

Implementation of the Genetically Modified Organisms Regulations in Ireland by the EPA

***GMO Technology
Conference***

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With thanks to:

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GMOAC

Outline of Presentation

- Definition-GMO-**Process** Based regulatory system-EU
- Importance of GMO Technology to Biopharma-Ireland
- Potential Benefits & Concerns of GMO Technology
- New plant breeding/genetic modification techniques-EU Working Group (**NTWG**): Whether the specific techniques under consideration yield GMOs as defined in the Directive(s)?
- Future for GMO at EU level?

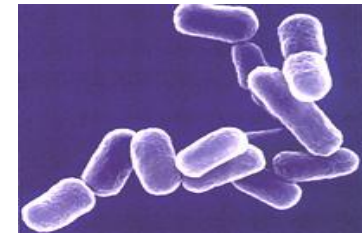
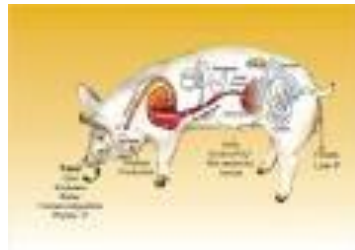
EU Legislation – Safe Use – Modern Biotechnology

- ✓ Directive 2009/41/EC - (Recast of Directive 90/219/EEC) - Contained use of GMMs – EPA – Competent Authority (CA) – **Minimum**
- ✓ Directive 2001/18/EC - Deliberate release of GMOs – EPA – CA – **Single market**
- ✓ Reg. 1946/03 – Transboundary Movement – Cartagena Protocol (CP) on Biosafety

Definitions - Genetically Modified Organism (GMO-DR/GMM-CU)

GMO/GMM:

- An organism/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.



List techniques (under Annexes) that:

- Give rise to genetic modification - 'altering' the genetic material....
- Are **not** considered to result in genetic modification - **conjugation** etc.
- Yield organisms – **are** excluded from the Directive – **mutagenesis, self-cloning-only for CU** etc.

EU Regulatory System – **Process** rather than **Product** Based

Clearfield OSR – HT
(Imidazolinone)-Mutagenesis -
non-GMO-not regulated-EU-
regulated in Canada - **Product**
based-**Novelty**-PNTs (traits)

Non-GMO



ORS-GT73-HT
(Glyphosate)-GMO-
Agrobacterium

GMO



Policy – Legislation – Spirit?

- ✓ “The development of biotechnology is such as to contribute to the economic expansion of the Member States” **Dir. 2009/41/EC.**
- ✓ “Modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health” - **CP on Biosafety**

Irish Policy

- **Food Harvest 2020** – *“With the aim of ensuring the competitiveness and viability of Irish production, DAFM should monitor and appraise policy, trade and commercial developments at EU and other relevant levels with respect to the use of existing and emerging technologies in areas such as biotechnology and genetically modified organisms (GMOs)”*
- **Strategy for Science Technology and Innovation – 2006-2013-DJEI-**
New Technologies – Knowledge-Based Bio-Economy- *“... risk evaluation of GMOs...implications for agri-food...a strong base in biotechnology is vital to building and profiting from the bio-economy”.*

Contained Use

Definition:

