Health & Safety Executive
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Merseyside
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Dear Sir or Madam

Consolidation of Genetically Modified Organisms (Contained Use) Regulations

In 2011, Professor Ragnor Löfstedt conducted an independent review of health and safety legislation to identify opportunities to simplify the rules. Amongst wide-ranging recommendation, the review identified that the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU) and three sets of amending regulations 2002, 2005, 2010) should be consolidated into one set of regulations. As part of the Government response to this review, HSE proposes to complete the consolidation of the GMO(CU) legislation by October 2014.

The GMO(CU) consolidation intends to reflect current industries practices; remove any unnecessary gold plating (i.e. where the UK regulations go beyond the requirements of the underpinning European Directive (2009/41/EC)); and where possible, simplify the regulations. The proposed changes will not compromise safety or increase risks to the environment and will assist employers to comply with the revised legislation.

Given that the regulations closely follow the European Directive and the positive feedback on the regulations from previous consultation exercises, it is likely that the changes will be limited. However, HSE intends to work closely with key stakeholders during the preparation of the consolidated regulations to ensure businesses are familiar with any proposed changes in advance of them coming into force. In advance of the formal public consultation (planned for later in 2013), HSE is gathering information on areas where the existing legislation could be simplified and would benefit from changes to improve clarity or remove unnecessary burden on new technologies and low risk activities. With this in mind, a member of HSE's consolidation team will aim to contact you in July, to discuss any views you have on the questions attached to this letter. You can also provide input to the questions via GMO Consolidation Web Community or directly to one of the policy team.

Your assistance with this is greatly appreciated.

Yours faithfully

HID Biological Agents Policy Team
Health & Safety Executive

- ***Consolidation of Genetically Modified Organisms (Contained Use) Regulations***

Fact finding questionnaire

1. In what capacity are you familiar with the GMO(CU) regulations?
(e.g. practioner, principal investigator, biosafety professional, member of professional institute, manager, company director)

GeneWatch UK is a not-for-profit organisation which aims to ensure that genetic science and technology is used in the public interest and that the public have a say. We have been familiar with the GMO(CU) regulations since a study we conducted in 1999 on the regulation of GM micro-organisms: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Contained_Use_Report___Final_A4.doc
More recently, we made a series of FOI requests regarding (i) plans by Oxitec to make open releases of GM insects under the regulations, based on their claim that their insects' GM lethality mechanism amounts to "biological containment";(ii) the production of GM insects by Oxitec in contained use facilities.

2. Do you have any views on the risk assessment process described in the regulations?
(e.g. length, complexity of process, use of jargon or technical terms, drawbacks, positive aspects)

There is a lack of transparency about how the risk assessment process works in practice, which is inadequate to protect the public. These issues will become more controversial as new technologies are introduced (e.g. new organisms and traits, larger scale production, synthetic biology).

In 1999, GeneWatch UK recommended:

- In taking decisions about GMMs - and given the uncertainties involved and the potential for serious irreversible harm - a precautionary approach must be adopted.
- Plasmids and naked DNA should be brought within the scope of the regulations.
- Users must be required to present a worst case scenario when notifying the use of a GMM to reveal the full extent of the uncertainties.
- The requirement for physical barriers to the release of GMMs should remain, together with the presumption (for all classes of GMMs) that there should be no releases of living GMMs into the environment. No discharges should be allowed unless reliable monitoring is available, a detailed risk assessment is presented which takes into account the local environment and the use of other GMMs, and a full justification for the need to discharge live GMMs or intact DNA is given.
- Provisions for liability for any environmental harm arising from the use of GMMs should be included in the new regulations.

We note also that plans for discharges from chemical plants etc. are normally published for public consultation, and that discharges from bioreactors should meet

the same standards in terms of public consultation and access to justice. The UK must now comply with the Aarhus Convention on such matters.

3. Do you currently, or have you previously experienced any issues with any of the containment measures specified for used at different containment levels? If so could you give me an example?

GeneWatch UK is concerned about:
(i) misleading industry definitions of "biological containment" as a means to avoid a full environmental risk assessment (being attempted by Oxitec for GM insects: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Regnbrief_fin2.pdf and Aquabounty for GM fish: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GeneWatch_FDAfish_Feb13_fin.pdf). Measures to limit reproductive capacity are not 100% effective and do not prevent contact with the environment: even if such products were genuinely "sterile" they could still have devastating effects on ecosystems;
(ii) Whether containment measures will be adequate for large-scale production (e.g. of biofuels) in bioreactors, as opposed to small-scale experiments: http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/Genewatch_Report_August_2009.pdf . This may be a particular concern for synthetic biology applications, due to the increased complexity and novelty of potential traits.

4. Do you have any views on the requirements related to dealing with contaminated waste?

In 1999 we recommended that pollution from GMMs must be monitored, policed and appropriate controls enforced:

- The development of effective monitoring techniques must be a priority.
- A legal system specifying the levels of GMM pollution that can be released in waste should be established. This would be consistent with other approaches to pollution control (e.g. chemicals), allow for prosecutions if breaches arise and drive a proper monitoring system.
- The Environment Agency should be made responsible for independent monitoring of environmental releases of GMMs via waste streams and air and for the policing of discharges.
- In addition, users of GMMs must be required to monitor to verify containment procedures and to implement systems for the detection of sudden leaks.
- There must be increased investment in policing and enforcement.

These recommendations still stand and will become more important as increased scale of production, e.g. for biofuels, and synthetic biology pose new challeges.

The importance of monitoring has been highlighted by a recent study by Chen et al. (2012): http://www.ncbi.nlm.nih.gov/pubmed/23215020

5. Do you have any views on the role and requirements of the genetic modification safety committee?
(e.g. frequency of meeting, approachability, composition, advice given, practicalities)

In 1999 we recommended that openness and transparency of the regulatory system must be established:

- Refusal to disclose information about releases of GMMs to the environment on the grounds of commercial confidentiality must not be allowed under any

circumstances. Users must supply details of any GMMs (including the species and how and why they have been genetically modified), the levels of release to the environment in waste and the monitoring systems in place.
- Representation of public interest groups should be increased on the advisory committees, meetings should take place in public, and annual reports summarising each year's activities should be produced.
- There should be greater public involvement in decision-making about the use of GMMs.

Minutes should be published much more promptly to be relevant to members of the public. Although FoI legislation has made a difference to the information that can be obtained, greater transparency is required, especially about risk assessments. There is still a need for a searchable public register of all centres registered for contained use, as GeneWatch also recommended in 1999. Information must include details of the organisms involved, how they are modified, why the modification is being undertaken, how the risk assessment has been arrived at, the dates use started and finished, what precautions are being taken to prevent release, and what monitoring takes place.

6. Are there particular aspects of the regulations you consider to be confusing or unclear? If so what are they?

More clarity may be needed in some areas in the light of new technologies and other developments.

7. Are there aspects of the regulations that are considered burdensome based on your practical experience of complying with the regulations?

GeneWatch UK does not agree that the starting point of the consultation should be that the regulations are too burdensome. There are legal obligations to protect human health and the environment as "contained use" production of GMOs increases in the future. Many more sites and traits may be involved, at a larger scale, and it is critically important that loopholes such as the lack of a public register and lack of monitoring are properly addressed.