Health and Safety
Executive

Northern BSO meeting
An update: the SRF and the HSL room disinfection project

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Callaghan Review
Single Regulatory Framework for human and animal pathogens

- Foot and mouth disease outbreak, Surrey - 2007
- Subsequent Government sponsored reviews and reports - Spratt, Callaghan …
- Opportunity for regulatory improvement
- Callaghan Review – Project Implementation Team to implement recommendations

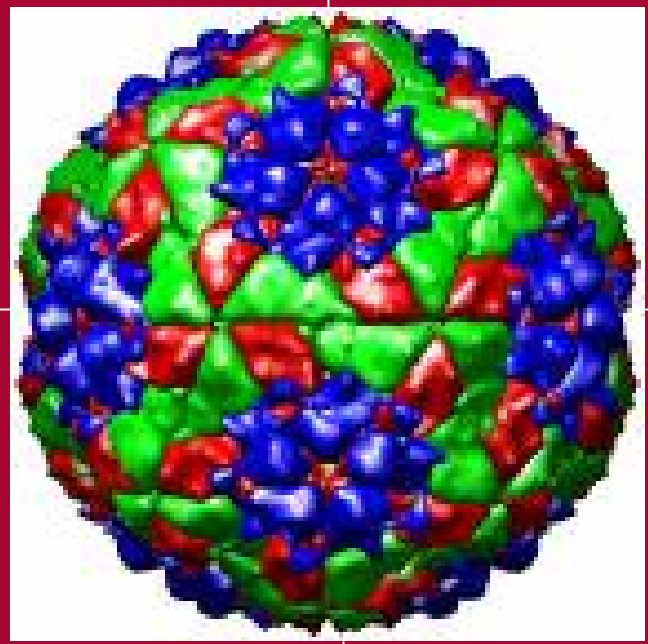
Phased Approach to implementation

- Phase I – Formalise HSE Support for SAPO inspections
- Phase II – Changes made to SAPO to designate HSE as the inspection and enforcement body
- Phase III – Implementing single risk-based regulatory framework for human and specified animal pathogens and GMOs
  - Single regulatory framework
  - Integrated Notifications
  - Cost recovery
  - Containment guidance
  - Devolved Administrations
  - Stakeholder engagement

What are we working with

HSWA/Animal Health/EU Directives

COSHH



GMO(CU)

SAPO

Developing the SRF

- Single set of ‘Biological Agents Contained Use’ Regulations
- Legislative Reform Order – to amend HSWA
- Assumptions

  - RA to be a key element of the SRF

  - All biological agents to be assigned to one of four Hazard Groups

  - All laboratories where work with BA is undertaken - assigned into one of four Containment Level equivalents

  - SRF will be activity based - each activity will be assigned into one of four Classes

Developing the SRF…

- Clear distinction between work at Class1/2 and Class 3/4
- Class 1/2 represents lower hazards - requiring proportionate regulatory activity
- Class 3/4 represents higher hazards - requiring more detailed regulatory activity
- Permission/consent required before work starts

Integrated Notifications - Why Notify?

For Dutyholders to inform:

- Premises – where work is taking place
- Activities – what that work is
- Risk management – how risks will be managed

For Regulator to:

- Assess risk management – hazard assessment & containment measures proposed
- Deliver targeted inspection programme
- Respond to wider requests: Select Committee reports, public register; parliamentary questions; FOI requests, Safety Alerts etc

