GeneWatch UK response to the Red Tape Challenge (GMOs)

September 2013

GeneWatch UK is a not-for-profit organisation which aims to ensure genetic science and technologies are used in the public interest. We are responding to the proposals to include regulations covering Genetically Modified Organisms (GMOs) in the Red Tape Challenge.

The following regulations are listed on the Cabinet Office website as under review:

Genetically Modified Organisms (Deliberate Release) (Amendment) Regulations 2004	Implement the consequential amendments made to EU Directive 2001/18 by EU Regulation 1830/2003	2411	http://www.legislation.gov.uk/uksi/2004/2411/contents/made
Genetically Modified Organisms (Deliberate Release) Regulations 2002	Implement EU Directive 2001/18 on the deliberate release of GMOs into the environment	2443	http://www.legislation.gov.uk/uksi/2002/2443/contents/made
Genetically Modified Organisms (Transboundary Movements) (England) Regulations 2004	Provide for enforcement of EU regulation 1946/2003 on GMO transboundary movements	2692	http://www.legislation.gov.uk/uksi/2004/2692/contents/made
Genetically Modified Organisms (Contained Use) Regulations 2000	Revoke and replace the Genetically Modified Organisms (Contained Use) Regulations 1992, as amended	2831	http://www.legislation.gov.uk/uksi/2000/2831/made
Genetically Modified Organisms (England) (Amendments) Regulations 2008	Correct errors in SI 2004/2412	2598	http://www.legislation.gov.uk/uksi/2008/2598/contents/sld/made
Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996	Limit scope of requirement at s.108(1)(a) of the Environmental Protection Act 1990 to carry out a risk assessment when importing or acquiring a genetically modified organism and specify that where assessments are undertaken, records must be kept for 10 years	1106	http://www.legislation.gov.uk/uksi/1996/1106/contents/made
Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004	Provide for enforcement of EU regulation 1830/2004 on the traceability and labelling of genetically modified organisms, and traceability of genetically modified food and feed products	2412	http://www.legislation.gov.uk/uksi/2004/2412/contents/made

The Cabinet Office has requested comments on how the regulations could be improved and why, being specific where possible, for example:

- Could their purpose be achieved in a non-regulatory way (e.g. through a voluntary code?) How?
- Could they be reformed, simplified or merged? How?

- Can we reduce their bureaucracy through better implementation? How?
- Can we make their enforcement less burdensome? How?
- Should we remove them or leave them as they are? Which?

GeneWatch UK disagrees with the presumption underlying the Red Tape Challenge, which is that regulations act mainly as a burden on companies making applications and do not fulfil a necessary role. In fact, regulations are designed to prevent undue burdens on persons other than the applicant for example by:

- Protecting human health;
- Protecting the environment;
- Protecting the markets and business interests of others.

Any attempts to weaken regulations on GMOs will increase burdens on others (such as conventional farmers, who will bear the costs of segregation and labelling of non-GM crops) or expose them to increased risks (for example, risks associated with liability for contamination of crops and food or discharges to the environment, recalls of products, or environmental clean-up). GeneWatch UK is particularly concerned about the implications of proposals under development to allow large-scale releases or escapes of GMOs under contained use legislation.

In reality, regulators are faced with a succession of new challenges, including regulating:

- Highly mobile species such as GM insects and fish;
- GM farm animals (mammals and birds), which raise significant animal welfare concerns and may include new traits (such as disease resistance) with new potential downsides (creation of reservoirs of disease or evolution of viruses);
- Mass production of industrial chemicals and biofuels using GM micro-organisms or synthetic biology, which may give rise to significant discharges of 'living pollution' into the environment;
- Next-generation GM crops, including crops engineered to be resistant to more toxic herbicides or to produce industrial chemicals or pharmaceuticals.

In considering whether existing regulations are fit for purpose, these new challenges must be addressed.

Our detailed comments are below.

Purpose of the regulations and relevant international instruments

The purpose of the regulatory system covering GMOs is to protect human health and the environment and to provide a level playing-field for trade within and outside the EU.

