



Rijksinstituut voor Volksgezondheid
en Milieu
*Ministerie van Volksgezondheid,
Welzijn en Sport*

ERA of LMOs for food, feed and processing in the European Union

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Environmental Risk Assessment of Import for FFP

- In principle no exposure of the environment (no cultivation)
- But, spills may occur

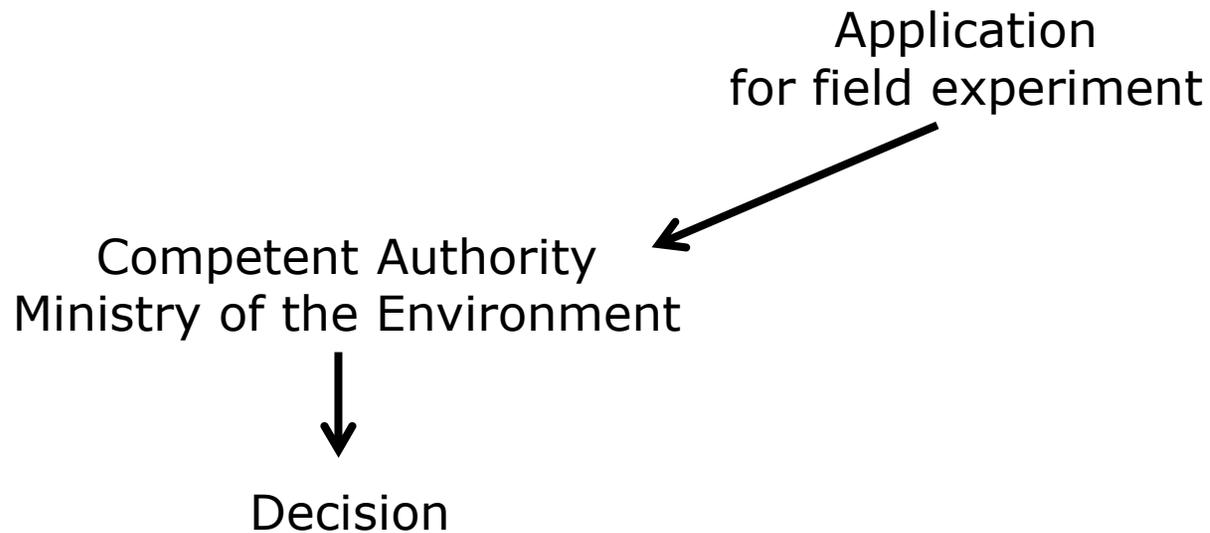


What the result of a 'spill' might look like ... compared to cultivation



Regulatory Framework in the Netherlands

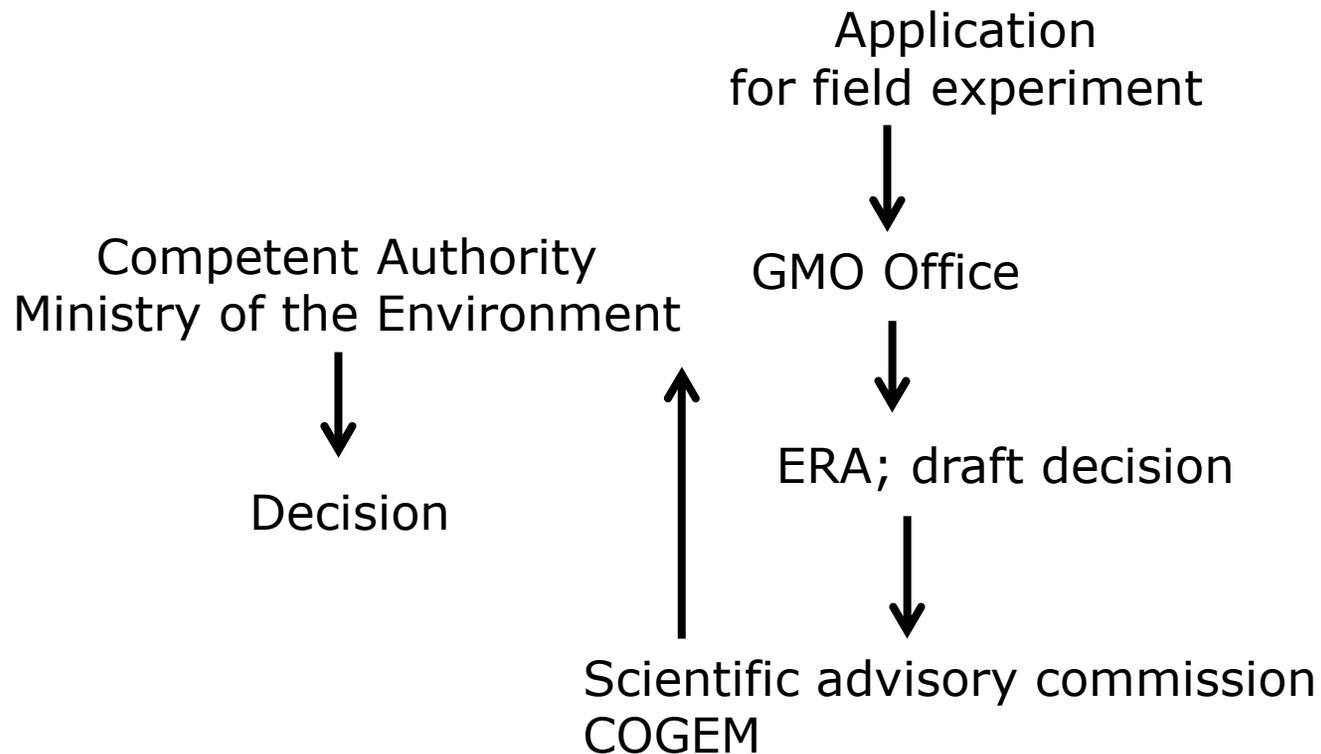
EU Directive 2001/18/EC





Regulatory Framework in the Netherlands

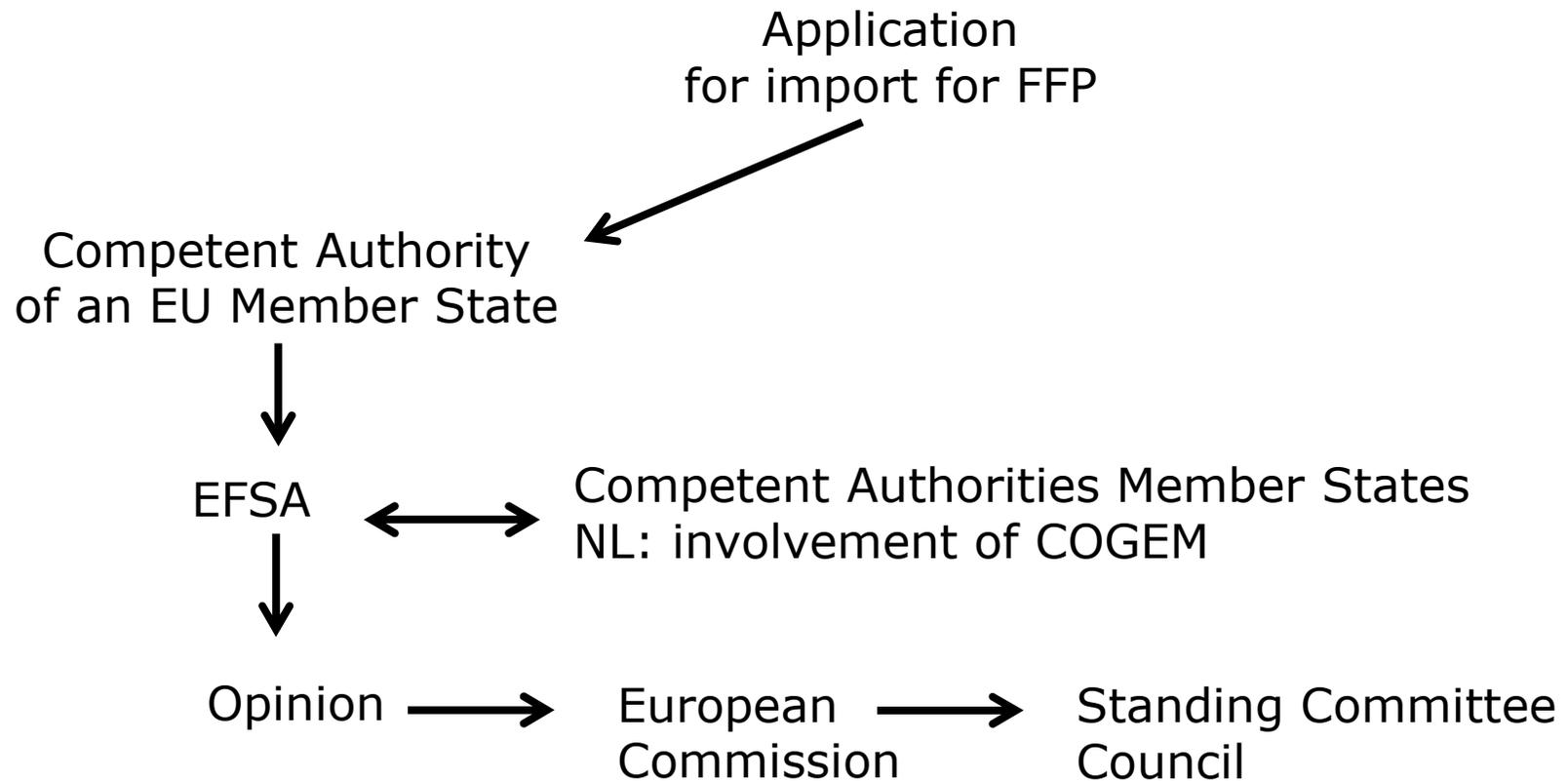
Directive 2001/18/EC





Regulatory Framework in the EU

Directive 2001/18/EC





Comparison 'spill' - Commercial release

- Commercial release
 - 'Unlimited': surface area of > thousands of ha (1 ha = 100 x 100 m.)
 - Many planned sites
- Spill
 - Limited – prevention and management of losses
 - Small surface area
 - Many sites, unplanned
- The environmental exposure due to a spill is expected to be low



Steps in field experiments and their ERA

- Field research of transgenic plants starts with small scale experiments, followed by larger scale and 'unconfined' experiments
