Health and Safety
Executive

HSE

The Strategy for Regulating Biological Agents in Great Britain:

Selecting, inspecting and what to be expecting…

Tom Baldwin/Mike Paton

The Health and Safety Executive

- HSE is the independent national regulator for health and safety in Great Britain's workplaces

The Health and Safety Executive

- HSE is an independent regulator which acts in the public interest
- HSE's goal is to prevent death, injury and ill health in GB workplaces
- Great Britain has one of the lowest accident rates in the EU
- New and serious risks brought by advancing technology
- Inspect, investigate and – where necessary – take enforcement action…

UK Health and Safety Legislation

Health and Safety at Work etc Act

General duties employers have to employees and members of the public

Management of Health and Safety at Work Regulations

Planning and organising - Implements Council Directive 89/391/EEC

Control of Substances Hazardous to Health Regulations

Controlling exposure - Implements 2000/54/EC (Biological Agents Directive)

Genetically Modified Organisms (Contained Use) Regulations

Containment - Implements 2009/41/EC (GM Contained Use Directive)

More Legislation

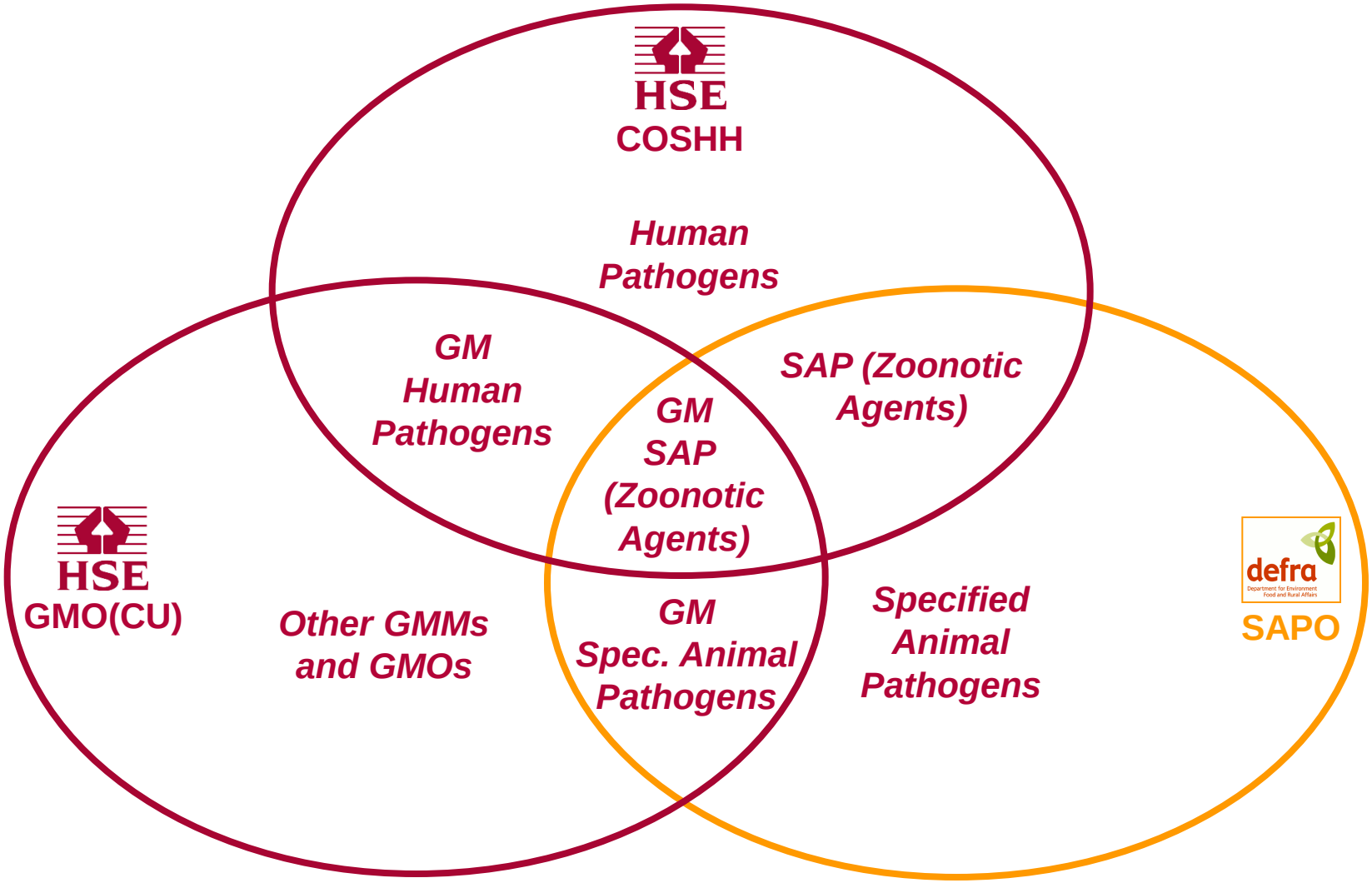
Environmental Protection Act

Over-arching legislation

Specified Animal Pathogens Orders England; Scotland; Wales; NI (SAPO)

Genetically Modified Organisms (Contained Use) Regulations

Human health and Animal health



HSE Business Plan

- Reduce the likelihood of low-frequency, high-impact incidents
- Use evidence and knowledge to guide and prioritise actions
  - Target inspections to those activities which give rise to the most serious risks or where risks are least well controlled
- Simplify and consolidate the regulatory framework
  - Negotiate and secure the best possible outcome in Europe for British industry

HSE and Biological Agents

Specialist Inspector Team (HID SI4 – Biological Agents Unit)

- Primary Inspection and enforcement of UK premises undertaking work with hazardous micro-organisms and/or GMOs under COSHH 2002 and GMO(CU) 2000
- Inspection and enforcement responsibilities under SAPO 2008