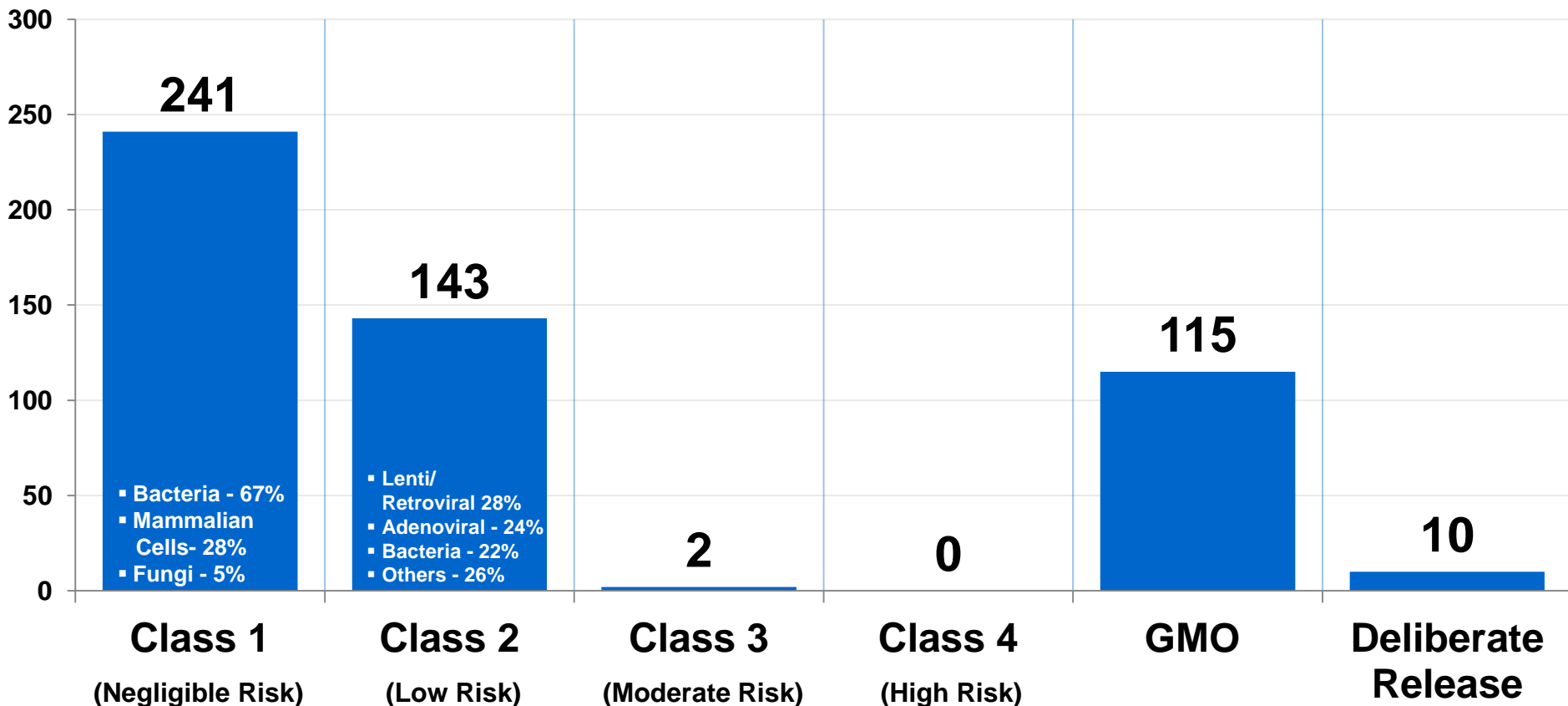
*‘any activity in which micro-organisms/organisms are genetically modified or in which such micro-organisms/organisms are **cultured, stored, transported, destroyed, disposed of** or used in any other way and for which **specific containment** and other protective measures are used to limit their contact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

Classification & Containment:

- Environmental Risk Assessment (ERA) – (Class 1-4 for GMMs)
- GMP
- GOSH
- Containment Measures
- Training

Register of GMO Users in Ireland – October 2013

- **511** approved registered users (**PI**)
- 98% -CU (Class 1,2 & 3 GMM; & GM animals/plants).
- 8% are industrial users: remaining-academic.



Enforcement – Site Inspections

- *To ensure compliance*

- *Risks to human health & environment - managed properly*

- *Promote high standard of biological safety*

- *Allay public concerns*

What we don't want...



