

The Red Tape Challenge and GMOs – Regulation is not red tape

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GM Freeze

GM Freeze is an alliance of organisations calling for a moratorium on GM foods, the growing of GM crops for any purpose and on patents on genetic resources in agriculture, food production and forestry until the need for and safety of GM technology has been established and alternative approaches have been fully evaluated.

GMO regulations in the UK

The regulation of genetically modified organisms in the UK transposes legislation in force in the European Union. Table 1 sets out the EU Directives and regulations and their corresponding Statutory Instruments in the UK.

Table 1 GMO Regulations

EU legislation	Domestic Act or Statutory Instruments	Devolved responsibility?	Issues covered
GMO Deliberate Release Directive 2001/18	Environmental Protection Act 1990 GMO (Deliberate release) regulations 2002 SI 2443 GMO deliberate Release Regulations (amendment) 2004 SI 2411	Partially – the approval of GM test sites is devolved. The UK Government votes on policy, marketing and cultivation applications at the European Council following negotiations between the four UK administrations in accordance with the terms of a non-binding concordat signed in 2007.	GM test sites (Part B consents) GM marketing and cultivation approvals (part C consents)
Regulation 1946/2003 on the Transboundary Movement of GMOs	Genetically Modified Organisms (Transboundary Movements) Regulations 2004 SI 2692	Yes – equivalent legislation in Wales, Scotland and Northern Ireland	Controls the export of GMOs outside the UK/EU and international exchange of information
Regulation 1829/2003 on Genetically Modified Food and Feed	GMO deliberate Release Regulations (amendment) 2004 SI 2411	No – but subject to discussion under the 2007 Concordat	Controls the placing on the market of GMOs and foodstuffs containing these, whether they are intended for consumption by humans or animals
Regulation 1830/2003 on the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products	Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004 SI 2412 Genetically Modified Organisms (England) (Amendments) Regulations 2008	Yes – equivalent legislation in Wales, Scotland and Northern Ireland	Controls the traceability and labelling of GMOs and products produced from them

Produced from Genetically Modified Organisms	SI 2598		
Directive 2009/41 on the Contained Use of Genetically Modified Microorganisms	Genetically Modified Organisms (Contained Use) Regulations 2000 SI 2831 Genetically Modified Organisms (Risk Assessment) (Records and Exemptions) Regulations 1996 SI 1106	No	Protects human health and safety and environmental protection from genetically modified micro-organisms in contained use, and additionally the human health and safety from genetically modified plants and animals.

As is clear from table 1 in some cases GMO regulation is a devolved matter and therefore any changes proposed as a result of the Red Tape Challenge may affect Wales, Scotland and Northern Ireland. The implementation of GMO regulations is the subject of a Concordat between the four UK administrations.

The Concordat

The GM Concordatⁱ agreed by the four administrations of the UK:

“Sets out the agreed framework for co-operation between the Department of the Environment in Northern Ireland (DoENI), the Department for Environment, Food and Rural Affairs (Defra), the Welsh Assembly Government (WAG), as the executive of the National Assembly for Wales, and the Scottish Executive (SE), on the administration and coordination of the regulatory frameworks established under:

- 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 Concordat is not a legally binding agreement or contract, but nevertheless if the UK Government decides to tinker with the interpretation of the GMO regulations there would need to be agreement from by the three other parties to the Concordat or EU legislation risks being applied differently on either side of national borders in the UK. Where the boundary passes directly across a field (as occurs for example on the Welsh border) the law could potentially be applied differently to two halves of the same crop, which would inevitably increase red tape.

At this point it is worth reminding the Government that administrations in Cardiff and Edinburgh have agricultural policies aimed at avoiding future cultivation of GM crops. These policies were recently reiterated in response to Owen Paterson’s speech at Rothamsted Research on 20 June 2013.ⁱⁱ

Red Tape – what does it mean?

“Red tape” is not well defined in the Red Tape Challenge, probably because it means different things to different people with different agendas. The closest the Government gets to offering a definition in the current consultation is:

“Good regulation is a good thing. It protects consumers, employees and the environment, it helps build a more fair society and can even save lives. But over the years, regulations – and the inspections and bureaucracy that go with them – have piled up and up. This has

hurt business, doing real damage to our economy. And it's done harm to our society too. When people are confronted by a raft of regulations whenever they try to volunteer or play a bigger part in their neighbourhood, they begin to think they shouldn't bother.

