



Workshop Session



Genetic Modification Safety Committee Considerations

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21st May 2019

NAATTC Presentation

Genetic Modification Safety Committee Considerations

Sheila Waugh

Consultant Virologist, Newcastle upon Tyne Hospitals

My Background

So you now where my expertise lies.....
and where it doesn't!

Glasgow
University



MBChB
BSc Genetics
PhD

Sick Kids
Aberdeen &
Glasgow



Paediatrics

Virology Training
FRCPATH (Virology)

West of Scotland
Specialist Virology Centre



HPA / Newcastle
Hospitals
Virology

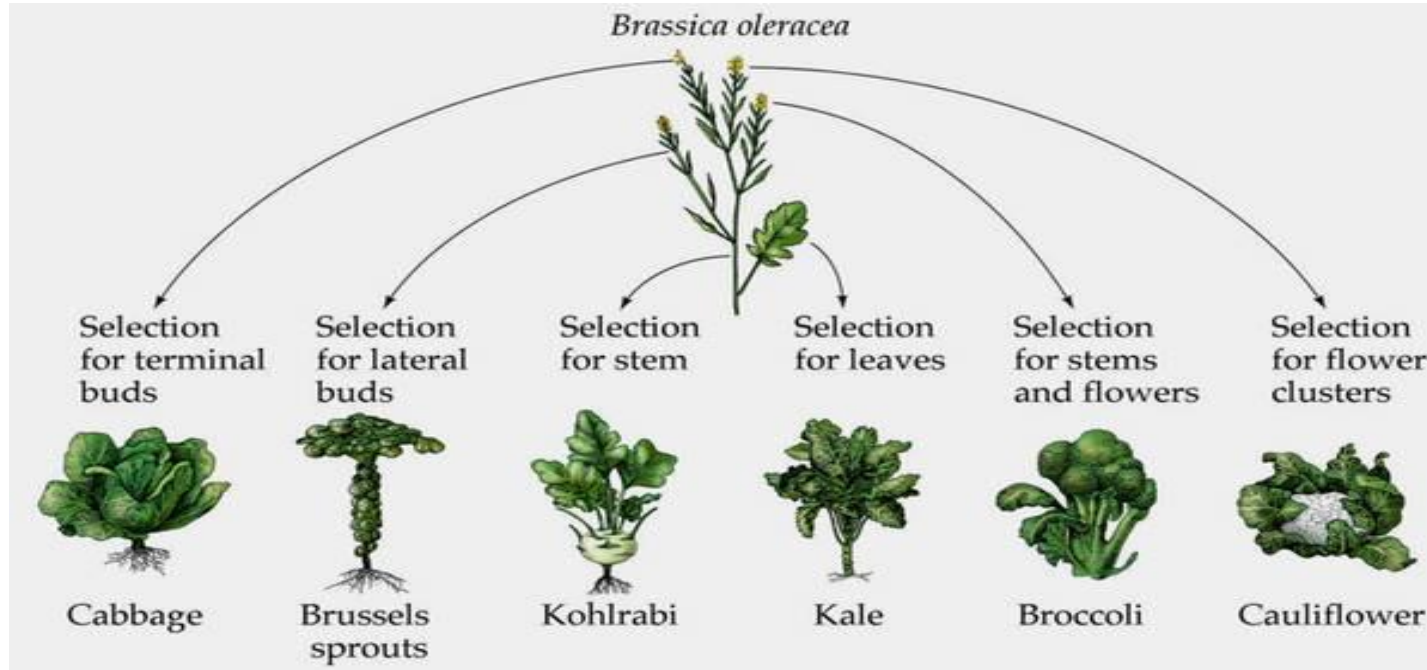
**Chair of the Newcastle Hospitals
Genetic Modification Safety Committee**



