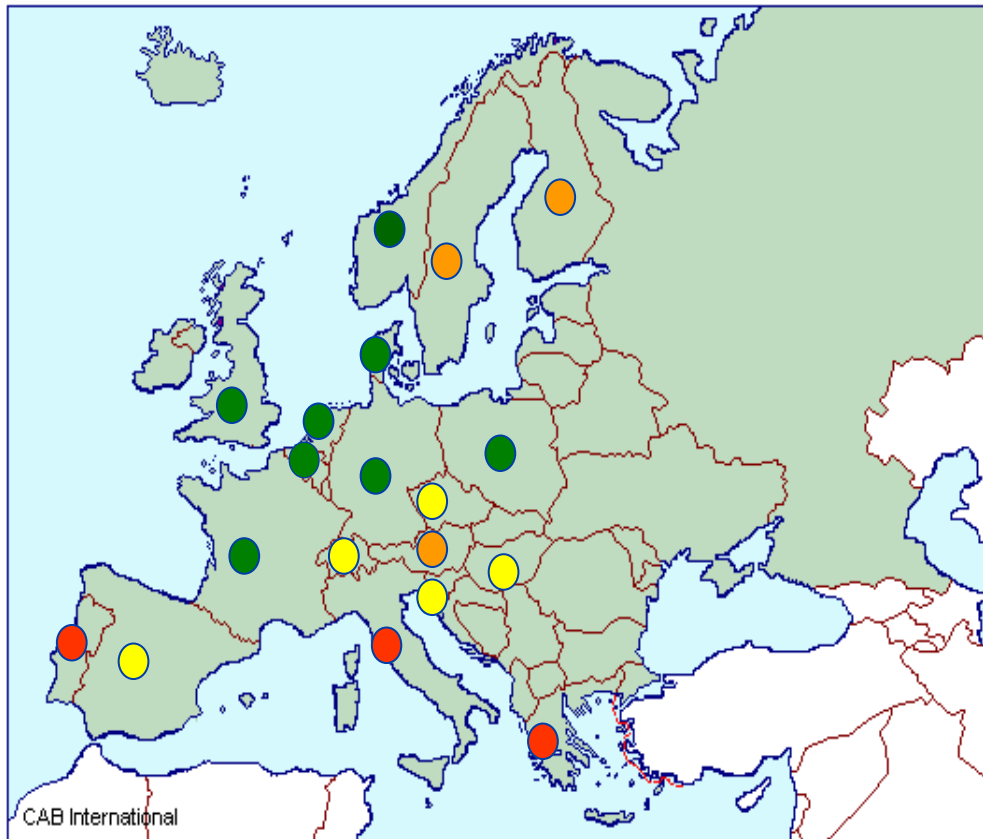
1. Pesticide acts
2. Plant health acts
3. Nature conservation acts



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# Legislative Instruments EU

