

# Generic regulation of GMO

Regulation of genetically-modified plants is primarily governed by generic legislation and guidelines

- **No harmonization**
- **Usually event based**
- **May require detailed molecular analysis per event**

# 1. Harmonization

- Cost of regulation makes entry to market in some small countries prohibitively expensive
  - Translation
  - multiple copies of written materials
  - local hearings, fees and travel.
- Some countries require a field trial
  - Products may have been grown and sold commercially for many years elsewhere
  - For a greenhouse grown crop the additional data adds little to the risk assessment process
  - Product may not be intended to be grown

## 2. Event based regulation



What largely differs between transgenic events is the parent variety and the flower colour shade produced



Regulation on a transformation vector basis should be more widely possible

It is reasonable to build on a history of use for a particular transgenic phenotype/crop combination



# 3. Molecular analysis

- Costs are very high
  - Full sequence of the transformation vector
  - Full sequence of inserts
  - Sequence of flanking sequence
- Relevance of BLAST analysis
  - Differences between non-GM cultivars can be greater than between a transgenic line and parent organism
  - Differences occur between naturally occurring ecotypes
  - Inserted genes are ubiquitous plant genes
- Eliminates some lines from commercialisation

Outcome

*Products left on the shelf*

*Markets excluded*



# Simplified/flexible procedures

## Candidate GMOs

- Not food or animal feed
- Not used to extract pharmaceutical products
- Similar GMOs have a history of safe use
- Parent organism is not a noxious weed
- Parent plant is not a common allergen source
- Low potential for gene flow
- Compounds produced as a result of the genetic modification are;
  - common
  - no known harmful effects

Thank  
you