**Member of UK Specialist Advisory Committee on
Genetic Modification (Clinical virology
representative since 2017)**

Advise UK government via UK Health and Safety Executive

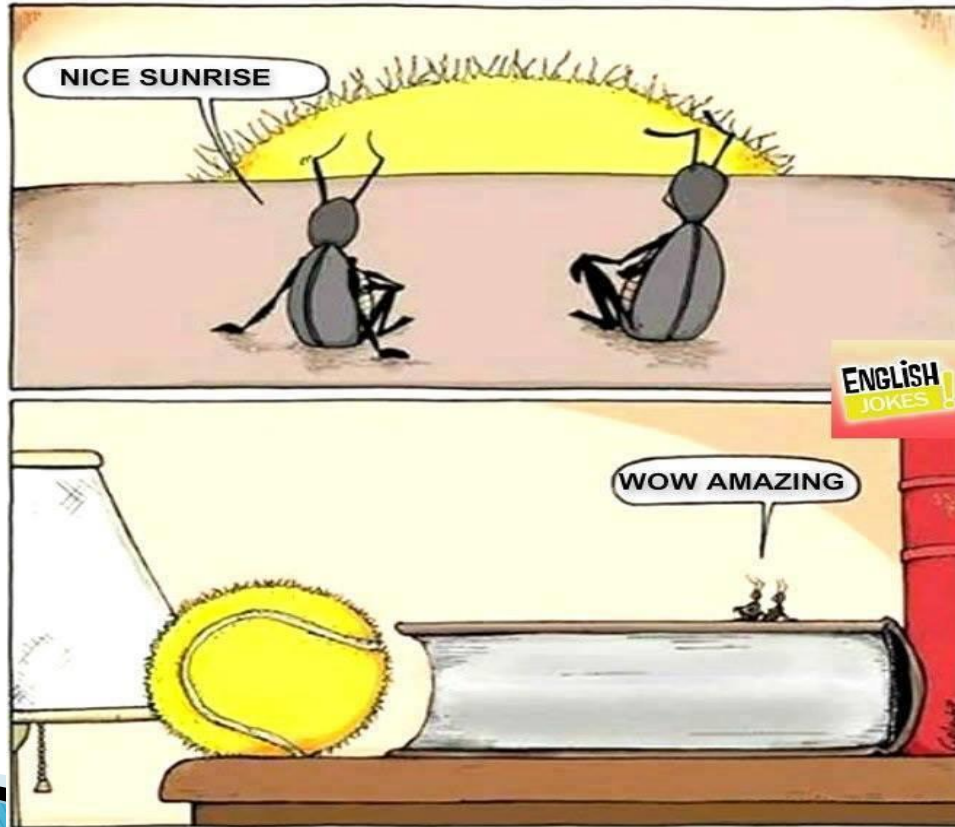
Manipulating genomes not a new phenomenon....



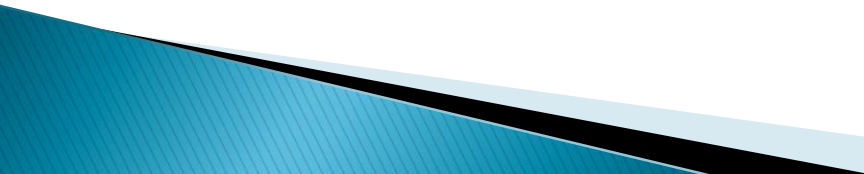
The term 'GM' usually infers deliberate engineering of an organism's genetic material



Public Perspective



The concerns

- ▶ **Relatively new and ‘unknown’**
 - ▶ **Ethical and Societal concerns**
 - ‘Designer babies’
 - Loss of biodiversity
 - ▶ **Safety:**
 - Potential to produce effects on cellular DNA e.g. integration events.
 - Potential for recombination or transfer of genetic material to another organism
 - Potential for heritability of the trait to new generations and unexpected effects
 - Potential for environmental effects on other plants and animals
- 

The pros...



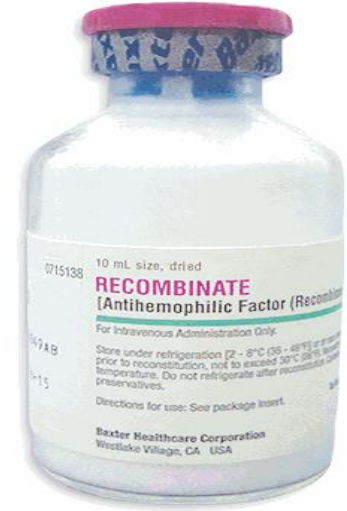
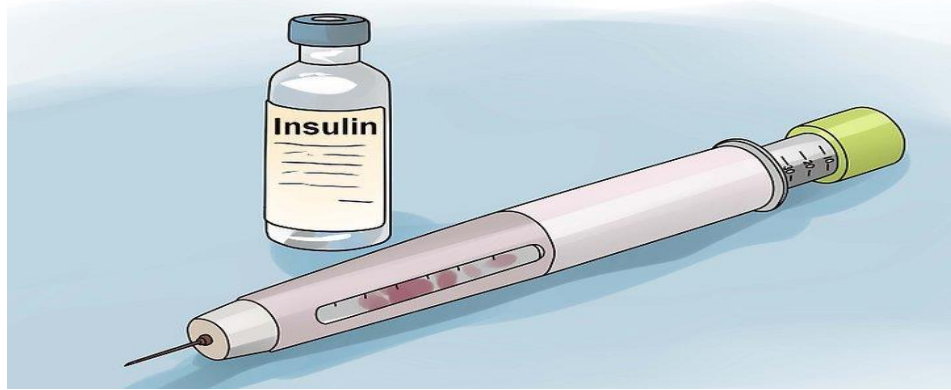
Research: critical part of basic and translational research.