"If we want to reverse this trend and encourage greater responsibility in our society, then we have got to trust people and give them more freedom to do the right thing. So this government has set a clear aim: to leave office having reduced the overall burden of regulation. With more than 21,000 regulations active in the UK today, this won't be an easy task – but we're determined to cut red tape."

"Red tape" is being partly blamed for the state of the economy and society with particular emphasis on the number of regulations that exist and the bureaucracy required to enforce them. However there is clear recognition that regulation, with associated "red tape", plays a key role in protecting health, the environment and making society fairer. It could also be argued that the state of the economy is, in part, due to the under regulation and the unregulated behaviour of companies and individuals within the financial sector.

These points support the argument for good regulation, not least because it provides a way to prevent individuals and companies behaving in antisocial and harmful ways. However The Red Tape Challenge omits the crucial role of regulation plays in protecting the health and welfare of future generations and the planet. Lack of regulation causes huge problems for future generations (and other species) who derived no benefit from the past use of poorly regulated technology, products or practices (eg, the impacts halocarbons on the ozone layer, the role of asbestos in lung disease, the BSE crisis and long-term ecological damage due to commercial activity such as the decline of fish stocks).^{iii and iv}

GM Freeze believes "red tape" is an unhelpful term which is poorly defined and can mean different things to different audiences. What are required are procedures to enforce regulations correctly, effectively and efficiently in order to achieve their objectives. There is always room to make regulation more efficient, but failure to regulate or enforce runs the risk of more serious problems developing.

No alternative to regulation

Regulation helps ensure that our society operates in a fair way that protects both the present and future from harmful or irresponsible activities by companies or individuals. Weak or absent regulation can lead to long-term harm (eg, the consequences of the release of thousands of industrial chemicals into the environment and food chain without due regard to their impacts on the health of humans and our fellow creatures are still not fully understood, for instance in the field of endocrine disruption, and it could be many years before the full impacts are felt).

Attempts to get avoid compliance with appropriate regulation often casts regulation as "red tape" to diminish its importance and portray it as an unnecessary burden. However without appropriate regulation our society and economy could not function properly and we would not be protecting future generations and the planet.

Self-regulation is often proposed, but where this has been attempted in food and agriculture it has frequently been replaced by formal regulation because the widespread corporate failure to comply with voluntary codes fails to achieve the objectives of the scheme. For example:

- The Pesticides Safety Precautions Scheme, used prior to 1985 as a voluntary scheme for the regulation of pesticides in the UK, was replaced by a statutory approval process in the 1980s.
- The Voluntary Code of Conduct on Pesticide Use was replaced by statutory control including operator training.
- The Straw Burning Code, introduced in the 1980s as a voluntary initiative by the National Farmers Union, failed to reduce the nuisance caused by smoke pollution and

damage to hedges, trees and property, so legislation was introduced to allow local by-laws restricting the practice. Eventually straw and stubble burning was banned in most circumstances by a statutory instrument in 1993 (Crop Residues Burning Regulations SI 1366/93).

GM Freeze view of regulation

GM Freeze supports strong well-enforced regulations of GMOs and would like to see comprehensive regulation enacted and enforced to:

- Prevent harm to human health and the environment now and in the future.
- Ensure that all operators act within the same legal framework to prevent freeloaders or economic advantage being gained by deliberate non-compliance.
- Enable farmers and consumers to make informed choices as to whether to buy GM seeds, feed or food using clear and comprehensive labelling.
- Protect third parties, including beekeepers and gardeners, from GM contamination.
- Ensure those holding GMO release and marketing consents are strictly liable for any harm caused by their products.
- Prevent companies gaining market shares that are not in the public interest (eg, monopoly or near monopoly control of markets or sectors).
- Prevent unapproved GM traits entering the food and feed chain or into the environment.
- Ensure that other countries are informed of the intention to export a GMO so they are able to give informed consent or to block it.