Legislation : different types, (1981) 1992-2004



**Substances (3)**

● pesticide

**Plant Health (5)**

● phytosanitary

**Nature Conservation (8)**

● environment

**No / other (3)**

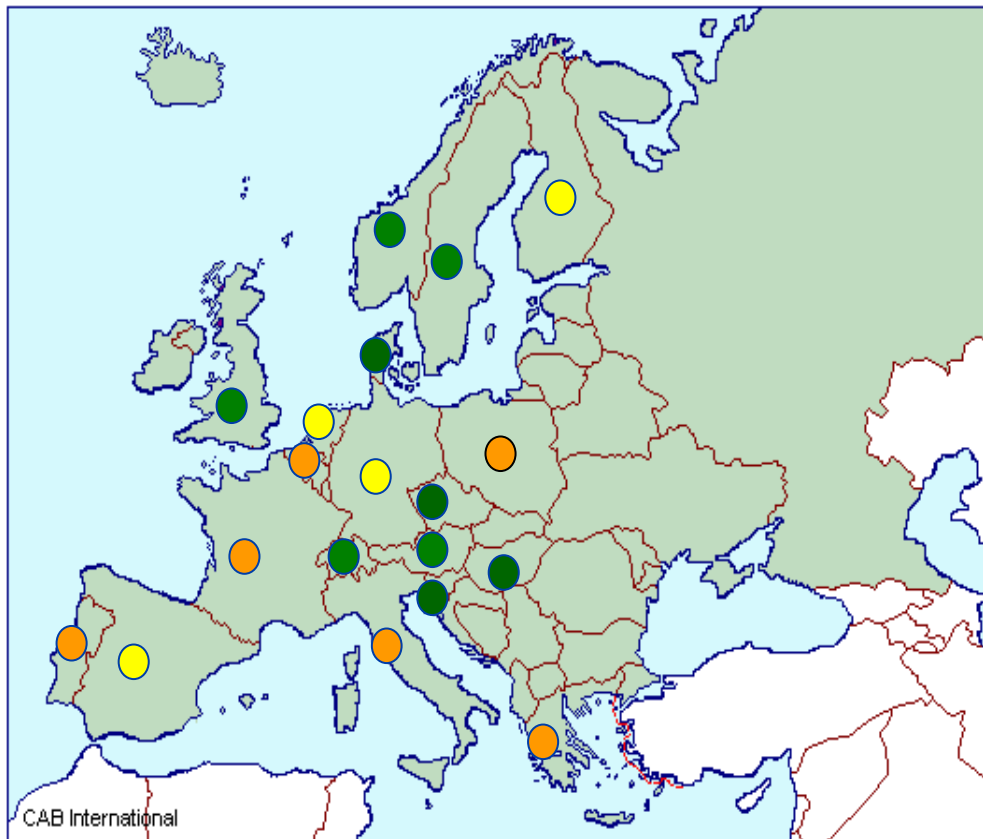
●



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# Legislative Instruments EU

Regulation in place?



● Implemented (9)

● In preparation (4)

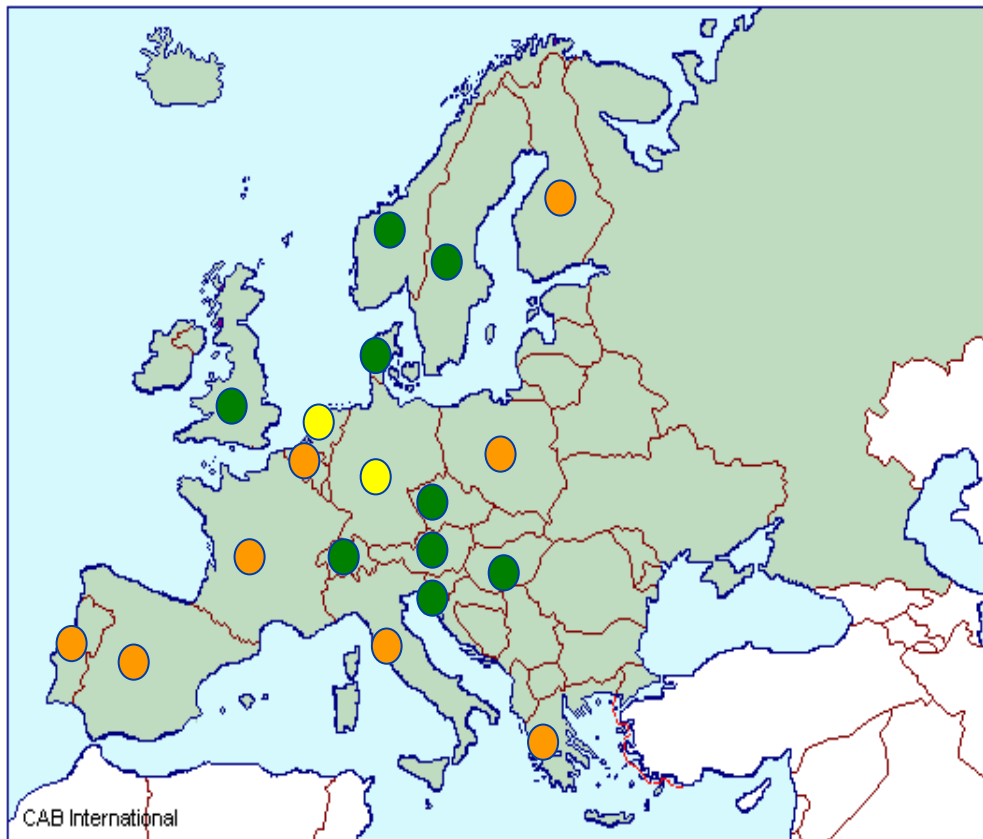
● No regulation (6)



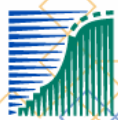
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# Legislative Instruments EU

Dossier for application required?

