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Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms

STEPHEN TROMANS

INTRODUCTION

Two statements, separated by twelve years, encapsulate the particular concerns as to the unpredictable potential effects of genetically modified organisms (GMOs) released into the environment. The first comes from the United Kingdom's Royal Commission on Environmental Pollution (Royal Commission) in its 1989 Report, *The Release of Genetically Engineered Organisms to the Environment*:

Organisms which survive and become established could affect the environment in a variety of ways—both beneficial and undesirable. Some releases may alter the diversity of species in the environment, including changing the composition of existing communities. Such effects could produce noticeable changes in the countryside, locally or more widely, and could also have an economic impact, for example if the new organisms proved to be successful predators, competitors, parasites or pathogens of crop plants. Such organisms could pose a threat to human health. At the most extreme, new organisms could conceivably affect major environmental processes such as weather patterns, the nitrogen cycle or other regenerative soil processes.¹

The second statement is contained in the recitals to the European Community's (EC) new Directive on the deliberate release into the environment of GMOs: "Living organisms, whether released into the environment in large or small amounts for experimental purposes or as

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¹ ROYAL COMM’N ON ENVTL. POLLUTION, THIRTEENTH REPORT, 1989, Cm. 720, at 18.
commercial products, may reproduce in the environment and cross national frontiers thereby affecting other member states. The effects of such releases on the environment may be irreversible."

GMOs therefore present a new twist on the traditional dilemma of balancing the benefits of a technology against its actual or potential adverse environmental consequences. There is no dispute that GMOs may provide immense benefits in terms of food production, medical treatment, and indeed, as the basis for new and less polluting industrial processes. Yet their behavior and characteristics in the environment, once released, cannot readily be known. As living entities, they will multiply, adapt, evolve, and interact in ways that traditional inanimate pollutants cannot. Once released, they cannot be recalled, retrieved, or neutralized. The timescales over which their effects may become apparent are large, and those effects may not be immediately obvious. They will not respect national boundaries or legal systems. The effectiveness of the regulatory procedures to control such releases is therefore critical in ensuring that the worst concerns of commentators do not come to pass. The main object of this paper is to consider how such systems have evolved, and how effective they are likely to prove in practice.

I. THE UNITED KINGDOM

The Royal Commission's Thirteenth Report concluded that though the environment was "generally resilient, resistant to invasion by alien organisms and robust to biological perturbations," it was probable that some organisms, once released, would become established; of these the majority were likely to pose no hazard, but others might cause varying degrees of disturbance, which, in extreme cases, might have serious environmental consequences. The Royal Commission made a series of recommendations, based around the central concept of a statutory scheme for controlling releases, including the screening of applications for "release licences," the registration of companies or organizations carrying out trial


3. ROYAL COMM’N ON ENV'TL. POLLUTION, supra note 1, at 84.
releases, general public access to information on releases, and imposition of
strict statutory liability on those carrying out releases in breach of these
requirements.\textsuperscript{4}

Prior to the Royal Commission’s report, the main statutory controls had
related to the contained use of GMOs, focusing on the health and safety of
the workers involved.\textsuperscript{5} However, there had been a growing awareness of
the wider environmental implications, under the scrutiny of first the Genetic
Manipulation Advisory Group (GMAG) and later the Advisory Committee
on Genetic Manipulation (ACGM). A non-statutory scheme, whereby
proposed releases were notified to ACGM for consideration, was replaced
by a statutory requirement that the releasing organization give prior notice
to the Health and Safety Executive and establish an internal risk assessment
committee.\textsuperscript{6} In addition, specific legislation regulated products comprising
or including GMOs.\textsuperscript{7} The Royal Commission was clear, however, that
fresh legislation was required to provide specifically for the control of
releases of all categories of GMOs.\textsuperscript{8}