Such regulations should be based on the Precautionary Principle, which applies to all EU environmental legislation. Failure to apply the Precautionary Principle can transfer the burden of the risk of a new technology, technique or product from the developer/permit holder to the citizens and environment. The potential harm caused by authorising a harmful product or technology could result in costs that far outweigh any economic benefits derived from the product or technique. In such situations the costs would be borne by people affected, the environment and taxpayers (eg, the National Health Service treating illness caused by the technology or the loss or severe reductions in populations of affected species). Gaps in data and scientific uncertainty should trigger the use of the Precautionary Principle and no approval should be made until these deficiencies have been satisfactorily resolved. The use of Post Market Monitoring conducted by consent holders should not be used as a way to avoid thorough risk assessment before approval is made.

When the role of GM regulation is to approve a product for the market or experimental release it is essential that the risk assessment is thorough and the scientific evidenced used of the highest quality so that all circumstances in which the GM trait is released or consumed are included and the impacts of its use over time considered. This process must include experiments looking at different exposures to GM crops, and the pesticides used on them, from short-term acute exposure to lifetime low-level exposure. Such requirements are not “red tape” impeding commercial advancement but a necessary process to ensure that only safe products are released into environment and food chain.

In the EU applicants are required to provide evidence of the indirect effects of GMOs on the environment and non-target species. In the case of GM herbicide tolerant (GMHT) crops this should also include changes in weed management in the crop.

In contrast to the EU the indirect impacts of GMHT crops do not feature in the US regulatory system. The EU requirement was introduced by Directive 2001/18, and this led to GMHT crops close to approval at that time being assessed in the Field Scale Evaluations (FSE) to meet the new criteria (ie, GMHT Winter and Spring oilseed rape, fodder maize and sugar/fodder beet). The results of the FSE led to four out of the five crops trialed not being approved because they were shown to cause greater reductions in weed and weed seeds in the field than conventionally-managed crops and that this would cause further reduction in farmland wildlife. In the US GMHT maize and soya have been widely grown in the Midwest since the late 1990s. The use of Roundup

Ready technology enables farmers to control Milkweed, a once very common weed in maize and soya fields. Unfortunately the larvae of the Monarch butterfly uses Milkweed as its main food plant, and US entomologists say that the significant decline in overall Monarch populations in the Eastern US is linked to the dramatic reduction of Milkweed in maize and soya fields following the introduction of GMHT crops:

“An initial survey conducted in 1999 found that low densities of common milkweed occurred in approximately 50% of Iowa corn and soybean fields. In 2009, common milkweed was present in only 8% of surveyed fields, and the area within infested fields occupied by common milkweed was reduced by approximately 90% compared to 1999. The widespread adoption of glyphosate resistant corn and soybean cultivars and the reliance on post-emergence applications of glyphosate for weed control in crop fields likely has contributed to the decline in common milkweed in agricultural fields.”^v

Some argue that the GMO approval process in the EU is too burdensome or slow and that the lack of GM approvals is holding back European farmers. However as the two cases referred to above illustrate there is more to agriculture than yield and the bottom line and that approving GM crops ahead of obtaining good data can prove disastrous. Delaying authorisations in order to improve the quality of scientific evidence used to assess health and environmental safety in the short- and long-term can be critical to avoiding huge problems in the future.

The need for effective enforcement and monitoring

Enforcement is an essential part of good regulation. Without sufficient budget to ensure that regulations are followed, the time put into drafting, consulting, debating and passing legislation is either wasted or proved to be window dressing. It is therefore important that the means of enforcement should be considered at the time regulations and bills are drafted.

Business managers and owners who are hostile to the paperwork and procedures of enforcement should be reminded that regulations are partly designed to ensure that reputable companies are protected from unscrupulous competitors who ignore or bend the rules to gain an unfair competitive advantage. Strong enforcement makes life difficult for those inclined to cheat, not those who obey the law.