Smallpox accident, Edinburgh, 2000



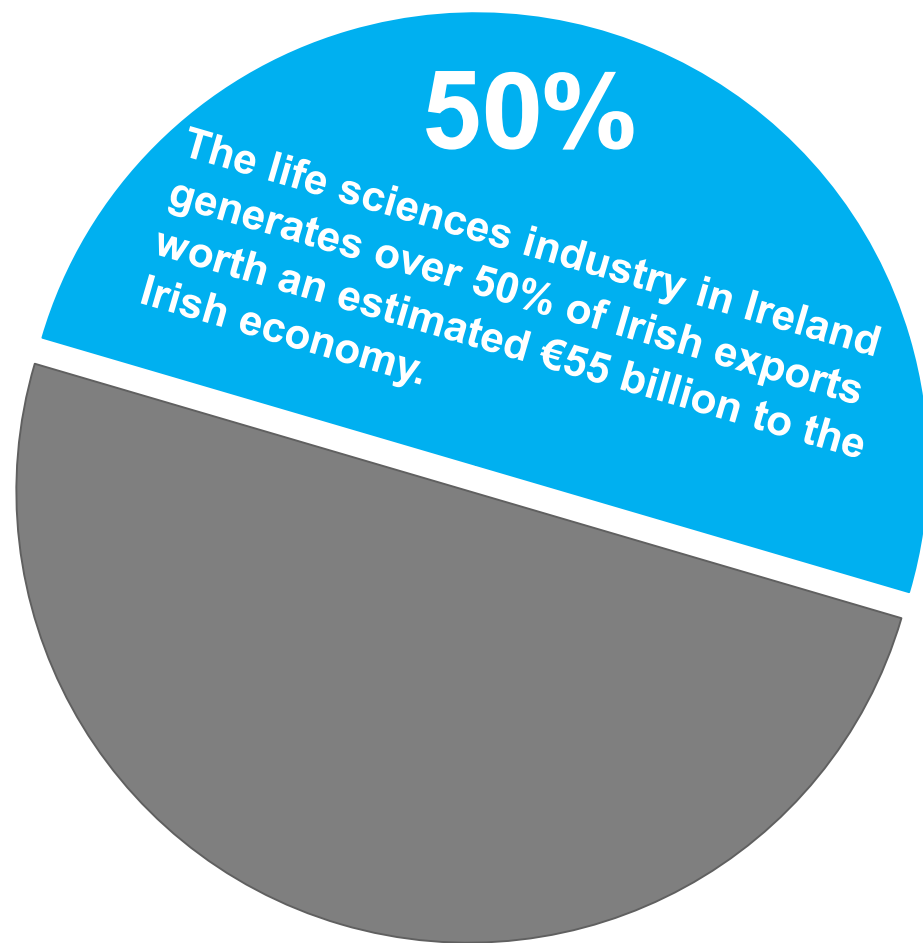
Foot & Mouth, Pirbright, 2007

EPA's risk-based approach to assessment and enforcement - Better Regulation

- Class 1 GMM – proportionate - **crippled** strains
 - ✓ Reducing administration burden
 - ✓ 6 year enforcement cycle for Class 1 GMM
- Provision-**Deregulation-Legislation**-40y experience
- Advice and Guidance on web page
- Liaising with Biological Safety Officers
- Presentations - 3rd level colleges
- European Enforcement project - CU/DR

The Importance of Life Science, including **Biopharma**, to the Irish Economy

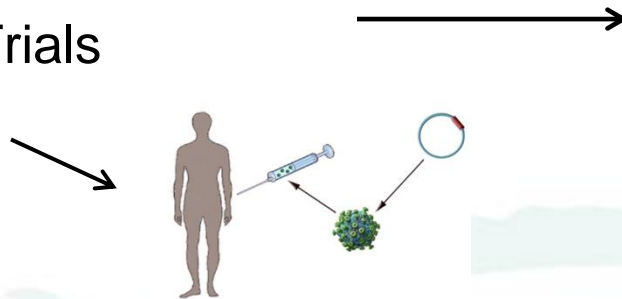
- Since the 1960s – Ireland – Life Science Companies in the areas of Pharmaceutical, Biotechnology, Medical Devices & Diagnostics – **50,000** people – indigenous and multinational.



9 of the top 10 global pharmaceutical companies are located in Ireland.