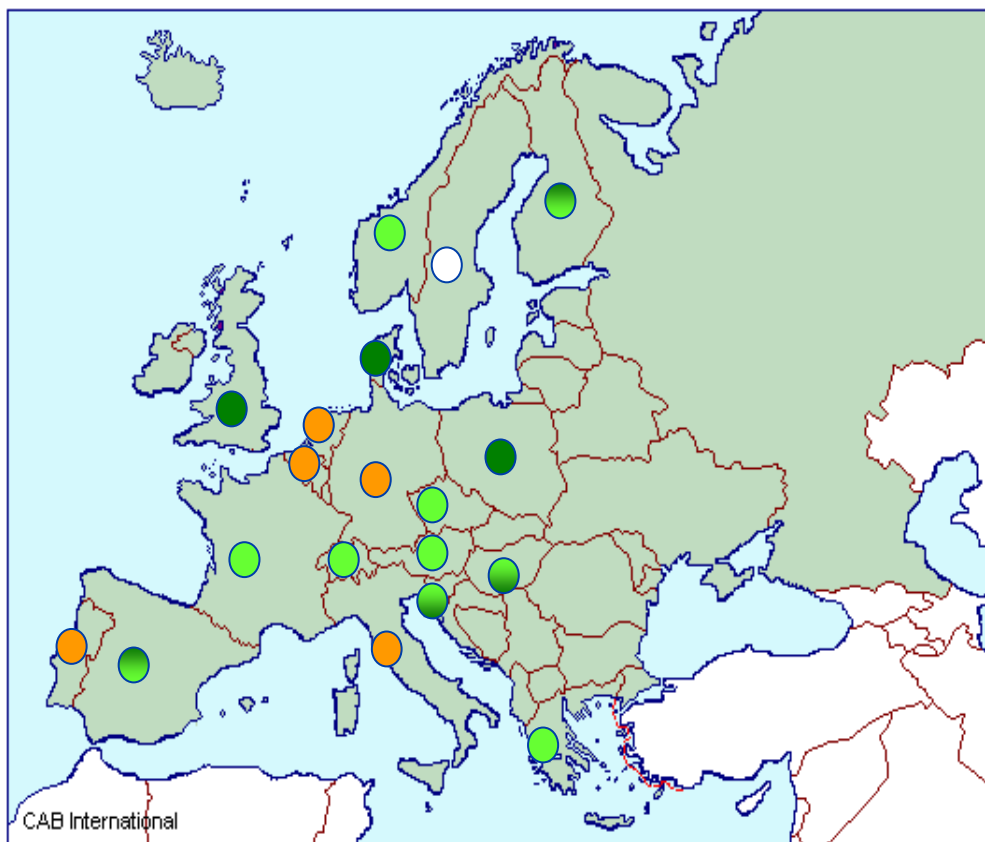


- Required (9)
- In preparation (2)
- No forms required (8)



# Legislative Instruments EU

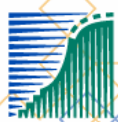
Competent / National Authority in place?



Assigned (14)

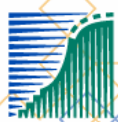
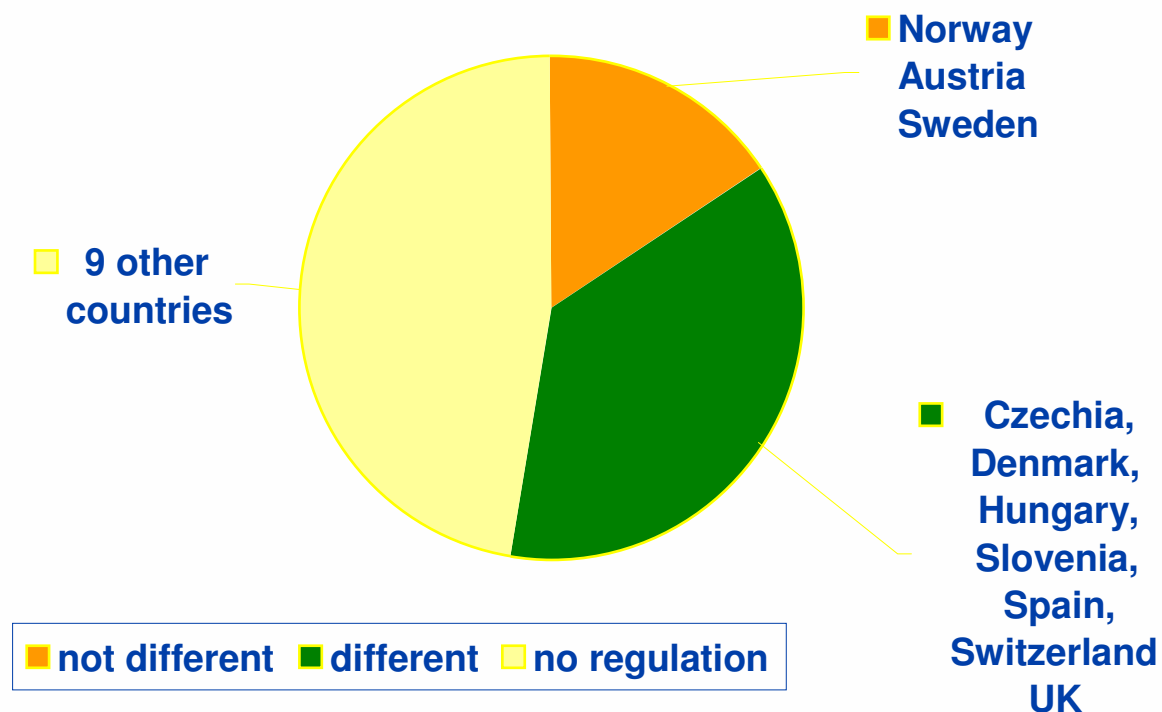
- environment
- plant health
- pesticides