The pros...



- ▶ **Agriculture:** increase crop yields and resistance to pests and weather. Potential major worldwide impact.

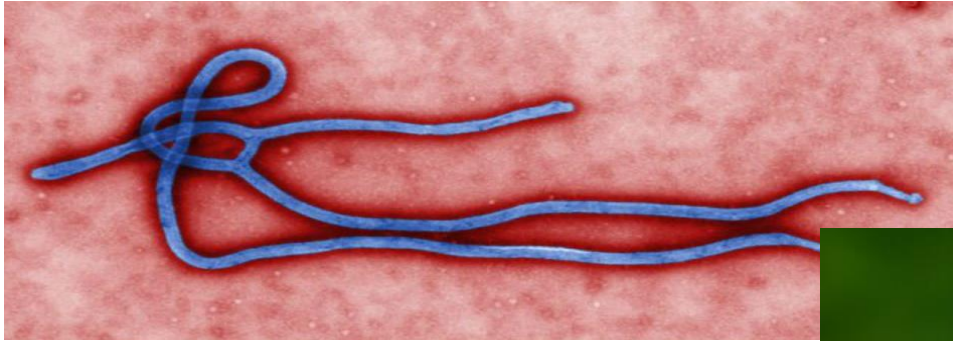
The pros...



► Medicine:

- Used in the production of proteins – such as recombinant insulin and clotting factors in haemophilia reducing infection risks from animal or human derived products.

The pros...

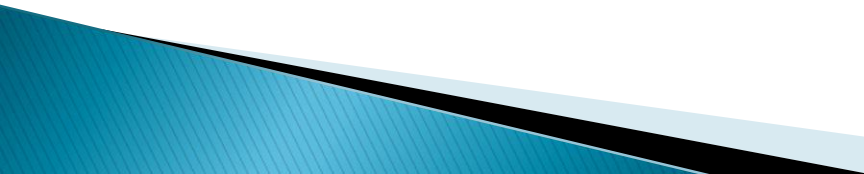


- ▶ **Medicine:**
 - **DNA Vaccines**



The pros...

‘Gene therapy’

- **Inherited (deficiency) disorders.**
 - **Non-inherited disorders e.g. cancer.**
- 

Controls and Safeguards

STATUTORY INSTRUMENTS

2002 No. 2443

ENVIRONMENTAL PROTECTION

**Genetically Modified Organisms (Deliberate Release)
Regulations 2002**

Made - - - - - 25th September 2002

Laid before Parliament 26th September 2002

Coming into force - - 17th October 2002

ARRANGEMENT OF REGULATIONS

http://www.legislation.gov.uk/uksi/2002/2443/pdfs/uksi_20022443_en.pdf

The Genetically Modified Organisms (Contained Use) Regulations 2014

Guidance on Regulations



The Genetically Modified Organisms (Contained Use) Regulations 2014 came into force on 1 October 2014. This fifth edition of L29 provides practical advice to help dutyholders comply with their legal duties in relation to working with GMOs in contained facilities. It describes the law that applies, sets out the containment measures and other controls that need to be considered and explains the role of the competent authority. The guidance covers carrying out the risk assessment, classifying the contained use work, notifying to the competent authority, applying the relevant control measures and accident reporting.

What is a 'Genetically Modified Organism'?

- ▶ *Micro-organism*: This term covers bacteria, fungi and viruses, **as well as cells** and tissue cultures from plants, animals or humans.
- ▶ Naked nucleic acid, oligonucleotides, synthetic DNA, plasmids or liposomes are not considered to be micro-organisms.

Regulation 9 Notification of premises to be used for contained use

(1) A user must not use premises for contained use unless the premises have been notified to the competent authority in accordance with this regulation.