The effectiveness of legislation in ensuring the safety of a product would be very hard to judge, especially for a new technology such as GM, unless it is adequately monitored. Effective monitoring requires reliable baselines on which to base comparisons with the current status. This immediately raises the question as to whether the current baseline is something to aspire to or if ecosystems are already so degraded that they represent a pale shadow of what once passed for a typical agroecosystems and regulation should aim to see improvements rather than maintenance of *status quo*. For instance in the UK farmland biodiversity has already been significantly damaged by current agricultural practices, and its current status is a poor guide to its real potential to be part of a vibrant and healthy, multifunctional ecosystem providing a wide range of benefits, including practical ones (eg, increased soil carbon) and aesthetics (eg, the singing skylark).

In the case of GM crops, plants, insects and animals reliable risk assessment can prove to be difficult because of the novel nature of what is being released into the environment, the lack of appropriate comparators and the potential for gene transfer to wild relatives. Uncertainties include rates of outcrossing to wild relatives and the effectiveness of development prevention mechanisms in GM insects or fish (eg, sterility mechanisms in GM salmon, and the GM traits in Oxitec's GM insects aiming to prevent female GM individuals from reaching maturity).

In the case of Oxitec's GM insects the genetic killing mechanism is turned off by the common antibiotic tetracycline leaving the distinct possibility that it could be triggered in the wild due to environmental contamination with the drug. Furthermore sterility and partial sterility creates complex interactions between released GMOs and wild target and non-target organisms which may impact adversely on wild populations (salmon), lead to increases in non-target pests (GM insects) or result in other unanticipated effects (other species moving in to fill the vacated niche).

An emerging area of concern is GM disease resistance, which may lead to evolution of pathogens or create a silent (non-symptomatic) reservoir of disease (eg, GM chickens).

We have identified several areas where enforcement, monitoring and inspections are used in the GM regulations including:

GMO Deliberate Release Regulations (amendment) 2004 – Enforcement of test site conditions by GM Inspectorate

GM Freeze does not believe there is a reasonable case supporting open-air GM trials, particularly considering the history of industry's inability to contain and control the trials it has conducted. If trials are to be conducted test site enforcement is an essential task to minimise the risk of gene transfer and other harm arising from GM crop test sites. Independent inspection by the GM Inspectorate is the only way to ensure that consent conditions are met.

The successful prosecution of Monsanto and Perryfields Holdings by the HSE for breaches of Part B consent conditions in Lincolnshire^{vi} is a reminder of the clear need for effective enforcement based on inspection. Some proponents of GM technology might say that inspection of GM test sites is unnecessary "red tape" and further that trial locations should not be in the public domain and that self-policing by consent holders would save money. The successful enforcement action mentioned above followed a routine inspection, and as a result would have sent out a warning to other companies releasing GM crops into the environment to adhere to the rules as well as correcting the observed breaches. Given the failure of industry to properly control GM trials, and given the failure of self-policing in many industrial areas, it is not acceptable to leave monitoring of GM trials to the companies with a clear vested interest in a positive trial outcome needed for commercial authorisation.

Post-release monitoring

Post-release monitoring is currently the responsibility of the consent holder of a Part B consent for a GM test site. From 1994-2003, when there were large numbers of test sites, the quality of post release monitoring reports was poor. For example:

- The post-release monitoring report submitted by Aventis CropScience (now Bayer CropScience), covering the Winter oilseed rape Farm Scale Trials in 2000/01, on 28 sites from Durham to Dorset, was just two sentences in length: "The plants grew normally in comparison to non-GM crops, no unexpected events occurred and proceeded to normal harvest, except for High Halden, which was sown late and never established properly. This was ploughed in November."
- Other post-release monitoring reports submitted to Defra showed clear evidence that consent holders had cut and pasted sections of their reports from those of others instead of producing a unique report on their sites based on field inspections as required. This type of sloppy behaviour could mean important changes or events resulting from the release being missed (eg, hybridisation with wild relatives) and demonstrates why both regulation and enforcement are needed to ensure that experimental GMOs are contained and destroyed after trials.
- In November 2001 Aventis (now Bayer CropScience) failed to notice and record the fact that a field of GM oilseed rape located at Witham-on-the-Hill in Lincolnshire (part of the Field Scale Evaluations) had re-flowered after harvest in the Autumn in technical breach of the Part B consent conditions which required post-harvest flowering to be prevented. It was left to local residents to report this incident to Defra, and the offending crop was eventually destroyed. No legal action was taken because of a legal technicality. A timely Autumn inspection by the company or GM Inspectorate could have prevented this incident, and the failure to publicly reprimand the company is not acceptable.

