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Sustainability, Regulatory Dilemmas and GMOs: The US and the EU Compared

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Abstract

Agency decision-making regarding the release of genetically modified organisms (GMOs) into the environment, which has the potential to affect the environment and human health, must be consistent with the principles of sustainable development. This requires adherence to the principles of intergenerational equity, the conservation of biological diversity, the precautionary principle, and the polluter pays principle. The potential risks associated with GMOs make public participation an essential element of agency decision-making. This is because the scientific evidence about the safety, or otherwise, of GMOs is sufficiently uncertain. In such a case, decisions to release them must be politically negotiated. Yet when the regulatory arrangements for dealing with GMOs in the United States and the European Union are compared and contrasted markedly different regulatory frameworks emerge. In the case of the US, the regulation of GMOs falls short of the sustainability benchmark, while the EU's seems entirely consistent with it. How do we explain, then, the paradox of a US public which is so accepting of food derived under a relatively lax regulatory and administrative framework, and a fearful EU public protected by extensive regulation and risk assessment processes?

Key words

Genetically modified organisms, sustainable development, regulatory frameworks, the precautionary principle, public participation, United States, European Union

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Introduction

There can be no argument that all agency decision-making which has the potential to affect the environment and human health must be made in accordance with the principles of sustainable development. This requires adherence to the principles of intergenerational equity, the conservation of biological diversity, the precautionary principle, and the polluter pays principle. Public participation is an essential element of sustainable development. These principles are enunciated in the Rio Declaration, Agenda 21, and the Convention on Biological Diversity, which are the international environmental instruments establishing the foundations of sustainable development.

Agency decision-making regarding the regulation of genetically modified organisms (GMOs)[1] is undeniably a case in point. The potential risks presented by genetically modified (GM) crops include: the impact on non-target organisms; gene transfer from the GM crop into related species; persistence or invasiveness of GM crops; presence of antibiotic resistance genes in the GM crop; and danger of GM crops to human health.[2] Yet the following analysis suggests an interesting paradox which poses a dilemma for agencies vested with responsibility for regulating GMOs. There seems to be no relationship between the level of regulatory activity in the area and the public's acceptance of GMOs. This is borne out when the regulatory arrangements for dealing with GMOs in the United States and the European Union are compared and contrasted. The analysis shows markedly different regulatory frameworks which, in the case of the US, falls short of the sustainability benchmark,[3] while the EU's seems entirely consistent with it. In the United States, for example, 99 per cent of releases of GMOs into the environment are authorised using a streamlined process of "notification". There, the developer of the GMO does a risk assessment, advises the regulator that there is no risk to the environment and human health and is given permission to undertake field tests. The developer may then apply for the GMO to be deregulated ready for full commercialisation. There is virtually no public participation, the US Environmental Protection Agency (EPA) is not involved in assessing releases into the environment, and there is no independent

1 Although "biotechnology" and "genetic modification" are commonly used interchangeably, genetic modification is a special set of technologies that alter the genetic makeup of such living organisms as animals, plants, or bacteria. Combining genes from different organisms is known as recombinant DNA technology, and the resulting organism is said to be "genetically modified", "genetically engineered", or "transgenic."

2 See T. Simpson "Environmental Risk Assessment of GMOs Under Directive 2001/18: An Effective Safety-Net or a 'Collective Illusion'" (2003) 25 *European Intellectual Property Review* 79 at 81.

3 See G. N. Mandel "Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals" (2004) 45 *William and Mary Law Review* 2167.

scientific review. Until very recently, GM foods have been dealt with by the regulator in the same way as any other foods derived using plant breeding and do not need to be labelled.

Yet the uptake of, and public acceptance of GMOs in the US is notable. GMOs are now grown on over one hundred million hectares of farmland. This is up from six million hectares in 1996. Interestingly, 81 per cent of soybeans, 40 per cent of corn, 73 per cent of cotton grown and over 50 per cent of canola and papaya are derived from GMO seeds. Grocery Manufacturers of America estimates that 70 per cent of food on grocery shelves is GM food. This includes cereals, crackers, juice, soda, salad dressing and sauces. These statistics show an enormous tolerance, and acceptance, on the part of the US public for GM crops. This sense of security is not in direct relation to the regulatory scheme governing the release of GMOs into the environment and the commercialisation of GM food.

