

GeneWatch UK response to the Scottish Executive's *consultation on options for implementing the Environmental Liability Directive*
March 2007

GeneWatch UK is a not-for-profit organization that monitors developments in genetic technologies from a public interest, environmental protection and animal welfare perspective. GeneWatch believes that the implementation of the ELD provides an important opportunity to improve environmental protection in the UK. Because GeneWatch's expertise is in genetically modified organisms (GMOs), our comments on the options for implementing the Environmental Liability Directive (ELD) are concerned with its relationship to activities using GMOs only.

In relation to GMOs, the ELD provides the regime that was promised in the Deliberate Release Directive (2001/18). As such it is one important component of the overall precautionary approach set out in that Directive and should be formulated with that context in mind as well as public attitudes to GMOs in the UK.

Below, our submission is in three parts. The first is related to three general points:

1. The approach of minimal transposition will lead to poor, confusing regulations that will fail to protect the environment from harm arising from the use of GMOs.
2. There is no evidence that there has been a rigorous analysis of the potential for harm arising from the use of GMOs and so the presentation of the options in the consultation cannot be relied upon.
3. Evidence shows that public attitudes to GMOs in the UK are sceptical at best. Whilst there is not complete opposition to their use, acceptance is predicated upon there bringing a public benefit and a robust regulatory regime.

The second part of our submission, relates to the issues associated with GMOs and the implementation of the ELD and questions framed in section 3 of the consultation document. GeneWatch's main points are that:

1. The scope of biodiversity falling within the scope of environmental liability laws should match the scope of that within the relevant environmental risk assessment legislation for GMOs. This would include all SSSIs, biodiversity action plan species and other natural ecosystems.
2. The permit and state of the art defences should not be allowed for GMOs or liability will become fault based not strict.
3. The use of GM animals and plants (not just microorganisms) in laboratories or other contained facilities should be included within the scope of strict liability for consistency with UK law.
4. The biotechnology industry should be brought within the scope of legal and financial liability, not only the users of end products.
5. Those with liability for GMOs should be required to have financial safeguards in the form of compulsory insurance.

A. General points

1. *Minimal transposition is not appropriate and will not provide environmental protection*

In this matter, GeneWatch endorses strongly the comments made by the RSPB in their response to the consultation in relation to regulatory and economic issues.

On page 9 of the consultation it states “Scottish Ministers have considered the options and have concluded that generally they should apply the directive without enhancement”.

The following reasons are cited:

- The civil law approach is new as an alternative to regulation, enforcement and penalty and needs to be tried initially.
- The relationship between new and existing regimes is complex and should be kept as simple as possible.
- The Directive is likely to create liability in a relatively small number of cases in any year so it would be better initially to create the most basic regime to support it.
- The better regulation priority initially is to create a workable regime going no further than necessary.

However, implementing the regulations in their most basic form will not provide a simple relationship between new and existing regulations. Instead minimum implementation will give rise to a complex mix of fault based or strict liability with unclear grounds for defense “based on circumstances” likely to be decided by courts at extra cost to both business and the tax payer.

Furthermore, minimum implementation would undermine the polluter pays principle in that key habitats and species will not be covered and those operating in, by definition, more risky industries (Annex III) may not be liable.

If the polluter pays principle is not to be implemented strictly, this amounts to a public subsidy of polluting industries, will unfairly benefit some business sectors and runs contrary to Scotland’s Sustainable Development Strategy “Choosing our future”.

2. *No analysis of the potential for harm arising from the use of GMOs*

The consultation document acknowledges that the permits given under Annex III are varied and that some are “...more rigorous than others” (paragraph 62) but no exploration is made of these differences or how the Scottish Executive would approach these differences. GeneWatch is concerned that the Scottish Executive will approach GMO permits with the same view as that of the DEFRA consultation where it was stated: “Any GMO placed on the market requires a consent. There is a rigorous decision-making process including a safety risk assessment for each product. It is considered extremely unlikely that a GMO could cause land damage. However, the possibility that a

farmed product containing an undesirable gene could 'escape' cannot be excluded entirely."¹ (p97)

This neglects many important issues including that:

