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PROPOSED GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2014; OUTCOME OF PUBLIC CONSULTATION

Purpose of the paper

1. To inform the HSE Board of the outcome of the public consultation on the proposed consolidated Genetically Modified Organisms (Contained Use) Regulations 2014. The regulations consolidate the original regulations made in 2000 and three sets of amending regulations (in 2002, 2005 and 2010).

2. To seek Board agreement to proceed with the implementation of these regulations. A number of annexes (Annexes 1- 4) are attached for information.

Background

3. Genetically modified organisms (GMOs) is one of the five 'sector' consolidations, which the Government, in response to the Löfstedt review, has committed to completing by the end of 2014. The Board was told about the consolidation exercise in April and proposed consultation in August 2013[1]. The eight-week public consultation on the consolidated regulations closed on 20 December 2013.

4. Contained use of GMOs is intended to limit contact between GMOs and humans and/or the environment, by the use of physical, chemical or biological barriers (containment measures). These activities are classified into four risk classes, with the majority of work being undertaken at the lowest Class 1 (no or negligible risk). The other risk classes increase in the level of hazard and consequently the level of containment required, culminating in the most hazardous risk Class 4 (high risk). The regulations need to balance permitting sufficient flexibility to allow growth and innovation within the biotechnology industry, whilst also achieving adequate control of new and novel risks.

5. Contained use of GMOs (including biotechnology) involves a diverse range of activities and is predominantly carried out in laboratories, plus some larger scale research and development and production facilities. Biotechnology is an area that the UK excels and has significant growth potential, attracting considerable research council funding. One aspect, namely synthetic biology was announced by UK Government as one of the eight great technologies supporting UK science and business[2], with the global market in synthetic

[1] HSE/13/33 – HSE Board paper entitled '*An update on HSE's work to consolidate legislation on human pathogens, animal pathogens and genetically modified organisms following the Callaghan and Löfstedt Reviews*'; HSE/13/90 - HSE Board paper entitled '*Proposed genetically modified organisms (contained use) regulations 2014: consultation package*'

[2] Eight great technologies, Department for Business Innovation and Skills (BIS) (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/249268/synthetic_biology_infographic.pdf)

biology expected to reach £62 billion by 2020. Synthetic biology is briefly defined as the design and construction of new biological parts, devices and systems but can also include redesign of existing, natural biological systems. This technology enables engineering of a range of compounds that are either difficult or impossible to make by conventional genetic engineering methods (e.g. polyketides used in clinical medicine and biofuels).

Argument

6. The consolidation of the regulations will contribute to the Government's red tape challenge objective by delivering the Löfstedt recommendation. As this is deregulatory, the consolidation has been fast tracked. The consolidation has been achieved in accordance with the Better Regulation Executive's guidelines, specifically addressing areas, which exceed the requirements of the European Directive on contained use of genetically modified microorganisms (2009/41/EC)).

7. As indicated to the Board in April 2013, the consolidation is also part of a multi-pronged approach to developing a single regulatory framework for contained use of biological agents (including genetically modified microorganisms (GMMs), human pathogens and specified animal pathogens (SAPO). This followed from recommendations by a number of Government led reviews[3] in 2008. Consequently, some of the proposed changes are intended to remove potential hurdles that may impede this development.

8. Based on experience of applying these regulations since 2000, the opportunity has been taken to make the regulations more risk based and proportionate. Consideration of current working practices and available technologies has enabled a more flexible approach (i.e. replacing prescriptive measures with risk based alternatives), to assist users to comply with the regulations. The proposed changes will therefore remove regulatory burden without any detriment to health, safety or environmental protection.

9. Prior to formal public consultation, HSE engaged with a range of stakeholders (Annex 1), which generated an evidence base, incorporating stakeholder opinions on the existing legislation and provided insight into current working practices and interconnections with Other Government Departments (OGDs). The feedback informed development of the proposed changes, with practical implementation a priority. HSE held a formal eight-week public consultation (28 October to 20 December 2013) on the draft Regulations hosted on the HSE website and actively targeted to key stakeholders (Annex 1).