The UK is a party to a number of relevant international instruments which establish the principles underlying much of the regulation. These include the Cartegena Protocol on Biosafety (CPB) to the Convention on Biological Diversity, which establishes the notification process for transboundary movements of living GMOs, and the Aarhus Convention, which establishes principles on public consultation and access to justice. The precautionary principle is cited in the Deliberate Release Directive (2001/18/EC) but also in the CPB and the Rio Declaration. Any reforms to regulation must remain compatible with these international instruments and hence cannot undermine these important underlying principles.

In addition, whilst the UK remains a member of the EU, any changes to legislation must be negotiated with other member states and the input of the European Parliament. Any attempts to weaken regulation unilaterally would be likely to have serious repercussions on trade within the EU and on global markets. For example, were GM crops and foods to be approved in the UK but not the EU, this would limit export markets for these crops and foods. Similarly, contamination, co-existence and liability rules must protect the markets of

conventional and organic farmers, who would face added costs to ensure segregation and labelling of their (higher value) products if GM crops were grown in Britain.

Role of the devolved administrations

The implementation of GMO regulations is the subject of a Concordat between the four UK administrations[1] which covers the implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms; and Regulation (EC) No.1946/2003 on transboundary movements of genetically modified organisms. The Scottish Government and Welsh Assembly Government are opposed to cultivation of GM crops and any UK-wide revision of these regulations would need to take account of the views of the devolved administrations.

Contained Use regulations are currently based on preventing discharges of GMOs (particularly genetically-modified micro-organisms, GMMs) to the environment. Any weakening of such regulations to allow large-scale discharges, escapes or releases of GMOs would also have impacts on the devolved administrations and would require their input.

Contained use

The Health and Safety Executive (HSE) is responsible for implementation of the contained use regulations for GMOs. Its Scientific Advisory Committee on Genetic Modification (Contained Use) (SACGM) is currently busy trying to revise the contained use regulations behind closed doors, with considerable involvement from industry 'stakeholders'. The SACGM is extremely tardy in publishing its minutes but GeneWatch has obtained a copy of the minutes for the November 2012 meeting on request. They state that during the proposed consolidation the opportunity would be taken to remove any "unnecessary gold plating" (instances where the UK standard is higher than the standard set in the Directive).

GeneWatch UK understands that the purpose of any proposed changes would be to allow large-scale discharges, releases or escapes of GMOs to the environment within the context of the Contained Use regulations. The proposed changes are likely to be relevant to releases of GM insects (which the UK company Oxitec claims have "biological containment" because the females are programmed to die before adulthood); GM fish (which the US company AquaBounty intends to produce in tanks on land); genetic modified micro-organisms (GMM) and products of synthetic biology (e.g. micro-organisms, algae with synthetic DNA) used for industrial-scale chemical production (including biofuels); and GM crops grown in greenhouses or polytunnels (e.g. for drug production, or in horticulture) or with Genetic Use Restriction Technologies (also known as 'terminator' technologies) to limit the reproductive viability of seeds.

In 2011, Oxitec sought to make open releases of GM diamond back moths (*Plutella xylostella*) under contained use regulations in the UK on the spurious grounds that its technology (in which females are genetically programmed to die at the larval stage, in the absence of an antidote which allows their breeding in the lab) is equivalent to "biological containment".[2,3,4,5,6,7,8,9] If the company had been successful, there would have been no published risk assessment or public consultation about open releases of these GM insects, and no monitoring of their impacts on human health or the environment. However, Oxitec's technology does not provide biological containment in the sense of the definition in the relevant regulations[10], because its GM male insects are intended to come into contact with and mate with wild females of the same species, which cannot be regarded as limiting their contact with the environment, and the insects are not 'sterile' but females are genetically programmed to die, mostly at the larval stage. Further, Oxitec has genetically modified a non-native strain of diamond back moth which is not allowed to be released in the UK under plant pest control regulations. To date, this proposal has not been approved.[11]

GeneWatch UK does not believe that any changes which allow significant discharges, releases or escapes of GMOs to the environment under so-called Contained Use regulations would provide adequate protection for human health or the environment, or be compatible with international obligations. For example, European contained use regulations cover GM micro-organisms (GMM) only, so deliberate releases of GM insects or fish under UK contained use regulations would likely breach EU legal requirements (as outlined in recent EFSA Guidance[12]); and the Aarhus convention requires a level of transparency and consultation which is not currently included in the risk assessment process for contained use applications.

