



Environmental Liability for damage caused by GM organisms: bringing the European Directive into national law

In April 2004, the European Union agreed a Directive on Environmental Liability (2004/35) which member states have to implement in national law by April 2007. The stimulus for the Directive was the continuing problem of biodiversity loss and the environmental damage that has arisen from industrial and other activities in the past, the costs of which have fallen on the public with those responsible for the harm taking no responsibility.

The intention of the Directive is to provide for payment for remediation (putting things right) after damage has occurred and so to implement the 'polluter pays' principle. It also aims to prevent environmental damage arising by requiring companies to take preventive measures and by providing strong incentives to prevent damage. The possible costs if harm does occur should make people think more carefully about how they act. The Directive covers many activities including GM organisms both when released into the environment (e.g. growing GM crops) and if used in laboratories or factories (e.g. to make enzymes from GM microbes). If environmental damage takes place as a result of using a GM organism, the company or person responsible should have to pay the costs of remediation.

The Directive forms a base for national laws and the fundamental principle of the Directive is to ensure that operators whose activities have caused environmental damage are held legally and financially liable. There are many areas where the Directive is unclear. It is important that the national implementing laws should clarify such areas, in particular in relation to a number of key issues (discussed below). It should be noted in this context, that implementing regulations can be more stringent and that the Environmental Liability Directive expressly states that its implementation and enforcement should be effective. Therefore, implementing laws, which added certainty and clarity, would comply with the Directive, even if they were more stringent. However, if this is not achieved, there is a danger that any new laws could prove to be completely ineffective in holding companies or institutions to account for any environmental damage that may arise from the use of GM organisms.

This briefing describes the main features of the Liability Directive in relation to GM organisms, identifies the areas where the Directive may prove to be ineffective and suggests ways in which national laws could improve the situation and give some teeth to environmental liability in relation to GM issues. It is intended to help people in influencing Governments as they build the Liability Directive into national law to get the strongest environmental protection possible.

Main features of the Environmental Liability Directive

The Environmental Liability Directive (ELD) covers environmental damage to:

- Biodiversity – but this is limited to protected species and habitats (under the 1979 Birds and 1992 Habitats Directives) where there is a significant adverse effect on reaching or maintaining a favourable conservation status. When damage to biodiversity occurs, an operator would be required to return the environment to the baseline condition.
- Water – where this is damage that has a significant adverse effect on the ecological, chemical or qualitative status of water as defined by the 2000 Water Framework Directive. When damage to water occurs, an operator would be required to return the environment to the baseline condition.
- Land – where damage from chemicals, organisms or micro-organisms contamination creates a significant risk of adverse effects on human health. When land damage occurs,

the operator has to remove any significant risk to human health.

There are two classes of activity which are subject to the provisions of the Directive which have different types of liability applied to them:

- Annex III activities – these are the potentially hazardous activities listed in Annex III to the Directive and include the deliberate and contained use of GM organisms. For these activities, where damage to biodiversity, water or land occurs, the operator conducting the activity is said to be ‘strictly’ liable. This means they do not have to have been negligent or at fault in any way to be required to pay for remediation. However, Member States can introduce provisions to exempt operators from having to pay for the restoration of environmental damage if they were operating under certain permits or according to the state of scientific and technical knowledge at the time the damage took place (and they can prove they were not at fault or negligent).
- All other activities – for biodiversity damage, operators have fault based liability so have to be shown to be at fault or to have acted negligently. There is no liability with respect to water and land damage.

Having liability requires operators to undertake:

- **preventive action without delay** – where there is imminent danger of harm arising;
- **immediate clean up and control** – to manage and limit the extent of damage;
- **long-term remedial action** – which, in the case of water and biodiversity, may be at the site affected or, where this is not possible, compensatory action at another site. There may also have to be compensatory action to make up interim losses. For land damage, removal of the risk to human health is all that is required.