By contrast, in the European Union a series of Directives and Regulations require a detailed environment risk assessment to be done before the release of GMOs into the environment and the introduction of GM food onto the market is authorised. All decision-making must be done in accordance with the precautionary principle and public consultation procedures are extensive. The EU Commission has stated that any risk assessment associated with the precautionary principle must be resolved politically. GM foods must be labelled and public registers must be established informing the public about GMOs placed on the market. In addition, there is a *de facto* ban in the EU on the importation of GM food into the EU. Monsanto has given up its quest to import GM wheat into the EU, while not denying that a dispute will be taken to the WTO dispute panel.[4]

How do we explain, then, the paradox of a US public which is so accepting of food derived under a relatively lax regulatory and administrative framework, and a fearful EU public protected by extensive regulation and risk assessment processes? Which comes first, the chicken or the egg? Does a lax regulatory approach have a reassuring effect on the public? Conversely, where cautious lawmakers and agencies do everything in their power to satisfy the public that the risks related to GMOs will be properly assessed and regulated, do they create fear? Or does the public demand a certain response from regulators? If so, how can lawmakers and regulatory agencies respond to public sentiments of "fear" and "deep mistrust" or, conversely, "feeling completely safe"? As this article shows, the efforts of agencies to assuage public antipathy to GMOs may not succeed.

4 See H. Krenzler and A. MacGregor "GM Food: The Next Major Transatlantic Water?" (2000) 5 *European Foreign Affairs Review* 287.

In contrast, agencies may face the situation where the public is supportive of GMOs, or perhaps even ignorant of their presence, in the environment or the food chain. What should they do and how can this be explained? Has the regulatory framework itself failed to bring the possible dangers to their attention? Should agencies continue along the path of "least said, soonest mended" or, based on comparative regulatory schemes in other jurisdictions, should these agencies reform their own processes and actively engage the public on the vexed issue of GMOs?

Agencies seem to be in a quite invidious position as they attempt, or even fail, to regulate GMOs. Those which allow the release of GMOs in the face of a resistant public will be scrutinised and criticised for their actions. Their decisions may be challenged before tribunals, courts or other administrative bodies. On the other hand, where agencies adopt a laissez faire attitude to GMOs, they run the risk of public disapprobation should any detrimental effects, either to the environment or human health, be detected in the future.

The role of GMOs in society is certainly unsettled. A wide range of disciplines has weighed into the debate concerning their use. These include scientists from an array of disciplines, ethicists, theologians, economists, and environmental lawyers. They are joined by multilateral agencies such as the World Bank, the Food and Agriculture Organization of the United Nations (FAO), and others. Non-government organisations (NGOs) and other lobby groups across the globe have expressed their differing and conflicting views. Multinational corporations, which develop the GMOs, are prominent actors in the fray.

The various aspects and sites of the controversy about GMOs make agency decision-making a near impossibility, especially where GMOs are regarded with suspicion. Yet decisions must be made, and the decisions must be made in a way that protects the future sustainability of the environment and human health. Ideally, the public should be consulted every step of the way. The difficulty with this is that even after extensive public consultation, as occurred with the United Kingdom's "GM Nation" debate, described below, regulators may discover that the pathway to decision-making is no clearer.

Stalworthy claims that the management of risk surrounding GMOs is ultimately a political question, and that levels of propriety and acceptability depend on the availability and quality of technical scientific assessment.[5] He goes on to say that "[t]he further from certainty we are the more politically problematic the decision".[6] The science of the risks of GMOs is far from certain. In any case, the precautionary principle recognises the limits to scientific certainty in requiring that, where there are

5 M. Stalworthy "Genetically Modified Food, Regulation and Free Trade: A Saga for Our Times" (2003) 14 *International Company and Commercial Law Review* 223.

6 Ibid at 224.

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

Given the scientific uncertainty about the risks inherent in the use of GMOs, and the greater reference by agencies to public attitudes to them, it seems that there is an urgent need to penetrate the "GM psyche" of a nation in order to better understand how lawmakers and regulators should respond. Certainly this is not the role of lawyers. Perhaps it is now time to develop a more extensive and cohesive interdisciplinary research project to explain this national GM psyche. Which disciplines are best placed to interpret for regulators the meaning of public attitudes, and suggest ways of counteracting them? Should regulators be calling on psychologists, social scientists and political scientists to join the efforts of ethicists, scientists, and economists to better understand how to manage GMOs? Can their work assist to design truly sustainable GMO frameworks that have the confidence of the public? As this article shows, there is certainly a need to explain, and attempt to resolve, the paradoxes which emerge when the regulation of GMOs, and public attitudes towards them, are analysed.

