Implementation of the GMO Legislation in Ireland - The Role of the EPA

Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

Dublin City University

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Introduction

- Legislation & Definitions
- Classification & Risk Assessments
- Containment Measures
- Enforcement, Annual Reports & Site Inspections
- Notifications
- Waste Inactivation & Disposal
- Deliberate Release
- Advisory Committee

Regulating GMOs in Ireland

- Government responsible for policy
- Dept of Environment, Community & Local Government
  - Contained Use (CU) and Deliberate Release (DR) into environment of GMOs
- Dept of Health & Children
  - Food safety aspects (FSAI)
- Dept of Agriculture, Fisheries & Food
  - Seed for cultivation
  - Animal feed
  - Co-existence
  - Use of Plant Protection Products on GMO crops

EPA's Role in Regulating GMOs in Ireland

- Implement the Regulations only
- Contained Use – laboratories & industry
- Deliberate Release into the environment
  - Research & Development Purposes - field trials, clinical trials
  - Placing GMO products on the market
    - European Food Safety Authority
    - European Medicines Agency

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Legislation

- Genetically Modified Organisms (Contained Use) Regulations, S.I. 73 of 2001
  - Amended by S.I. No. 442/2010 — Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2010
- Genetically Modified Organisms (Deliberate Release Regulations), S.I. 500 of 2003

Definitions

- Genetically Modified Organism (GMO)

  means an organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both

- Genetically Modified Micro-organism (GMM)

  means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating or natural recombination, or by a combination of both

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Definitions contd.

- Contained Use

'any activity in which micro-organisms are genetically modified or in which such micro-organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which specific containment and other protective measures are used to limit their contact with the general public and the environment'

Definitions contd.

- User

  'any legal or natural person responsible for a contained use or for giving notification of, or for meeting any other requirements in relation to, a proposed contained use'

- Article 5 of the Regulations - Obligations

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

Environmental Risk Assessment contd.

- Potentially harmful effects shall include:
  - Disease to humans including allergenic/toxic effects
  - Disease to animals or plants

- 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

- Provisional allocation to Class 1, 2, 3 or 4
- Identification of potentially harmful effects:
  - Recipient Micro-organism
  - Genetic insert
  - Vector
  - Donor micro-organism
  - Resulting GMM
- Assessment of potentially harmful effects occurring
- Assign appropriate containment level
- Review and confirm classification

Containment Measures

- Training & Awareness
- Containment equipment
- Fourth Schedule of the Regulations
  - General principles of Good Microbiological Practice (GMP) and Good Occupational Safety and Hygiene (GOSH)
  - Tables of containment measures

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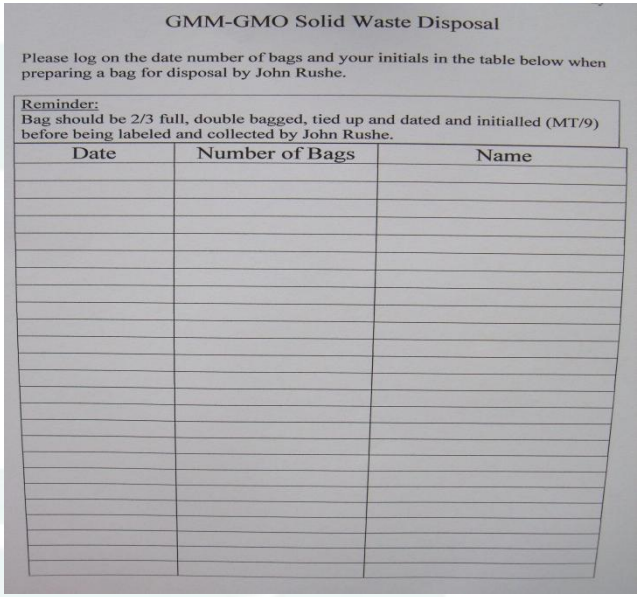
Containment Measures – GMMs in a Laboratory

