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A precautionary approach to genetic modification

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Abstract European Council directive 2001/18/EC will establish a new legal regime for the deliberate release of genetically modified organisms (GMOs) into the European environment, whether as products, as crops or for research. The new regime will be in place in the UK by October this year, and while the basic process for approvals is similar to the existing system there are many new features. Among these is a requirement that the EC member states take the 'Precautionary Principle' into account when implementing the new directive. Recently the European Commission has attempted to define more clearly the relevance and meaning of the Precautionary Principle. It has also been briefly considered by European and English courts. This paper considers these developments as well as the possible effect of the Precautionary Principle on decisions about GMO releases, and on consumers' expectations for GM products.

Keywords: genetic modification, GMO, Precautionary Principle, 2001/18/EC, Environmental Protection Act 1990

Introduction

On 12th March, 2001, the European Parliament and Council adopted a new directive (2001/18/EC) governing deliberate releases into the environment of genetically modified organisms (GMOs). The new directive is intended to increase the transparency and consistency of decisions on GM crops, foods and other products in the EU. Significantly, member states must implement it 'in accordance with the Precautionary Principle'.

The new directive

The new directive will replace a 1990 directive (1990/220/EEC), which was implemented in this country by part VI of the Environmental Protection Act 1990. The new directive will require amendments to the Act. Firms that were authorised to release genetically modified organisms

(GMOs) under the 1990 directive must re-apply under the new one by 2005, although in the meanwhile their authorisations will continue. The implementation deadline is 17th October, 2002, and the Department of the Environment, Food and Rural Affairs is expected to begin drafting the amendments shortly, following public consultation.

Both directives define GMOs and require member states to regulate their deliberate release into the wider environment, whether as manufactured products, as agricultural crops or for research. Each state must designate a 'Competent Authority' (in this country, the Secretary of State for the Environment), to consider applications to release or market GMOs. Persons wishing to release or market an unauthorised GMO must apply to the Competent Authority in the state where the GMO is first to be placed on the market. The application must include certain detailed information, including an environmental risk assessment.

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The Competent Authority must assess the application and either grant or withhold permission for the GMO to be marketed. In either case it must also forward the application to the European Commission which must in turn forward it to all the other member states. Either they or the Commission itself may object to a decision by the Competent Authority to grant the application. Where these objections cannot be resolved by mediation, a committee of member state representatives may make the final decision, subject to mandatory consultation with the Commission's scientific committees.

Among other changes, the new directive standardises the labelling requirements and risk assessment methods for products containing GMOs. It introduces post-release monitoring requirements for approved GMOs and greater requirements for public consultation, and requires member states to maintain a public register of the locations of GM crops. It also introduces a new requirement that 'Member states shall, *in accordance with the Precautionary Principle*, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs' (Article 4(1); italics added).

The objective of the directive is 'to approximate the laws . . . of the Member States and to protect human health and the environment' when releasing GMOs or placing them on the market, and this objective is to be applied 'in accordance with the Precautionary Principle' (Article 1). Similarly, the principle 'must be taken into account' when implementing the new directive (Recital 8).

While it remains to be seen how these requirements will be applied in the amendments to the Act, they may make the marketing or release of GMOs more difficult and uncertain. That would seem to be at odds with the current policy of the European Commission. A recent policy paper by the Commission stated that the new directive will help 'to overcome the present standstill in authorising new [GMO]

products',¹ a de facto political moratorium stemming from consumer concern which has prevented the authorisation of any new GMO releases in the EC for almost five years. The paper also recommended accelerating proposals for further new legislation on traceability and labelling of GMOs and foods derived from them, and for monitoring their environmental effects.² Under the new directive the Commission apparently envisages more GMO releases, not fewer.

The Precautionary Principle

The Precautionary Principle ('the Principle') was defined in the 1992 Rio Declaration by the UN Conference on Environment and Development as follows:

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

In other words, 'better safe than sorry'. Article 174(2) of the EC Treaty provides that EC environmental policy is to be based on the Principle. This provision was introduced in 1993, and is the only explicit mention of the Principle in the EC Treaty.

There is still no authoritative statement of the Principle in treaties or international law. However, in February 2000 the European Commission issued a Communication containing guidelines for its application.³ While the guidelines are not legally binding, they may affect both the amendments to the Act to implement the new GMO directive and decisions on specific GMOs.

The Communication explained that although the Principle is explicitly prescribed in the EC Treaty only as regards environmental protection, in practice it is also applicable to other policy areas potentially affecting health, such as food and product safety. It may apply in situations where potential hazards have been identified but where scientific evaluation does not yet allow those risks to be determined with sufficient certainty. In these circumstances, the Principle is relevant

to *political* decisions about what is an acceptable level of risk for society and how that risk should be managed, particularly where the level of risk cannot be clearly determined. By contrast, it is not relevant to the *scientific* assessment of risk, and it should not be confused with the caution that scientists apply in their assessment of scientific data.

The guidelines recommend that implementation of a precautionary approach should begin with a scientific evaluation identifying the degree of uncertainty. Any measures taken based on the Principle, such as restrictions on the release of GMOs, should be *proportional* to the level of protection required, *non-discriminatory* in their application, *consistent* with measures taken in equivalent areas, based on consideration of all the potential *benefits and costs*, and *subject to review* in the light of new evidence.

Applying the Precautionary Principle

While several decisions of the European Court of Justice (ECJ) have considered the circumstances in which the Principle may properly be applied,⁴ there has been less focus on its potential to affect the substantive outcome of regulatory decisions. However in the 1998 BSE case⁵ the ECJ found that a single dissenting opinion from a member of a scientific committee could suffice to demonstrate scientific 'uncertainty', which the European Commission guidelines later identified as a precondition for the application of the Principle.