Structure of integrated notification system

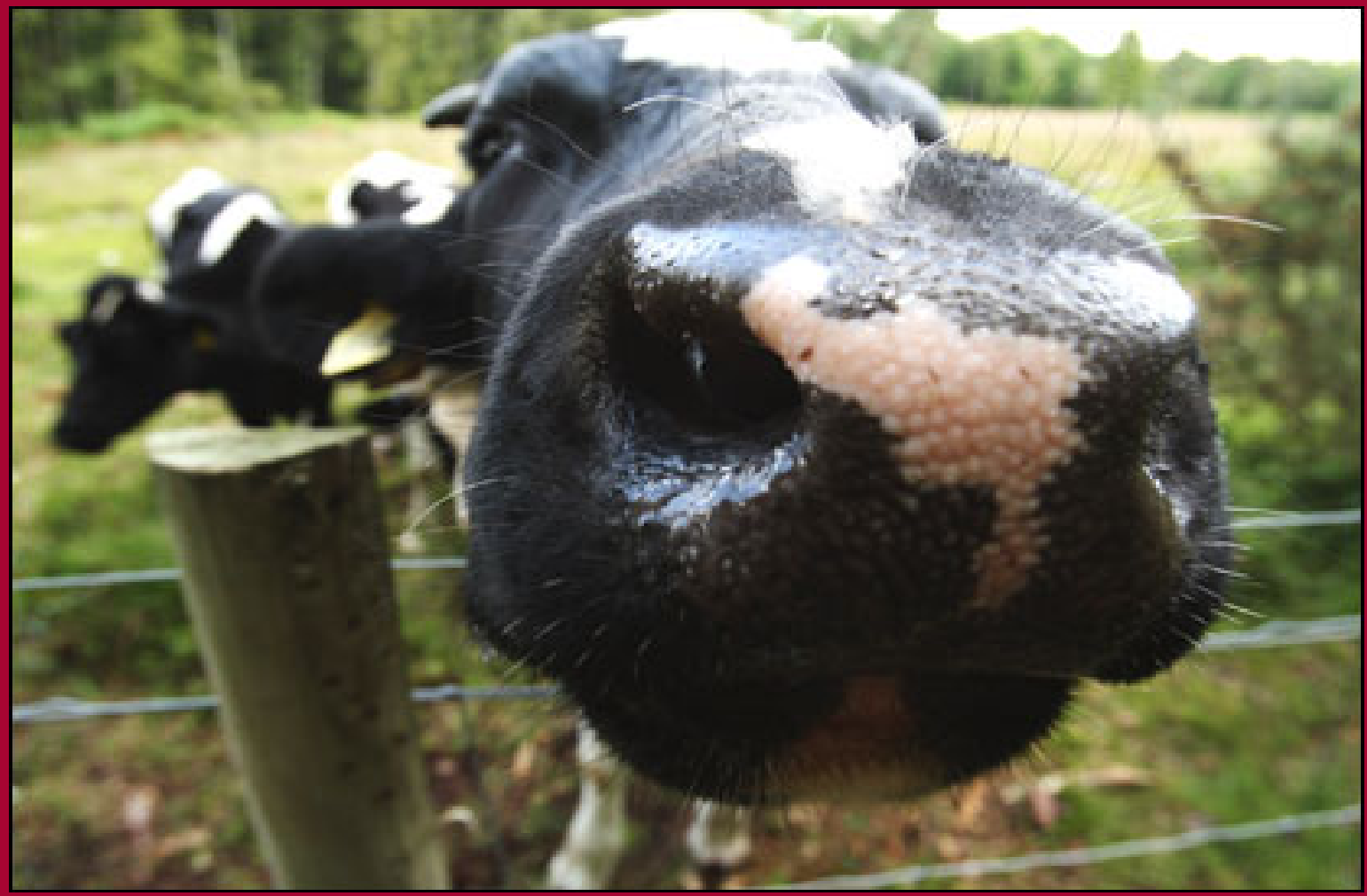
Single integrated system:

- Structured on current GM system
- Separate premises & activity notifications
- Derogations, connected programmes…to to remain
- Class 1 & 2 - Reduced regulation
- Class 3 & 4 - Robust permissioning regime – HSE focus

Cost Recovery

- Government policy and Callaghan recommendation
- Several options considered and proposals for cost recovery to include:
  - ‘front-end’ i.e. receiving, evaluating notifications and associated inspection work + ‘downstream’ i.e. all inspection and investigation work
- Fee based – risk-related i.e., links with notification requirements
- Fixed rate v hourly rate approach?
- Cost recovery restricted to activities that pose moderate to high risk i.e., Class 3 and 4?
- Impact on ‘routine’ diagnostic work – should there be any?
- Proposals subject to impact assessment and consultation

Containment Guidance



Containment Working group

- Callaghan review recommended that there should be common set of containment measures to support new SRF
- ACDP tasked with producing the new guidance document
- Important to ensure effective links with SACGM

ACDP working group

- Expert members – key players
  - human pathogens
  - animal pathogens
  - containment
  - diagnostic/clinical
  - large scale
  - genetic modification
- Chaired by Professor George Griffin
- HSE Secretariat

Milestones for working group

- Five meetings in total
  - Sept, Nov, Jan, March and May
- Formal feedback to ACDP / SACGM
- Final draft of guidance - June 2009
- Formal consultation exercise
- Amendments & preparation for publication

Working group objectives

- Clear technical guidance covering deliberate use of both human & Specified Animal Pathogens
- 4 defined hazard groups (new definitions) for all pathogens within scope
- New Approved list of biological agents
- Common set of 4 containment levels covering laboratory & animal work, also large scale and GM plants

Working group objectives

- Risk-based approach to selection of control measures (subject to restrictions imposed by EU Directives)
- Activity-based – each activity assigned a risk class
- Appropriate use of derogations

Hazard groups

HG3

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. This group also encompasses biological agents that are either exotic, or produce notifiable disease in animals, and have a moderate likelihood of spread to susceptible animal populations