Measures		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required for bench	Required for bench	Required for bench and floor	Required for bench, floor, ceiling and walls
4	Entry to laboratory via airlock	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required	Required
6	Extract and input air from the laboratory should be HEPA–filtered	Not required	Not required	Required	Required for input and extract air
7	Microbiological safety cabinet	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite	Double-ended autoclave in laboratory
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required to minimise	Required to prevent	Required to prevent
12	Shower	Not required	Not required	Optional	Required
13	Protective clothing	Suitable protective clothing	Suitable protective clothing; footwear optional	Suitable protective clothing and footwear	Complete change of clothing and footwear before entry and exit
14	Gloves	Not required	Optional	Required	Required
15	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Inactivation of GMMs/GMOs

- Autoclave and/or chemical inactivation
- Annual validation
- Maintain records
- Monthly use of control measures (e.g. spore strips)



GMM-GMO Solid Waste Disposal

Please log on the date number of bags and your initials in the table below when preparing a bag for disposal by John Rushe.

Reminder:
Bag should be 2/3 full, double bagged, tied up and dated and initialled (MT/9) before being labeled and collected by John Rushe.

Date	Number of Bags	Name

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Inactivation of GMMs/GMOs, *contd;*

- Class 1 GMM → off-site inactivation facility
  - Off-site facility must registered
  - Records of GMM inactivation must be retained
- Class 2 GMM → inactivation on same site as contained use
- GM animals or animals inoculated with GMMs
  - on-site decontamination is not feasible/practicable, the animal remains containing any surviving GMM may be sent off site to a decontamination facility

GMP & GOSH

- Provide washing & decontamination facilities
- Adequate records & codes of practice
- Safe storage
- Effective disinfectants & decontamination procedures
- Prohibit eating, drinking, smoking, etc

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Biological Safety Committee

- Statutory requirement
- Include external, non-GM users
- Biological Safety Officer – executive responsibility
- Provide advice
- Review risk assessments
- Contact point for the Agency
- Meetings & Minutes

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GMO Advisory Committee

- Part VI Deliberate Release Regulations
  - Government Departments
  - Government Organisations
  - Support Organisations
  - Non-Governmental Organisations
- 14 Members
- Three year Term of Office
- Meetings approx once/yr
- Electronic correspondence

Notification to the Agency

- Risk Assessment
- Part A or B of 5th Schedule of Regulations - GMMs
- 7th Schedule of Regulations - GMOs
- Pay the relevant fee for the class of GMM
- No fee for GMOs

Notification to the Agency – 5th Schedule (GMMs)

- Name of User
- Training & Qualifications
- Biological Committees or sub-committees
- Address & General Description of the premises
- A description of the nature of the work
- The class of the contained use
- Risk Assessment
- Information on waste management

Notification to the Agency – Fees

- Eight Schedule of GMO (Contained Use) Regulations
- First time contained use of a Class 1 GMM under Article 16 – €250
- First time use of a premises (Class 2) under Article 16 – €1,875 (€250 + €1,625)
- Subsequent use of Class 2 GMM – €625

