Risk Assessments for Genetically Modified Organisms and Micro-organisms

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Introduction

- Classification of GMMs
- Risk assessment for GMMs
- Risk assessment for GMOs

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Classification of GMMs

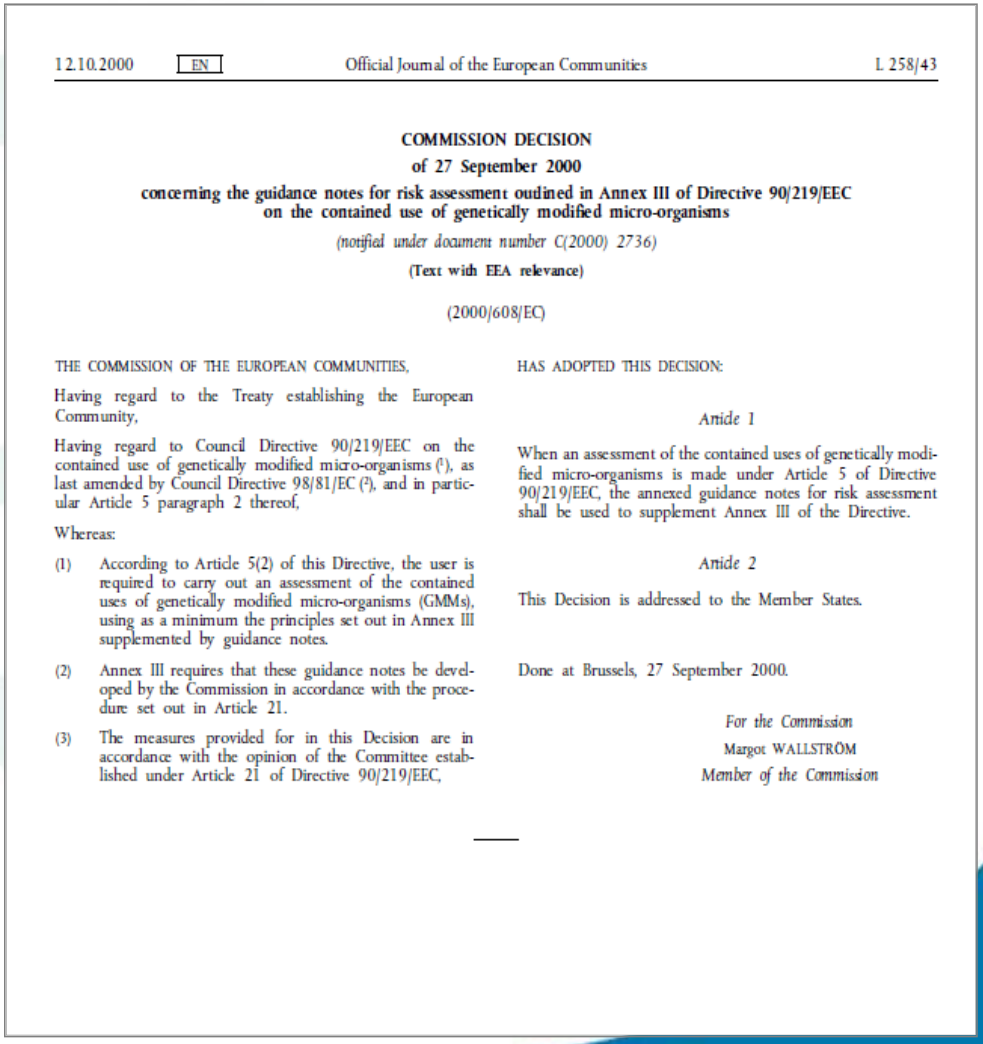
- Activities classified into 1 of 4 classes (Class 1, 2, 3, or 4)
  - Class 1 - activities of no or negligible risk, Containment Level 1 (CL1) is appropriate
  - Class 2 - activities of low risk, CL2
  - Class 3 - activities of moderate risk, CL3
  - Class 4 - activities of high risk, CL4
- Appropriate level of containment required to control risk to human health and the environment.

Environmental Risk Assessment

- Cornerstone of EU GM legislation
- Identify and evaluate any potential adverse effects, direct or indirect on human health and the environment
- Article 13 - General duty to conduct risk assessment
- Level of containment required for the GMM corresponds directly to the risk
- Higher containment in biopharma companies to protect the product

Contained Use Risk Assessment for GMMs

- Commission Decision 2000/608/EC
- Guidance notes for risk assessment



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COMMISSION DECISION

of 27 September 2000

concerning the guidance notes for risk assessment outlined in Annex III of Directive 90/219/EEC on the contained use of genetically modified micro-organisms

(notified under document number C(2000) 2736)

(Text with EEA relevance)

(2000/608/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/219/EEC on the contained use of genetically modified micro-organisms (1), as last amended by Council Directive 98/81/EC (2), and in particular Article 5 paragraph 2 thereof,

Whereas:

(1) According to Article 5(2) of this Directive, the user is required to carry out an assessment of the contained uses of genetically modified micro-organisms (GMMs), using as a minimum the principles set out in Annex III supplemented by guidance notes.

(2) Annex III requires that these guidance notes be developed by the Commission in accordance with the procedure set out in Article 21.