Seed imports

It is an offence under GMO Deliberate Release Regulations 2002 and 2004 (EU Regulation 1829/2003 and Directive 2001/18) to import unauthorised GMOs into the UK and to release them into the environment. Since 2000 there have been three known cases of imported seed being

contaminated with unauthorised GM traits. All three involved herbicide tolerant oilseed rape:

1. Advanta Seeds UK marketed a non-GM Spring oilseed rape known as Hyola 308, which was planted by about 600 farmers on 4700 hectares. GM contamination levels averaged around 1%, but were as high as 2.8% in some batches. Eventually the oilseed rape crops were destroyed, and the farmers involved received compensation of up to £370/hectare from Advanta Seeds UK. The Canadian Food Inspection Agency investigation into the contamination reported that separation distances of 800 metres between the seed crop and the nearest crop of oilseed were used,^{vii} but Advanta's evidence to the House of Commons Agriculture Committee in 2000 stated the actual separation distance was stated as four kilometres^{viii} – five times the separation distance required by Canadian regulators for seed production. This incident could have been prevented if seed imported from countries with a high risk of GM contamination was monitored for GM presence before being put on the market.
2. The seed used in the Farm Scale Evaluation of GM Spring oilseed rape in England and Scotland was contaminated with three unapproved GM traits for antibiotic resistance. The contamination was detected by unofficial sampling at the Scottish Agricultural College, and the maximum contamination rate was found to be 2.8%. Neither the Advisory Committee on Releases to the Environment, the Government's GM Inspectorate based at the Central Science Laboratory at York or Bayer CropScience have ever explained how the contamination occurred. Insisting that the consent holder demonstrate the GM seed sowed was the one authorised for the trial could have prevented this incident.
3. In 2008 the Scottish Government announced that Monsanto's GT73 GM oilseed rape had contaminated seed being grown on non-GM trial sites. The trials were immediately discontinued. Subsequently Defra announced that a Winter oilseed crop in Somerset was contaminated to a level of 0.05% GM and had further contaminated a spread to a neighbouring field to a level of 0.01%. The purpose of this planting is unknown and the source of the contamination remains a mystery, but it could have been prevented if all seed imports from high risk countries, such as the US, were routinely analysed for GM presence.

No legal action was taken against the companies involved in any of these incidents,

All three cases illustrate why proper regulation and enforcement are needed to prevent GM contamination of seed supplies (and consequently harvested crops). The current approach, adopted after the Advanta Seeds incident in 2000, relies heavily on audits conducted by seed companies themselves. No analysis for GM content in imported or UK-produced seed was done in 2010/11 (the last date that data is available on the FERA website).^{ix} GM Freeze finds it extraordinary that no seed samples were analysed for GM presence during this period, especially as nine lots came from countries with a higher risk of GM contamination (5 oilseed rape and three sweet corn seed lots from the US and one oilseed rape from Canada). Companies previously implicated in contamination incidents, such as Bayer CropScience, imported oilseed rape seeds which were not subject to analysis, and Monsanto "did not participate" in the monitoring scheme at all.

The use of self-auditing encourages companies to ensure that procedures to prevent contamination are in place, but does little to ensure they are properly operated.

Inspection, enforcement and monitoring of traceability and labelling

The requirement for all GMOs to be traceable serves several purposes:

- It enables accurate and truthful labelling.
- It enables farmers and consumers to make an informed choice as to whether or not to buy a GM product.
- It enables food/feed containing GM ingredients to be withdrawn from the market should a problem emerge.

- It potentially enables the monitoring of health effects of GMOs – something that would be impossible in the US where there is no GM labelling.

None of these purposes can be achieved without a robust regime of inspection, monitoring and enforcement to ensure adherence to Regulations. Enforcement activities by UK public bodies, Port Health Authorities, Trading Standards and Environmental Health and the GM Inspectorate can only be effective if backed up by analysis of products for GM content (approved and unapproved) to demonstrate that labelling is accurate. Access to the results of such monitoring should be freely available to the general public. The monitoring of results also enables enforcement action against companies in breach of the law.