Not assigned yet (5)



# Legislative Instruments EU

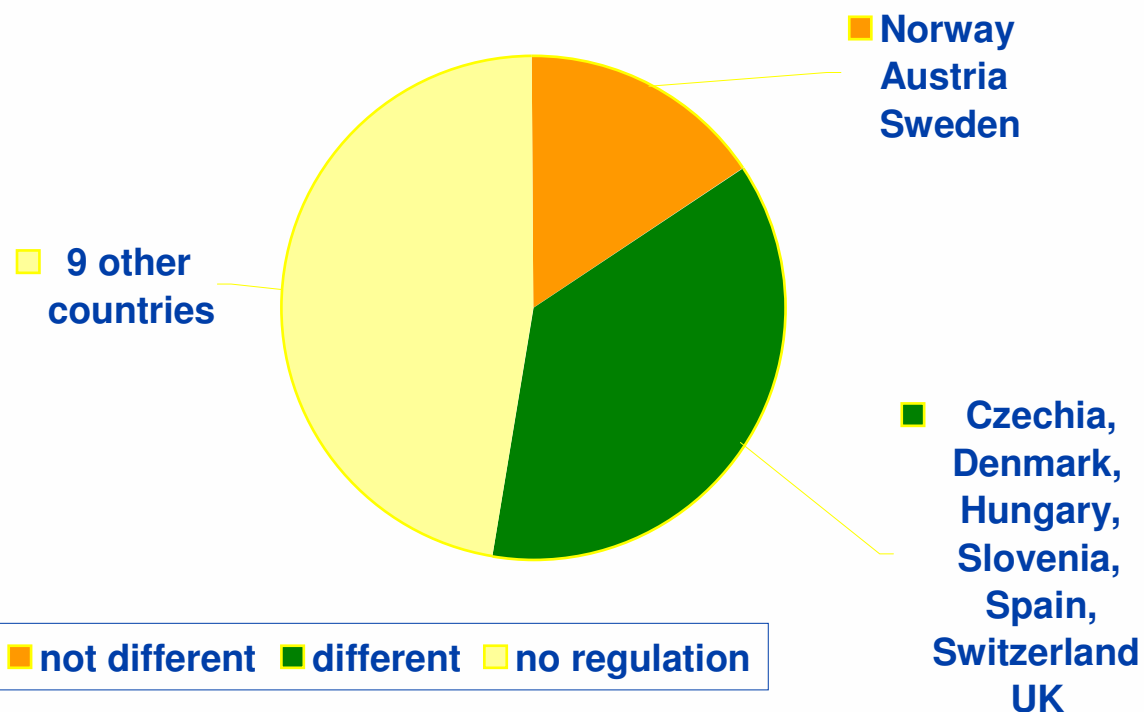
Regulation exotic-native IBCAs different?