In each Member State there will be a ‘competent authority’ responsible to the operation of the Directive. In the UK, this is likely to be Natural England in relation to GMOs, in combination with certain other authorities, e.g. local authorities. The competent authority can require that an operator takes remedial action as outlined above, or undertake the work itself and recover the costs later. Affected persons and non-governmental organisations (NGOs), with an interest in environmental protection (such as the RSPB or Bird Life International), can make a request for action to the competent authority by providing evidence of environmental damage. An NGO cannot take an operator to court to establish liability although they can challenge the competent authority’s decision not to act.

Shortcomings, confusion and possible loopholes

This section relates to the problems of establishing liability in the case of harm arising from the deliberate release or contained use of GM organisms. Similar and additional problems may arise in relation to other non-GM activities, but are not considered here. Scenarios are described to illustrate the problems.

Who is the operator?

The ‘operator’ is the person or entity (such as a company) that is considered responsible for causing the environmental harm and is thus liable for it. Under Article 2(6) of the Directive, the “operator” can mean “any ... person who ... controls the occupational activity or, where this is provided for in national legislation, to whom decisive economic power over the technical functioning of such an activity has been delegated”. Being clear about who this means is crucial if action is to be taken. Because the use of GM organisms will usually be a so-called Annex III activity, there is some possible confusion when it comes to liability for any harm that might arise from growing GM crops – will it be the biotechnology company or the farmer growing a GM crop?

An Annex III activity means that what is taking place is an activity regulated by certain EU Directives listed in Annex III. In relation to GMOs, activities subject to the Deliberate Release Directive (2001/18) and the Contained Use Directive (90/219/EEC) are caught as Annex III activities.

For a GM crop, a license will have been given under the Deliberate Release Directive (2001/18) to **market** the crop. This license will be given to the biotechnology company who developed the crop. However, it is likely to be the growing (not the act of marketing) the GM crop that actually causes any eventual environmental harm. **In this case, it could be the farmer not the biotechnology company who is considered to be the operator and held liable for the damage**, unless it is decided that “decisive power over the technical functioning of such an activity has been delegated” to the biotechnology company. If it is the farmer who is held liable, he will not have carried out an Annex III activity. This means he cannot be held strictly liable for any environmental damage caused. He can only be held liable for biodiversity damage if he was at fault.

Exemptions from clean-up obligations

On the face of it, under the ELD, there should be strict liability for environmental harm arising from the use of GM organisms – fault or negligence should not have to be established. However, the Directive allows Member States to make provision for exemptions from the obligation to pay for clean-up based on whether a permit under an Annex III Directive has been granted for the activity or that the harm could not have been predicted from the state of scientific knowledge at the time the activity took place.

It is possible that companies would only be held liable for any environmental harm arising from the use of GM organisms under very limited set of circumstances e.g where:

- they did not possess the requisite authorisation; or
- if the state of scientific and technical knowledge at the time of the authorisation or the damage indicated that damage was likely; or
- they have been at fault or negligent; or
- they are unable to demonstrate that they have complied with their authorisation, operated according to the state of the art, or have not been at fault or negligent.

Legally, to be “at fault”, the GM company would have had to act carelessly, recklessly or intentionally in causing the damage. To be negligent, very roughly speaking, the operator would have had to have failed to take reasonable precautions to avoid causing reasonably foreseeable harm. This would generally only be the case:

- in the unlikely event that the damage was unanticipated but reasonably foreseeable, e.g. because it was simply not considered in the risk assessment;
- one or more assumptions in the risk assessment leading to the authorisation of the GMO were faulty and/or the risk assessment was not carried out properly or with the appropriate amount of care and this was not detected during the licensing process;
- instructions on use of the GMO (e.g. cultivation of GM seed) were unclear or insufficient;
- the GM company deliberately or carelessly falsified the risk assessment or omitted certain data.