What Does the Sustainable Regulation of GMOs Entail?

Sustainable regulation must be consistent with the internationally recognised principles of sustainable development. Sustainable development may be defined as development which meets the needs of present generations without compromising the ability of future generations to meet their needs. This definition, which has been adopted by the international community, first appeared in *Our Common Future* (the Brundtland Report). This 1987 report, produced by the World Commission on Environment and Development, was the culmination of international research and investigation into the state of the global environment. The 21 member Commission, chaired by Norwegian Prime Minister, Gro Harlem Brundtland, heard evidence from public meetings held on all five continents over three years. The report included environmental strategies for achieving sustainable development by the year 2000 and beyond, and was hailed by the United Nations Environment Program as the most important document of the decade.

The principles of sustainable development — intergenerational equity, the polluter pays principle, the precautionary principle, and conservation of biological diversity — are now well-known. They were clearly articulated in the documents which emanated from the 1992 United Nations Conference on Environment and Development (the Rio Conference). These include the Rio Declaration and Agenda 21.

The Rio Declaration

The principle objectives of the Rio Declaration were to establish "a new and equitable global partnership through the creation of new levels of cooperation among States, key sectors of societies and people" and to develop international agreements which would "respect the interests of all and protect the integrity of the global environmental and developmental system".[7] The Declaration proclaimed human beings, entitled to a healthy and productive life in harmony with nature, to be at the centre of concerns of sustainable development.[8] It also reaffirmed the sovereign right of states to exploit their resources, while bearing in mind their obligation to prevent domestic activities causing transboundary damage to the environment.[9]

Perhaps the most influential principles of the Declaration have proved to be the principles of intergenerational equity,[10] the precautionary principle,[11] and the polluter pays principle.[12] Intergenerational equity requires current rates of development to equitably meet the development and environmental needs of present and future generations. The precautionary approach has already been enunciated above. The polluter pays principle envisages the internalisation of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution. All of these principles are relevant to the development of a framework to sustainably regulate the environmental impacts of biotechnology.

Other enduring Rio principles are poverty alleviation,[13] the common but differentiated responsibilities of countries to achieve sustainable development,[14] capacity building and technology transfer,[15] and public participation in decision-making (including women and indigenous people).[16] States were also called upon to enact effective environmental laws,[17] including the provision of compensation for

7 1992 Rio Declaration on Environment and Development (1992) 31 ILM 874.
8 Ibid, Principle 1.
9 Ibid, Principle 2.
10 Ibid, Principle 3.
11 Ibid, Principle 15.
12 Ibid, Principle 16.
13 Ibid, Principle 5.
14 Ibid, Principle 7.
15 Ibid, Principle 9.
16 Ibid, Principles 10, 20 and 22.
17 Ibid, Principle 11.

the effects of pollution and other forms of environmental degradation,[18] environmental impact assessment,[19] and effective legal remedies.[20]

Of course, the other crucially important international conventions relevant to the environmental impacts of biotechnology are the Convention on Biological Diversity[21] and the Cartagena Protocol on Biosafety.[22]

The Convention on Biological Diversity and the Cartagena Protocol

The Cartagena Protocol acknowledges growing public concern over the rapid expansion of modern biotechnology and its potential to impact adversely on biological diversity and human health. It also recognises, however, that if modern biotechnology is used with adequate safety measures for the environment and human health, it has great potential for human well-being. But clearly, many countries, particularly developing countries, have little capacity to cope with the potential risks associated with living modified organisms. The Preamble of the Protocol also states that trade and environment agreements should be framed in a way that is supportive of sustainable development.[23]

Consequently, the objective of the Protocol is to ensure an adequate level of protection for the safe transfer, handling and use of living modified organisms (hereafter "organisms") derived from modern biotechnology. Relying on the precautionary principle, the level of protection should take into account risks to biological diversity and human health, and should focus on transboundary movements.[24] The Protocol does not apply to the transboundary movement of organisms which are pharmaceuticals for humans, as these are regulated under other relevant international agreements or organisations.[25]

The centrepiece of the Protocol is the "advance informed agreement procedure" which requires the exporting Party to notify the competent national authority[26] of the importing Party about its first intentional transboundary movement of an organism.[27] The importing Party must acknowledge receipt of the notification[28] and