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 →

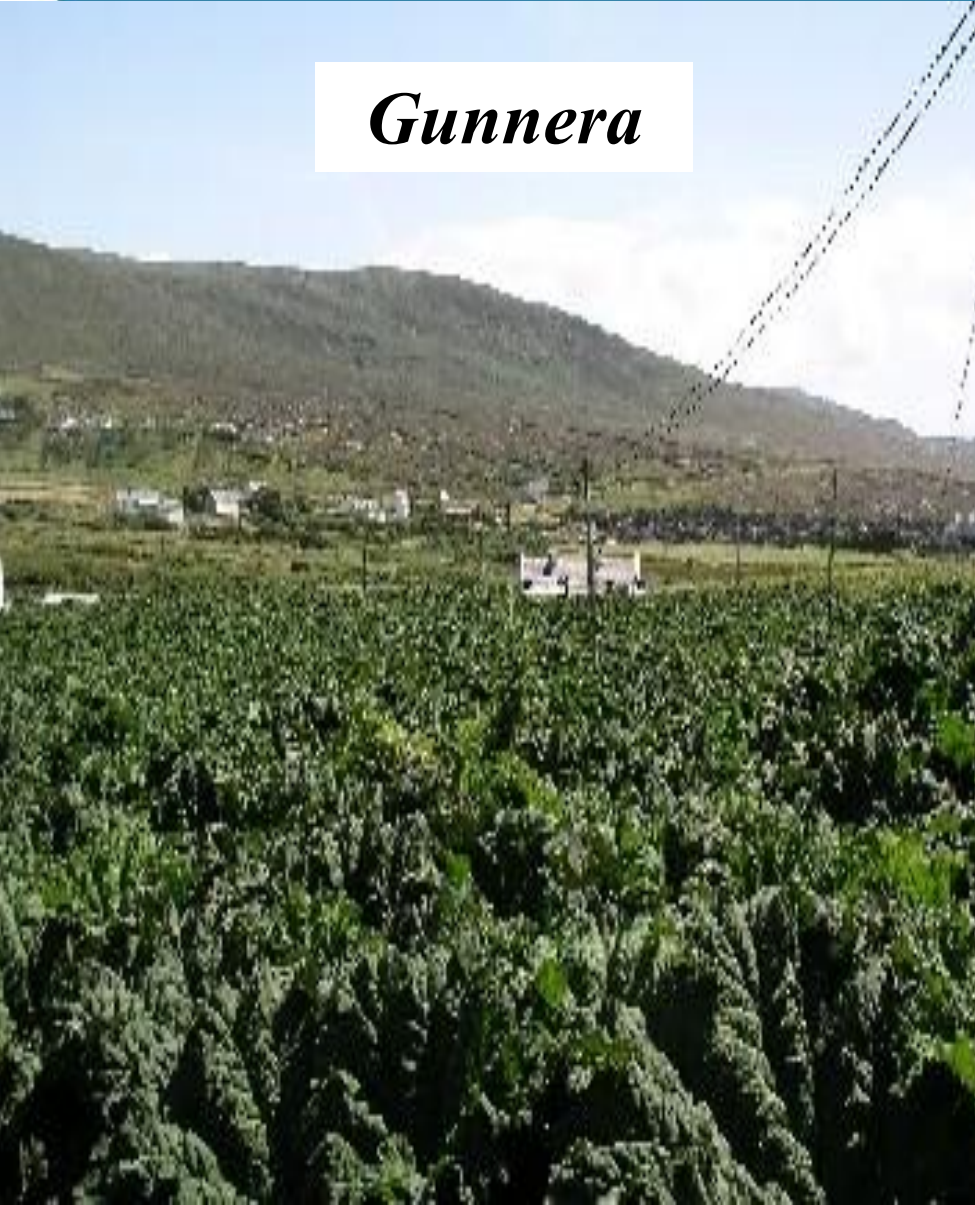


Potential Benefits & Concerns of GMOs

Benefits	Concerns
EU farmers rely on imported animal feed. In 2012, 55% of total feed used on Irish farms -ingredients from GM crops - maize & soya	Ethical concerns
Produce food: 2050-population of 9B	GMO-not a 'cure all'-only 1 part of the armoury
Sustainable agriculture - less pesticides use, e.g. Bt Maize, GM potato-tolerant to the blight fungus	Potential effects on Biodiversity PMEM studies in Spain (13y) with Bt maize-no adverse effects reported.
Climate change - Drought tolerant crops, Ash Dieback fungus, Schmallenberg virus	GM (HT) crops-weeds become resistant to herbicides
GM mosquito to control Dengue fever	'Superweeds' - gene flow from GM HT crops to related weed species - Invasive species

Invasive Species in the West of Ireland

Gunnera



Japanese Knotweed

EU Legislation – Placing GMO on the market in the EU

Sectoral Legislation – ‘1 door 1 key’

