Potential Changes in Biorisk Policy
UK Perspective

Steve Copping
Head of Compliance, Regulatory Affairs and Risk
Institute for Animal Health

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Aims

- Surrey, 2007
- Changes in UK legislation
- Risk-based regulation
- Risk and the need for safety targets

Surrey, 2007

"There is very little doubt that the foot-and-mouth disease outbreak was caused by foot- and-mouth disease virus from one of these two facilities at Pirbright."

Professor Spratt

Independent Review of Safety of UK facilities handling foot-and-mouth disease virus

Government response

- Review of the regulatory framework for Animal pathogens should be undertaken
- Position of Defra as regulator, licensor and inspector of SAPO 4 regulation and as a major customer of major animal pathogens research and diagnostics should be reviewed
- Callaghan report

Key recommendations

- Risk assessment should be a key element of a SRF
- ACDP be tasked with formulating a common set of containment measures to apply to both human and animal pathogens
- The regulator under the SRF is given discretion to agree with operators` departures from the containment measures drawn up by ACDP, based on risk assessment
- The regulatory outcome we are seeking to achieve must be that the system provides an **assurance that the risk of accidental release is close to zero**

Key issues

There is no such thing as zero risk!

How safe is safe enough?

What is an acceptable risk?

Single Regulatory Framework

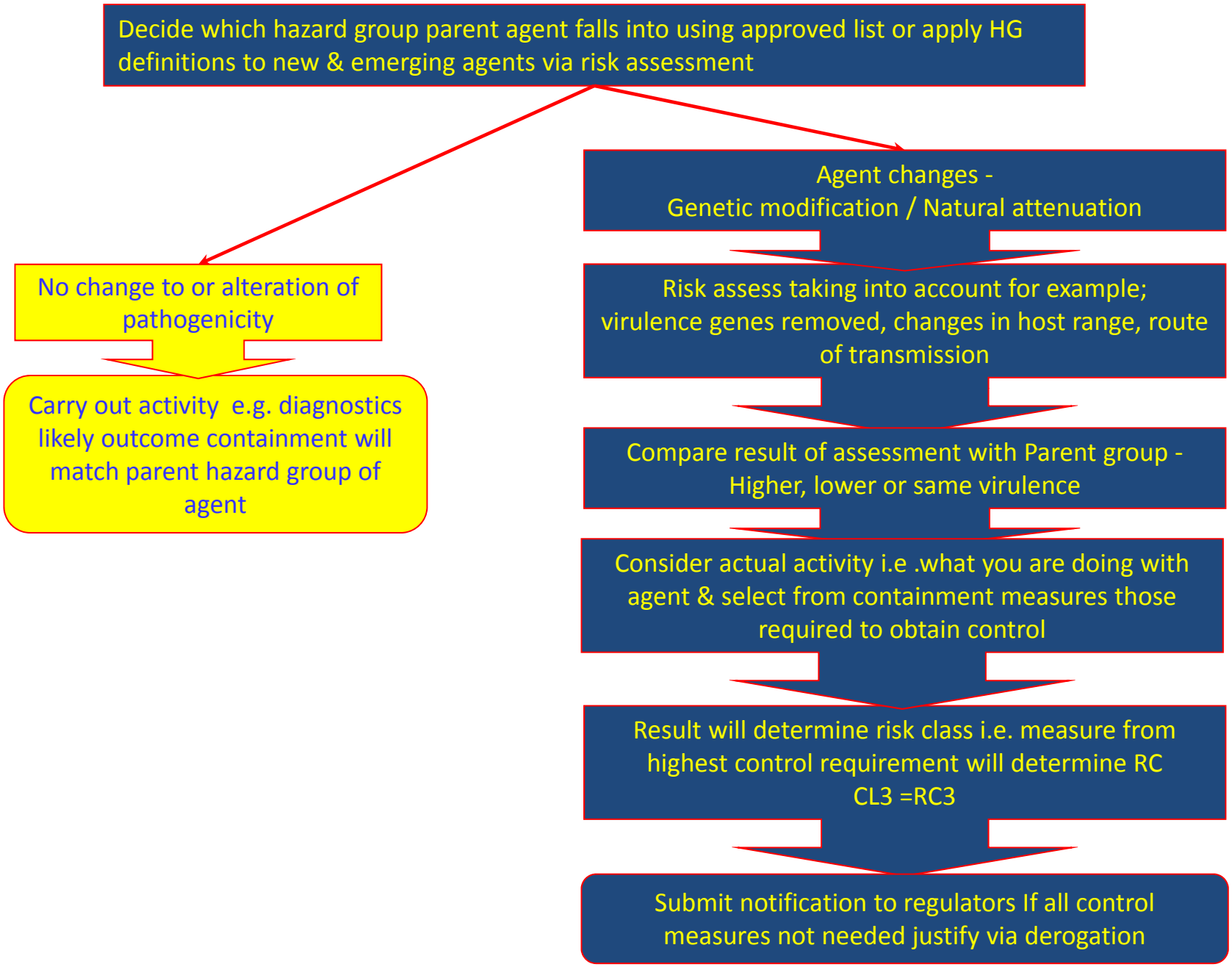
- Govern work with human and animal pathogens
- Consistent regulatory model and enforcement powers
  - Legislative Reform Order
    - Amend S1 HSWA
- Standalone legislation and accompanying guidance
  - Risk based approach

