Changes to the GMO (CU) Regulations:

Genetically Modified Organisms (Contained Use) Regulations 2014

Why are we talking about this now?

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Changes to administrative arrangements	
All	Amendments to the language/layout of the regulations
Regulation 2	Replacement of the term ‘genetically modified organisms other than micro-organism’ with the term ‘larger genetically modified organisms’
Regulation 8	Amendment to the requirements for a genetic modification safety committee – advice on class 1 risk assessments can be provided by individuals with appropriate expertise
Regulation 21	Amendment of the requirement for an emergency plan – the requirement is risk based
Regulation 26	Removal of the requirement for a hard copy of the public register of notifications – provision of an online version only
Regulation 31	Replacement and simplification of the appeals procedure with online guidance
Regulation 33	Amendment of the savings and transitional arrangements

Changes to containment measures in Schedule 8	
Table 1a	Removal of the duplicated requirement for disinfection procedures
Table 1a	Removal of the requirement for inward airflow containment level (CL) 2
Table 1a	Amendment of the requirement for inward airflow where there is non-airborne transmission at CL3
Table 1a	Amendment of the requirement for HEPA filtration where non-airborne transmission at CL3
Table 1a	Amendment of the microbiological safety cabinet (MSC) requirement at CL4 – selection of the most appropriate MSC is based on the risk assessment
Table 1a	Amendment of the requirement for waste inactivation at CL1
Table 1a	Amendment of the requirement for an observation window at CL3
Table 1a	Amendment of the requirement for training records at CL2
Table 1c	Removal of the requirement for an incinerator for animal carcasses
Table 1c	Removal of the requirement for isolators at CL1
Table 2	Removal of the duplicated requirement for decontamination facilities
Table 2	Removal of the requirement for the controlled area to be purpose built at CL4
Table 2	Removal of the requirement for biohazard sign at CL1
Table 2	Amendment of the requirement for waste inactivation at CL1

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65 Regulation 8 requires the person responsible to ensure that expert advice on risk assessments is obtained. It is proportionate in many circumstances that such advice on class 1 risk assessments can be provided by a competent individual (e.g. Biological Safety Officer/Advisor), but for other activities including class 2 and above, the advice must be provided by a committee. The individual or committee providing the advice on risk assessment should:
(a) have enough knowledge and experience to understand the risks to both human health and the environment arising from the proposed contained use;
(b) understand the extent to which those risks are uncertain;
(c) be able to judge the adequacy of the risk assessment made under regulation 5 or 6; and
(d) where appropriate and necessary, test emerging conclusions by discussion with relevant experts, either within or outside their institution.

66 It is likely that institutions which already have an established genetic modification safety committee (GMSC) will continue to use the committee for all contained uses. Similarly, there may be circumstances where it is more appropriate for a committee rather than an individual to provide expert opinion for class 1 risk assessments (e.g. a clinical environment).

Competent advice for class 1 Risk Assessment

- **GM safety committee no longer required, can be competent individual**
- **BSO?**

- **Speed up 'approval' for simpler, more common work**
- **Reduce call on other peoples' time**

BUT

- **Knowledge and experience?**
- **Appointment criteria**
- **Time, responsibility burdens**
- **Departmental knowledge?**

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134 Contained uses will generate contaminated waste, which must be inactivated by a validated means at class 2, 3 and 4. Inactivation at class 1 is not required only where all of the following criteria are met**:**

(a) do not have the potential to cause harm to human health or the environment;

(b) must be biologically contained (e.g. possess multiple disabling mutations or restrictive nutrient requirements that cannot be met outside the laboratory);

(c) do not have the capacity to establish and multiply in the environment; and

(d) do not have capacity to transfer genetic material to other micro-organisms (e.g. non-mobilisable plasmid).

Containment Measures	Containment Levels			
	1	2	3	4
Inactivation of GMMs in contaminated material and waste	required by validated means where and to the extent the risk assessment shows it is required	required by validated means	required by validated means within lab suite	required by validated means within lab suite

Waste – Inactivation of CL 1 down to Risk Assessment

- Absolute requirement to inactivate CL 1 waste removed
- Where there is no human health or environmental risk

- "Great, most of ours could go straight to landfill"
- Time, energy cost savings

BUT

- Managing more waste streams - mistakes
- Robust risk assessments to justify
- Offensive waste?
- Contractor position?
- Still required to have access to autoclave ('on site')

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Containment Measures	Containment Levels			
	1	2	3	4
Negative pressure relative to the pressure of the immediate surroundings	not required	not required	required except for activities where transmission does not occur by the airborne route	required
HEPA filtered extract and input air	not required	not required	required for extract air except for activities where transmission does not occur by the airborne route	required for input and extract
An observation window or alternative so that occupants can be seen	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	required where and to the extent the risk assessment shows it is required	required

CL3 – Negative pressure and HEPA filters on extract

- **No longer required when there is no airborne transmission of agent (GMM)** **(obs. window – only where risk assessment shows required)**

- **Simpler and cheaper lab design and maintenance**
- **Flexibility?**

BUT

- **Lab designation – 'CL3' vs 'HIV' lab. Keeping track?**
- **Fumigation?**
- **Flexibility? Limit use, costs of retrofitting**
- **CoSHH (SAPO?) conflict? GM vs wt - Risk Assessment**
  (HSE Biological Agents eBulletin, June 2015)

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130 Certain GMMs may also fall within the definition of ‘biological agent’ under COSHH. The selection of control measures for biological agents under COSHH is prescribed according to their risk to human health, while these Regulations set out containment measures appropriate to both human health **and environmental** protection. Paragraph 10 explains that where control measures under COSHH differ to these Regulations, the more stringent requirements must be applied**.**

133 In Table 1a, the requirement for an observation window at CL3 is risk-based. COSHH does not allow such flexibility, so an observation window is required for class 3 contained use involving a GMM that presents a risk to human health**.**

HSE Biological Agents eBulletin – June 2015

2. Application of inward airflow and HEPA filtration (extract air) for specific non-airborne biological agents

GMO(CU) introduced, amongst a number of changes, a risk based approach to the application of inward airflow and HEPA filtration (for extract air) at containment level (CL) 3. These control measures are intended to prevent the dispersal of airborne biological agents beyond the confines of the laboratory. Where the risk assessment for the activity concludes that there is no risk of airborne transmission, these specific measures **may** not be required.

This approach is consistent with the requirements of COSHH. Although, the containment tables in Schedule 3 of COSHH indicate that inward airflow and HEPA filtration (for extract air) are required at CL3, these requirements can be adjusted through reference to the Approved List classification. The classification identifies certain biological agents (denoted by an asterix), that are not normally infectious to humans via the airborne route (e.g. blood-borne viruses) and provides guidelines on circumstances where these measures may not be required. Similar to GMO(CU), their application is subject to the outcome of a local risk assessment.

It is recognised that the new approach is not consistent with that set out in Biological agents: Managing the risks in laboratories and healthcare premises. While the guidance recognises that not all containment measures are required for diagnostic activities involving non-airborne hazard group (HG) 3 biological agents, it specifically states that full CL3 is required where the work involves the intentional use of HG3 biological agents (i.e. concentration or propagation). HSE is in the process of revising this guidance and will remove this inconsistency. In the interim period, the requirement for inward airflow and HEPA filtration (for extract air) for activities involving such biological agents (denoted by an asterix on the Approved List), whether genetically modified or not, should be determined by a local risk assessment. While the specific physical containment measures can be dispensed with, the other procedural/management measures normally required at CL3 (above those required at CL2) must still be in place.