That recommendation was accepted, and the legislation was duly
introduced as Part VI of the Environmental Protection Act 1990.\textsuperscript{9} The
purpose of the scheme is stated at section 106(1) as “preventing or
minimising any damage to the environment which may arise from the
escape or release from human control of genetically modified organisms.”\textsuperscript{10}
At the same time, the government established the Advisory Committee on
Releases to the Environment (ACRE) to advise as a single expert
committee on both the environmental and human health risks of releases.
Part VI has been used to control deliberate release and marketing of GMOs,
their contained use being regulated under other legislation.\textsuperscript{11} The essential
scheme of Part VI is to require, as a minimum, that all persons proposing to

\begin{thebibliography}{11}
\bibitem{4} Id. at 92-99.
\bibitem{5} See Health and Safety at Work etc. Act, 1974, c. 37 (Eng.); The Health and Safety (Genetic
\bibitem{7} See Consumer Protection Act, 1987, c. 43 (Eng.); Food and Environment Protection Act, 1985, c.
48 (Eng.); Food Act, 1984, c. 30 (Eng.); Medicines Act, 1971, c. 69 (Eng.); Medicines Act, 1968, c. 67
(Eng.); Plant Health Act, 1967, c. 8 (Eng.).
\bibitem{8} ROYAL COMM’N ON ENVTL. POLLUTION, supra note 1.
\bibitem{9} Environmental Protection Act, 1990, c. 43, pt. VI (Eng.).
\bibitem{10} Id. § 106(1).
\end{thebibliography}
import, acquire, keep, release, or market GMOs should carry out a risk assessment of possible environmental damage resulting from those acts and should, where prescribed, notify the Secretary of State of their intentions to act.\textsuperscript{12} Section 109 imposes a series of general duties on such persons to identify the risks of damage to the environment, and to cease their activities if it appears that, despite the precautions that could be taken, there is a risk of damage to the environment.\textsuperscript{13} The Secretary of State can enforce these duties by way of prohibition notices,\textsuperscript{14} and the breach of these duties entails criminal liability under section 118.\textsuperscript{15} Additionally, in prescribed situations, these activities require a specific consent from the Secretary of State under section 111.\textsuperscript{16} Public registers of information on consents, notices, and other matters are required to be kept under section 122.\textsuperscript{17} In reality, the regulations made under the regime require that express consent be obtained in all cases, so that section 111 provides the exclusive means of control, rather than the more minimalist, general requirements of sections 108 through 110.

As with much U.K. environmental legislation, the statute provides only a framework, and gives relatively little guidance as to how the controls might actually be applied. However, it is apparent from the face of the legislation that the provision of information and risk assessment are essential parts of the procedure.\textsuperscript{18} The applicant for consent must provide substantial information, including the names and qualifications of the scientific personnel involved, a full description of the scientific properties of the organism, a statement of all the various techniques involved, the location of release sites, and details of all possible predators, prey, hosts, competitors, and traits.\textsuperscript{19} In addition, under the regulations, any application for consent to release a GMO must be accompanied by "a statement

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\item \textsuperscript{12} Environmental Protection Act, supra note 9, § 108.
\item \textsuperscript{13} Id. § 109.
\item \textsuperscript{14} Id. § 110.
\item \textsuperscript{15} Id. § 118(1)(d).
\item \textsuperscript{16} Id. § 111; see The Genetically Modified Organisms (Deliberate Release) Regulations, (1992) SI 1992/3280, pt. II, § 5.
\item \textsuperscript{17} Environmental Protection Act, supra note 9, § 122.
\item \textsuperscript{18} See, e.g., ROYAL COMM’N ON ENVTL. POLLUTION, FOURTEENTH REPORT, 1991, Cm. 1557 (seeking to adapt the procedures known as HAZOP (hazard and operability studies) used in the chemicals industry).
\end{itemize}
\end{footnotesize}
evaluating the impacts and risks posed to human health and the environment by the release of the organisms.\textsuperscript{20} Guidance issued by the Department of Environment recommends the steps to be included in this risk assessment, though the format of the statement is left to individual applicants. The Secretary of State is required to act on the application within ninety days.\textsuperscript{21}

Applications for consent to release certain GMOs for research and development purposes are subject to a “fast track” procedure if the GMOs concerned are recognized by ACRE as being of low hazard, the release conditions proposed are considered low risk, and no repetition of trials is involved.\textsuperscript{22} The British government has a voluntary agreement with the biotechnology industry body, Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), whereby marketing of genetically modified crops in the United Kingdom is to be delayed until the results of farm-scale trials are evaluated, which will not be until 2002. This allows up to 12,000 acres of genetically modified crops, including sugar beet, oilseed rape, and fodder maize, to be grown each year in a trial program running from 2000 to 2002.