Nor has the Principle yet been comprehensively evaluated by a UK court. However the 1995 Court of Appeal case of *Duddridge*⁶ suggests that the Principle could potentially lower the threshold of risk required for a decision maker to restrict an activity or the release of a product such as a GMO.

The sole issue in *Duddridge* was whether the Secretary of State had acted lawfully in refusing to take action under the Electricity Act 1989 to limit the levels of electromagnetic

fields generated by electric cables laid near the applicants' homes. All parties accepted that the Secretary was required to act to protect the public from any risk of injury arising from the cables. It was also agreed that while the expert evidence did not currently establish that there was such a risk, nor could it be dismissed. The applicants claimed that, in deciding whether to act, article 174(2) of the EC Treaty (mentioned above) required the Secretary of State to apply the Precautionary Principle if there was evidence of a *possible* risk.

The Court of Appeal rejected this claim, finding that article 174(2) did not impose any direct obligations on the Secretary of State and that the Principle was therefore inapplicable. However the High Court had earlier found that had the Secretary been under a legal obligation to apply the Principle then the possibility of a risk raised by the expert evidence would have been sufficient to justify its application, even though no actual risk had been identified. The Court of Appeal did not dissent from this finding.

The effect on GMO releases

Most of the authorisations for GMO releases under the 1990 directive were given by the European Commission notwithstanding objections from one or more of the member states on the grounds of the possible effects on the environment or human health. While in some of these cases the Commission subsequently found that there was 'no reason to believe that there will be any adverse effects on human health and the environment' from the GMO in question,⁷ in several others it was less emphatic, concluding that the potential risks were 'not expected to be significant'.⁸ It is questionable whether decisions in this latter category are consistent with the precautionary approach required by the new directive and considered in the BSE decision and *Duddridge*.

Civil liability

The new directive is not directly concerned with civil liability for the effects of GMOs on

consumers' health or the environment, although it refers to forthcoming EC legislation that will govern liability for environmental damage resulting from both GMOs and more conventional causes.⁹

In the UK, civil liability for injury suffered by consumers of defective products is governed by the Consumer Protection Act 1988 ('the CP Act'), which implemented the EC Product Liability Directive 85/374 ('the PL directive'). As a recent UK case has confirmed,¹⁰ products that do not provide the level of safety that consumers are entitled to expect are classed as defective under the CP Act and PL Directive. The producer is liable for any injury which those products cause, regardless of fault. He or she may escape liability if he or she can show that 'the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the effect to be discovered' (PL directive article 7(e)). However to qualify for this defence he or she must show that no objectively accessible scientific or technical information existed worldwide which would have enabled the defect to be discovered. This requirement could well prove insurmountable for the producer of a defective GM product.

It is not yet clear whether the application of the Precautionary Principle to decisions on GMO releases will influence UK Courts' interpretations of legitimate public expectation for the safety of GM products under the CP Act and PL Directive. Requiring regulators to adopt a precautionary regime specifically for GM products may help to create a public expectation that products approved under that regime are free of any possible risk. A GM product presenting even a slight risk to health could fail to meet this expectation, thus exposing the manufacturer to liability for any effects on the consumer.

Comment

The Commission's Communication on the Precautionary Principle helps to clarify the purposes for which the Principle may

validly be used. However it does not answer the criticism that a precautionary approach by regulators effectively duplicates the prudence already exercised by scientists in evaluating scientific data. Nor does it clarify what level of risk suffices to invoke the principle and so serve as a basis for restriction.

The application of the Principle to decisions on GMO releases itself represents a substantive decision to protect the consumer, not only from actual risks associated with GMOs but also from any possible risks. That decision reflects a growing risk aversion among consumers, already heightened by the series of recent threats to public health arising from problems allegedly caused by increasingly 'industrial' approaches to food production. It may affect both consumers' expectations regarding their own safety and manufacturers' liability if those expectations are not met.

The potential effects of GMOs on the environment and on human health remain the subject of public concern and scientific debate. The BSE decision and the High Court's comments in *Duddridge* suggest that applying the Principle in such situations could affect the substantive outcome of decisions. Whether the amendments to the Act resulting from the new directive will tilt the balance against the authorised release of GMOs remains to be seen. The outcome will be relevant not only to GMOs but also to other areas of health and environmental policy where regulators must make decisions in the absence of scientific certainty.

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References

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2. 'Life Sciences and Biotechnology - a Strategy for Europe', 23.1.2002 Com (2002) 27, pp. 31-32.
3. Comm (2000) 1.
4. For instance *United Kingdom v Commissioner of European Communities* [1998] ECR I-2265; *Pfizer Animal Health SA/NV v Council of the European Union* [1999] ECR II-1961; *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-5681; *Eurostock Meat*

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5. *United Kingdom v Commissioner of European Communities* [1998] ECR I-2265.
 6. *R v Secretary of State for Trade and Industry, Ex Parte Duddridge and Others* [1996] Env L.R. 325.
 7. For instance European Commission Decisions 96/158/EC of 06/02/1996 (regarding marketing of herbicide-tolerant swede-rape seeds); 96/281/EC of 03/04/1996 (marketing of herbicide-tolerant soya beans); 97/98/EC of 23/01/97 (marketing of herbicide-tolerant and insecticidal maize).
 8. For instance European Commission Decisions 93/572/EC of 19/10/1993 (regarding marketing of a GM rabies vaccine) and 94/385/EC of 08/06/1994 (marketing of seed for herbicide resistant tobacco).
 9. See the Commission's White Paper on Environmental Liability of 9th February, 2000, Com 2000 (66).
 10. *A and Others v The National Blood Authority and Others* [2001] 3 All ER 289.