

Consolidation, simplification and alignment of regulatory regimes



Regulations, regulatory approach and SAPO transition – University of Cambridge, Biological Safety Officers' Event - 19 May 2015

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- the GMO(CU) 2014 regulations- changes in practice
- the revised SAPO arrangements- transfer of additional functions to HSE
- SAPO transition arrangements at Cambridge
- HSE regulation- the ‘single portal’

The GMO regulations



Genetically Modified Organisms (Contained Use) Regulations 2014



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



Main changes

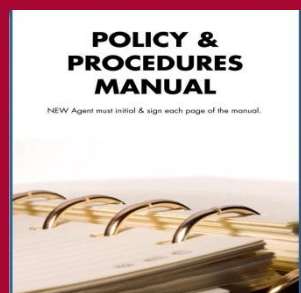
- some measures removed from the containment tables
- changes to specific measures at a each containment level
- change to source of competent advice
- restructure & technical tidy up

Changes at CL1



Measure	2000 regulations	2014 regulations
Biohazard sign	Required where RA shows required	Not required
Inactivation of waste	Required	Required where RA shows required
Use of isolators	Required where RA shows required	Not required

Changes at CL2



Measure	2000 regulations	2014 regulations
Inward airflow	Required where RA shows required	Not required
Written procedures	Not required	Required where RA shows required

Changes at CL3

	Measure	2000 regulations	2014 regulations
	Inward airflow	Required	Required except for activities where transmission does not occur via airborne route
	HEPA filters	Required	Required except for activities where transmission does not occur via airborne route
	Observation window	Required	Required where RA shows required

Summary of impact

- no practical changes observed relating to the inactivation of class 1 waste
- biggest change relates to the ability to dispense with HEPA filtration and inward airflow at CL3
- expectations will be clarified in revised ACDP guidance and e-bulletin

Compendium of Guidance revision is underway – the current on-line version does not reflect the changes in the 2014 regulations

Revised SAPO arrangements

- all licensing functions transferred to HSE
- risk assessment as basis for selection of controls/ derogations
- restructuring of licences/ conditions
- revision of guidance to reflect changes and better align with other biological agents guidance



Licence contents

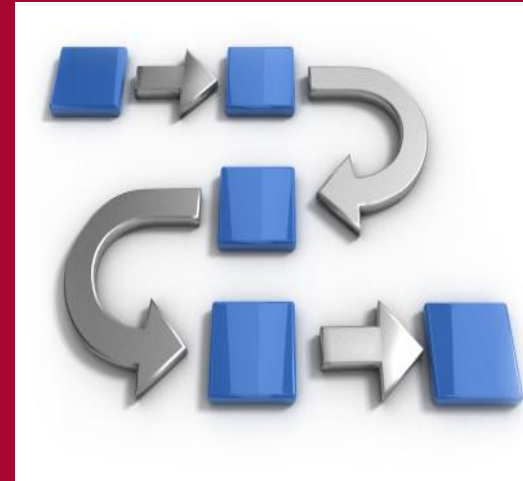
- risk assessment requirement
- application of control measures
- management arrangements
- emergency arrangements
- provisions for the transport of SAPO agents



goal setting and risk based rather than prescriptive

Transitional arrangements

- Cambridge to be issued with new style SAPO licence on 30 November 2015
- read new guidance, work out implementation plan
- confirm details relating to the name, address and pathogens correct and any derogations required
- 6 weeks before compliance date, write to HSE to confirm details



bioagents@hse.gsi.gov.uk

The single portal - HSE

- single point of contact/ source of advice
- single notification portal- SAPO, COSHH, GMO
- single regulator
- single set of expectations- a common framework



overall aim to better align regulatory regimes for biological agents and simplify what you need to do

Notifications

- currently CBA1, CU1/2 & SAPO1
- new single application being designed
 - common administrative information once
 - work that spans different regimes
 - only relevant sections are ‘unlocked’ for completion



hopefully available soon

Where we inspect

- time since last inspection
- inherent hazard
 - nature of the work (*in vitro/ in vivo/ storage*)
 - extent of high-containment work
 - complexity of the work
- safety performance from previous inspections (including previous enforcement issues)



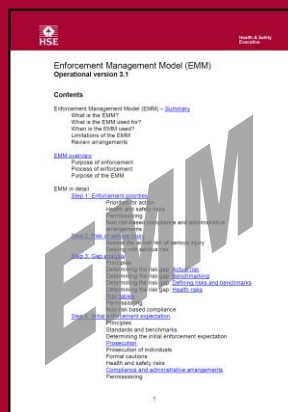
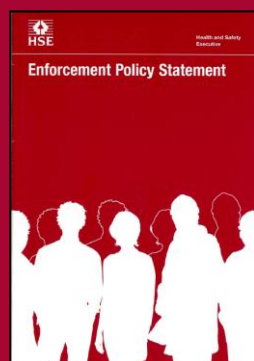
What we expect

- 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 are being appropriately maintained
 - air handling
 - sealability



Inspection outcomes

- no matters arising and advice
- requirements and actions given verbally
- requirements set out in official letter
- improvement notice
- prohibition notice
- prosecution



Further information

<http://www.hse.gov.uk/biosafety/index.htm>

Biosafety

Safety notices

- + The regulation of specified animal pathogens
- + Infections at work
- Blood-borne viruses
- + Genetically modified organisms (GMOs)

Contacts

Subscribe

Biosafety and microbiological containment

This page provides links to the home pages for three sites that contain information relating to microbiological safety. These sites cover **occupationally-acquired infections**, the contained use of **genetically modified organisms (GMOs)** and work with **specified animal pathogens**.

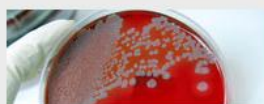
- ▶ Safety notices
- ▶ Contacts



Related content

- Control of Substances Hazardous to Health (COSHH)
- Legionnaires' disease
- Hazardous Installations Directorate (HID)

Infections at work



Advice on ill health caused by exposure to micro-organisms such as bacteria and viruses (commonly known as pathogens, bugs and germs) during work activities.

▶ More on infections at work

GMOs



Advice on genetically modified organisms (GMOs) in contained facilities, such as research laboratories or biotechnology production facilities.

▶ More about GMOs

Specified animal pathogens order (SAPO)

Advice on specified animal pathogens in contained facilities, such as research laboratories, manufacturing plants or animal research facilities.

▶ More information

Thanks



any questions?