- Investigate accidents and incidents (RIDDOR and GMO(CU))
- Manage the COSHH and GMO(CU) statutory notification schemes
- Part of the secretariat for both ACDP and SACGM

The Policy Team

- Negotiate and implement EU and international law
- Develop national legislation (Single Regulatory Framework)
- Ensure regimes are in line with over-arching government policies

HID SI4 – Biological Agents Unit

- 11 Operational Specialist Inspectors
- All have a career background in Microbiology, Biotechnology, Biosafety and/or GM
- All trained as regulatory inspectors
  - Legal training as well as operation inspector training
  - Ensure compliance and promote high standards of biological safety
  - Provide assurance to public, government & others that required standards are being met

Working to enable the UK biological sciences to operate, develop and innovate in a safe way

Inspection strategy – Selecting sites

CL4 sites

- Containment level 4 sites have an *intervention plan*

CL3 laboratories

- Time since last inspection
- Inherent hazard
  - Nature of the work (Diagnostic/*in* vitro/*in vivo*/storage)
  - Extent of high containment work
  - Complexity of the work
- Safety performance from previous inspections (incl. previous enforcement issues)
- Issues arising (e.g. from a GM notification)

Inspection strategy - topics

Risk Assessment

Containment and Control Measures

Training and Competence

Operating Procedures

Waste Management

Auditing and Inspection

Maintenance Procedures

Management of Contractors

Emergency Procedures

Specimen Transport

Plant Design

Plant Commissioning

Storage

Occupational Health provision

Safety Performance Indicators

Competence Management System

Safety Leadership

Asset integrity

Inspection strategy - process

- Office discussion
  - Management systems in place
  - Evidence - documentation (RA, SOPs, certificates, training records, local inspections)
- Laboratory
  - Containment and control measures
  - Practices and standards
- Meet Employees and their Representatives
- Wash up session

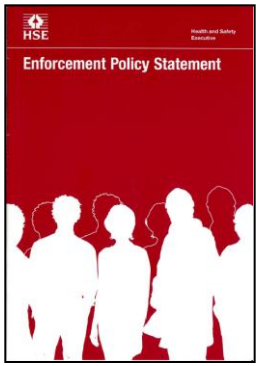
Inspections - what are we looking for?