Genetic Modification Safety Committee (GMSC)

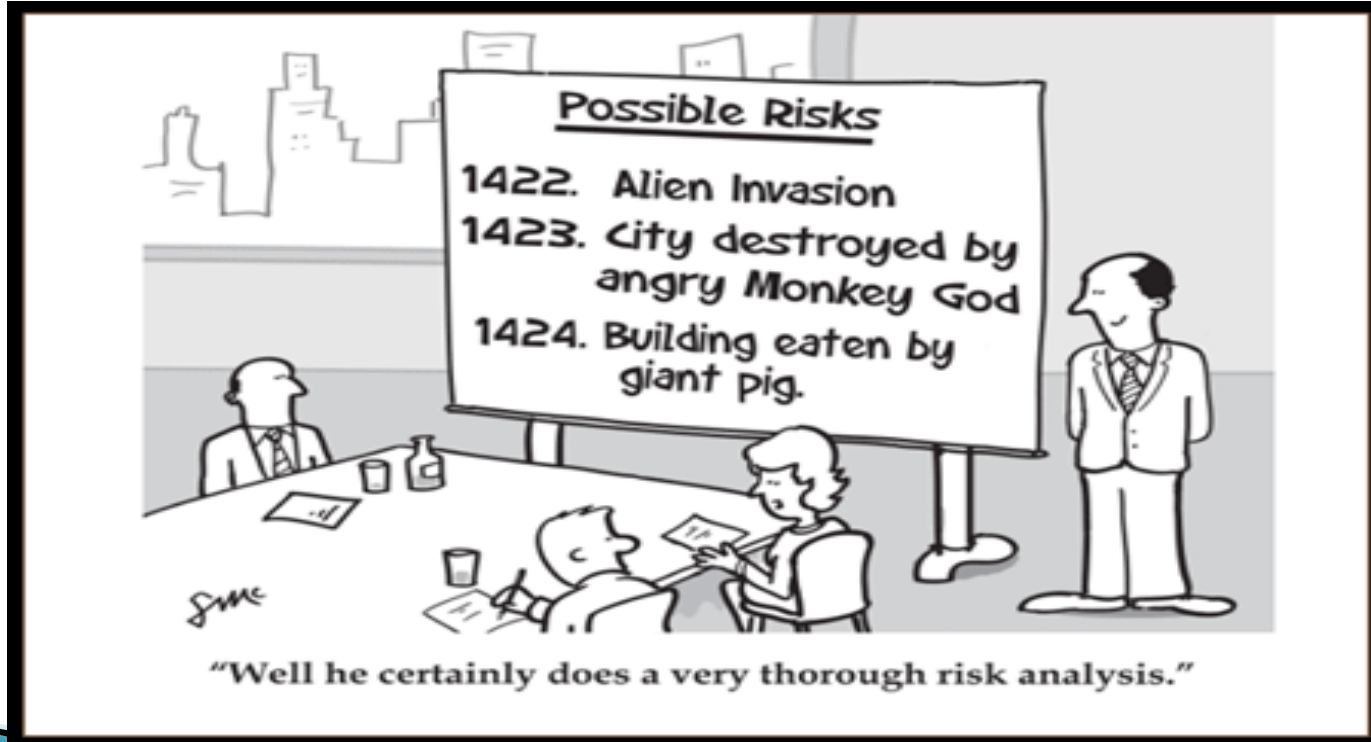


The SACGM Compendium of guidance

(Part 6)

‘The sole statutory purpose of the GMSC is to advise the management of the notifying organisation on the adequacy of any risk assessments undertaken relating to GM activities’

The GM Risk assessment

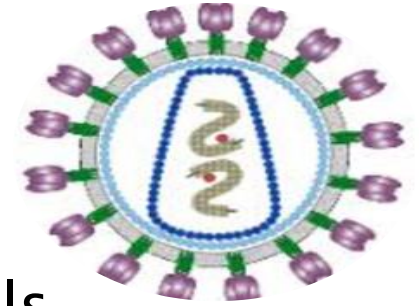


The GM Risk assessment 1

Overall nature of the intended GMM.
Assessment of the relative risks it may pose to human health and the environment.

Risk Classification

- ▶ What is the vector?
 - Pathogenicity in humans and animals
 - (host range, route of transmission, stability in environment)
- ▶ To what extent has it been attenuated



What is the insert?

Information box: Hazard group definitions

When classifying a biological agent it should be assigned to one of the following groups according to its level of risk of infection to humans.

Group 1	Unlikely to cause human disease.
Group 2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
Group 3	Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available.
Group 4	Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

The GM Risk assessment 2

**Nature of the Work
and Control Measures**



Handling of the GM product prior to administration.