If the permit and ‘state of the art’ exceptions are included in national laws, the difficulties in making companies pay for cleaning up environmental damage they have caused as a result of the use of a GM crop or other organism are likely to be enormous. Companies are likely to argue that by gaining approval for GM crops they should not have to pay for environmental damage.

The ELD shifts the burden of proof onto the operator to show that one of the exceptions applies in his specific case. However, the usefulness of this will depend on what level of proof is required and what is considered to be the state of the art in relation to scientific knowledge at the time.

Scenario: a GM virus damages protected biodiversity in a completely unexpected way

A GM virus is developed and approved for release to control certain insect pests. Extensive testing indicates that the host range is restricted to the targeted insect pest species and that modifications to the virus making it temperature sensitive ensure that multiplication and dissemination in the environment cannot take place. Several years after it has been used successfully in biological insect control systems (where it is applied annually), it is discovered that the virus has hybridised with another virus and the resulting virus is now able to disseminate, infect and kill a much wider range of species including the larvae of some butterflies. In certain areas of the UK, where the GM virus was used close to certain nature reserves, populations of butterflies are in decline as a result. Research shows that a mutation in the GM virus allowed the hybridisation to take place. No data available at the time of the approval indicated that this would take place.

Liability under the Directive – the release of a GM virus is an Annex III activity under the ELD and strict liability should apply. Because the reserve and butterfly species were protected, they come within the scope of the ELD. However, the virus did have a license and because the event was unanticipated, the company will argue that it should not contribute to remediation costs. It is also possible that the farmers using the product, not the biotechnology company, who marketed the crop are considered liable.

Changes to National Law needed – the ‘state of the art’ and permit exemptions should not be adopted in National laws. Clarity is needed that it is the biotechnology company that will be liable for environmental harm, not farmers using their products to agricultural ecosystems.

Scenario: GM crop causes unanticipated damage to agricultural ecosystems

A GM oilseed rape crop is developed which has an altered oil profile to making the oil extracted from it more ‘healthy’. There is not thought to be any human or environmental health concerns associated with the new oil as it is safe to eat. Although the oilseed rape can hybridise with some wild related plants, this is considered to be a rare event and that there will be no competitive advantage given by the trait so hybrids will not persist or cause problems. After growing the GM oilseed rape for some time, it is discovered that feral populations of oilseed rape are becoming more widespread and invasive and that new populations of oilseed rape/wild turnip hybrids have become established and are causing weed problems for farmers. The ecology of some areas is being altered as a result. It is subsequently found that the altered oil profile affects seed germination characteristics, enabling both volunteers and hybrids to compete more successfully.

Liability under the Directive – the release of the GM oilseed rape is an Annex III activity under the Directive and strict liability should apply. However, because the plants and ecosystem affected are not listed under the Habitats Directive or are not habitats used by protected species, they do not fall within the scope of the ELD.

Changes to National Law needed – the definition of damage should be widened and made consistent with the scope of assessment under the Deliberate Release Directive and National assessments.

Biodiversity - limited land and species protected

In relation to biodiversity (the plants, animals and micro-organisms in the environment), the ELD is very restricted in what is within its scope. GM organisms could harm biodiversity, for example, as a result of gene transfer to a wild species or as a secondary consequence of changed farming practice and altered herbicide or other chemical use. However, if the Directive is implemented as is, only protected habitats and species would be covered. This would not include the large majority of species of plants or birds or the majority of agricultural habitats and land. It may not even include all SSSIs (Sites of Special Scientific Interest) in the UK.

The restriction of harm to protected species and habitats that is seen in the ELD is not consistent with the approach taken in the Deliberate Release Directive, where the requirement to avoid harm is much wider. It is also likely to be inconsistent with national approaches to GMOs. For example, the UK's Environmental Protection Act (EPA) Parts IIA and VI protects species and habitats, including ecosystems, and risk assessments by the UK's advisors on GMOs also include a much wider range of species to be assessed.