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# Legislative Instruments EU

## Regulation exotic-native IBCAs different?



### **UK**

- exotics only

### **Hungary**

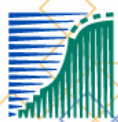
- natives no measures
- exotics approval

### **Switzerland**

- import permit exotics
- era exotics > natives

### **Spain**

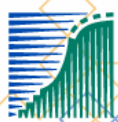
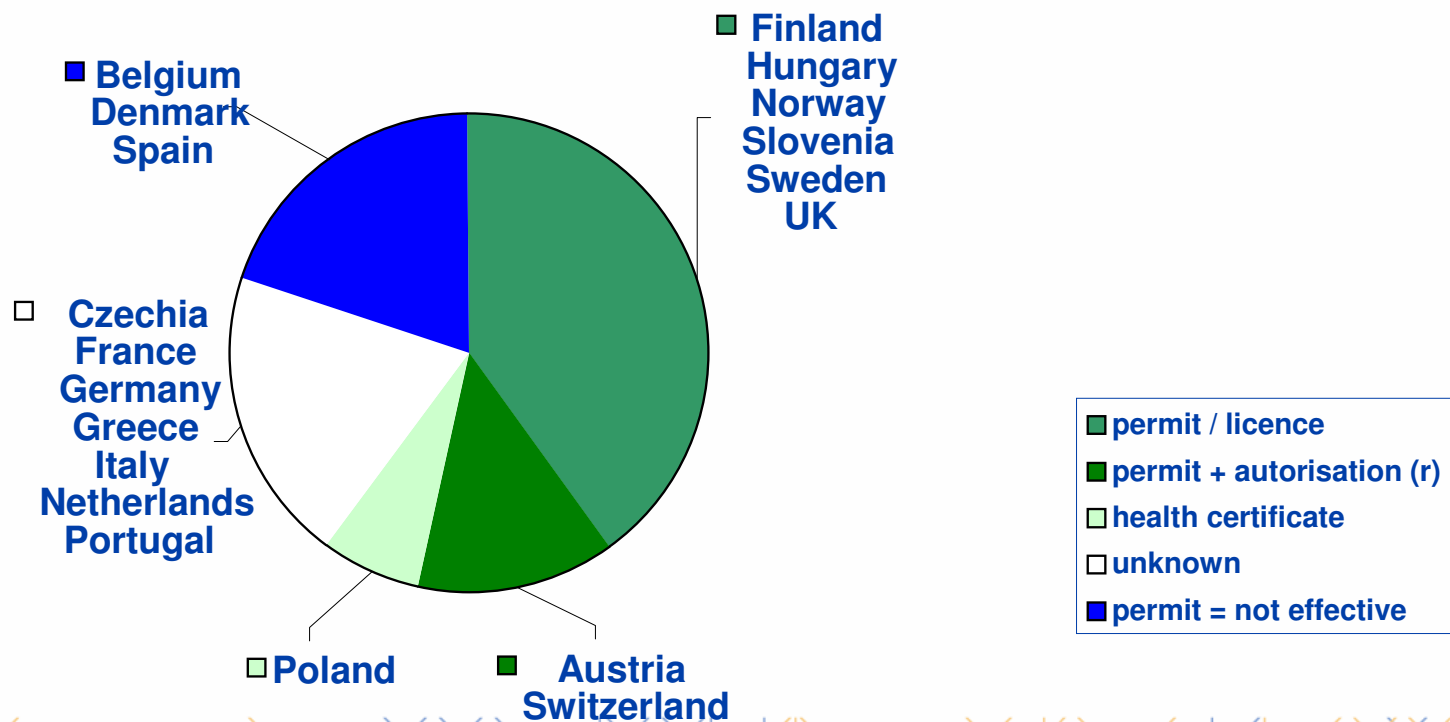
- exotics permit
- natives notification



# Legislative Instruments EU

System: autorisation, permit, license, etc.