10. Of ~850 visitors who downloaded the consultative document (CD263) from the HSE website, 42 visitors submitted a response (two were included, which were received after the December deadline). Based on responses to previous GMO contained use consultations, the response level exceeded expectations. The responses were received largely from stakeholders involved in genetic modification work (60% (25 out of 42) from the academic sector) including all

3Sir Bill Callaghan (2008) *Review of the Regulatory Framework for Handling Animal Pathogens;* House of Commons DIUS Select Committee Report (2008) *Biosecurity in UK research laboratories*

the large Universities, Research Institutes, Government laboratories as well as industry. Health and safety professionals contributed over half the responses (53% (22)), whilst a small number of responses were received from NGOs (5% (2)) and Trade Unions (2% (1)). HSE did not receive any responses from members of the public. Overall, HSE is content that the consultation was sufficient and responses well informed. A summary and the HSE detailed analysis of the responses is provided at Annex 2 of this paper.

Overall response

11. Overall, there was very good support for the proposed changes. An average of 83% of responses supported the amendments to the containment tables; and 88% supported changes to the layout and language. Support for individual proposals ranged between 66% (25) & 97% (37). Respondents were most appreciative of the increased flexibility, supporting their application of the regulations and also welcomed the changes where risk based selection had replaced prescriptive measures.

Issues raised and HSE response

12. Annex 2 of the paper provides detailed HSE responses to the matters raised. Several areas where respondents raised concern are set out as follows:

a) The two responses from NGOs were not supportive of the proposals and requested greater monitoring and enforcement. The NGOs were concerned that the proposals would increase risks to the environment; HSE considers the proposed changes in the GMO regulations are risk based and proportionate and so consequently do not increase the risk to the environment or human health. The proposed changes offer greater flexibility and align with the contained use directive.

b) There were requests for greater clarification of definitions (e.g. biological containment, larger GMOs), technical matters and processes (e.g. notification of connected programmes and significant changes); HSE is content that the revision of the *Guide to the Regulations* (L29) and subsequent update of the technical guidance will address all the points of clarification on definitions, technical matters and processes;

c) Differences in containment requirements between the GMO regulations and related legislation (e.g. Control of Substances Hazardous to Health (COSHH) Regulations, Specified Animal Pathogens Order)) were highlighted; The differences in containment requirements have been examined in detail in Annex 2 of this paper. The revision of the *Guide to the Regulations* (and related guidance for human pathogens) will address the differences and ensure clarity for implementation and application. There are two specific containment measures, where the COSHH regulations are more prescriptive than the GMO regulations. This will be highlighted in the *Guide to the Regulations*, where those working on human pathogens will have to apply a more prescriptive measure (in practice this affects two GM premises working at Class 4, which already have the measures in place);

d) Improvement to the public register of notifications was requested; Whilst HSE is content that the public register of notifications meets the minimum requirements, a cost-effective means of improving the current arrangements will be explored.

13. Since completion of the consultation, HSE has presented the findings from the consultation and proposed way forward, to key stakeholders in academia and industry (Annex 1 - two separate meetings of regional biosafety officers in Cardiff (15 participants) and London (30 participants)) as well as a cross-Government/industry governance subgroup on synthetic biology. Participants in these meetings did not foresee any practical implementation issues and were content with the proposed consolidation.

14. Stakeholder views on the revision of the *Guide to the Regulations* will be sought via the HSE on-line community (which currently has 42 industry members). In parallel, the consultation feedback will inform the revision of guidance for laboratories working with human pathogens (*Biological Agents: Managing the risks in laboratories and healthcare*), to ensure consistency between the requirements of the COSHH and GMO regulations.

15. The Final Impact Assessment (Annex 3) has been signed off by HSE's Chief Economist and provides details of the overall cost savings that will result from the consolidation. As this relates to a small sector, the net savings are modest. The cost savings will constitute an 'Out'. The Impact Assessment will be submitted to the Regulatory Policy Committee for its validation.

Communications

16. HSE will keep the community informed of progress via the HSE Biological Agents eBulletin. HSE will continue to work with the network of biosafety officers, through their regional meetings across GB, to promote the new regulations. HSE will launch the new legislation and guidance at the Scientific Advisory Committee for Genetic Modification open meeting in October 2014.