- ▶ Receipt
- ▶ Storage
- ▶ Preparation
 - Biological safety cabinet
 - Personal protective Equipment (PPE)
 - Separation from other Pharmacy Processes
 - Decontamination of the Cabinet
 - Transport to site of administration

Administration of the GM product

- ▶ How
 - Intrathecal, Intramuscular, Intravenous, nebuliser
 - Risk of needle stick
 - Risk of aerosol
- ▶ Where
 - Ward, theatre, cubicle, pressure room




Administration of the GM product

- ▶ Who
 - Restrictions – Skin conditions, immunosuppressed, pregnant?
- ▶ PPE
 - Gown, gloves, mask?
- ▶ Disinfection
- ▶ Spills



Will there be shedding

- ▶ Where from and for how long?
 - Stool, urine, respiratory tract, injection site?
 - ▶ How long is isolation required?
 - ▶ What happens after discharge?
 - ▶ Laboratory samples?
 - ▶ Bed linen?
- 

Waste

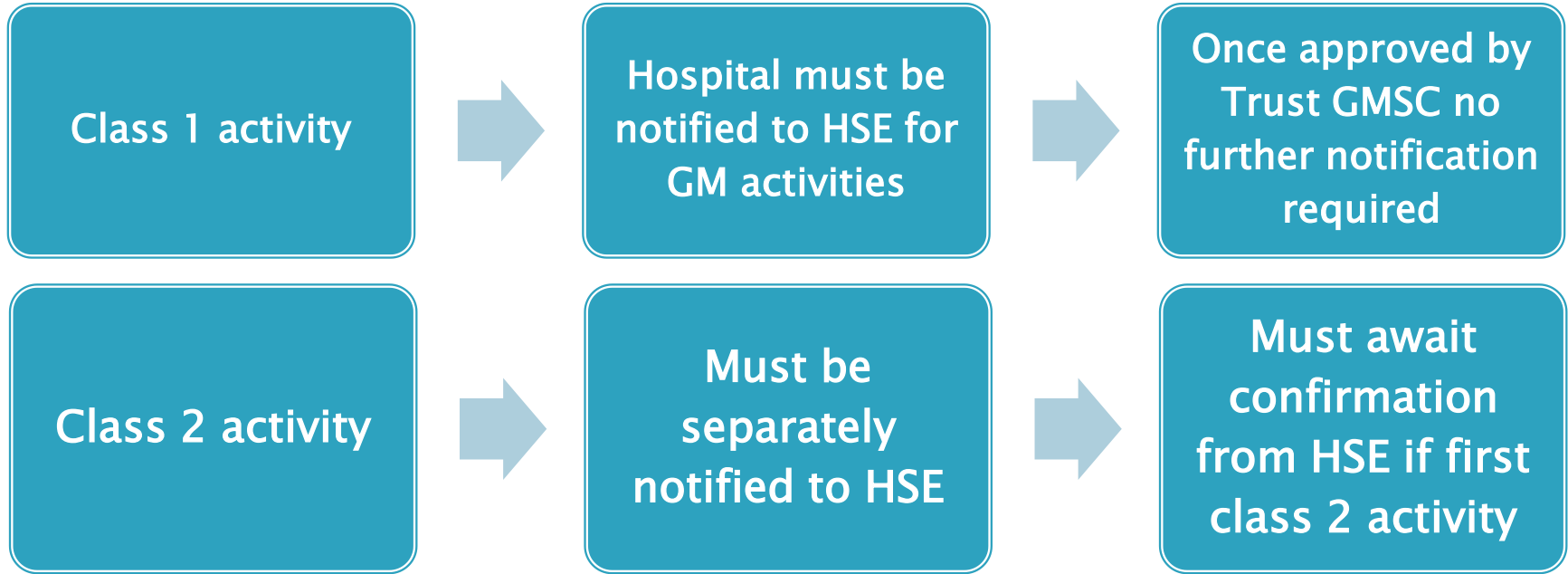
- ▶ Unused product
- ▶ Administration –
e.g. syringes, giving set.
- ▶ Dressings
- ▶ Urine, stool, nappies?
Pre and post discharge

Waste – potential options

- ▶ Incineration (off-site)
- ▶ Autoclave.
- ▶ Rotaclave
(high temperature)
Trust orange bag waste



Notification



Resources for risk assessment

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<http://www.hse.gov.uk/pubns/priced/l29.pdf>

The SACGM Compendium of guidance

Guidance from the Scientific Advisory Committee on Genetic Modification

<http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/>

The study sponsors



- ▶ Local GMSC Chair and members
 - Pharmacy
 - Infection Prevention and Control (IPC)
 - Waste Officer

- ▶ Local Hospital IPC and waste and policies and procedures



Intranet


The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Policies and Procedural Documents

Clinical Guidelines and Protocols

Thank you!

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