Regulation Forms

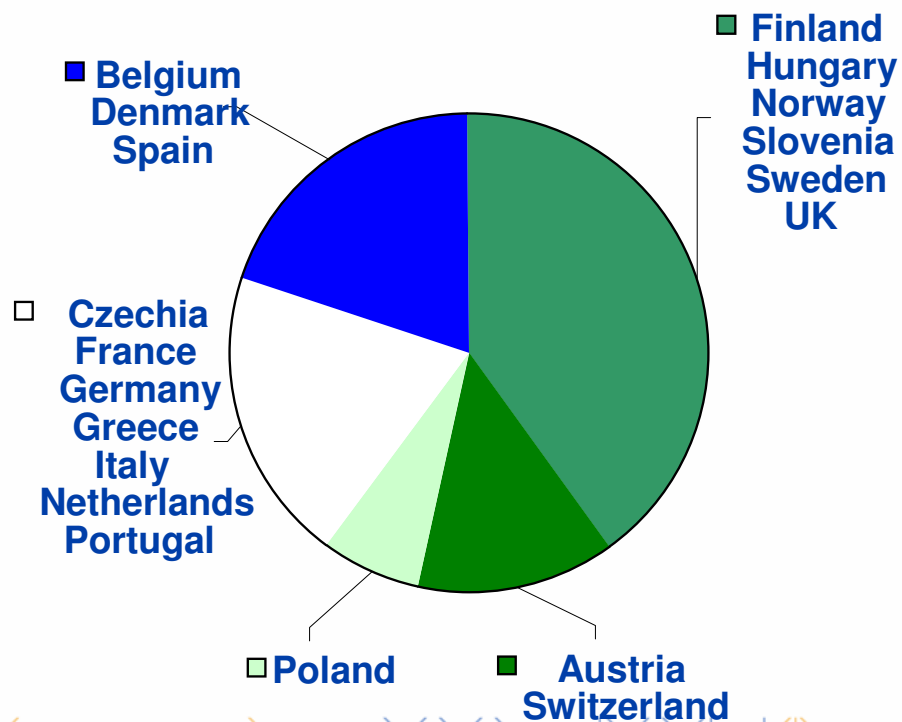


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# Legislative Instruments EU

System: autorisation, permit, license, etc.

Regulation Forms



Period: depending

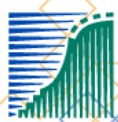
1-2 years

import > renewal

5 – 10 years

registration

- permit / licence
- permit + autorisation (r)
- health certificate
- unknown
- permit = not effective



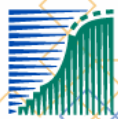
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# Summary & Conclusions

**Almost all have legislation, but very different**

- **Most countries have assigned a National Authority**





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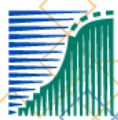




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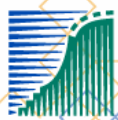




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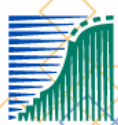
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## Harmonisation useful



# Case: legislation – regulation The Netherlands



# Legislative Instruments NL

## Legislation in The Netherlands

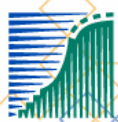
### Plant Health Act ('Plantenziektenwet')

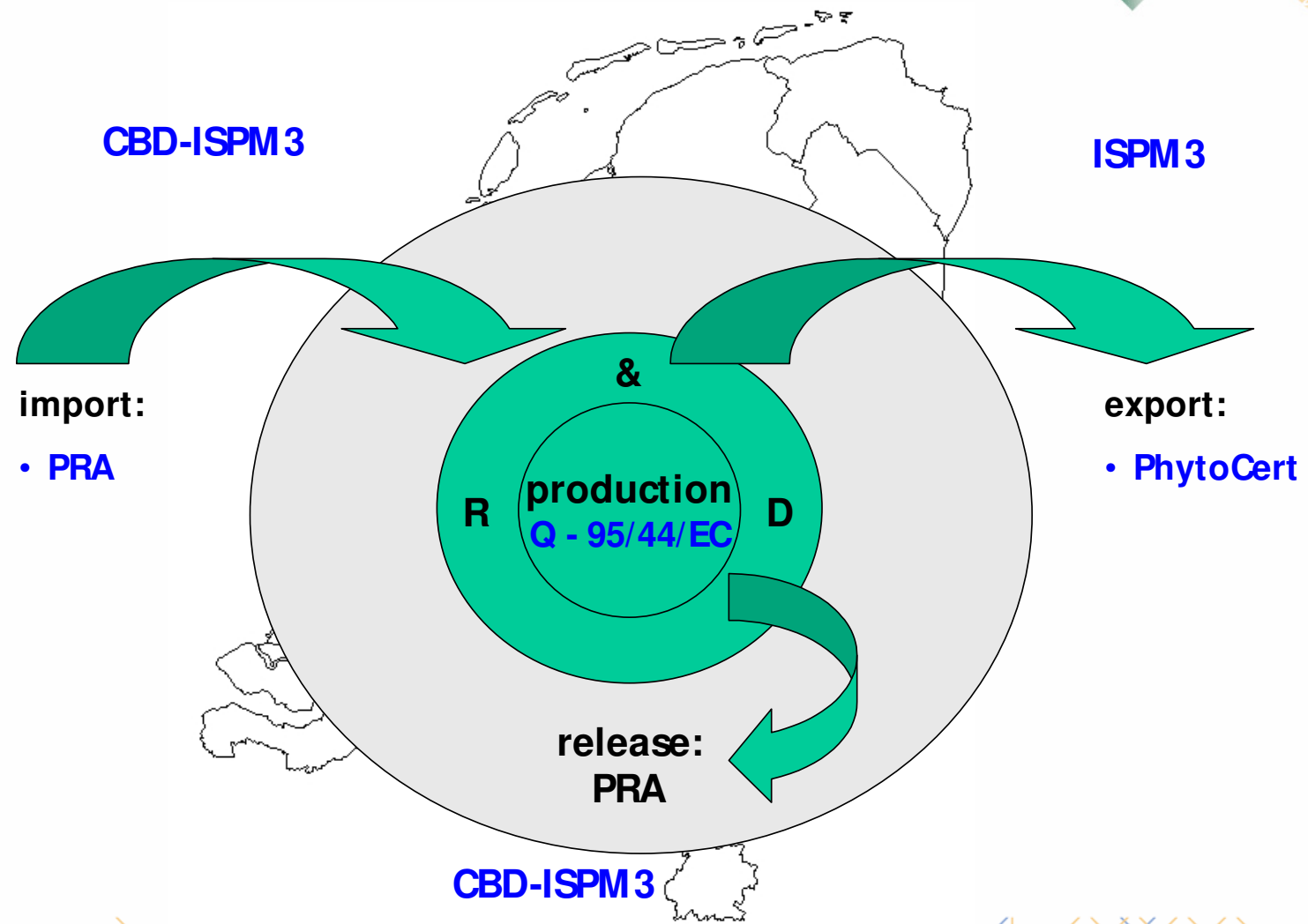
- 'phytosanitary' (Q + pest species)