In fact, the issue of field-scale trials of GMOs in the United Kingdom has proved immensely controversial, with arguments as to the adequacy of “buffer zones” imposed between the GMOs and other crops, and with direct action by environmental protestors in the form of pulling up or destroying the modified crops.\textsuperscript{23} Such trials are necessary not only to assess environmental risks, but also in terms of EC and U.K. law for seeds to be listed under the Seeds (National Lists of Varieties) Regulations 1982.\textsuperscript{24}

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20. Id. pt. II, § 6(1)(c).
22. Id.
23. The most widely publicized example involved the acquittal in 2000 of twenty-nine Greenpeace protestors, including their Executive Director Lord Melchett, by a jury at Norwich Crown Court on charges of criminal damage to genetically modified maize crops being grown on trials. Life in this case imitated art, since a long running story line in the radio agricultural soap “The Archers” (a British institution for decades) had involved Tommy Archer, a teenage protestor, similarly maintaining a defense of lawful excuse in identical circumstances. An attack on oilseed rape being grown in Oxfordshire in 1999 by 400 demonstrators was one of the largest acts of civil disobedience in recent British history. Another attack in County Durham in 1999 led to the protestors being found guilty of criminal damage, but given a conditional discharge on the basis that the judge accepted their honest belief that their actions had “a positive purpose.”
\end{flushleft}
(Regulations) to allow marketing in the United Kingdom, and admission to the “common catalogue” of seeds allowed for marketing throughout the EC. In February 2001, the Government announced a significant expansion in the trials program, sanctioning ninety-six farm-scale trials, twice the number approved in 2000. In particular, environmental groups were outraged that no extension was made to the minimum separation distances or buffer zones from other crops, with distances set between eighty and 100 meters, when research suggested that cross-contamination could occur at distances of up to 4,000 meters.

The issue of direct release for marketing is dealt with separately under the Regulations. Again, risk assessment is central, but the procedure differs significantly from that for other releases because placing a product on the market involves a much greater level of interaction with the European Commission (Commission).

II. THE EC DIMENSION

At the same time as the British legislation described above was evolving, the EC was developing measures to address the risks of GMOs, in terms of both their contained use and their deliberate release. These measures were implemented by Directive 90/219/EEC on the contained use of genetically modified microorganisms and Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

It will be noted that the contained use Directive applies only to microorganisms. The Directive was a response to the growth in biotechnology research work during the 1970s in many member states, and the establishment in 1985 of the Commission’s Biotechnology Regulation Interservice Committee. The Directive was based on classification of different types of operations (basically small-scale operations for teaching,

research, and other non-commercial activities on the one hand, and all other operations on the other) and different groups of GMOs (depending on their inherent hazard). This rather complex and inflexible system was amended by Directive 98/81/EC to provide a less bureaucratic, more risk-based approach.

The deliberate release Directive has proved much more controversial. At the time it was originally published as a proposal, national policy in member states was relatively unformed, though guidelines and regulatory structures were beginning to be developed, in particular in Germany and Denmark.\(^30\) The Directive governs both deliberate release and marketing of GMOs and was promoted under article 100a of the European Treaty\(^31\) as a measure to harmonize provisions in member states having as their object the establishment and functioning of the internal market.

The Directive placed a general obligation on member states to “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 placing on the market of GMOs.”\(^32\) It established two systems for notification—one for the deliberate release of GMOs for research and development and other non-marketing purposes, and the other for placing on the market products containing GMOs. The approach, as explained in the Recitals to the Directive, is one of “step by step,” whereby containment is reduced and the scale of release increased gradually when the evaluation of earlier steps indicates that the next steps can be taken.\(^33\)

The system for deliberate release requires notification, including a technical dossier and an impact and risk evaluation statement to be submitted to the competent authority in the member state concerned.\(^34\) A tight timescale then applies under which the competent authority must

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31. See Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities and Certain Related Acts, Oct. 2, 1997, art. 95, O.J. (C 340) 1 (1997) [hereinafter Treaty of Amsterdam] (article 95 was originally adopted by the Single European Act as article 100(a)).
33. Id. recitals.
34. See id. art. 5 & Annex II. This includes information on the GMO, conditions of release, receiving environment, interactions between the GMO and the environment, monitoring, control, and emergency plans.
examine and evaluate the proposal and forward a summary of the notification to the Commission, which, in turn, forwards it to other member states, which have thirty days to request further information and to provide comments.\(^\text{35}\) The competent authority must consider any such comments, and must inform the notifier of the decision to approve or reject the request for release within ninety days of the original notification.\(^\text{36}\) One problem with this system was the relatively weak requirements for public consultation, which simply provided that the member state could provide, if it thought it appropriate, that particular groups or the public should be consulted on any aspect of the proposed release.\(^\text{37}\)