It is regrettable that very little publicly-funded analysis of food or feed for GM presence is carried out in the UK to ensure that any GMOs present are approved and that products/cargoes are correctly labelled. The general public is very supportive of labelling for all uses of GM in the food/feed chain including on meat, milk and eggs produced using GM feed.^x The paucity of enforcement of the Regulations means there is little or no independent verification of labelling accuracy. There is a good case for some additional enforcement activity, not less, to ensure that those wanting to make an informed choice about purchasing GM products can do so in the full confidence that the labels are accurate.

The absence of routine testing for GM present also leaves the UK farming, food and feed sectors very vulnerable to the presence of unauthorised GM traits. The UK has already experienced several such incidents (eg, LL601 rice from the US, Bt10 maize from the US, a number of authorised GM rice strains from China^{xi} and Triffid flax from Canada^{xii}). The cost of dealing with contamination once it is in the food/feed chain can be very high and is borne by retailers and suppliers rather than the companies who own the GM traits involved and fail to properly contain it. Increasing enforcement activity at ports would be the most efficient means of detecting unauthorised GM presence, preventing it entering the food chain and avoiding the costs of product withdrawal, clean-up procedures and potential compensation to affected parties.

Transboundary movement of GMOs

The movement of GMOs from the UK to countries outside the EU is covered by the Biosafety Protocol and any regulation or enforcement activity involved is necessary to ensure that third countries are aware of developments.

Oxford-based company Oxitec failed to follow the procedures laid down in the Biosafety Protocol, Directive 1946/2003 and Genetically Modified Organisms (Transboundary Movements) Regulations 2004^{xiii} when it transferred GM mosquitoes to the Cayman Islands and Brazil. Flouting international agreements and regulations in this manner cannot be excused. The regulations overseeing the export of Live Modified Organisms (LMOs) is designed to ensure that they are only released with prior consent of the receiving country and that the international community (in particular close neighbours) are aware of the releases. Risk assessments are supposed to meet EU standards and be publicly available for independent scrutiny.

Oxitec's cavalier attitude to the regulations does not cast the UK in a good light and is extremely disrespectful of countries aiming for the proper regulation of GM plants and animals. It is unclear why no enforcement action has been taken against Oxitec.

Contained use

The GMO (Contained Use) Regulations 2000 provide an important protection for public health and the environment from experimentation with GMOs in laboratories or other contained facilities like glasshouses. Commercial production involving genetically modified microorganisms in vessels is also regulated under these rules.

The experimental nature of some of the activities carried out under these regulations requires the containment of the GMOs and their destruction after trials must be thorough to prevent escapes into the environment. Some of the GMOs contain DNA sequences for human diseases. Others

may contain GM traits that could cause significant harm if established in the environment or may impact negatively on ecosystems.

Oxitec's recent request to release GM Diamondback moths under the GMO (Contained Use) Regulations rather than the GMO Deliberate Release Regulations^{xiv} raised important questions about the interface of the contained and open release systems. Defra and the HSE informed Oxitec that, "Biological barriers alone were not sufficient to bring the proposed open field trial within the scope of the Contained Use Regulations."^{xv} The main reason for Oxitec's request was to avoid the costly requirement in the Deliberate Releases Regulations to carry out a full environmental risk assessment as part of the application process. On this occasion Defra recognised that strict adherence to the regulations was required to avoid a potentially harmful release.

Oxitec has conducted experimental releases in the Cayman Islands, Brazil and Malaysia of mosquitoes using the same genetic modification. The company provided minimal and incomplete risk assessment information. It is unacceptable for a publicly-funded UK company to exploit weaker regulations overseas to carry out environmental releases that clearly would have required a full environmental risk assessment in the UK. This illustrates why thorough, cooperative international regulation is needed to police the activities of companies in a manner that is consistent and provides sufficient protection for people and the environment.

GM crops bring their own red tape

The Government is committed to introducing rules to allow the coexistence of GM, non-GM and organic crops. We submit that these rules must cover beekeepers and gardeners.

