

# GM Legislation in UK and Europe

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# Talk overview

- Introduction
- Overview of legislation
- Specific legislation
- Guidance
- Risk assessment
- Containment issues
- Environmental issues
- Summary

# Legislation covering GM work

- EU Directive 98/81/EC (amended 90/219/EC)
- Genetically Modified Organisms (Contained Use) Regulations 2000
- Environmental Protection Act 1990
- Genetically Modified Organisms (Risk Assessment)(Records and Exemptions) Regulations 1996

# Legislation covering GM work (continued)

- EU Directive 95/44/EC
- Plant Health (Great Britain) Order 1993
- Plant Health Directive 2000/29/EC

# EU Directive 98/81/EC

- Limited to work with genetically modified micro-organisms (GMMs)
- Covers environmental protection and human health considerations
- Establishes 4 levels of containment
- Classification is on basis of containment
- Notification

# Genetically Modified Organisms (Contained Use) Regulations 2000

- Implements 98/81/EC – limited to GMMs
- Scope extended to cover all GMOs
- Notification required for “first use”
- Activity notification – class 2
- Formal consent for class 3 and 4 activities
- GM animals and plants – activity notification only if risk to human health

# EU Directive 95/44/EC

- Implemented as Plant Health (Great Britain) Order 1993
- Licence permits import of quarantine organisms for research
- Also covers other organisms deemed to pose a risk to UK plants including GMOs
- Does not impose risk classes but specifies containment on a case-by-case basis

As well as controlling organisms listed in the Directive, plant health licences also used to control work on other organisms deemed to pose a risk to UK plant health. This includes GMO's which are considered plant pests and diseases.

# Environmental Protection Act 1990

- Part VI covers GMOs
- Implemented into legislation by the Genetically Modified Organisms (Risk Assessment)(Records and Exemptions) Regulations 1996
- Requires environmental risk assessment
- No prescribed containment measures



# Guidance documents

- ACGM Compendium of guidance
  - Risk assessment GM plants
  - Risk assessment GM microorganisms
  - Laboratory containment
  - Containment of GM plants
  - Containment of plants associated with GMMs

# Risk assessment

- Mandatory procedures for GMMs
- Guidance for GM viruses and bacteria/fungi
- Classification on basis of containment requirements
- Modified pathogens – class 2 minimum?
- Relationship between licence and classification?

**Note that the majority of organisms capable of infecting plants require class 2 containment. Only one class 3 facility currently in UK, but there are questions whether chimeric viruses with altered pathogenicity, such as spread, or altered mode of transmission should be 3.**

# Risk assessment

Based on

- Biological properties of host, and effect of the modification
- Likelihood of survival outside containment
- Ability to transfer genetic material
- Likelihood of harm being caused

# Containment of GM plants – regulatory requirements

- Use of physical, chemical or biological barriers (or combination of such barriers) to limit contact with and provide a high level of protection, for humans and the environment
- Reduce harm to humans to the lowest level that is reasonably practicable

# Containment of plants associated with GM microorganisms

- Physical, chemical or biological barriers
- The exposure of humans and the environment to GMMs must be reduced to the lowest level that is reasonably practicable
- Containment measures outlined in Schedules 7 and 8 must be applied as indicated by risk assessment

# Containment

Consists of

- Combination of physical and procedural measures
- Containment levels 1 – 4 for GMMs
- Glasshouse A or B for transgenic plants
- Biological containment
- Chemical containment

# Containment levels 1 – 4.

- Applies to GMMs not GM plants
- Apply measures for laboratories plus additional measures for glasshouses and growth rooms
- Minimum standards are mandatory – users must apply for permission not to apply certain measures

# Glasshouse A or B

- Applies only to GM plants
- Containment A recommended where plants are unlikely to cause environmental harm
- Containment B recommended where harm could arise if the plant or descendants could enter the environment
- Containment B – no set standard,  
Containment A – requires additional measures



# Glasshouse A

Applies to

- Plants incapable of survival outdoors in UK
- Species with a limited ability to transfer genetic material to UK species, either naturally or through debudding, bagging etc
- Risk assessed as negligible or low

# Glasshouse B

Applies to

- Plants with ability to transfer novel genetic material to UK plant species
- Plants that could establish outside the facility and cause harm
- Plants expressing plant pest-derived sequences which could cause harm outside
- Plants expressing hazardous substances

# Key containment measures

- Restricted access
- Need training and local rules
- Control of seed and pollen dispersal
- Vector control
- Mesh on vents, drains etc.
- Safe transfer procedures
- Debudding, bagging, altered growing season etc.
- Waste management

# Environmental issues

- Broad definition of harm
- Threshold of harm – transfer of any GM sequence to other plants?
- Monitoring outside of containment?
- Ability of pests to act as vectors – “biopharming”

# Summary

- A range of national and European legislation
- Work with GMMs associated with plants is tightly controlled with mandatory procedures for risk assessment and containment
- GM plants – environmental controls are not stipulated, guidance is available
- Risk assessment – definition of harm?