18 Ibid, Principle 13.
19 Ibid, Principle 17.
20 Ibid, Principle 10.
21 1992 Convention on Biological Diversity (1992) 31 ILM 818.
22 2000 Cartagena Protocol on Biosafety (2000) 39 ILM 1027.
23 Ibid, Preamble.
24 Ibid, Art. 1.
25 Ibid, Art. 5.
26 Ibid, Art. 19.
27 Ibid, Arts. 8–10 and 12. Annex I of the Protocol sets out the information that must be included in such notification.
28 Ibid, Art. 9.

then decide, within 90 days of notification, whether the importation can proceed with or without the written consent of the importing party.[29] If importation is only allowed upon written consent, the importing Party must notify the notifier and the Biosafety Clearing-House[30] of its decision to approve the import, with or without conditions, including how the decision will apply to subsequent imports of the same organism; to prohibit the import; or to request additional relevant information.[31] The importing Party's decision must be based on a risk assessment process and be consistent with the precautionary principle.[32] The advance informed agreement procedure does not apply to organisms in transit or destined for contained use in the importing country.[33] Different provisions apply to organisms intended for direct use as food or feed, or for processing.[34]

Parties should also develop risk management strategies to deal with the risks associated with the transboundary movement of organisms.[35] They must also notify potentially affected States and the Biosafety Clearing-House if an unintentional transboundary movement occurs.[36] Parties must also ensure that organisms that are subject to intentional transboundary movement are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.[37]

Appropriate domestic measures aimed at preventing and penalising illegal transboundary movements of organisms should be adopted by parties. The affected Party may also request the Party of origin to dispose of the organisms by repatriation or destruction at its own expense. The Biosafety Clearing-House must be informed of all cases of illegal transboundary movements.[38]

29 Ibid, Art. 10(2).
30 Ibid, Art. 20. The Biosafety Clearing-House provides a mechanism to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and assists Parties to implement the Protocol, taking into account the special needs of developing countries and small island States.
31 Ibid, Art. 10(3). This notification must take place within 270 days of notification by the exporting Party.
32 Ibid, Arts. 10(1), (6), 12.
33 Ibid, Art. 6.
34 Ibid, Art. 11.
35 Ibid, Art. 16.
36 Ibid, Art. 17.
37 Ibid, Art. 18.
38 Ibid, Art. 25.

Basic Requirements for the Sustainable Regulation of Biotechnology

From the above analysis, it is clear that any regulatory scheme which purports to sustainably regulate the impacts of organisms modified by biotechnology must be consistent with the principles of intergenerational equity, the precautionary principle, the polluter pays principle, and the conservation of biological diversity. In addition, the scheme must regulate the transboundary movement of such organisms in accordance with the Cartagena Protocol. Regulatory schemes should also provide for public participation in the decision-making processes under relevant legislation. Requiring compensation for the environmental and human health impacts of biotechnology, an adequate risk assessment process, and effective legal remedies would all be integral aspects of a holistic regulatory framework.

Regulating GMOs in the US

GMOs are regulated in the US under three principal pieces of legislation and by three administrative agencies. Releases into the environment are governed by the *Plant Protection Act*.[39] The relevant agency is the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), which exercises its powers under Regulation 7 CFR 340. APHIS states that it has overseen the "safe" release of 10,000 GMOs, and the deregulation for purposes of commercialisation of 60 genetically engineered (GE) products.[40] The safety of commercial food is regulated by the Food and Drug Administration (FDA) under the *Public Health Act*,[41] while the US EPA has authority under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA).[42]

Releases into the Environment in the US

In order to release a GMO into the environment, the developer of the organisms must apply for a field-test permit. If the plant falls under APHIS's "eligibility criteria", a streamlined permitting method known as the Notification Process is used. This means that the developer makes a risk assessment of the possible impacts on the environment and human health and notifies APHIS that there is no risk associated

39 7 U.S.C. 7701.

40 See APHIS New Release No. 0033.04, available at <http://www.usda.gov/Newsroom/0033.04.html> (17 August 2004).

41 21 U.S.C. 342(a)(1) s. 402(a)(1).