The procedures for placing products containing GMOs on the market are more rigorous. The manufacturer or importer must submit a notification to the competent authority when the product is to be placed on the market for the first time.\(^\text{38}\) This must be accompanied by a technical dossier, risk assessment for the environment and human health, details of conditions for use and handling, and proposals as to labeling and packaging (which must meet the requirements of Annex III).\(^\text{39}\) The competent authority must either reject the application within ninety days or send the dossier to the Commission with a favorable opinion.\(^\text{40}\) The Commission forwards the dossier to other member states, which have sixty days to raise objections.\(^\text{41}\) If no objections are received, the competent authority is to give its consent within sixty days.\(^\text{42}\) If there are unresolved objections, the decision is taken by the Commission, in consultation with an expert advisory committee set up under the Directive and composed of national representatives chaired by a Commission representative.\(^\text{43}\) The Chairman submits a proposal on which

\(^{35}\) *Id.* arts. 6, 9.

\(^{36}\) *Id.* art. 6(2).

\(^{37}\) *Id.* art. 7.

\(^{38}\) *Id.* art. 11(1).

\(^{39}\) *Id.* Annex III requires the identification of potentially harmful effects associated with the GMO, the vector and any inserted genetic material. Such harmful effects are defined to include human, animal, or plant diseases, resistance to treatments or prophylactics for disease, and deleterious effects due to establishment or dissemination in the environment, or to the natural transfer of inserted genetic material to other organisms. The severity and the likelihood of those potentially harmful events being realized should then be assessed.

\(^{40}\) *Id.* art. 12(2).

\(^{41}\) *Id.* art. 13(2).

\(^{42}\) *Id.*

\(^{43}\) *Id.* arts. 13(3), 21.
the Committee delivers its opinion by a weighted majority: the measure is adopted if agreed to by the Committee and the Chairman; otherwise, the matter goes to the European Council (Council) for a decision on a qualified majority basis.\footnote{44} Once consent has been given, the product may be used throughout the EC provided that any conditions of the consent are strictly complied with, and member states may not prohibit, restrict or impede such use.\footnote{45} There is, however, a procedure of limited scope but high political significance, which allows a member state, with justifiable reasons to consider that the notified product constitutes a risk to human health or to the environment, provisionally to restrict or prohibit its use or sale in its territory.\footnote{46} The Commission must be notified, and a decision made as to the GMOs continued marketing within three months, under the article 21 Committee procedure.\footnote{47}

During the 1990s, the Directive was subject to some fine-tuning in terms of its procedures, the information required with notification, and the introduction in 1997 of compulsory labeling of products containing GMOs.\footnote{48} However, in 1996, the Commission published a review of the Directive after consultation with competent authorities, environmental and other interest groups, and industry. This led to the adoption in 1997 of a proposal to amend the Directive,\footnote{49} which, in turn, opened a highly controversial debate. The proposal for amendment contemplated a much stricter regime, including more rigorous scientific consultation requirements, fixed-term consents, compulsory monitoring of environmental impact after the product was placed on the market, and the possibility for the Council to refuse approval of a product by simple majority.\footnote{50} The European Parliament was not satisfied, however, and in

\footnote{44}{Id. art. 21; Treaty of Amsterdam, \textit{supra} note 31, art. 205 (article 205 was originally adopted by the TREATY ESTABLISHING THE EUROPEAN ECONOMIC COMMUNITY as article 148). If the Council fails to act within three months of the referral, the Commission will adopt the measures. Council Directive 90/220/EEC, \textit{supra} note 26, art. 21.}


\footnote{46}{Id. art. 16(1).}

\footnote{47}{Id. art. 16(2).}


\footnote{50}{Id.}
February 1999 adopted 101 amendments to the proposal. These included the imposition of strict liability on those releasing GMOs for harm to human health or the environment, extension of the requirements for environmental risk assessment, stricter rules on labeling, and a ban on the inclusion of antibiotic-resistant genes or traces of toxic substances in GMOs. In addition, the Environment Committee of the Parliament argued for a moratorium on all new market releases of GMOs pending revision of the Directive. The Council, however, felt there was no legal basis for such a moratorium.