Devolved Administrations

17. HSE's regulatory remit extends across Great Britain. Scottish and Welsh Government officials (along with Defra officials) are members of the consolidation project board and have been fully engaged in the consolidation. Northern Ireland officials have been kept informed. The FCO lead on Gibraltar has also been informed.

Action

18. The Board is invited to:

(i) agree that The Genetically Modified Organisms (Contained Use) Regulations 2014 (see Annex 4) are implemented; AND

(ii) make a recommendation to the Secretary of State on the final legislative proposals.

19. The intention is to lay the regulations in June with a coming into force date of 1 October 2014.

Paper clearance

20. This paper has been cleared on behalf of the Senior Management Team.

Annex 1 – Summary of stakeholder engagement to support the consolidation

Prior to formal public consultation

1) Stakeholders were engaged via fact-finding questionnaires, telecoms, participation in conferences and dialogue with industry groups, officials in OGDs and individual companies, with practical implementation of the consolidation a priority. This included:

    a) Fact finding questionnaire circulated to registered GM centres & other stakeholders (e.g. GO Science, Public Health England, Ministry of Defence, Home Office, Biotechnology Industry Association, Natural England, GeneWatch) - responses collated via telecom or from email;
    b) Fact finding questionnaire circulated to 33 members of the European Enforcement Project, an organisation of regulators responsible for GMO contained use directive – 9 responses were used to learn from how other countries had transposed specific directive requirements;
    c) Participation in the biosafety steering group meeting of the Institute for Safety in Technology and Research (ISTR) to engage and canvas views from the organisers of the largest group biosafety practitioners;
    d) Presentation at the National Conference for biosafety officers in York (~80 delegates from academia and industry) - Forum was used to inform practitioners of the consolidation; encourage completion of the fact-finding questionnaire; emphasise the importance of participation in HSE's on-line community;
    e) Engagement with interested OGDs including meetings with officials from Devolved Governments, BIS, Defra – this was particularly important in informing the approach to synthetic biology and inclusion of questions in the consultation document
    f) Updated relevant Scientific Advisory Committees (Scientific Advisory Committee for Genetic Modification (SACGM) and Advisory Committee for Dangerous Pathogens (ACDP)) – SACGM provide independent scientific advice on contained use of GMOs

2) The feedback was used to inform the proposed changes, particularly related to waste inactivation, source of technical advice, inclusion of emerging technologies (e.g. synthetic biology) and clarifying notification issues (e.g. significant changes; connected programmes of work).

Publicising the formal consultation

3) The consultation was publicised in a number of ways:

    a) >700 stakeholders across the biotechology community (GM centres, academia, research, healthcare, advisory committees, NGOs, OGDs, trade unions) were alerted by email with a link to CD263;
    b) >4000 subscribers to the HSE Biological Agents eBulletin were provided with a link to CD263 via the ebulletin;

c) Synthetic Biology Leadership Council and the synthetic biology special interest group (>750 members) were provided with background and with a link to CD263 to share with members;
d) Secretariat for the Society for General Microbiology was provided with background and with a link to CD263 to share with members;
e) Attendance at stakeholder meetings to promote and discuss CD263 (e.g. Northern Biological Safety Officers (Glasgow), University Of Wales (Cardiff), SACGM);
f) Article published in the Royal Society for Prevention of Accidents (RoSPA) Occupational Safety & Health Journal;
g) Additional engagement with key stakeholders was undertaken to gather data on the costs and savings of the proposed changes and to finalise the impact assessment.

Post consultation engagement

4) Following conclusion of the consultation and analysis of the responses, HSE has gone back to industry in January and February 2014 to provide feedback from the consultation and explain the proposed way forward. These meetings have been welcomed and stakeholders have not raised any concerns with the proposed way forward. These meetings have involved:

a) Synthetic Biology Leadership Council Governance Subgroup – includes representatives from across Government (BIS, Defra) research councils, industry, NGOs, legal advisors, academia;
b) Southern Biosafety Officers Regional Group (London) – 30 participants from key players in academia and industry
c) Midlands, South West and Wales Biosafety Officers Regional Group (Cardiff) – 15 participants from key players in academia and industry