### Flora and Fauna Act ('Flora en faunawet')

- 'biodiversity' act
- regulation IBCAs > Order in Council ('AMvB')

### Pesticide Act ('Bestrijdingsmiddelenwet')

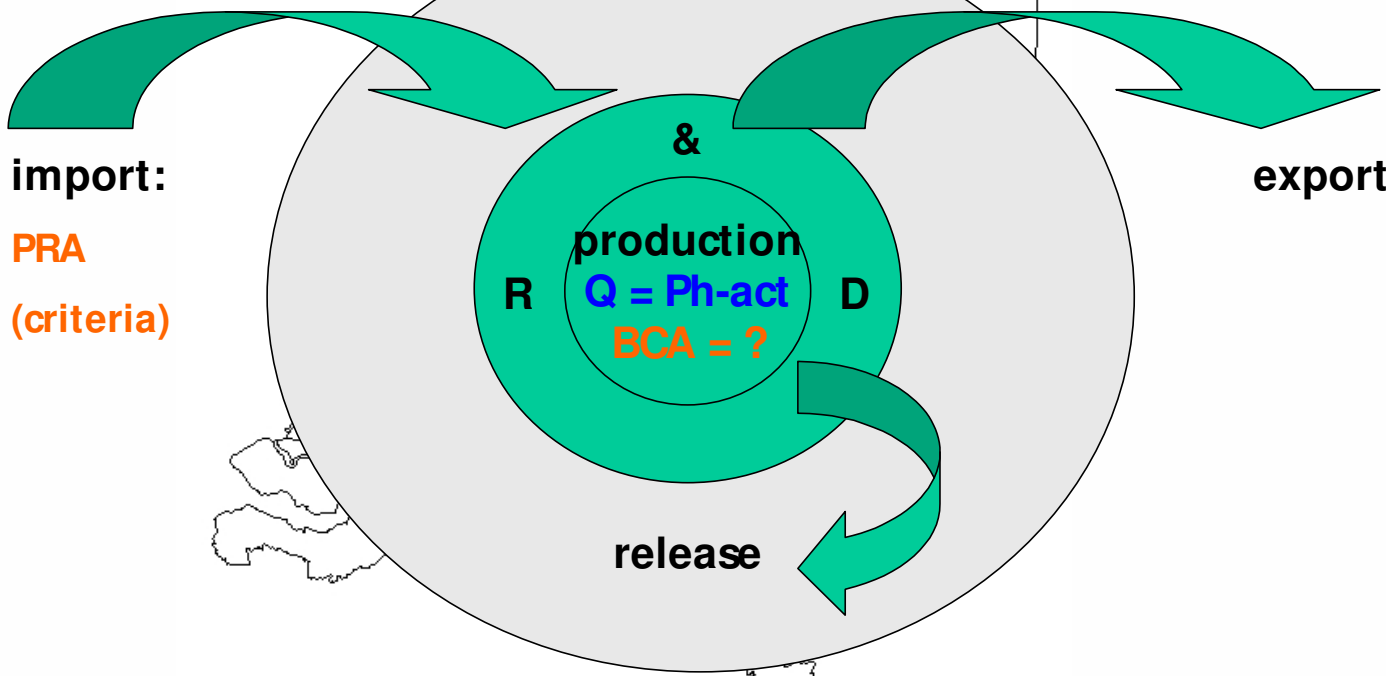






**BCA = no regulation**  
**Q = Plant Health Act**

**importing country**



**import:**  
**PRA**  
**(criteria)**

**export**

**&**  
**production**  
**Q = Ph-act**  
**BCA = ?**

**release**

**FF-wet – AMvB**

**PRA (criteria)**



# Procedures

## Plant Health Act

### FF Act :

- prohibition, to release ... exotic AND native species, but
  - appointed species ...
    - black list (cf. quarantine lists)
    - white list > exemption list (general)
  - derogation (individual)





# Procedures

## Criteria for risk – assessment

BCAs already in use (repair policy) > quick scan

BCAs new > comprehensive analysis

Criteria same:

- identity
- health (animal, human)
- environmental effects > 5 ecological factors
- (efficacy)