- Reg1829/03-Food & Feed-
 - **European Food Safety Authority** – Centralised procedure – F&F & cultivation - **ERA** - Directive 2001/18/EC
 - **Scientific opinion for Policy makers - Decision making process**
- Reg. (EC) No 726/2004 repealing Reg. 2309/93 - Medicinal & Veterinary
 - **European Medicines Agency** – Centralised procedure – **ERA**

GMO - Part B Releases in Ireland



**13 field trials - GM
herbicide tolerant
sugar beet**

1997 - 2000

**Consent to RCSI-
CT on patients to
assess the safety &
immunogenicity of
a new malaria
vaccine, using two
GMMs**



**Consent to Teagasc,
Oakpark for GM
blight tolerant
potatoes**

2011

2012

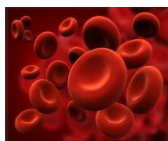
2013

**Consent to
Intervet, NL -
GM vaccine -
Equilis RhodE**



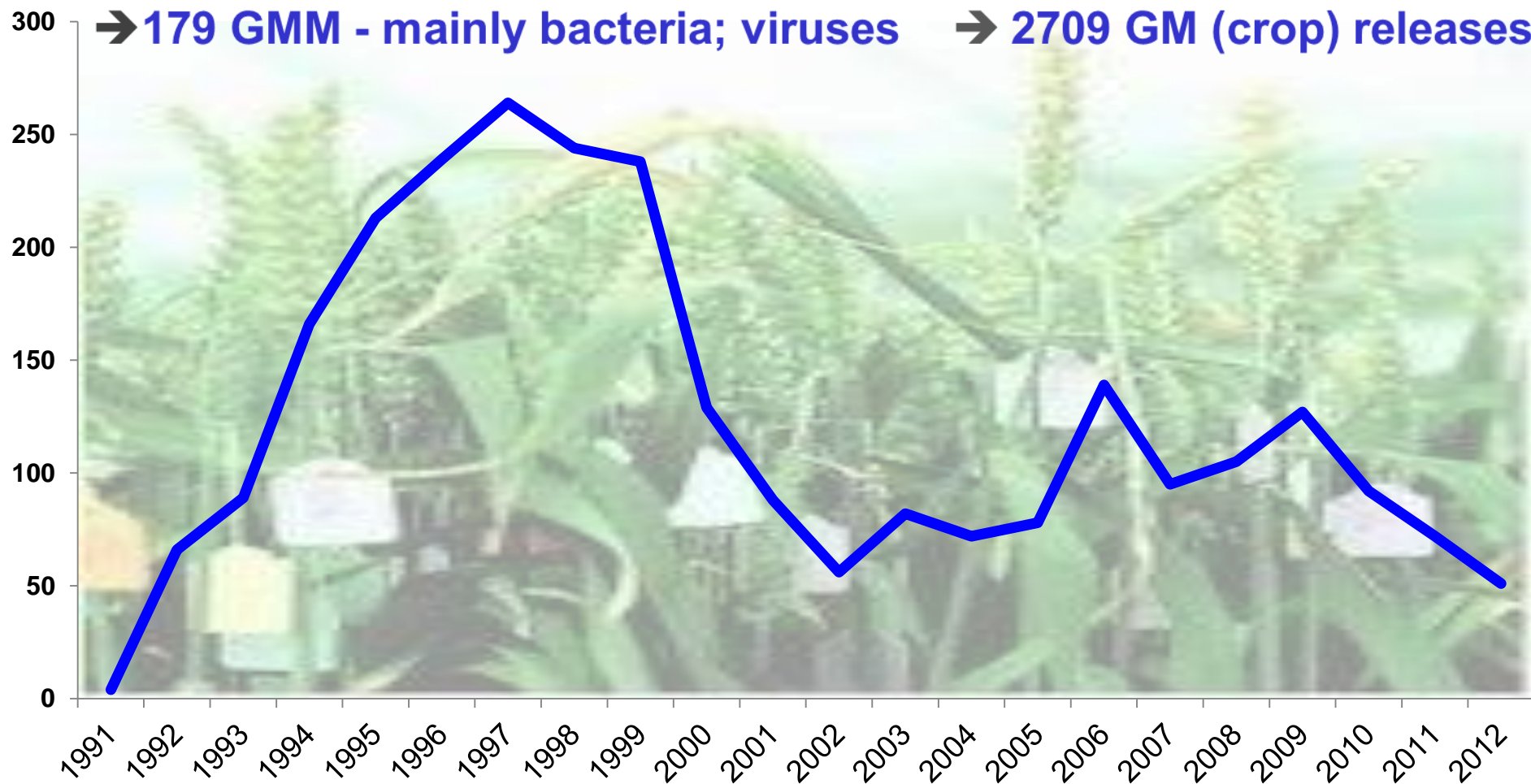
**St. James'
Hospital,
Haemophilia B-
Factor IX
deficiency**