SRF Assumptions

- 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 required before work starts

SRF Assumptions

- All biological agents will be assigned into one of four hazard groups using an approved list
- All laboratories where work with BA is undertaken will be assigned into one of four Containment Level equivalents
- The SRF will be activity based
- Each activity will be assigned into one of four Classes depending on the risk assessment


Decide which hazard group parent agent falls into using approved list or apply HG definitions to new & emerging agents via risk assessment
No change to or alteration of pathogenicity
Carry out activity e.g. diagnostics likely outcome containment will match parent hazard group of agent
Agent changes - Genetic modification / Natural attenuation
Risk assess taking into account for example; virulence genes removed, changes in host range, route of transmission
Compare result of assessment with Parent group - Higher, lower or same virulence
Consider actual activity i.e .what you are doing with agent & select from containment measures those required to obtain control
Result will determine risk class i.e. measure from highest control requirement will determine RC CL3 =RC3
Submit notification to regulators If all control measures not needed justify via derogation

Hazard groups

HG3

Can cause severe human disease and may be 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

Hazard groups

HG4

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

SRF Implementation

- Integrated notification scheme
  - Single system for all work on biological agents in contained use activities
  - Replacement of existing notification schemes
  - Clear differentiation between low hazard and high hazard work
  - Increased self regulation at CL2 and below?
  - Consent/permissions required for work at CL3 & CL4
  - Identifies location and activity at the premise
- Full cost recovery
  - Consultation early 2011
- Timeframe
  - implementation October 2010!

Risk-based regulation

- SRF with single set of regulations covering work with human and animal pathogens is a positive step forward
- Risk based approach with derogation facility is scientific and rational and provides the operator with opportunities over a more deterministic regulatory approach
- However
  - Consent/ permissioning system shifts emphasis (not responsibility) away from the dutyholder
  - Political, public and legislative ramifications (Regulator must provide assurance)
  - *There is no such thing as zero risk!*
  - *How safe is safe enough?*
  - *What is an acceptable risk?*

Legislative architecture

- European Sources of Law
  - Regulation (e.g. REACH)
  - Directives (e.g. Biocidal Products Directive)
- UK legislation
  - Acts (e.g.Health and Safety at Work Act, 1974)
  - Regulation (e.g. COSHH)
  - Approved Codes of Practice
  - Guidance

Risk-Informed Regulation

- Process safety industry
  - process of learning by mistakes no longer acceptable
- High profile incidents with major impact
  - Seveso (Italy, 1976)
  - Piper Alpha (UK, offshore)
- New Regulation
  - Control of Industrial Major Hazards Regs, 1984
  - Control of Major Accident Hazards Regs, 1999
- Need for more formal guidance
  - IEC 61508

The need for safety targets

- Risk assessment
  - frequency & magnitude of consequence of risks
  - loosely defined target values
- Dual approach to determine functional safety
  - Safety related systems where failure will affect people and the environment
- Consistent, robust quantitative risk assessment methodologies
  - safety critical and safety related equipment
  - life cycle approach

New UK Regulatory strategy

- To reduce the likelihood of low frequency, high impact incidents
  - Ensure the adequate control of major accident hazards
- To encourage strong leadership
  - Board engagement backed up by cascade of messages and adequate investment of resources
  - Effective use of safety performance indicators (SPIs) by Directors and Boards
- To encourage an increase in competence
  - Development of competence management systems

Key aspects of the regulatory strategy

- Avoiding catastrophe
  - Partnership approach to measuring health and safety performance
  - Use of process safety performance indicators
- Leadership
  - Development of a High hazard BA leadership group
- Competence
  - competence on engineering substantiation requirements for high containment

Key drivers from across sector

- Incidents from across human, animal and GM contained use work
  - Human factors issues (e.g. adherence to procedures, competence)
  - Risk assessment quality (e.g. failure to identify safety critical steps in activity)
- Wider strategic issues at CL4
  - Engineering competence at CL4 (particularly in relation to C&I issues)
  - Major accident hazard assessment

Summary

- Premises where work with high consequence biological agents is undertaken are now considered as high hazard sites
  - Alignment with nuclear, chemical and off-shore industry
- Promotion of process safety initiatives and leadership within high hazard biological agents sector
- Requirement to set safety targets using robust quantitative risk assessement methodologies