42 7 U.S.C. 136.

with the GMO. The release into the environment is then authorised. The only public participation provisions are where APHIS releases lists of notifications to "interested parties" *upon request*. If the plants are not "eligible", APHIS prepares an Environmental Assessment and issues a permit subject to detailed conditions. Penalties exist for non-compliance with these conditions. According to APHIS, 99 per cent of all field-tests, importations and interstate movements of GMO plants take place under this notification system. When the developer has sufficient field-test data, it may apply to APHIS for deregulation of the tested organism so that it can be commercialised. APHIS then issues a notice in the Federal Register that it has undertaken an Environmental Assessment and copies must be *ordered* by members of the public for the purpose of making submissions. There is no post-deregulation monitoring by APHIS for unexpected impacts. APHIS does not subject data supplied by the developer of the GMO to external scientific review. The only role that the US EPA plays in the scheme is under FIFRA, which gives the agency the power to regulate GM pest-protected plants as "pesticides", and pesticide residues in food.[43] It does not have regulatory authority to ensure that releases of GMOs into the environment do not impact on biological diversity.

On 29 June 2004, the US National Academy of Sciences warned APHIS that its regulation of transgenic plants (to produce pesticides) is "superficial", as most are approved using the Notification Process. The Academy noted that APHIS is relying too heavily on scientific literature rather than requiring the developer to develop experimental data.[44]

Due to increasing public concern about GMOs, in 2003/2004 APHIS announced its intention to enhance its risk assessment procedures for field-testing GMOs.[45] APHIS intends to introduce specific risk-based categories for different types of engineered plants to replace the notification system. It will revise the regulation regarding the release of plants engineered to produce pharmaceutical or industrial compounds, noxious weeds risks and biological control agents. New biological and safety information will be required of the developer as part of the application process, as well as information on confinement conditions, and there will be greater opportunities for public participation. The date for making submissions on these proposals closed very recently. Also in 2003 a new compliance and enforcement unit was established under APHIS Biotechnology Regulatory Service.

43 Ibid.

44 See <http://www4.nationalacademies.org/news.nsf/isbn/0309092094?OpenDocument> (18 April 2005).

45 *Federal Register*/ Vol. 69, No. 15/ January 23, 2004/ Notices 3271–3272. See also <http://www.aphis.usda.gov/lpa/issues/biotechcomp/biotechcomp.html> (26 August 2004).

Approving and Labelling GM Food in the US

GM food is regulated in the US under the *Federal Food Drug and Cosmetic Act*.[46] The relevant administrative agency is the FDA, which is given broad authority to initiate legal action against a food that is adulterated or misbranded within the meaning of the Act. Producers of new foods have an obligation to ensure that the foods they offer consumers are safe and in compliance with applicable legal requirements.[47] According to the FDA, the Act is used most frequently to regulate the presence of contaminants like lead, mercury, dioxin and aflatoxin in foods.[48] The FDA first disclosed its regulatory approach to regulating GM Foods in its 1992 Statement of Policy: Foods Derived from New Plant Varieties.[49] Here, the FDA stated that:

> In most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils and carbohydrates.[50]

The FDA also states that it is the responsibility of the producer of a new food to evaluate the safety of its products, relying on the guidance in the Statement of Policy. Where producers are not certain of the safety of their foods they are *encouraged* (not required) to consult with the FDA. However, it seems likely that whether producers are likely to consult with the FDA depends on the agency's policies regarding certain types of foods. The statement above regarding the FDA's view on GM modification of a plant does not suggest that consultation is needed.

The FDA also has authority to regulate "food additives"[51] and where a GMO has in fact altered the composition of a plant such that it is not "generally recognised as safe" (GRAS) it will be regarded as a "food additive". However, the Statement of Policy expressly states that:

> With respect to transferred genetic material (nucleic acids), generally, FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation ... Likewise, minor variation in molecular structure would not require regulation as an additive ... it is possible, however, that the intended expression product in a food could be a protein, carbohydrate, fat or oil that differs significantly in structure, function or composition from substances found currently in food ... and may require regulation.[52]

46 21 U.S.C. 343–1.

47 Under s. 402(a)(1) of the Act, food is deemed to be adulterated and unlawful if it bears or contains an added poisonous or deleterious substance that may render the food injurious to health or a naturally occurring substance that is ordinarily injurious. Foods that are adulterated are subject to a range of enforcement measures including seizure, injunction and criminal prosecution.

48 *Federal Register*/ Vol. 57, No. 104/ May 29, 1992/ Notices 22985 at 22989.

49 Ibid.

50 Ibid at 22985.

51 21 U.S.C. 348 s. 409.

