# Written evidence from the Health and Safety Executive (HSE) (ENB0048)

## Overview

1. The Health and Safety Executive (HSE) is Great Britain's national regulator for workplace health and safety. All work activities connected with genetic modification are covered generally by the Health and Safety at Work Act 1974 and the Management of Health and Safety at Work Regulations 1999, and specifically by regulatory frameworks for working with biological agents.

2. HSE regulates work with biological agents across several sectors, including biotechnology and biomedical research, industrial vaccine and pharmaceutical production, healthcare, agriculture and food.

3. The Genetically Modified Organisms (Contained Use) Regulations 2014 (GMO(CU))[1] are made under the powers of the Health and Safety at Work Act 1974. This legislation focuses on the prevention of harm to human health that arises from contained use involving genetically modified organisms (GMOs). Genetically modified animals, plants and insects are collectively known as larger genetically modified organisms (LGMOs). This legislation does not focus directly on engineering biology.

4. HSE has national inspection and enforcement responsibilities for containment, research and commercial laboratories, infectious disease units and all work connected with GMOs in containment. The UK competent authority for GMO(CU) consists of HSE and the Department for Environment Food and Rural Affairs (Defra) in Wales; HSE and The Scottish Government in Scotland; and the Health and Safety Executive for Northern Ireland (HSENI) and the Department of Agriculture, Environment and Rural Affairs (DAERA) in Northern Ireland.

5. In the context of GMO(CU), contained use means that physical, chemical or biological barriers are used to limit contact between GMOs and humans or the environment. In practical terms contained use facilities therefore include; laboratories, animal houses, plant growth rooms and glasshouses, industrial production facilities, and facilities to contain genetically modified animals.

6. GMO(CU) covers the prevention of harm to the environment arising from contained use involving genetically modified micro-organisms (GMMs). Protection of the environment from contained uses

[1] The Genetically Modified Organisms (Contained Use) Regulations 2014

involving LGMOs is achieved through relevant sections of the Environmental Protection Act 1990 and the Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996. Defra is responsible for this legislation.

7. HSE's regulatory activities in the area of contained use activities with GMOs are supported by an external scientific advisory committee, the Scientific Advisory Committee for Genetic Modification (Contained Use). This committee provides technical expertise and advice on hazard identification, risk assessment and emerging or novel biosafety risks involving GMOs, thereby supporting the development of new technologies, whilst maintaining the appropriate standards of biosafety.

8. HSE is an active participant in relevant stakeholder and cross government groups, such as the cross-Whitehall Engineering Biology Stakeholder Group and the Engineering Biology Regulators Network, and will continue to use its influence to promote the safe handling of GMOs. Engagement within such groups ensures that HSE are aware of emerging technologies and can actively engage with industry at an early stage of development to ensure proportionate control measures are in place.

**Enforcement of biosafety standards in relation to activities involving genetic modification**

9. GMO(CU), enforced by HSE, seeks to prevent misuse or misapplication of GMOs in contained use settings by mandating that everyone must notify the competent authority before they can start work with GMOs, and by requiring that robust risk assessments are undertaken. Having conducted a suitable and sufficient risk assessment, duty-holders must then ensure that proportionate controls measures are applied to limit the contact of GMOs with humans and the environment.

10. The GMO contained use regulatory regime adopts a four tier approach to application of containment level measures, with higher risks requiring more rigorous controls. By definition, class 1 activities are of no or negligible risk, whereas class 4 activities are high risk and require highly stringent control measures to protect human health and the environment. The framework ensures that GMOs are managed safely, proportionately and according to the risks involved, protecting the health of people and the environment.

11. Biosafety inspection and enforcement is the responsibility of HSE and therefore HSE may intervene to ensure the control measures utilised for GMOs are adequate.

12. Through Agency Agreements, HSE also perform inspection and enforcement functions on behalf of the Competent Authority relating to the Deliberate Release of GMOs in GM medical and veterinary trials.