Scenario: risk mitigation plans do not function as expected and bird populations affected

A GM herbicide tolerant sugar beet is developed and a management scheme is introduced to ensure that a certain level of weed growth is allowed to provide seed for farmland birds without compromising crop yields. The system involves applying the herbicide at certain times and leaving a small proportion of the field unsprayed. Both the GM seed and the herbicide contain instructions directing farmers to use the products in this way. Over time, it is discovered that certain populations of farmland birds, including the Biodiversity Action Plan species, the skylark, are not recovering population numbers in areas where GM sugar beet is widely grown and declines are being experienced in certain localities. Investigation shows that farmers have found the management systems to be inflexible and have adapted them particularly because there have been a series of very wet springs when getting machinery onto land at the appropriate time was difficult. Therefore, weed seed supplies for farmland bird life have declined rather than increased as the management plan promised.

Liability under the Directive – the release of the GM sugar beet is an Annex III activity under the Directive and strict liability should apply because protected species were involved. However, because the release had a license and the approved management plans were not followed, the company will argue that they should not have liability. They will also argue that the scientific knowledge at the time considered harm would not arise. It is also possible that the farmers using the product, not the biotechnology company, who marketed the crop are considered liable.

Changes to National Law needed – the state of the art and permit exclusions should not be included. Clarity is needed that it is the biotechnology company that will be liable for environmental harm, not farmers using their products, unless farmers acted negligently.

Land damage

The Environmental Liability Directive restricts land damage to situations where there are risks to human health. GM organisms could cause environmental damage to land if toxins were released from the roots of plants that affected soil fertility or GM micro-organisms in the waste from factories could also disturb normal soil function. However, such harm would fall outside the basic provisions of the Directive.

Scenario: GM micro-organisms and environmental land damage

Waste from a factory using GM micro-organisms to produce enzymes for industrial purposes is used as a manure on agricultural land, particularly grassland. The waste is inactivated before being spread on the land and the organisms are not considered able to become established in the environment or cause harm if they did. Waste treatment also partially, but not completely, degrades the DNA in the waste. However, over time, horizontal gene transfer takes place either from organisms that become established or through uptake of naked DNA and a population of organisms that produce the enzyme becomes established. The enzyme damages the roots of some grass species and the land becomes unusable.

Liability under the Directive – the use of GM microorganisms is an Annex III activity under the Contained Use Directive and strict liability should apply. However, the factory will have been notified to the authorities as using low-risk Genetically Modified Micro-organisms (GMMs), and therefore could claim the permit exemption or argue that based on current scientific knowledge that the harm was not considered possible. Because the damage to land was ecological, and not a risk to human health, it would not fall under the liability provisions for land damage in the Directive.

Changes to National Law needed – the 'state of the art' and permit exemptions should not be adopted in National laws. Harm to land should be extended to include ecological or environmental damage or brought in line with existing contaminated land legislation.

Scenario: land damage from a GM crop

A GM potato and several other crops are developed which contain a toxin to kill insect pests feeding upon them. The host range of the toxin is restricted to the pests but may also affect some soil invertebrates. However, expression of the toxin is restricted to the green tissues of the crop, not the roots, and experimental trials did not detect any adverse effects on soil flora or fauna. When the crops have been grown for many years, it is discovered that soil fertility is declining in some sites where several of the same family of GM crops have been used in the rotation. It is discovered that the presence of the toxin in the soil has built up over time where plant residues have not been removed from the fields but incorporated into the soil after harvest of the crop [there were no guidelines that suggested that farmers should not do this]. The build up of toxin has damaged the invertebrate population, especially earthworms, and led to the declines in fertility. Although the sensitivity of some soil organisms to the toxin was known, it was not considered that levels would be high enough to cause damage or that invertebrate levels would affect soil fertility.