There then followed two intertwined processes: first, the formal procedures for agreement on the new Directive, and second, political maneuvering as to the conditions for dealing with new applications. The formal process was protracted, both because of the dispute as to the demands of the European Parliament for tougher legislation and because of the need to take into account the development and implementation of the Biosafety Protocol, agreed to in Montreal in January 2000 and adopted on behalf of the EC in May 2000.

At the same time, pressure was maintained for a European Union (EU)-wide moratorium. Following the Environment Council meeting in June 1999, a legal moratorium was rejected, essentially because of concerns as to its legality and the possibility of legal action by the United States under the World Trade Organization (WTO). However, two separate formal reservations were made, one a "Declaration of Suspension" by France, Denmark, Greece, Italy, and Luxembourg, and the second, a weaker version by Germany, Austria, Belgium, Sweden, Finland, and the Netherlands. The latter countries called for the introduction of more stringent rules and indicated that, in the meantime, on the basis of the precautionary principle, they would authorize no further releases. In practice, this amounted to a de facto moratorium. At that point, some fourteen applications for consent were pending.

In the case of three products pending approval, the biotechnology companies concerned agreed to comply in advance with the stricter rules likely to be introduced under the new Directive. In an attempt to improve this unsatisfactory situation, the Commission produced, in July 1999 a new strategy for accelerated adoption of the new rules, once they were agreed, as well as labeling and traceability procedures. However, the French Presidency of the Council organized an informal meeting of ministers in
July 2000, at which it was agreed that all new GMO approvals for the EU market would be postponed.

Particular attention has centered on the licensing of genetically modified maize for sale in the EU. In December 1996, the Commission decided to authorize its marketing, in the face of outraged opposition by thirteen member states. The maize (Bt maize) was genetically engineered by Novartis to be resistant to an herbicide and toxic to a pest (the European corn-borer); in addition, it contained a marker gene making it resistant to an antibiotic (ampicillin). One concern was that if the maize was not processed before use in animal feed, the antibiotic resistance could be transferred to bacteria. Under the comitology procedure of Directive 90/220, the Council of Ministers could only reject the proposal by unanimous vote, which was impossible because France supported the application as the competent authority to which it had been made. Following informal advice from the three EU scientific committees (on Food, Animal Nutrition, and Pesticides) the Commission authorized the placing of the genetically modified maize on the market. It has since been grown commercially in Spain and, on a smaller scale, in France and Portugal.

Two countries, Austria and Luxembourg, introduced ministerial decrees banning the use of the genetically modified maize, relying on article 16 of the Directive. The Commission, having consulted the three scientific committees, determined that these bans were not justified under the terms of article 16. However, there was opposition to the Commission taking action to force Austria and Luxembourg to lift the bans, and they remained in place. At the same time, interest groups including Friends of the Earth and Greenpeace took legal action in France to challenge the marketing of the maize on the basis that it contravened the precautionary principle. The French Conseil d'Etat suspended the approval in September 1998 and referred the matter to the European Court of Justice.

Work published by U.S. scientists in May 1999 suggested that pollen from insect-resistant genetically modified maize of the Bt Novartis variety

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51. See generally INST. FOR EUR. ENVTL. POLICY, supra note 30, § 7.14, at 10-12 (explaining in detail the dispute over licensing of genetically modified maize).
killed almost half of the Monarch butterflies exposed to it in laboratory conditions. This led to the Commission freezing the authorization process for a similar genetically modified maize variety produced by Pioneer-Hi-Bred. However, in October 1999 the EU’s scientific advisers concluded that this evidence did not “constitute new significant information” warranting reassessment of Bt maize. This was met by public uproar and demands by environmental groups for authorizations for Bt maize to be withdrawn.

Further concern arose in December 1999 in response to findings from Cornell University that insect-killing toxins from Bt maize could leach into soil and persist there for weeks, with the ability to kill larvae after twenty-five days. As well as killing the intended pests, the concern was that the toxin could also kill benign organisms and affect soil ecology. As a result of these concerns, Germany took steps in February 2000 to prevent marketing and large-scale growing of Bt maize, relying on article 16 of the Directive.