We have made a preliminary response the HSE's pre-consultation on these matters[13] and will respond in more detail to its planned public consultation when this is issued later in the year.

GeneWatch UK undertook an in-depth study of the contained use regulations for genetically modified micro-organisms in 1999.[14] We noted that an effective regulatory system requires:

- knowledge of what activities are taking place;
- a system of risk evaluation which is robust;
- an effective system of monitoring;
- proper policing and enforcement of regulations;
- transparency and openness to public scrutiny.

We recommended that 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. We also made a number of recommendations to improve risk evaluations, increase transparency and provide better monitoring and enforcement. These recommendations remain relevant today.

Transboundary movement of GMOs

Regulation (EC) No.1946/2003 implements the requirements of the CPB on notifications of exports of GMOs for open release, and includes some additional transparency requirements consistent with the UK (and EU) obligations under the Aarhus Convention.

GeneWatch UK has documented in detail the failure of the UK company Oxitec to meet its obligations under this regulation when exporting GM mosquito eggs for open release in the Cayman Islands, Malaysia and Brazil. Problems included[15]:

- Sending copies of notifications late or not at all to the required UK and EU authorities;
- Failure to meet EU standards for risk assessments;
- Considerable delay in releasing documents for public scrutiny and excessive redactions of important risk assessment information.

GeneWatch UK has subsequently made repeated requests to the relevant authorities in order to monitor the notification process.

We recommend the following improvements:

- The creation of an EU register for transboundary notifications, which is kept up-to-date (for example by inclusion in the existing register for EU deliberate release applications), removing the need for civil servants to respond to repeated individual requests for information, and improving transparency;

- Addition of an explicit requirement for exporters to copy the notification and associated documents to the UK and EU authorities in a timely way (i.e. when it is sent to the importing authority);
- A system of independent oversight to ensure that risk assessments provided by exporters meet the standards required by the deliberate release Directive 2001/18/EC, as required by the Regulation.

Deliberate release
Deliberate releases of GMOs in the EU are governed by Directive 2001/18/EC.

The Advisory Committee for Releases into the Environment (ACRE) has recently made proposals for a significant revision of this regulation.[16,17,18] In GeneWatch's view these proposals are poorly argued, counterproductive (i.e. will damage access to markets as well as the environment), and lack a credible route for implementation. ACRE's documentation ignores the very significant problems now being experienced in other countries with resistant weeds (superweeds) and resistant pests associated with growing the two main types of GM crops currently in cultivation.[19] Whilst acknowledging that existing herbicide-tolerant and insect-resistant commodity crops have higher profit margins (report 2, page 7), ACRE claims that weaker regulation would facilitate a new generation of more environmentally friendly crops: this is not consistent with the evidence from the USA that, despite more than 14,000 field trials and a very weak regulatory system, such crops have not been delivered. In reality, a new generation of GM crops which are tolerant to more toxic herbicides have begun to be approved in the USA, and the EU pipeline for cultivation includes mainly stacked traits tolerant to one or more herbicides combined with (sometimes multiple) Bt toxins. Speeding up commercial approvals for such traits would impose unnecessary costs on non-GM farmers, associated with the costs of labelling, segregation and contamination incidents, as well as (in the longer term) evolution of resistant weeds and pests. Further, the Farm Scale Evaluations and more recent evidence from other countries (e.g. regarding impacts on Monarch butterflies in the USA) show that there would be negative impacts on the environment.

There are also significant practical difficulties with ACRE's approach. Commission Decision 2002/623/EC, which implements 2001/18/EC, provides for review and adaption of the guidance notes contained in its own Annex, and Annex II of Directive 2001/18/EC, and/or for a Member State's competent authority to make a proposal for a derogation from the usual notification procedure, provided "sufficient experience" has been gained with releases of comparable GMOs into certain ecosystems. However, no experience has been obtained with commercial release of any GMO in the UK, and commercial releases elsewhere in the EU have also been very limited (mainly consisting of planting of MON810 Bt maize in Spain, for use in animal feed, a crop which is not suitable for growing in the UK). It is therefore unclear what mechanism the UK would use should it wish to follow ACRE's advice and water down the interpretation of this legislation or speed up approvals.