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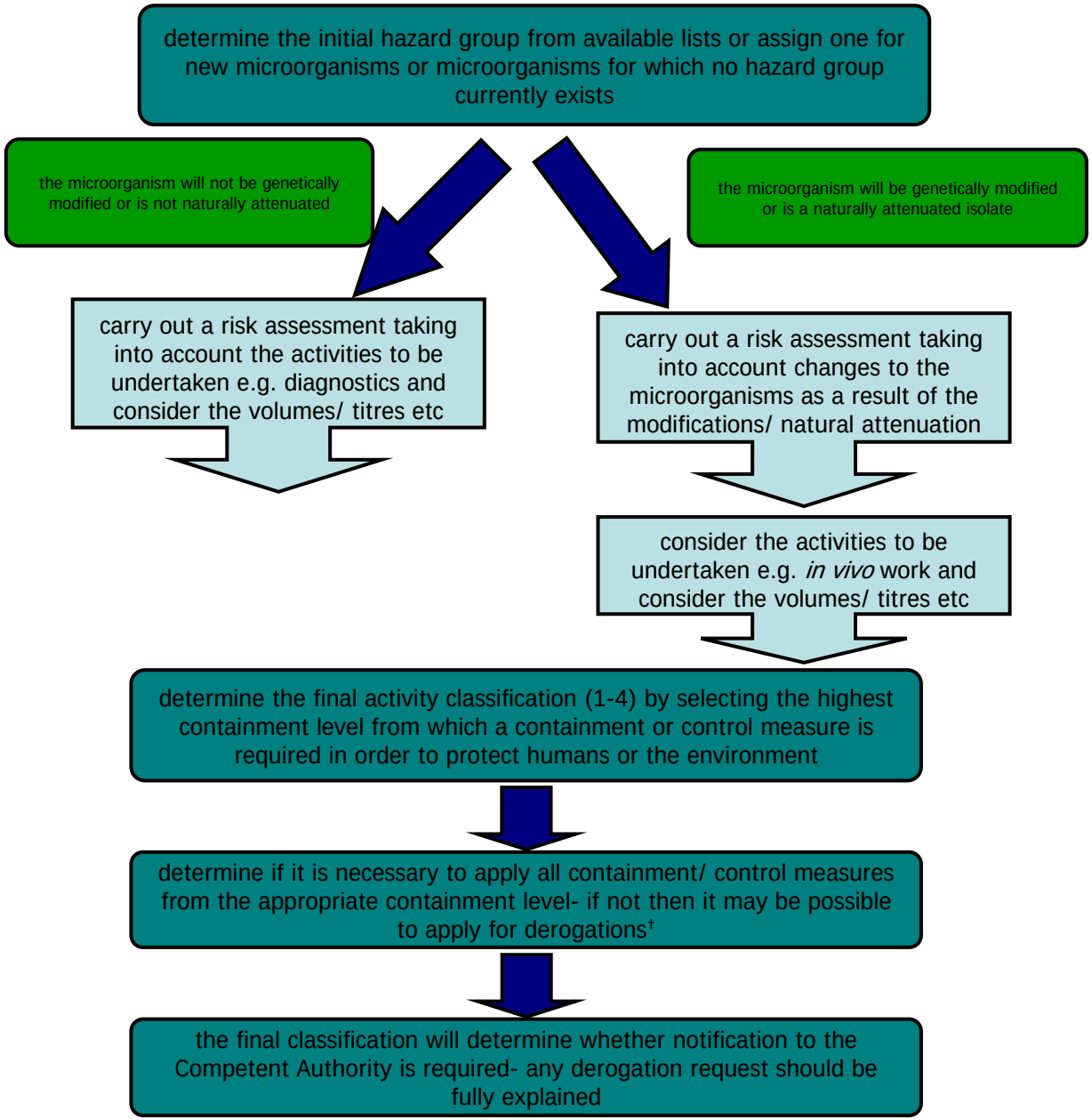

† derogations can be requested for work with any GMMs and specified animal pathogens but only certain wild-type human pathogens

Containment tables

- Combined containment measures from COSHH, GMO(CU) and SAPO
- Must comply with minimum standards required by EU Directives – only ‘gold-plate’ where scientifically justifiable and appropriate
- Separate containment tables for lab work, animal work, large scale activity and GM plants
- Four containment levels (1 to 4)

What next?

- 1st draft - ACDP (Feb); Update to SACGM (Mar)
- Close links with Lawyers – containment tables
- Identify and iron out problem areas
- ‘Near’ final draft - ACDP June meeting in preparation for formal consultation
- Amendments following consultation
- Publication
  - electronic document
  - .pdf version for download & print

What next for the SRF?.....

- Final draft of ‘Biological Agents Contained Use’ Regulations and Guide to the Regulations
- Legislative Reform Order
- Impact Assessment
- ‘Consultation package’ – Formal consultation
- Amendments following consultation
- Implementation

Whole room decontamination study

- Performed by colleagues at HSL
- Microbiology team
  - Health Exposure Section