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Notification Process

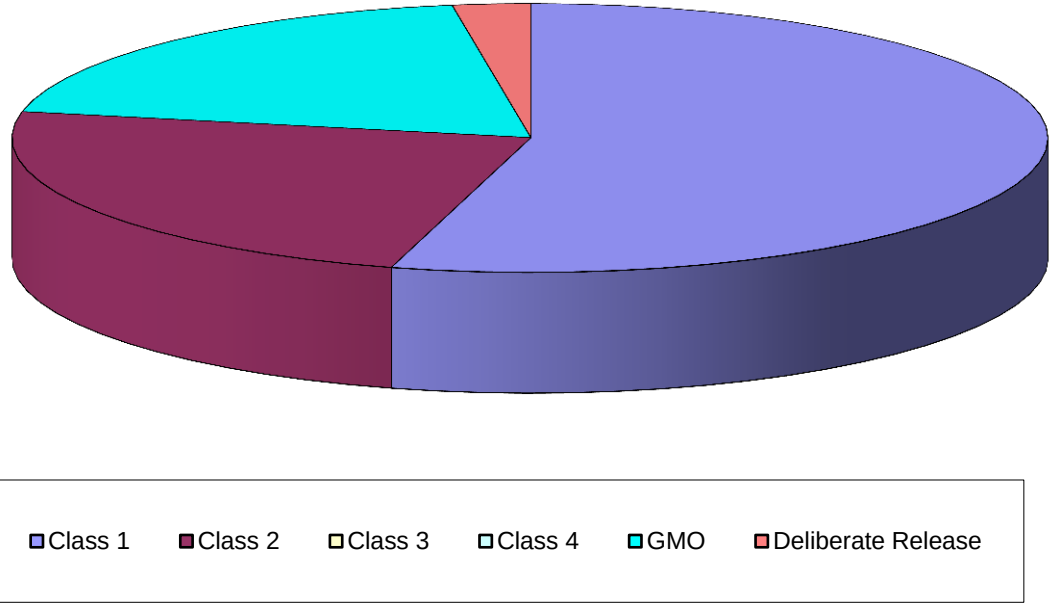
- Agency receives valid application
- Register entry sent to user for approval
- Inspector's Report and draft Consent Conditions sent to OCLR Director for approval
- Timelines: Agency must issue a decision within:
  - Class 1/2/GMO – 45 days for first time use
  - Class 2 – 10 days for subsequent use
  - Class 3/4 - 90 days for first time use
  - Class 3/4 – 45 days for subsequent use

Notification Process - Register of Users

- Name and address of notifier
- Location of the Contained Use
- Description & Purpose of each GMO/GMM
- Date of receipt of a record, notification
- Date of request/receipt of further information
- Date & nature of the decision

Register of GMO users in Ireland – January 2012

- 466 registered users
- 78% contained use consents (Class 1 & 2)



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Confidential Information

- Certain information
- Request in writing
- Separate documentation
- Memo to the Director
- Approval letter to notifier

Enforcement

- To ensure compliance
- Risks to human health & environment - managed properly
- Promote high standard of biological safety
- Allay public concerns

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Enforcement – Annual Reporting

- 31st March each year
- Forms available on www.epa.ie
  - GMMs
  - GM Plants
  - GM Animals

Annual Report for the contained use of Genetically Modified Organisms (GMOs) (i.e. GM Animals) for 2010.

A completed Annual Report for the year **2010** must be submitted to the EPA before 31st March 2011.

Annual reporting requirements (refer to notes 1 – 15)*	Annual reporting information
1. Name of user	
2. Contact e-mail address	
3. Address of premises	
4. GMO Register No.	
5. Project number	
6. Has there been any change to • GMO Register Entry • Risk Assessment • Containment measures applied	
7. If you have answered 'Yes' to any of the points under Item 6, please clarify/provide details.	
8. Are the GM animals inoculated with • GMMs • Other biological agents (non GM)	
9. If you have answered 'Yes' to any of the points under Item 8, please clarify/provide details.	
10. The number of GMOs imported during the 12 month reporting period to 31st December 2006	
11. The number of GMOs used for breeding purposes during the 12 month reporting period to 31st December 2006.	
12. The number of GMOs bred during the 12 month reporting period to 31st December 2006	
13. The total number of GMOs held in house at the end of the 12-month reporting period to 31st December 2006.	
14. The total number of GM animals disposed of during the 12 month reporting period to 31st December 2006.	
15. Provide details of decontamination / disposal procedures employed for GM animal remains.	

***Notes**

1. In addition to the name of the user, please provide the name of the Principal Investigator under whose name the GMO contained use facility/activity is registered.
2. Contact e-mail address such that the Agency may revert to you should further clarification be required.