- *It is not only GM products that have been assessed for marketing that are covered by the ELD* and that may lead to damage to biodiversity, land or water. For example, the contained use of genetically modified microorganisms (GMMs) in factories and laboratories frequently involves the routine discharge of living microorganisms to water and land. The risk assessments for these are less rigorous than for marketing of GMOs. In addition, businesses or research institutes already having a registered centre using GM plants or animals in containment do not have to seek independent assessment if the nature of their experiments and creation of a new GMO increases the risk to the environment.
- *Experience shows that experimental releases have caused most problems to date* - experimental GMOs that are being tested in the environment are covered by the Deliberate Release Directive and thus the ELD. By their very nature, there are elements of uncertainty about their behaviour in the environment and their risk assessment is limited. The escape of genes from GM grass being grown in field trials in the USA into wild grass has already been detected.² This needs to be factored into the regulatory impact assessment particularly because GMOs may also cross national boundaries and risk assessments in Europe cannot necessarily protect against GMOs from other countries – GM fish, grass and trees are immediate and obvious examples of uncontrollable organisms. GM organisms designed to produce biologically active compounds are being tested in the environment and pose additional environmental hazards.
- *The nature of GMOs is very different from other Annex III hazardous activities* – they are living with the potential to multiply in the environment and could be difficult to contain. The Executive Summary of the UK Government's 2003 Science Review First report said that³ "No other plant breeding technique permits the incorporation of genetic material from such diverse biological sources. Inevitably this raises the possibility that some new consequences of GM plant breeding may be unexpected". Implementation of the Environmental Liability Directive is intended to prevent harm and needs to take account of the fact that experience with other technologies will be of limited use in the prediction of the likelihood of harm. This has not been recognised in the consultation.
- *Experience with GMOs is limited* – the consultation draws on experience with other activities, such as the discharge of pollutants, where there is a relatively large body of knowledge to draw upon. It is inconceivable that our knowledge about the environmental impacts of GMOs is as comprehensive as for these other activities. This introduces a much greater degree of uncertainty that should be included. The UK Government's 2003 Science Review said that "the regulatory system in the UK should continue to operate so that it is sensitive to the degree of risk and uncertainty, recognises the distinctive features of GM, divergent scientific perspectives and associated gaps in knowledge, as well as

1 Environmental Liability Directive – Consultation document on options for implementing in England, Wales and Northern Ireland Partial Regulatory Impact Assessment, Page 97, An.B.102.

² Reichman, JR., Watrud LS, Lee EH, Burdick CA, Bollman MA, Storm MA, King GA & Mallory-Smith C. (2006) Establishment of transgenic herbicide-resistant creeping bentgrass (*Agrostis stolonifera* L.) in nonagronomic habitats. *Molecular Ecology* 15: 4243-4255.

³ <http://www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-pt1.pdf>

taking into account the conventional breeding context and baselines.” However, the proposed approach to the implementation of the ELD does not appear to have done that.

2. The public want rigorous laws for GMOs

There is undoubtedly public scepticism about the benefits of GM crops and foods in particular in the UK. It is extremely unlikely that the British public would welcome anything other than strict liability for GMOs in the UK. Although there has been no specific research on this subject (this is something that could usefully have been conducted by the executive to inform the decision about where the balance of interests should lie), the findings of the Government’s public debate ‘GM Nation?’ revealed that although people were not opposed to GM in principle they wanted, among other things, ‘firm regulation’.⁴

GeneWatch believes that the Executive’s proposed approach does not meet the definition of ‘firm regulation’ because it adopts a path of minimal implementation and, through the defences it proposes to adopt and narrow scope of biodiversity to be included, will create an ineffective fault-based liability regime for GMOs that does not reinforce the existing regime as was contemplated when the European safety system for GMOs was overhauled in 2001. As such it leaves the whole system vulnerable to failure because there is no effective financial incentive for the precautionary approach to be implemented in full. This will leave the Government vulnerable to further lack of confidence in their willingness to regulate GMOs in the public interest.

Specific issues

1. The test of a significant adverse effect (Q1)

GeneWatch supports the RSPB’s comments on this subject and additionally believes that the test of significant adverse damage must be related to the specific site and/or species affected and its ability to meet a favourable conservation status. Without this approach, over time, damage at more than one site could accumulate and be much more difficult to reverse. Furthermore, the presence of a particular site and species is often of enormous significance for a variety of reasons, including social and economic. The restriction to Natura 2000 sites is not appropriate for GMOs as detailed below in relation to scope of protected biodiversity.