In February 2001, the revised Directive—described by the British Labour MEP and European Parliament Rapporteur as “the tightest GM laws in the world”—was finally approved and will replace Directive 90/220/EC as of October 17, 2002. However, this is not the end of the debate. The Commission has announced its intention to lift the moratorium, but five member states, led by France, insisted that it must remain in place.

The stated objectives of the new Directive 2001/18/EC remain the same as for 90/220/EEC, save for the insertion of an express reference to the precautionary principle. The general obligations of member states and the Commission are spelled out more fully, in terms of accurate assessment of direct or indirect potential adverse effects being required on a case-by-case basis, and in a requirement to ensure traceability of marketed GMOs. There is a new provision dealing with how modifications or unintended

56. Id. art. 4. Specific reference is also made to the assessment of risk from antibiotic resistance markers in GMOs, with a view to their phase-out by the end of 2004 for Part C releases and 2008 for Part B releases.
57. Id. art. 4(6).
changes to releases, or new information on risks, are to be handled. The inadequate provision of public consultation is replaced by a firm requirement to consult the public and, where appropriate, groups, on proposed deliberate releases. The procedures for consent to marketing GMOs have been substantially overhauled, with a maximum duration of ten years for any consent and specific provisions as to renewal of consent. When there are objections to marketing from another member state, the procedures are spelled out much more clearly in the amended Directive than in the original Directive. Where consent is given, there are now firmer labeling requirements, including a requirement that the words "[t]his product contains genetically modified organisms" shall appear either on a label or on a document accompanying the product. There are clearer provisions on making information available to the public and on the exchange of information and reporting. There is an express invitation to the Commission to bring forward as soon as possible—and in any event before July 2001—a proposal for implementing in detail the Cartagena Protocol on Biosafety to complement, and if necessary amend, the provisions of the Directive.

Despite these significant improvements to the EC system of control, six countries, led by France, issued a Statement noting that these improvements were only partial, seeking early new legislation on traceability and labeling and on environmental liability, and reaffirming their intention, when exercising the powers conferred upon them, of ensuring that new authorizations for cultivating and marketing GMOs be suspended "pending the adoption of effective provisions concerning complete traceability of GMOs that guarantees reliable labelling of all GMO products." Given that the new Directive contains a national "safeguard clause" allowing for provisional restrictions, broadly similar to

58. Id. art. 8.
59. Id. art. 9.
61. Id. art. 17.
62. Id. arts. 18, 28-30.
63. Id. arts. 19(3)(c), 21.
64. Id. art. 24.
65. Id. art. 31.
66. Id. art. 32(1).
67. Austria, Denmark, France, Greece, Italy, and Luxembourg.
article 16 of the original Directive, it can be anticipated that such clause will be the means used to that end. 68

III. THE COURTS AND THE GMO DEBATE

Few cases have as yet come before the courts in the United Kingdom and Europe on the control of and liability for GMOs. The leading decision in the United Kingdom is *R v. Secretary of State for Environment and Ministry of Agriculture Fisheries and Food, ex parte Watson.* 69 Mr. Watson was an organic farmer who grew vegetables, including sweet corn. 70 He feared that genetically modified maize being grown for trials on an adjacent farm would cross-pollinate with his crops, threatening his accredited status as an organic farmer with the Soil Association of Great Britain. 71 Trials in the United Kingdom were required to satisfy the requirements of the regulations as to the value for cultivation and use of the seeds. 72 Consent for the release of the genetically modified maize for trials had been given under section 111 of the Environmental Protection Act 1990. 73 Watson's solicitors wrote to the Ministers asking that the trial not be commenced. 74 His sweet corn crop was some two kilometers from the trial site, and ACRE advised the Ministers that at such a distance the risk of cross-pollination was likely to be zero. 75 On that basis, the Ministers refused to revoke or vary the consent. 76 Watson challenged that decision for various reasons. The first basis of challenge was that the Ministers had acted irrationally in relying on the ACRE advice. It was argued that assessment of the risk at “zero” was too narrow an approach, which did not adequately assess the degree of the risk or address the disastrous consequences for Watson's business if the risk were to eventuate. 77