How coexistence is managed, if it proves possible, will become pressing if proposals to introduce GM crops in the England materialise. Coexistence is an issue for seed growers trying to meet seed purity standards, and the separation distances required to meet seed purity standards need to be sufficient and effective to prevent GM contamination. The only way farmers could avoid the compliance with GM coexistence rules would be to ban growing any GM crops in the UK. Introduction of GM crops for food or seed production inevitably leads to regulation and enforcement to ensure coexistence rules are upheld to protect farms, exports and supply chains from contamination. The main UK insurance companies do not provide cover for farmers growing GM crops, so the costs of contamination will likely fall upon farmers, food companies and ultimately consumers rather than the company that holds the consent for the GM trait. A comprehensive scheme placing strict liability on GM companies for all economic and environmental harm cause by their products is overdue.

Conclusion

The implementation and enforcement of GMO regulations is not "red tape". It is a necessary check against the actions of companies with a vested interest the commercialisation of GMOs. It is also insurance against potential negative impacts of GM food and crops being revealed by the considerable scientific uncertainty about the effects and performance of GM food and crops. Any attempt to weaken the GMO regulations by "reducing red tape" will create a range of fresh problems for farmers, suppliers, consumers and ultimately taxpayers. Any changes in the regulations or their implementation will need to be agreed with the administrations in Wales, Scotland and Northern Ireland.

Even the UK's very limited experience of GM crop cultivation illustrates what can happen when enforcement of regulations is lax or lacking. If GM cultivation is initiated in the UK GM contamination will be a constant threat to existing markets regardless of how much regulation is in place as no regime can avoid human error or prevent natural forces like wind from operating.

The growing uncertainty about the safety of GM food and crops requires improved and strengthened regulations, not reduction of regulation, and that the Precautionary Principle must be applied where data gaps or scientific uncertainty exist. Experience shows that not waiting for scientific evidence to build up can cause major ecological changes, such as the continuing dramatic decline in Monarch Butterfly populations in the eastern US where there is no regulatory

requirement to carry out a risk assessment of the indirect effects of GMOs prior to release.

Notes

- ⁱ Concordat on the Implementation of Directive 2001/18/EC and Regulation 1946/2003/EC An agreement between the Department of the Environment in Northern Ireland, the National Assembly for Wales, the Scottish Executive and the UK Government. Available at www.scotland.gov.uk/Publications/2007/04/GMConcordat#a4
- ⁱⁱ Farmers Guardian, 20 June 2013. "[Scotland and Wales remain opposed to GM crops](#)"
- ⁱⁱⁱ European Environment Agency, 2002. "Late lessons from early warnings: The precautionary principle 1896-2000"
- ^{iv} European Environment Agency, 2013. "Late Lessons from early warnings: Science precaution and innovation"
- ^v Hartzler, RG, 2010. "Reduction in common milkweed (*Asclepias syriaca*) occurrence in Iowa cropland from 1999 to 2009". *Crop Protection*, 29, 1542–1544
- ^{vi} BBC, 17 February 1999. "[GM firms fined for safety breach](#)"
- ^{vii} Canadian Food Inspection Agency, 2002. "Trace Amounts of Genetically Modified Materials in Canola Seed Exported to Europe"
- ^{viii} House of Commons Agriculture Committee, 2000. [Oral evidence from David Buckridge and Mike Ruthven Advanta Seeds UK 18 July 2000](#).
- ^{ix} The Food and Environment Research Agency, 2001. [Summary Reports for 2010/2011 Audit Programme](#)
- ^x Food Standards Agency, 2013. [GM Labelling: Exploring public responses to the labelling of GM food and the use of GM-free labelling](#). Qualitative and Quantitative Findings were based on research carried out by Define Research and Insight
- ^{xi} GM Freeze, 31 May 2007. [GM contamination: Imports of food and feed at risk - measures needed to reduce the threat](#)
- ^{xii} GM Freeze, 30 November 2009. [GM Flax contamination from Canada](#)
- ^{xiii} Wallace HM, 2013. [Genetically modified mosquitoes: ongoing concerns](#). Third World Network
- ^{xiv} Defra, 2011. [Minutes of 1 December 2011](#) meeting, see item 10.4
- ^{xv} Defra, 24 January 2012. Letter to Oxitec