2. Strict and fault based liability (Q1)

The risk assessments for GMOs consider their potential for harm to biodiversity, water and land (or soil as it is referred to in this context). Therefore, the approach taken to damage should apply consistently across all these environmental ‘compartments’. GeneWatch believes that liability for harm arising from all uses of GMOs should be strict and not fault based. In relation to land, liability should be strict for all activities including all non-Annex III organisms. This is because unless this approach is adopted, the contained use of GM plants and animals would have fault based liability and that from GM microorganisms would be strict and this would conflict with the approach taken in the UK’s safety regulations. In UK law, all GMOs (not only microorganisms) were brought within the scope of regulations implementing the European Contained Use Directive.

⁴ http://www.gmnation.org.uk/ut_09/ut_9_6.htm#download

There is a risk of environmental harm (to biodiversity, land or water) if GM insects or a plant modified to produce a biologically active compound escaped from confinement in an unpredicted manner. It is illogical that any harm caused would fall within the scope of environmental liability laws if the GMO were deliberately released to the environment but not if it escaped containment.

3. Scope of biodiversity protection (Q1)

GeneWatch is opposed to limiting the scope of biodiversity protection to sites and species with international protection. This approach is at odds with the protection of the environment required for GMOs under the Deliberate Release Directive (2001/18) and the Food and Feed Regulations (1829/2003). These rules require an assessment of *all* risks to the environment, including all species (not only those sufficiently harmed already to require special protection), land and water. Therefore, for example, the use of a GMO could lead to genetic pollution of a native plant which led to its becoming a pest or to its decline, but remediation of the damage would not be required. This is even though the release of the GMO would not have been allowed if the potential harm has been predicted.

GeneWatch believes that for GMOs at least, the scope of biodiversity included has to map onto that in the national approach for assessing the risks of environmental harm. Paragraph 107 (6) of the Environmental Protection Act 1990 (Part VI) states in relation to GMOs that:

“Harm” means harm to the health of humans or other living organisms or other interference with the ecological systems of which they form part and, in the case of man, includes offence caused to any of his senses or harm to his property.”

In relation to GM crops, the UK has advanced changes to the assessment of GM crops to include both direct and indirect impacts on biodiversity which led to the farm-scale trials with GM crops and the revision of the Deliberate Release Directive in 2001. The implementation of the ELD has to be conducted in a way which is consistent with, and reinforces how existing law is being implemented. Otherwise, as the following example illustrates, a confusing, illogical and unscientific approach will be taken.

In 2001, the UK joint GMO regulatory authorities and statutory advisers, the Advisory Committee on Releases to the Environment (ACRE) said that “Given the UK Biodiversity Action Plan commitments to stop and where possible reverse wildlife declines, it is important that the risk assessment process now identifies GM crops whose use may lead to increasingly intensive agricultural management practices.”⁵ Under ACRE’s guidance, those seeking to use GM crops are explicitly asked to consider the following Biodiversity Action Plan Species that are important on arable land:

Mammals

**Brown Hare* (excluded under the Executive’s preferred ELD option)

Pipistrelle Bat

Birds

Skylark

⁵ Advisory Committee On Releases To The Environment (ACRE) 2001. Subgroup On Wider Biodiversity Issues. Guidance on the assessment of the impact on wider biodiversity from proposed cultivation of GM crops.
<http://www.defra.gov.uk/environment/acre/biodiversity/guidance/pdf/assess-guide.pdf>

*Corn Bunting (excluded under the Executive's preferred ELD option)

*Linnet (excluded under the Executive's preferred ELD option)

Grey Partridge

Song Thrush

Plants

*Tower Mustard (*Arabis glabra*) (excluded under the Executive's preferred ELD option)

*Cornflower (*Centaurea cyanus*) (excluded under the Executive's preferred ELD option)

Therefore, in this example, of the nine species identified by ACRE as requiring consideration to ensure commitments to BAP species are met when assessing GM crops, five would not fall within the scope of the implementation of the ELD under the Scottish Executive's proposals. This means that the additional precautionary intention of environmental liability laws would not be available to back up the risk assessment process.