- This is known as the 'step-by-step' approach
- We learn from each step so we can make the next step
- The steps are limited by the possibility to do an ERA of the next step → they are limited by the knowledge that we **need** for the ERA
- Exposure increases in each step: risk may increase

COGEM: advice on necessary information in different steps



Categories for field experiments

Category 1. *Small scale field experiment with confinement measures*

- 5 locations, each maximally 1 ha
- Expected genotype; expected function(s) in the plant
- Management measures: potential harm limited to the site

Category 2. *Field experiment without confinement measures*

- No restrictions to number of sites, in total maximally 10 ha
- Map of the genetic elements; expected function(s) when expressed in the plant
- Results of small scale field experiments indicate no harm →
No harm expected from outcrossing to wild relatives

Category 3. *Large scale (unconfined) non-commercial activities*

- Full molecular characterization available for each event.
- ERA according to the rules for commercial applications



What applies to a 'spill'?

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Need-to-know information for ERA of a spill

- Map of the genetic elements; **expected function(s) when expressed in the plant**
- Any **results from previous small scale field experiments** with the same or similar plants
- **No indication of (potential) harm from previous experiments**
- **No harm expected if and when outcrossing to wild relatives occurs**

- Remember, for FFP:
Large amount of data on food/feed safety will be available, including molecular characterization

Situation for corn – potato – oilseed rape



Potential harm: crop plant outcrossing, establishment, invasiveness

- Corn

- No wild relatives in the Netherlands (EU)
- No survival → no invasiveness

- Potato

- Hybridization with *Solanum nigrum*: only by embryo rescue
→ no outcrossing
- Limited survival, no observed invasiveness

- Oilseed rape (*Brassica napus*)

- Hybridization with *Brassica rapa*: between part of the genome
 $B. napus = B. rapa \times B. oleracea$
- Limited survival and invasiveness of oilseed rape



Potential harm: trait

Insect resistance, Herbicide tolerance

- Corn
 - Insect resistance
 - › effects on NTO; low exposure
- Oilseed rape
 - Herbicide tolerance
 - › herbicide not used in the environment
no selective pressure