# Procedures

## Criteria for risk – assessment

### Approach:

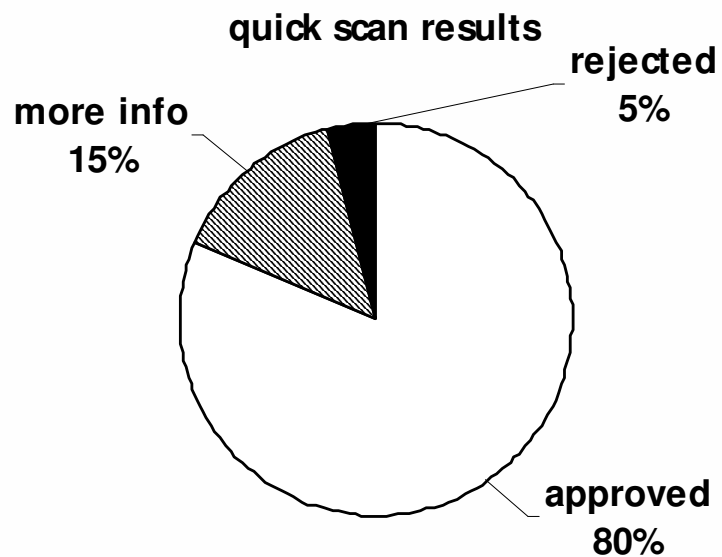
#### BCAs already in use (repair policy) > quick scan

- based on arguments NOT to (continue) release (Ministry)
  - evidence NT effects / expected risks extrapolated NL
  - ‘benefit of doubt’: no risks known = exempted
    - for and against: available information + or -

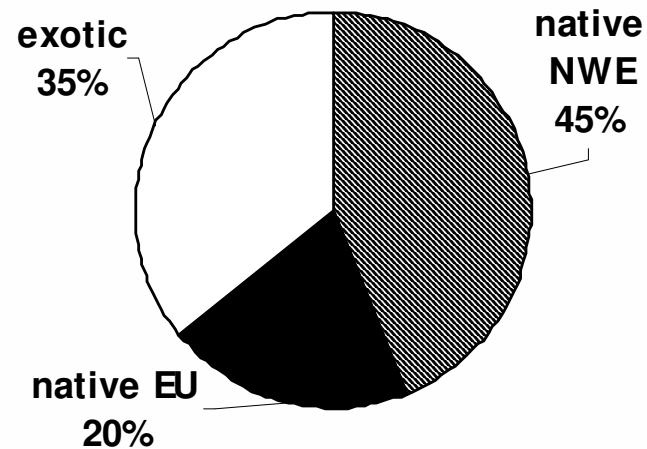
#### BCAs new > comprehensive analysis

- based on arguments for SAFE release (Applicant)

# Procedures: quick scan



quick scan approved - origin BCAs



**Ultimate result: approved or not**

**Approved = List of exempted species ('vrijstellingenlijst')**

**134 species exempted**





## Procedures: **new organisms**

FF act:

**Approach (currently in development):**

**application for derogation ('ontheffing')**

- **dossier required information (applicant)**
- **information & evaluation format (*Bigler et al., 2005 BNI*):**
  - **OECD guidance IBCAs, refined in IOBC guidance**
  - **Comprehensive analysis ERA [PRA]**