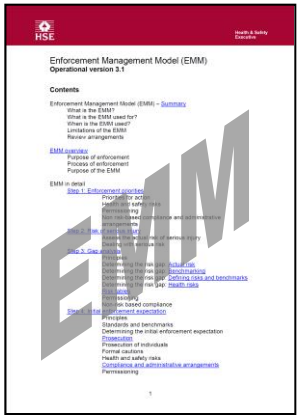
- Assurance that risks are being sensibly managed
  - Evidence that H&S systems are effective
    - Training and competence
    - Risk Assessment
    - Operating procedures
    - Emergency procedures
    - Audit and inspection
  - Evidence that containment and control systems are effective and being appropriately maintained
    - Air handling
    - Sealability
    - Waste management
- Compliance

Inspection strategy - outcomes

- No matters arising
- Advice, requirements and actions given verbally
- Requirements set out in official letter
- Improvement notice
- Prohibition notice
- Prosecution

Enforcement!





The Principles of Enforcement

- **Proportionality**
  - Relating enforcement action to the risks
- **Targeting**
  - Focus on activities that give rise to the most serious risks
- **Consistency**
  - Similar circumstances → similar approach → similar outcome
- **Transparency**
  - Helping duty holders understand what to expect
- **Accountability**
  - HSE is accountable for it's actions, and inactions…

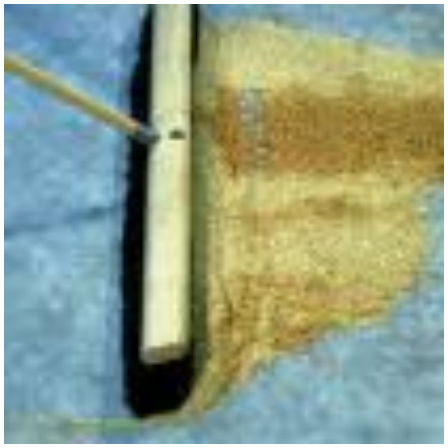
Research project

Human factors that lead to non compliance with standard operating procedures in CL3 laboratories

Prepared by the Health and Safety Laboratory for the Health and Safety Executive 2012

RR919 Published HSE website 16 May 2012

Accidents happen



Biological agents – facts & figures

	02/03	03/04	04/05	05/06	06/07	07/08	08/09	09/10	10/11	11/12
	22	26	21	21	28	20	30	27	38	30

Review of incidents in last 2 years

- 66% reports from clinical diagnostic;
- 34% research (incl 12% Universities)
- 33% relate to specimens handled at wrong containment
- 6% lab acquired infection

Compliance with procedures

- Procedures important for quality purposes but key part of safety management system
- In particular operating and maintenance procedures, are important for the prevention of accidents and ill health
- Written procedures are vital in maintaining consistency and in ensuring that everyone has the same basic level of information
- Also serve as an effective training tool
- human factors (environmental, organisational and job factors, and human and individual characteristics) known to influence compliance with procedures

Research approach

- Focus groups (semi-structured group discussions) with CL3 laboratory staff led by human factors specialists from HSL
- Discussed up to three scenarios based on RIDDOR data and appropriate for type of work
- Determine the types of human factors that underpin noncompliant behaviour
- Explore types of control measures that may be utilised to reduce the likelihood of such incidents in the future.