Liability under the Directive – the release of a GM crop is an Annex III activity under the Directive and strict liability should apply. However, the GM crops did have marketing consents and therefore could claim the permit exemption or argue that based on current scientific knowledge that the harm was not considered possible. Because the damage to land was ecological, and not a risk to human health, it would not fall under the liability provisions for land damage in the Directive.

Changes to National Law needed – the ‘state of the art’ and permit exemptions should not be adopted in National laws. Harm to land should be extended to include ecological or environmental damage.

Water damage

Damage to aquatic ecosystems as result of the deliberate or contained use of GM organisms should fall within the scope of the Environmental Liability Directive although exemptions could limit the protection (see below).

GM fish displace native species

A GM salmon is developed which grows more rapidly than non-modified salmon and is also modified so it will not breed with wild salmon. The fish are approved for use in fish farms in Canada, the USA and Norway, under their own GM regulations. Over time, some of the salmon escape from the sea cages and are found coming to rivers in Scotland. The fish do not cross with UK native salmon, but their aggressive behaviour and large size leads to the displacement and then replacement of the local fish.

Liability under Directive – aquatic ecosystems fall within the scope of the Directive and GM fish would be an Annex III activity if they were to be produced in sea cages under the Deliberate Release Directive. However, it is not clear how their escape from different jurisdictions, where they were licensed, would affect liability. It is worth noting, that within the EU, the ELD imposes certain duties in relation to information exchange in cases of transboundary damage, and, more importantly, it also gives the Member State in which the damage has taken place the right to seek to recover the costs it has incurred on preventive and remedial measures.

Improvements needed – international liability laws are required as part of the Cartagena Biosafety Protocol, but Member States could make it clear that such a transboundary movement would be considered negligence.

Are all GMOs fully covered?

For GMOs, damage caused by any contained use involving genetically modified micro-organisms as defined by the Contained Use Directive or by any deliberate release, transport and placing on the market as defined by the Deliberate Release Directive falls within the ELD provisions for strict liability. These are the ‘Annex III activities’. Other uses of GMOs are covered by fault-based liability to biodiversity only.

Many GM crops and foods intended to be used for food and animal feed in Europe are not evaluated under the Deliberate Release Directive but under the Food and Feed Regulations (1829/03). Although there are connected definitions in the Deliberate Release Directive and these other approval processes, there are some differences. So it is unclear whether the Food and Feed Regulations would be seen as a part of the Deliberate Release Directive and therefore

an Annex III activity or whether there could be a loophole in the laws.

Another area where there is clearly a gap in the scope of the Liability Directive in relation to GM organisms, is the use of GM plants and animals in laboratories or other contained facilities. The Contained Use Directive only applies to GM micro-organisms, not plants and animals. So if a GM insect escaped from a laboratory and no negligence or fault could be proved, no one would be liable if any environmental harm arose.

Scenario: experimental GM crops

Experiments are being conducted in greenhouses with oilseed rape crops that express novel proteins making them more resistant to disease. These are still in the early stages of development but no toxicity issues are expected. Pollen escapes either on the wind or via insects when ventilation has to be increased because of an exceptionally hot summer. Cross pollination of oilseed rape crops and feral populations of oilseed rape growing near by, takes place. The novel proteins gives the feral populations a significant competitive advantage in the following season when an outbreak of disease occurs. The feral oilseed rape is then able to invade new ecosystems.

Liability under Directive – ‘contained use’ of GM plants and animals is not an Annex III activity. Liability would only be for damage to protected species if negligence proven.

Improvements needed – national laws should include the ‘contained use’ of GM plants and animals under strict liability provisions and extend biodiversity protection to be consistent with the scope of the environmental risk assessment of GMOs in national and European law.

Scenario: GM insects in a greenhouse

Trials are being conducted in a greenhouse with genetically modified leaf feeding beetles which it is hoped might be used to control invasive rhododendron. The insects have been modified in various ways to increase their survival and are being tested to establish what kinds of plants they will feed on. Safety precautions to prevent their escape include the construction of the greenhouse and genetic modification intended to make the insects sterile. Despite the precautions, which complied with all guidelines, some of the insects do escape and breed. The beetles prove to be damaging to a wide range of plant species and cause extensive damage to natural habitats.