Alternatively, if the UK (in practice England, and perhaps Northern Ireland, since Scotland and Wales are opposed to GM crops) were to 'go it alone' and either negotiate devolved decision-making or withdraw from the EU, access to EU (and other) markets for the resulting GM crops and foods, and probably also for potentially contaminated conventional or organic products, would be damaged, with serious negative economic impacts for farmers and the UK as a whole. Similarly, questions raised by ACRE about which techniques fall within the scope of the Directive must be resolved at EU level to avoid negative impacts on trade.

In reality, there are a number of major regulatory gaps which must be addressed in the UK before GM crops could be approved for commercial cultivation. For example, the UK has yet to adopt any provisions for the co-existence of GM crops and conventionally grown or organic crops, to protect non-GM markets, and there is no legislation in place to provide for

liability for contamination incidents. Currently, costs of segregation and labelling would fall on conventional and organic farmers if GM crops were grown commercially in the UK. Lack of regulations to protect (more lucrative) non-GM markets is a major omission from the current regulatory framework.

Directive 2001/18/EC contains provisions for the deliberate release of GMOs other than plants, including GM animals. The European Food Safety Authority (EFSA) has recently adopted Guidance on the environmental risk assessment of GM animals (including fish, insects, birds and mammals) under 2001/18/EC (cited above). This Guidance has considerably improved since consultation but remains the subject of a complaint by GeneWatch UK to the European ombudsman, regarding conflicts-of-interest on EFSA's GM insects working group and the failure to consult on or properly address the issue of GM insects in the food chain (see further below). Further, significant concerns remain regarding environmental impacts of GM insects, fish, birds and mammals and it is unclear whether consumers will regard the large numbers of premature and still births of GM mammals during the development phase as acceptable.

Since no experience has yet been gained with experimental or commercial releases of GM insects, fish or birds in the EU, and only limited experience with experimental production of GM mammals, it would be premature to seek revision of the Directive for such products.

Traceability and labelling

A case-by-case assessment of GM food and feed is essential to provide confidence in the food chain. However, risk assessments based on animal studies cannot provide definitive evidence of safety, and new traits can always introduce new risks. It is therefore extremely important that traceability and labelling requirements remain in place, to facilitate consumer choice and allow product recalls should anything go wrong.

New safety challenges will be posed by the recent decision by the US Environment Protection Agency (EPA) to double the allowed levels of glyphosate (brandname RoundUp), used on Monsanto's existing 'RoundUp Ready' GM crops, entering the food chain; and by the second-generation of GM crops now beginning to be approved by the US Department of Agriculture (USDA) which are resistant to more toxic weedkillers.[20]

GeneWatch UK supports the introduction of an EU-wide GM-free labelling scheme to improve consumer choice, particularly in the case of meat, milk and eggs fed on GM feed, which are currently not covered by statutory labelling requirements.[21] Consumers' desire for labelling is likely to be enhanced by reports of serious environmental problems caused by GM crops grown overseas, such as the devastating effect on Monarch butterflies associated with the destruction of the milkweed habitat where they lay their eggs, caused by blanket spraying.[22,23]

Lobbying by industry to allow "low level presence" (LLP) of unauthorised GM crops in food imports should be resisted, as the lack of safety data and clear traceability/labelling of such products would significantly increase the risk of expensive contamination incidents and product recalls.

Enforcement activities and sampling of shipments have been cut back and must be reinstated if expensive contamination incidents are to be avoided.

Safety assessment, traceability and labelling of crops produced with GM insects, which may contain large numbers of dead or living GM larvae in the crop, has not yet been addressed. This regulatory loophole must be closed to ensure protection of human health and the environment, and to safeguard access to GM-free markets.[24]

Public consultation and involvement
The existing framework of regulation for GMOs is intended to protect the health and the environment of the general public, preserve consumer choice, and protect access to GM-free markets for farmers, retailers and other businesses. GeneWatch UK is therefore extremely concerned that much of the so-called 'stakeholder' engagement on these issues is taking place with lobbyists behind closed doors, including in the context of the current US-EU free trade negotiations.

Conclusions
There are significant regulatory gaps in current GMO regulation which needs to be strengthened to address forthcoming challenges. Reduced burdens on applicants would translate to increased burdens on members of the public, farmers, retailers and others who would be exposed to unnecessary risks.

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