(3) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 21 of Directive 90/219/EEC,

HAS ADOPTED THIS DECISION:

Article 1

When an assessment of the contained uses of genetically modified micro-organisms is made under Article 5 of Directive 90/219/EEC, the annexed guidance notes for risk assessment shall be used to supplement Annex III of the Directive.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 27 September 2000.

For the Commission

Margot WALLSTRÖM

Member of the Commission

Environmental Protection Agency
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Environmental Risk Assessment contd.

- Potentially harmful effects may give rise to:
  - Disease
  - Render prophylaxis or treatment ineffective
  - Promote establishment and/or dissemination into the environment which gives rise to harmful effects on organisms or natural populations present or harmful effects arising form gene transfer to other organisms.

- Safety of GMM depends on:
  - The inserted genetic material
  - The resulting GMM from the genetic modification
  - The receiving environment
  - The interaction between the GMM and the environment

Elements of the Risk Assessment

- Identify potential harmful properties of the GMM and allocate the GMM to the initial class.
- Assessment of the possibility of harmful effects occurring by consideration of exposure.
- Determination of the final classification and containment measures required.

Identification of harmful properties of the GMM

- Essentially identifying the hazards of the GMM.
- Recipient organisms, the donor organism, the characteristics and location of the inserted genetic material and any vector.
- Decreased, increased or unchanged ability to cause harm.

Aspects that should be considered

- Recipient Micro-organism
- Genetic insert
- Vector
- Donor micro-organism
- Resulting GMM

Human health considerations

- Expected toxic or allergenic effects of the GMM and/or its metabolic products
- Comparison of the pathogenicity of the GMM to the recipient or parental organism
- Expected capacity for colonisation
- Pathogenic to humans who are immuno-competent

Environmental Considerations

- Ecosystems
- Survivability, multiplication and extent of dissemination
- Expected interaction with other organisms or micro-organisms
- Known or predicted effects
- Involvement in biogeochemical processes

Initial Classification of the GMM

- Identify the harmful properties of the GMM
- Identification of hazards associated with the recipient, donor organisms, vector and insert (where appropriate)
- Human health and environmental considerations

Assessment of possibility of harmful effects occurring

- Activities to be undertaken
- Concentration and scale
- Culture conditions
  - Environment likely to be exposed
  - Presence of susceptible species
  - Whether the environment can support the survival of the GMM
  - Effects on the physical environment

Determination of final classification and containment measures

- Revisit initial classification
  - Activities and characteristics of the operations proposed

- Three possible outcomes
  - Initial classification too low, harmful effects not adequately taken into account
  - Initial classification correct
  - Initial classification too high, containment measures of a lower classification appropriate

Confirmation of adequacy of final containment measures

- Assess level of human and environmental exposure
  - Identify potential harmful properties of the GMM and allocate the GMM to the initial class.
  - Assessment of the possibility of harmful effects occurring by consideration of exposure.

Risk Assessment for GM Animals/Plants

- General duty to conduct a risk assessment
- Part III, Article 36 & 7th Schedule

Risk Assessment for GM Animals/Plants, contd

- Elements of assessment
  - Disease to humans
  - Acting as human disease vector
  - Adverse effects to humans (change in behaviour or in physical nature)
- Potentially harmful effects, severity & likelihood
- Characteristics of the activity
- No classification system with GMOs

To conclude….

The overriding concern of the Environmental Protection Agency

* To ensure the use of GMOs does not have an adverse effect on human health or the environment

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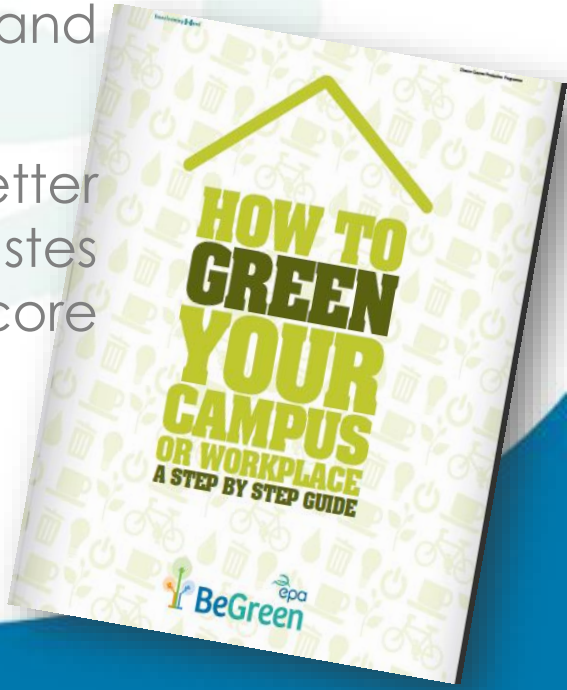
- CIT Sustainable Campus Programme (funded by the EPA, CGPP).
- A whole campus Programme involving **staff and students**.
- Ethos of **waste prevention** applied throughout.
- Reducing the use of material, water and energy resources in order to **reduce waste generation**; resulted in environmental, economic and awareness raising benefits.
- Led to improved working environment, better staff and student morale while reducing wastes and emissions without affecting core educational aims and activities.



The 9 Steps

epa BeGreen
PREVENTING WASTE & SAVING MONEY

Any Questions?

Go raibh maith agaibh

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