2013



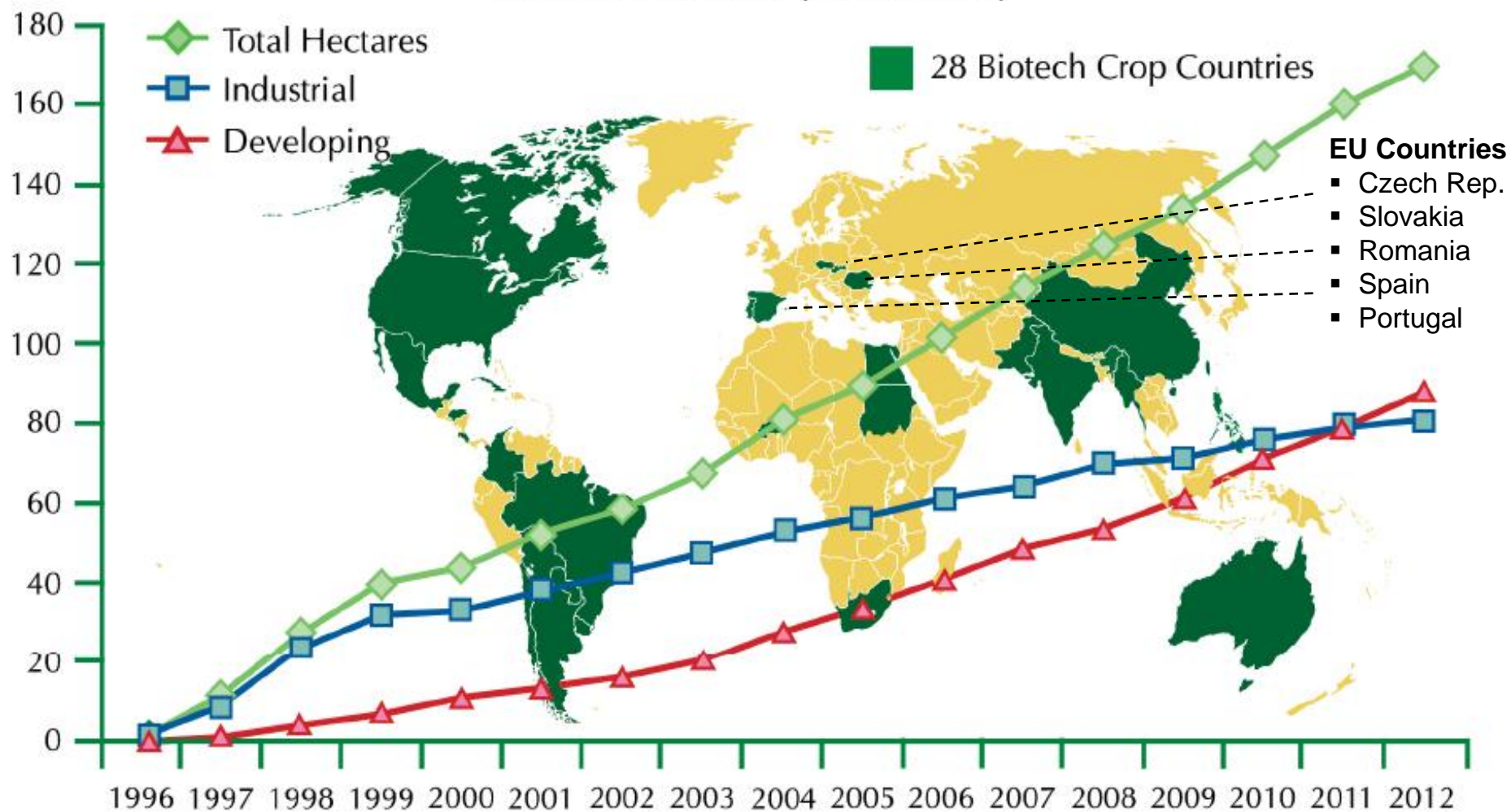
European Union Field Trial Notifications 1991 – 2012

