

GMO(CU) UK Competent Authority Meetings			GMOUKCA/P1A/2015
Type of Paper:	Note of meeting	TRIM (HSE use only)	2016/44335
Meeting Date:	8 December 2015	Open Govt. Status:	Open
Exemptions:			

**Note of meeting held on 8 December 2015
Defra, Nobel House, London/ via telecom**

Genetically Modified Organisms (Contained Use) UK Competent Authority (UKCA)

Welcome and apologies

1. This was the second meeting of representatives of the UKCA since completion of the consolidation of the Genetically Modified Organisms (Contained Use) 2014 Regulations (2014 Regulations). The purpose was to discuss working arrangements and communications within the UKCA, and provide updates on a number of issues.
2. Representatives from the Health and Safety Executive (HSE), Department for Environment, Food and Rural Affairs (Defra), the Scottish Government (SG), HSE (Northern Ireland) (HSENI), the Welsh Government (WG) and Science and Advice for Scottish Agriculture (SASA) participated in the meeting. Apologies had been received from one member of SASA who was unable to attend.

Notes and Actions from previous meeting

3. The minutes of the meeting on 10 February had been previously circulated and were agreed at this meeting.

Memorandum of Understanding (MoU)

4. A near final version of the MoU which sets out working arrangements for the 2014 Regulations between HSE, Defra and the Scottish and Welsh Governments was discussed. Participants were asked that any final amendments were sent to HSE with a view to the MoU being signed off preferably by the end of 2015.
5. A separate MoU relating to the Genetically Modified Organisms (Contained Use) Northern Ireland 2015 Regulations will be developed to provide HSENI with technical support from HSE.

2014 Regulations – post implementation review

6. HSE is at the early stages of developing an approach for the post implementation review of the 2014 Regulations. The purpose of the PIR is to consider whether the expected impact on business which was assessed in advance of the regulations coming into force, was realised in practice. To avoid duplication of effort this review will be aligned with the three yearly implementation report (relating to Directive 2009/41/EC) which is requested by

the European Commission. The next call for information is expected in 2017 or 2018.

7. The plan at this stage is to define which parameters need to be measured to assess the impact of the 2014 Regulations and whether they have met the intended objectives.

Operational feedback on notifications under the 2014 Regulations

8. An analysis of the number of notifications received in 2014/15, previously sent to participants, was summarised. There was no clear trend of numbers increasing (Table 1 refers):

Table 1

Number of Notifications received for 2014/15	
Quarter end	
30/06/2014	54
30/09/2014	38
31/12/2014	44
31/03/2015	56
Total	192

9. An outline of HSE's inspection programme for contained use was given. For containment levels (CL) 3 and 4, work is undertaken in line with HSE's strategy relating to major hazards (avoiding catastrophe). Inspections focus on measuring compliance with the 2014 Regulations as well as the Control of Substances Hazardous Health (COSHH) Regulations and the Specified Animal Pathogens Orders (SAPO) 2008, 2009.
10. There were no accidents, relating to the 2014 Regulations, notified in 2014/15.

Synthetic Biology

11. An overview of the synthetic biology work, which HSE and Defra are involved in, was provided. The UK is seen as a world leader in synthetic biology research and development. Since 2013 when the UK roadmap for synthetic biology was developed there has been investment in six synthetic biology research centres. The roadmap is being refreshed and a new strategy is expected to be published in 2016, which will focus on commercialisation.
12. Both the European Commission and the Convention on Biological Diversity (CBD) have commissioned work/information gathering exercises. The EC scientific advisory committees have published three opinions on different aspects of synthetic biology. These were to be discussed at an EC organised workshop.
13. The CBD is deciding whether synthetic biology is an emerging issue for them, through evidence gathering via an open-ended on-line forum and subsequent meeting of the Ad Hoc Technical Expert Group (AHTEG) on synthetic biology in September 2015. The outcome of the meeting is available [here](#) and will be used to support deliberations at the next meeting of the CBD's standing scientific (Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)) committee in April 2016.

Feedback on the Scientific Advisory Committee for Genetic Modification (SACGM)

14. The last two meetings of SACGM had been held on 24 March and 6 November 2015. The main area of SACGM's business is providing advice on notifications. The agenda and minutes of the meetings are published on the HSE website.
15. The SACGM Compendium of Guidance provides assistance for users on risk assessment and containment requirements in different contained use settings. Part 3 of the Compendium which covers containment measures for work with genetically modified micro-organisms has been prioritised for revision following the changes to the containment measures introduced in the 2014 Regulations. A revised version of Part 3 should be available in 2016.

Date of next meeting

16. The next meeting is likely to take place in October 2016 provided it will be able to coincide with a meeting of SACGM. The date will be set when the SACGM meetings for 2016 have been agreed.

Any other business

17. The meeting was advised that the World Health Organisation (WHO) had confirmed eradication of the Type 2 polio virus. Consequently the intention is to remove this component from the oral polio vaccine. To minimise the risks of inadvertent release of type 2 polio virus from a laboratory (or vaccine manufacturer), the containment requirements for such work will be increased in line with the WHO Global Action Plan for containment. In the UK, the first step in this process was for the Advisory Committee of Dangerous Pathogens (ACDP) to advise on the hazard classification of type 2 polio virus. ACDP has advised that type 2 polio virus (including attenuated strains) be reclassified from Hazard Group (HG)2 to HG3. It is intended to reflect these changes in a revised version of the Approved List of Biological Agents and for this change to take effect from April 2016.