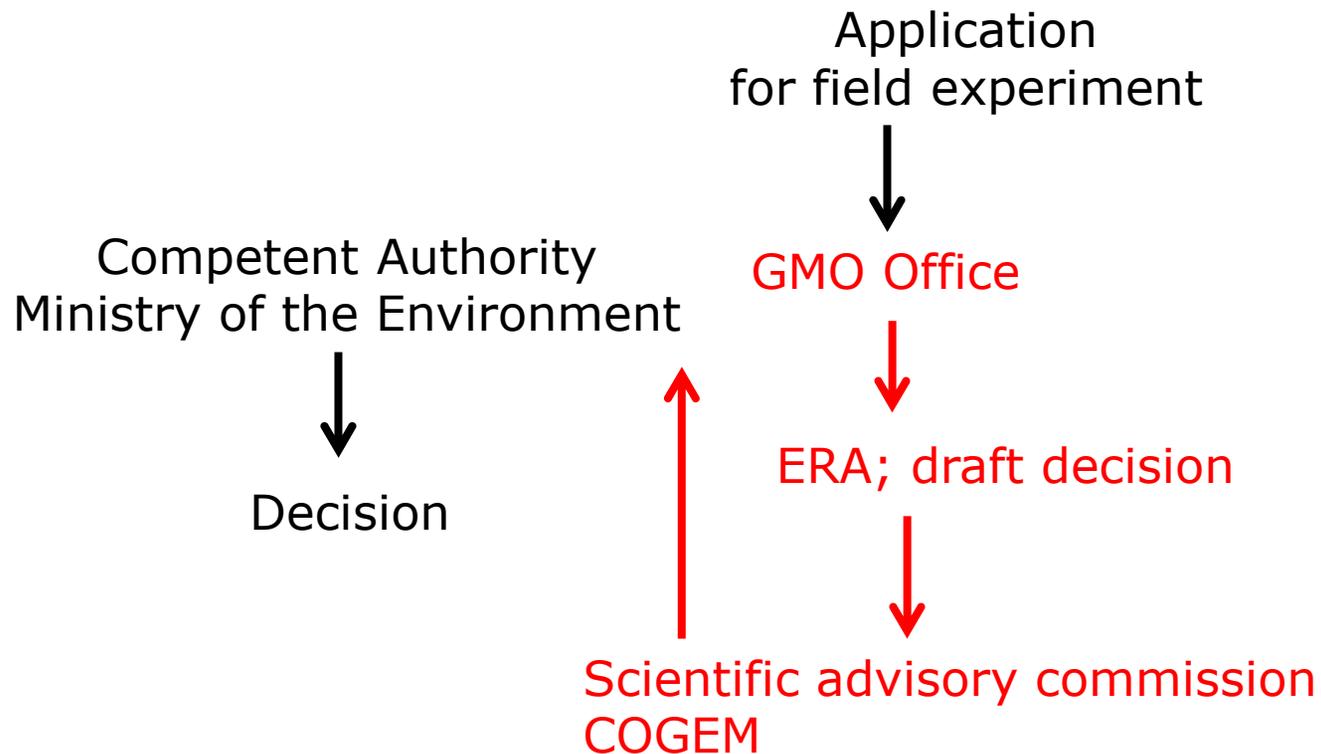
ERA for LMOs for food, feed and processing

- Exposure of the environment is expected to be low
- Need for information, e.g., molecular characterization, is for food/feed safety assessment
- Pathway to harm for the environment:
based on an appropriate argumentation
 - HT oilseed rape: outcrossing may occur
no selective pressure in the environment
 - Insect resistant corn: low exposure
considerations for NTOs
- Risk evaluation: based on limited exposure of the environment