➔ 179 GMM - mainly bacteria; viruses ➔ 2709 GM (crop) releases



After a steep decline from 1998 onwards, field trial notifications increased after 2002, peaked in 2006 and despite a slight resurgence in the year 2009, they have declined steadily ever since.

GLOBAL AREA OF BIOTECH CROPS Million Hectares (1996-2012)



17.3 million farmers, in 28 countries, planted 170.3 million hectares (420 million acres) in 2012, a sustained increase of 6% or 10.3 million hectares (25 million acres) over 2011.

Products Approved under Directive 2001/18/EEC in the EU

- MON810 GM maize (insect tolerant)
- Starch potato (amylopectin little or no amylase)-**BASF withdrawn**

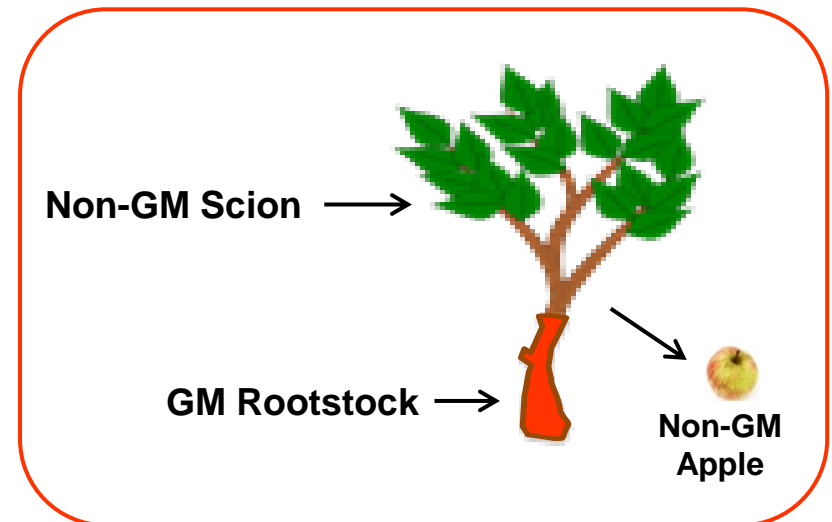
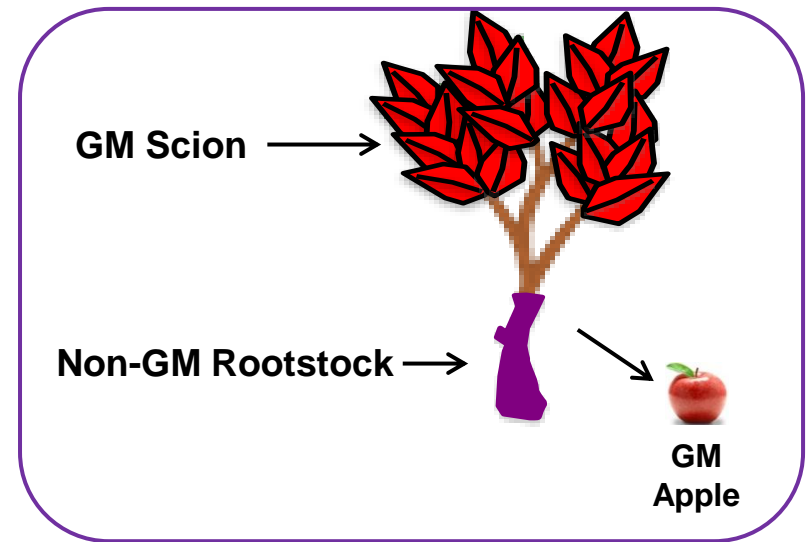
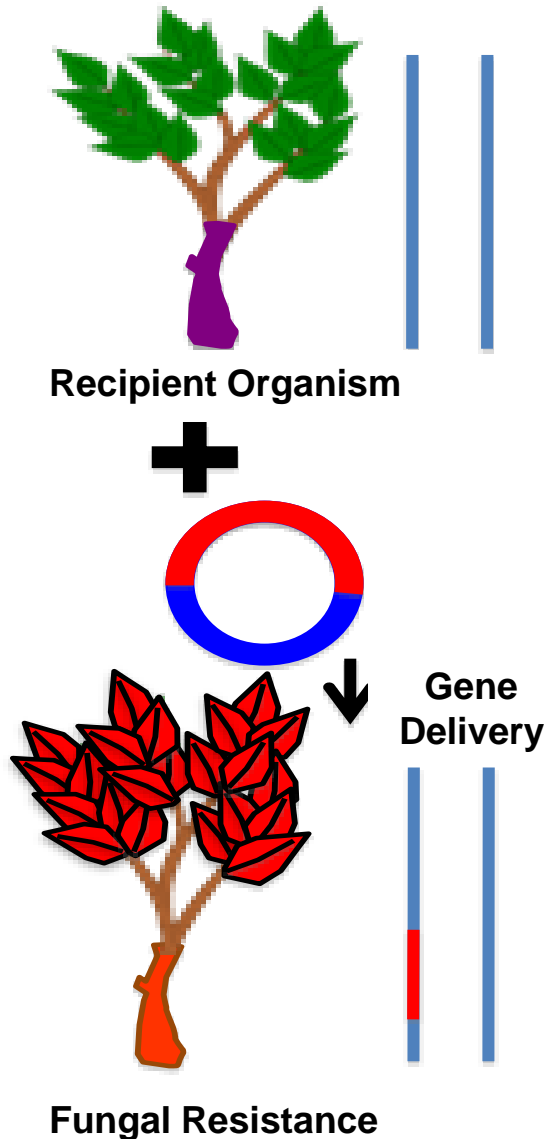