70. *Id.* at 312.
71. *Id.*
72. *Id.* at 313.
73. See Environmental Protection Act, 1990, c. 43, pt. VI, § 111 (Eng.); see also *Watson,* supra note 69, at 313-14.
75. *Id.*
76. *Id.*
77. *Id.*
Looking at the basis on which ACRE had given this advice, the Watson Court concluded that it constituted "a reasonably confident assessment that realistically there is no more than minimal risk":

Of course, this falls short of the guarantee that the applicant and Friends of the Earth were looking for. But it seems to me a perfectly reasonable point at which to strike the balance between the competing interests in play. Whether events prove the assessment to have been too sanguine remains to be seen. That, however, as all parties before us recognize, is not a matter for this Court.\footnote{Id. at 316.}

Challenges were made on other bases, unsuccessfully, as to the scope of the consent in terms of who could actually undertake the trials and as to procedural irregularities under the Regulations.\footnote{Id. at 316-23. It was found that there were indeed procedural defects, but these did not go to the issue of environmental risk to Watson's crops, and so did not entitle him to relief. Id.}

The first judgment of the European Court of Justice concerning the Deliberate Release Directive was Association Greenpeace France v. Ministère de l'Agriculture et de la Peche.\footnote{See Case C-6/99, Ass'n Greenpeace France & Others v. Ministère de l'Agriculture et de la Peche & Others.} This was a challenge to the decision of the French Ministry to authorize herbicide-tolerant genetically modified maize that had gone through the EC procedures successfully following objections by other member states. As explained above, article 13 of the Directive requires the national competent authority to give its consent in writing, which the French government did by way of decree. Greenpeace sought to identify procedural defects in the earlier national stages of the procedure, before the French dossier had been sent to the Commission. The European Court rejected the arguments of Greenpeace that there was a residual discretion to withhold consent under article 13 once a favorable decision had been given at EC level. Greenpeace had relied particularly in this context on the precautionary principle, a line of argument to which the European Court has increasingly been receptive. But in this case, the Court held that the precautionary principle was satisfied by the structure of the Directive as a whole, including the
obligation on the notifier under article 11 to draw the attention of the competent authority to any new information on risks, and the powers of member states to take provisional measures under article 16. On the issue of procedural defects, the European Court held that when they (as here) were alleged to affect the validity of a Community measure, it was a matter for the European Court rather than national courts.

IV. CONCLUSION: POLITICS, RISK, AND PUBLIC ACCEPTANCE

There is no doubt that politicians in Europe fear the GMO debate, and with good reason. There are high levels of public mistrust and a general lack of acceptance of the new technology. The Prime Minister of the United Kingdom, Tony Blair, has suffered damage from accusations that his government has been over-influenced by the multinational interests concerned. In France, a political wedge has been driven between the Socialist Prime Minister, Lionel Jospin, and the President, Jacques Chirac, over the issue. As explained above, faced with legally tenuous use of article 16 provisional restriction procedures by Member States, the European Commission has not directly challenged practice under article 16, but has instead focused on administrative procedures.

As will be appreciated from the account above, the EC procedures are complex and are a product of political compromise. Concern over decisions taken on a “comitology” basis is not confined to the GMO debate, and extends to many other areas of health and environmental risk assessment. The EC procedures must deal with the paradox of the denationalization of risk issues, set against the growing importance of national interests and national perceptions on risk, while at the same time having to take decisions which are defensible in international fora, such as the WTO. This involves a search for legitimacy in the EC’s decisions, backed by greater participation by stakeholders. The current

81. This is made worse by scandals over Bovine Spongiform Encephalopathy (BSE) and over food in Belgium contaminated by dioxins.
83. It is noteworthy that a lack of public information, consultation, and transparency were generally seen as the key defects in the handling of the BSE/nvCJD crisis in the United Kingdom between 1986 and 1988. See 1 LORD PHILLIPS OF WORTH MATRAVERS ET AL., THE BSE INQUIRY 34-35 (2000).
shortcomings relate principally to such issues, and especially to the lack of a coherent concept of risk regulation within the EC.\textsuperscript{84}

On the broader global political scale, there must also be a search for harmonized procedures and accepted risk assessment criteria, for example as between the European Commission and the U.S. Food and Drug Administration and Department of Agriculture. While the United States is currently perceived within Europe as having taken a less strident approach to GMOs, with fewer threats of complaint to the WTO, and a significant softening of free trade rhetoric, the international debate is most certainly not over. The United States will no doubt be concerned that European antipathy to GMOs could easily spread to North America, as witness the protests at the Seattle WTO meeting. Moreover, profits will not be made from GMOs if consumers are simply unwilling to buy them.\textsuperscript{85} Demand for GMO-free products has soared in Europe, Japan, and some Pacific Rim countries, leading to demand for guaranteed non-genetically modified supplies. In response to such concerns, U.S. producers have been reported as increasingly tending to segregate genetically modified crops.