Liability under Directive – ‘contained use’ of GM plants and animals is not an Annex III activity. Liability would only be for damage to protected species and habitats if negligence proven.

Improvements needed – national laws should include the ‘contained use’ of GM plants and animals under strict liability provisions and extend biodiversity protection to be consistent with the scope of the environmental risk assessment of GMOs in national and European law.

Opportunities to strengthen laws at a national level

The important fact is that Member States can go further than the ELD in their national laws, so there are some real opportunities to make clarifications and close loop-holes in the interests of environmental protection. To give environmental liability laws real purchase in relation to GMOs the following is needed:

GM companies (not farmers) to be responsible: Holders of GM marketing or experimental release consents (i.e. the biotechnology company) should be deemed to be the party responsible for any environmental damage caused by the GMO, unless the person who directly caused the damage, e.g. a farmer, acted negligently.

Making liability strict in practice: The permit and state of the art exceptions should not be introduced into National law. This is especially important for GM organisms due to the nature of the underlying scientific uncertainty, legal, practical and ethical issues particularly in the light of skeptical public opinion. Consents to release GM organisms are usually on a Europe wide basis and may fail to consider properly locally important populations of plants or animals. If permit and

state of the art exemptions are allowed, then courts should have the discretion to decide whether they should be allowed, on a case-by-case basis and the burden of proof on the company to show that an exemption applies should be “beyond reasonable doubt”. The state of the art exception in relation to the knowledge available at the time, should expressly include a precautionary approach.

Protecting the whole environment: In relation to GMOs only, the scope of the protection of biodiversity must be made consistent with existing national and European GMOs laws and be extended to cover a wider definition of biodiversity, if necessary. Many species, such as the skylark, linnet and brown hare, only became protected once degradation of the agricultural environment had become so severe that this status was required to prevent further decline. Maintaining and improving the agricultural environment as well as the natural environment is important in biodiversity protection as a whole. The UK Government’s Biodiversity indicators reflect this importance of the agricultural environment by including criteria such as ‘the extent and condition of farmland habitat features in England’ and ‘Trends in plant diversity in fields and field margins in England’. The ELD must be consistent with national approaches to protecting biodiversity. Land damage must include environment harm, not only risks to human health.

Ensuring no GMOs fall through the net: It must be made clear that if GMOs are licensed for marketing under any legislation (such as the Food and Feed Regulations), rather than the Deliberate Release Directive, these must clearly fall with the scope of the liability laws. Liability laws need to include GM plants and animals used in containment, not only GM micro-organisms.

Transboundary effects – the need for international liability laws: Because some GMOs may have the ability to cross national boundaries and be exceptionally difficult to contain (for example fish or the pollen from grass and trees), clarification is needed in relation to how damage arising in such cases will be considered. A permit in the country of origin should not be considered a defense and strict liability should apply. The European Community should also seek to progress liability negotiations as part of the Cartagena Protocol on Biosafety.

Conclusions

Member States will have to go further than the ELD if there is to be any realistic chance of companies being required to pay for remediation of any environmental damage arising from the use of GM organisms. Ensuring that more of a state’s environment is within the scope of the laws and consistent with GMO legislation more generally, and that a European wide permit cannot be used to argue against liability for environmental harm in one area, are particularly important issues. Industry is likely to lobby strongly against such environmental safeguards, but if they are confident in their products and the risk assessments that are undertaken, they should not have concerns. If they are not confident, why should the environment suffer and the public pay the cost of trying to put things right? As the hypothetical, but plausible, scenarios in this briefing show – if the ELD is implemented by Member States as it exists, the likelihood of biotech companies contributing to remediation in the case of harm arising, is extremely remote.

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