EU working group looked at regulation of 8 New techniques (NT) of Genetic Modification -how to regulate?-GMO or not?

- 1. Oligonucleotide Directed Mutagenesis (ODM);**
- 2. Zinc Finger Nuclease Technology (ZFN) comprising ZFN-1, ZFN-2 and ZFN-3;**
- 3. Cisgenesis comprising Intragenesis;**
- 4. Grafting;**
- 5. Agro-infiltration;**
- 6. RNA-dependent DNA methylation (RdDM);**
- 7. Reverse breeding;**
- 8. Synthetic genomics.**

- Unclear whether such techniques fall within the scope of the legislation**
- Changes introduced are similar to those achievable by conventional breeding**
- The EU has not **yet** decided how to regulate such plants**

Example of Grafting



The Future of GMOs at EU Level

- The regulation of New Techniques at EU level will have ramifications for EU SME's
- The potential for a more flexible legislative approach for the cultivation of GM crops within the EU (**2011 Evaluation of EU GMO legislation**) i.e. to allow member states to decide on the cultivation of GM crops on their territories – e.g. in Spain with Bt maize?
- **Climate change** - Will EU agriculture suffer if we do not use GMO technology - water stress and emerging pathogens?
- **Future Developments:**
 - Production of food and feed products with enhanced qualities -omega-3 fatty acids
 - Production of GM animals - enviropig, GM salmon (FDA)
 - Production of plant-made pharmaceutical products
 - CAP-post 2014 - more stringent controls re Plant Protection Products
 - Other: Biofuels-algae; Bio-economy/low carbon; can biotech help?

Conclusions

- Application of GMOs - Contained Use is accepted by public
- GMO Technology is important for the Biopharma industry in Ireland
- In Ireland we are dependent on the importation of animal feed derived from GMO
- GMO technology is not per se riskier than conventional plant breeding – a decade of EU funded GMO Research-2010
- Better Regulation Principles re GMO technology at EU:
 - Product-based regulation (not the technique that produces it) in line with rest of world
 - proportionate to the risks
 - risk vs. benefits
 - economic development –keep Biotech jobs in the EU-Lisbon Strategy?

*Go raibh
maith agaibh.*