The focus of public concern has so far been on possible human health effects from foodstuffs containing GMOs (as witness the “Frankenstein foods” tag used by the British tabloid press on the occasions when the story has surfaced). However, it is perhaps the wider environmental concerns that are less well understood and more worrying. It was the possible indirect and cumulative effects of GMO use that concerned the House of Lords Select Committee on the European Communities when it considered the proposed reform of Directive 90/220/EEC in 1998.\textsuperscript{86} Similarly, the


\textsuperscript{85} A report by Deutsche Bank referred to GMOs as good science but disastrously perceived, suggesting that agricultural biotechnology companies were dubious investments, and that increasingly GMOs were becoming a liability to farmers. See DEUTSCHE BANK, AG BIOTECH: THANKS, BUT NO THANKS?, http://www.biotech-info.net/Deutsche.html (last modified Sept. 9, 1999).

Advisory Committee on Releases to the Environment, in issued guidelines on risk reduction from gene flow in October 2000, stressed that more could be done to reduce the risk of indirect effects from genetically modified crops, in particular through the use of technologies such as engineered sterility and gene activation, and the minimization of DNA addition (for example in marker genes). The Department of Environment in October 2000 issued a guidance document on assessing the risks posed by the cultivation of GMO crops to wider biodiversity. What is required appears to be a more inclusive and holistic approach, in terms of both the process and the content of the debate. The United Kingdom has recently created a new body, the Agriculture and Environment Biotechnology Commission, with the mandate of advising on “all other aspects of biotechnology except food” and on “ethical considerations regarding the acceptability of genetic modification.”

The deep philosophical differences on the issue are epitomized by the membership of the Commission, which contains both pro-GMO members and GMO skeptics. Whether the Commission will succeed in engaging the public on the issues remains to be seen: the resources available to it may be a constraint. The revised Directive on deliberate release will, as discussed above, require greater openness and engagement with the public in consultation. The Government is beginning to grapple with the appropriate mechanisms.

90. The AEBC’s first major piece of work has been its report on farm scale evaluations of GMO crops, published in September 2001. See AGRIC. ENV’T & BIOTECH. COMM’N, CROPS ON TRIAL: A REPORT BY THE AEBC (2001), http://www.aebc.gov.uk/aebc/publications/crops.pdf. The whole thrust of that report, which is in places critical of the previous processes used for such trials, is that a much more open and inclusive process of decisionmaking as to the future commercial growing of such crops must be developed, with comprehensive public discussion of the ecological and ethical—including socioeconomic—issues.
The genetically modified industry is itself acutely aware of the need to engage more positively in the public dialogue.\textsuperscript{92} However, in the final analysis, there is no escaping the fact that genetic engineering is a new and inherently uncertain technology. As one commentator has suggested, "engineering" is altogether too precise an approach to be acceptable as an analogy: "Engineers (at least when operating in well-worked fields!) are precise. They achieve exactly what they intend, entirely predictably. . . . Genetic engineers \textit{at best} are like gardeners, who plant a seed and must then stand back and let nature take its course."\textsuperscript{93}

The challenge for policymakers, legislators, and regulators is to allow progress at an acceptable pace in terms not only of risk assessment, but also of public and ethical acceptance. The public sees some technologies as "convivial,"\textsuperscript{94} which, in turn, depends not only on their utility, but also on the perceived nature of risks involved, and the ethos of how they are used. GMOs do not at this point fall into the category of perceived "convivial" technology, at least in Europe.

\textsuperscript{92} See GM CROPS: UNDERSTANDING THE ISSUES (2001) (published with the support of the U.K. Agricultural Biotechnology Industry) (covering issues such as separation distances, genetic purity, herbicide tolerant crops, gene flow, food safety, and the regulation process).


\textsuperscript{94} \textit{Id.} at 349.