Regulatory Framework in the Netherlands

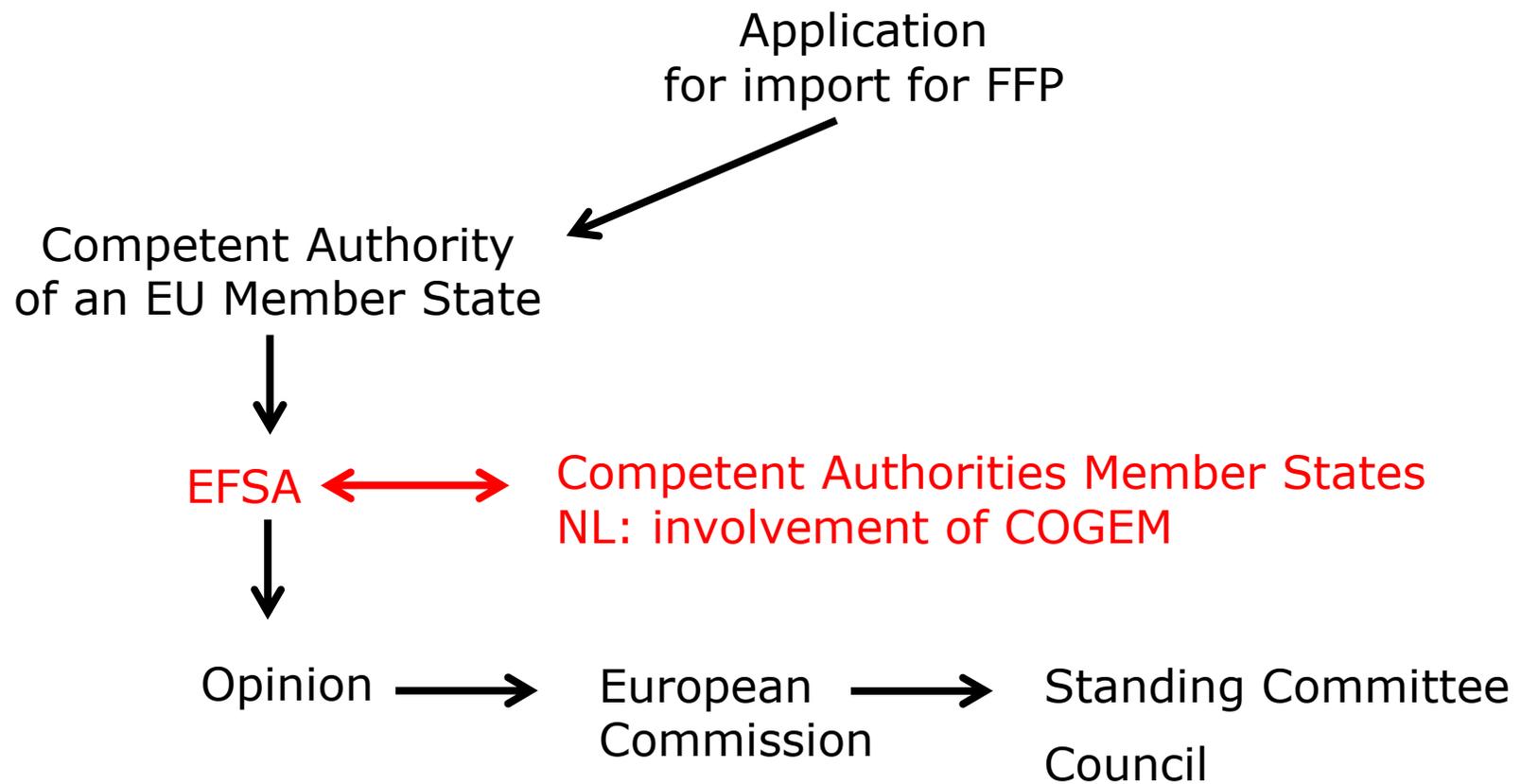
Differences in approaches





Regulatory Framework in the EU

Differences in approaches





Different approaches in the ERA hazards caused by outcrossing from *Brassica napus*

Decision maker

Need-to-know information

Outcrossing: if it may occur, it will occur
Worst case scenario for trait effects

Scientific advisory commission

Scientific curiosity
More open to 'what if'

Quantification of outcrossing - modelling
How to measure potential for invasiveness?

Similar differences apply between Member States of the EU



ERA of LMOs imported for FFP

- Protection goals
- Pathway to harm
 - Take into account: limitations for environmental exposure
 - potential for outcrossing
 - expected effects of the trait
- Environmental risk assessment based on information such as would be needed for intermediate scale field experiments



Thank you!