13. Deliberate Release is defined as any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment.

**How does HSE's risk-based approach provide the flexibility to support and enable innovation and to respond quickly to emerging technologies?**

14. Under GMO(CU) those parties undertaking a particular activity involving genetic modification are required to notify the competent authority in advance of starting the activity. These notifications are reviewed by the competent authority who, via HSE, issue permission for the work to go ahead. This advanced notification also gives the competent authority the opportunity, prior to the activity starting, to obtain further information on the activity itself, the proposed classification of the activity, the controls to be applied, or any other element where there is uncertainty or a lack of clarity.

15. Through this permissioning process the competent authority therefore has the power to stop an activity involving genetic modification in contained use from taking place until sufficient assurance can be obtained that it can be done with appropriate controls to protect those undertaking the work and also the environment.

16. This assessment by the competent authority focuses on whether the classification is appropriate for the activity concerned, and if appropriate control measures are in place to ensure that the activity can be done safely by those people doing the work and that the environment is sufficiently protected from the contained use. On average this process takes around 55 days, but can take less for relatively straightforward notifications. Importantly, this assessment does not consider the political, ethical or philosophical implications of whether a particular activity should be undertaken or not – such considerations are outside of the requirements of GMO(CU) and HSE's regulatory remit.

17. Notification requirements under GMO(CU) are based on the genetic modification activity being undertaken. If a party initiates a completely new activity, or wants to change the controls applied or processes for an activity with a GMO for which permission has previously been given by the competent authority, then this needs to be notified to the competent authority. The competent authority then assess the application to ensure that the control measures are appropriate and that the activity has been appropriately classified. This allows HSE and the competent authority to keep up with technological change and respond in real time as technology develops, whilst ensuring that the control measures applied remain relevant and proportionate as the technology progresses through the development cycle.

18. Risk assessment and proportionate application of control measures are the fundamental and underpinning principles to GMO(CU). This legislation requires those

parties considering undertaking a particular contained use activity to assess the risks as the first step, and then identify which control measures are necessary to control those risks; these control measures are then used by the notifier to determine the class of the activity in terms of risk and required control measures. Lower risk class activities require the application of less stringent and easier to apply control measures, whereas high risk class activities require more robust, stringent and complex control measures to ensure the work can be done safely. This process is led by those parties undertaking the genetic modification activity concerned.

19. In 2022/2023, 220 low risk activities were notified compared to 20 high risk activities[2]. As the focus of engineering biology is to develop products, applications and services that will ultimately be commercialised, it is envisaged that the majority of engineering biology projects involving genetic modification will fall into the lower risk activity classes which require the application of relatively simple control measures, thereby avoiding the creation of a significant regulatory burden on the sector.

20. HSE and the competent authority can also issue permission for parties undertaking genetic modification to derogate the application of specific control measures when the notifier can demonstrate (on the basis of risk) that a particular control measure is not required for the particular activity that is to be undertaken. Rather than providing a highly prescriptive list of control measures that must be applied to all activities in a particular class, this provides a high degree of flexibility and proportionality to regulation of contained use activities through GMO(CU).

21. Demonstrating that engineering biology projects can be developed and delivered safely is essential for investor confidence and public reassurance. Working within the regulatory framework of GMO(CU) can enable innovation in this area by allowing the sector to demonstrate it is operating in accordance with the relevant regulatory frameworks for biosafety and help to demonstrate the safety profile of early-stage products or applications in the controlled environment of the contained use setting.

22. Based on the above, HSE believes that the current regulatory framework for genetic modification in

[2] For the purpose of this statistic, Class 1 and Class 2 activities are considered low risk, whilst Class 3 and Class 4 activities are considered high risk. This is an approximate figure that is accurate within a 5% range.

contained use settings provided by GMO(CU) is appropriate and adequate, and that it strikes the right balance between public assurance and ensuring that the work can be undertaken safely by the workers and without risks to the environment, whilst providing the agility and flexibility to respond rapidly to changing or emerging technologies to support and enable innovation.

**HSE Science and Research Centre**

23. HSE does have a microbiological containment laboratory at its Science and Research Centre in Buxton. Whilst this laboratory does from time to time undertake research on behalf of HSE that supports regulatory activities in the microbiology sector, this laboratory has no current role in the oversight of regulation in the field of emerging technologies in engineering biology.

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