This example relates to GM crops only and GMOs is a much wider category. Therefore, the broad approach to biodiversity adopted in the GM environmental protection regulations should be adopted with guidance for different categories of organism.

4. Land and water damage (Qs 2 and 3)

GeneWatch endorses the response of the RSPB. However, in relation to land damage, GeneWatch believe this should not be limited to risks that pose a threat to human health alone. Environmental harm to soil should also be included. This is needed to bring consistency with the risk assessment of GMOs under the Deliberate Release Directive and Food and Feed Regulations.

5. The permit defence (Qs 4,5 and 6)

GeneWatch does not believe that the permit defence should be allowed for GMOs and supports the Welsh Assembly Government in the position it has taken. The practical effect of the permit defence, especially in combination with the state of the art defence, is to make strict liability fault-based. This is because it is only when an operator did not have a permit or did not comply with the permit that it would be considered liable.

For GMOs, there are compelling reasons why the permit defence should not be allowed. In particular, and in contrast to many other Annex III activities, the permit for the use of a GMO may (for marketing consents at least) be general and not site specific. In fact, it may be Europe wide, data on environmental safety may have been collected in other countries and the UK may have voted against a marketing consent on safety grounds and have been overruled because of the qualified majority voting procedure for GMOs in Europe (this was the case in relation to UK human safety concerns over Bt176 maize).

The permit defence also places considerable burdens on the authorities to demonstrate that an operator had been at fault or negligent. This can be onerous, especially if relatively long periods of time elapsed between the use of a GMO and harm arising. The broad, permissive nature of GMOs consents and limited policing once a marketing consent has been granted, could render environmental liability an hollow concept for GMOs.

6. The state of knowledge defence (Q 7)

GeneWatch believes that allowing the state of knowledge defence is dangerous for the advancement of scientific knowledge because it will be advantageous in terms of future

liabilities to remain ignorant of possible future harmful effects of GMOs. The incentive, in terms of environmental impact, will be to know as little as possible, not as much as possible. Absence of evidence is not evidence of absence of potential harm, yet this is the climate that would emerge if the state of knowledge defence is allowed.

7. Time limit (Q4.5)

GeneWatch does not believe that there should be a 30 year time limit to environmental liability for GMOs. This is because harm may not become evident for many years – for example, following the introduction of some exotic species some 40 or 50 years have passed until their adverse environmental effects were detected. Whilst it may become more difficult to locate operators following long periods of time, the possibility should not be lost. Furthermore, if liability for very long-term effects is not within the scope of environmental liability rules, the incentive to avoid such effects will not be present.

8. The operator (Q 8)

GeneWatch wishes to raise the question of who the ‘operator’ should be in relation to the use of GMOs. GeneWatch understands that in the case of GM crops this is the farmer, or with GM vaccines this will be the doctor or veterinarian. Whilst GeneWatch appreciates that the end user of a product should take some responsibility for it, we believe placing all the liability on the end user is inappropriate. It would be exceedingly difficult and expensive for an end user to take proceedings against a biotechnology company that produced the GMO, even though it was the company who was responsible for obtaining the permit, promoting the product and so on and will have profited from sales.

In addition, if the operator is the final end user it will be difficult to attribute harm to one operator or another if, for example, a GMO developed into an invasive pest over many years – records are unlikely to exist on who used what and when. However, the permit holder for a particular GMO that may cause damage will be much easier to identify because each GMO has a unique identifier and this is linked into the permit system. Therefore, GeneWatch considers that in the case of GMOs that the permit holder or developer of a GMO should be the ‘operator’ for purposes of environmental liability. The biotechnology company can have contracts with the end users of products so that they can claim if products are not used appropriately.

9. Compulsory insurance

The issue of ability to pay for remediation is not addressed in detail in the consultation document. GeneWatch believes that whoever the ‘operator’ is deemed to be, that there should be a requirement for them to have insurance cover for remediation of environmental damage. Without this, companies may be able to use a variety of tactics to avoid liability and may simply become insolvent and remediation costs not be recoverable in full. Compulsory insurance would protect against this risk.

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