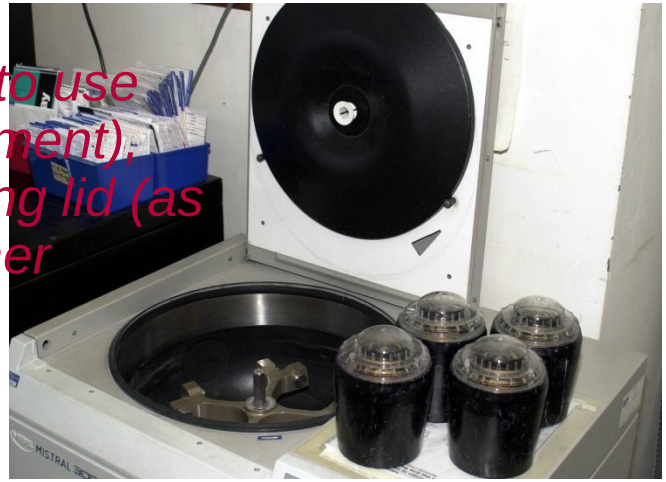
Scale of research

Date	Laboratory type	Pathogen type	No. people
19/5/11	Research	Human pathogens	6
24/5/11	Diagnostic	Human pathogens	7
25/5/11	Diagnostic	Human pathogens	4
27/5/11	Research	Animal pathogens	5
7/7/11	Diagnostic	Animal pathogens	5
28/7/11	Research	Genetic engineering	8

6 different CL3 establishments involving 35 participants
- qualitative assessment

Example scenario

- CL3 worker infecting mammalian cells with a GM bacteria (*Francisella tularensis)* involved centrifuging the 24-well culture plates, when the centrifuge made an unusual noise and would not stop (appear to speed up) when the control panel was activated. Consequently the researcher turned off the centrifuge at the mains switch. However, the lid was opened immediately and, as one of the culture plates was observed to be empty and not seated correctly on the plate carrier, three individuals were potentially exposed to an aerosol of GM *F. tularensis*
- *Issues: Agent transmissible by aerosol, failure to use sealed buckets (as specified in the risk assessment), failure to wait for aerosol to settle before opening lid (as specified in the Code of Practice), involving other colleagues therefore getting them exposed.*



Main findings

- SOPs, in the main, useable and fit for purpose ie upto date, right level detail, reflected practicalities, matched task
- Situational factors most common area leading to non-compliance:
  - **time pressure**, **workload**, and **staffing levels**
  - **insufficient training** and **supervision** of CL3 staff (general understanding, inaccessibility of SOP, technical underpinning);
  - **insufficient facilities** (workspace, equipment, consumables), **poor standards of housekeeping**, and **insufficient pre-work preparation**

Main findings…other reasons

- Individual characteristics deemed important i.e. personality, attitude and complacency
- Impractical SOPs
- Exploratory nature of research work

Controls…..

- Key role of management to effectively managing resources hence optimise conditions for compliance with SOPs
  - time and resource management
  - predicting peaks in demand,
  - planning a realistically achievable workload, and
  - engendering an organisational culture where staff feel able to challenge management pressure
- Training, monitoring and supervision
- Communication between CL3 workers (including sharing experience/lessons)
- Selection of staff to work at CL3 - most suited type of CL3 worker, described as being conscientious, patient, willing to comply, and confident but not overconfident

Next steps

- Some differences apparent from various CL3 laboratories but agreement on main issues – further work in individual areas?
- Use intelligence to inform HSE's intervention strategy – work with CL3 managers to look at organisational factors
- Some work already done at CL4
- More effective systems for sharing lessons learned between laboratories
- Further information on human factors work 'HSG48 – Reducing error and influencing behaviour'

Questions?

- Human factors – types of non-compliance
  - Violations (intentional) – routine (*normal way of behaving*); situational (*factors dictated by the employee's immediate workspace or environment);* exceptional *(solve problems in unusual situations);* Optimising *(optimise a work situation);*
  - *Errors (unintentional) – skill based (slips/lapses) or mistakes (knowledge, rule based)*