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Enforcement - Site Inspections

- European Enforcement Project Checklist
  - General Information about the premises
  - Containment measures in place
    - Restricted access
    - Biohazard signs
    - Procedures
    - Training
    - Microbiological Safety Cabinet
    - Personal protective measures
    - GMP / GOSH
    - Hand-washing facilities
    - Write up area

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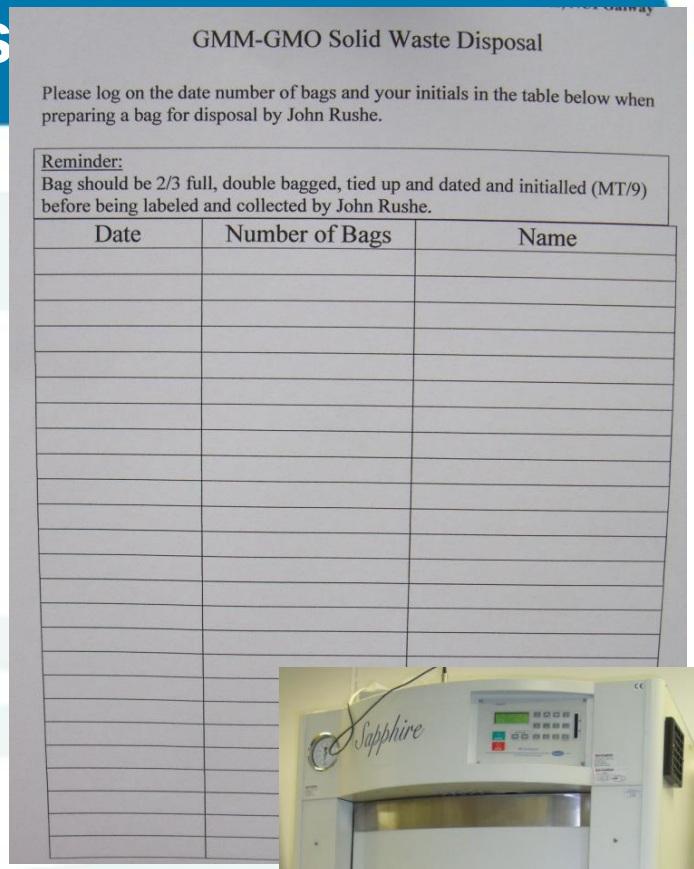
Enforcement - Site Inspections

- GMM Storage
  - Location /in lab?/ elsewhere? / inventory
- Waste Inactivation
  - Location of autoclave relative to lab
  - Last date of validation
  - Procedure for decontamination
  - Procedure for treatment of spillages
  - Procedure for reporting of accidents / incidents
  - Log of waste inactivation
- Are GMOs/GMMs used for teaching purposes?



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Enforcement - Site Inspection Follow Up

- Site inspection report
- Letter of non-compliance to registered user (if required)
  - Annual reporting
  - Where user has relocated activity and has not informed the Agency
  - SOPs
  - Non-notified activity
  - BSC - management structure
  - Prosecution of Offences
- High Court injunction
- Notice to Take Measures

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Deliberate Release of GMOs

'any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms for which no specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment, and cognate words and expressions shall be construed accordingly.'

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Deliberate Release of GMOs

- Part B Release – R&D purposes
  - Field Trials for crops
  - Clinical Trials
- Part C Release
  - Placing a product on the market

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Deliberate Release – EPA Remit Clinical Trials

- The patient receiving the treatment insofar as they are part of the general population and the wider environment
- The potential risk of the GMM moving from the patient to the general population and the consequences of such a risk
- The potential environmental concerns from the use of GMMs

Deliberate Release – Remit of other Agencies

IRISH MEDICINES BOARD

- Irish Medicines Board
  - Patient risk from the treatment
  - Clinical Trials Directive (2001/20/EC)

- Health & Safety Authority
  - Worker protection legislation
  - Safety, Health & Welfare at Work Act, 2005

HEALTH AND SAFETY AUTHORITY

epa Environmental Protection Agency
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Common Omissions in notifications

- Contact details (Phone number, email address)
- GM animals
  - Number of animals to be used during project
  - Description of the GM animals
  - Overall purpose of the work, e.g. Alzheimer's research
- GMMs
  - Separate RAs for GMMs
  - Laboratory name/number
  - Waste inactivation (time, temperature & pressure)

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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Useful Links

- www.epa.ie
- www.environ.ie
- www.hse.gov.uk/biosafety
- www.irishstatutebook.ie
- www.gmoinfo.ie
- http://ec.europa.eu/environment/index_en.htm

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Go raibh maith agaibh

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