52 Note 48 at 22990.

With respect to labelling, the Statement of Policy states that "the agency does not believe that the method of development of a new plant variety[53] is material information and would not usually be required to be disclosed in labelling."[54]

The Statement of Policy includes an extensive Guidance for Industry for foods derived from new plant varieties to assess the safety of their foods.[55]

More recently, in 2001, the FDA issued a proposed rule requiring Pre-Market Notice Concerning Bioengineered Foods [56] giving the FDA authority to declare that the safety of a GM food had not been proved prior to its release onto the market. In this Notice, the FDA recognised that because the consultation process is voluntary, domestic and overseas food producers could choose not to notify the FDA about the placement of GM food on the market. The FDA also acknowledged for the first time that since a wider range of sources for genetic engineering of plants has become available to bioengineers GM food might be significantly different from substances historically consumed in food. Consequently, the proposed rule would require a notifier to submit a pre-market biotechnology notice (PBN) to the FDA 120 days before the food is marketed. The PBN contains seven parts and is very detailed.[57] Under the proposed rule, the notifier will be encouraged to consult with the FDA regarding the safety of the food. Information about the consultation will become public under the *Freedom of Information Act*[58] unless it can be shown to be confidential. The PBN will then be sent to the Center for Food Safety and Applied Nutrition and the Center for Veterinary Medicine. The FDA will evaluate the PBN and inform the notifier either that the food is, or is not, safe, or that the FDA needs more time to evaluate it. The FDA's evaluation of the food will be placed on the Internet or in a newspaper for public review. The tone of the proposed rule is that the FDA is not expecting to find that GM foods are significantly different from those developed using traditional plant breeding methods.

Also in 2001, the FDA released a Guidance for Industry entitled Voluntary Labelling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering. The Guidance is voluntary since the FDA reiterates its view that

53 Including hybridisation, chemical or radiation-induced mutagenesis, protoplast fusion, embryo rescue, somacional variation, or any other method; ibid at 22991.

54 Ibid.

55 *Federal Register*, note 48, see s. VII.

56 *Federal Register*/ Vol 66, No 12/ January 18, 2001/ 4706.

57 Ibid, s. 192.25. Information needed includes a letter, a synopsis, an administrative statement about the status of review of the food by other Federal agencies or by foreign government; data or information about the method of development; a discussion of any newly inserted genes that encode resistance to an antiobiotic; data or information about substances introduced into or modified in the food; and data or information about the food.

58 5 U.S.C. 552.

bioengineered food does not require special labelling, as bioengineering is not a "material fact". Nevertheless, consumers may be interested in having the information, hence the Guidance.[59] There have been no updates on this Guidance by the FDA.

Conclusions about the Sustainability of GMO Regulations in the US

If we analyse the GMO regulatory framework in the US, we may well have some concerns about whether it satisfies international norms of sustainability. As can be seen, the philosophy of regulators, until 2003–2004, has been that there is no difference between GMOs and other types of plant breeding regulation, and consequently risk assessment of releases into the environment has been minimal. Until 2001, the FDA regarded GM food as no different from food derived from traditional breeding methods. The proposed rule Pre-Market Notice Concerning Bioengineered Foods still appears to be in draft form, as does the voluntary Guidance on labelling of GM foods.

As a result of this, there may well be risks for present and future generations. In the entire regulatory framework there is not one mention of the precautionary principle, and risk assessments submitted to, or undertaken by, APHIS are not subjected to external scientific review. Given this, and the minimal role played by the US EPA in the scheme, can we be satisfied that potential risks to biodiversity are adequately assessed? Certainly, the legislation provides for penalties for failure to observe permit conditions, but no direct liability for compensation is imposed on developers for the detrimental effects of their products. Also, there is minimal public participation in the decision-making processes of agencies. Generally this occurs only where interested and affected stakeholders request further information, order copies of environmental impact assessment statements, or make FOI applications.

It may be concluded that the GMO regulatory scheme in the US does not seem to satisfy the criteria for sustainable regulation.

59 US Food and Drug Administration, Center for Food Safety and Applied Nutrition, January 2001.

Regulation in the EU

Releasing GMOs into the Environment in the EU

The release of GMOs into the environment is governed by Directive 2001/18/EC on the Deliberate Release of GMOs, the Placing of GM Products on the Market and Labelling.[60] In accordance with the precautionary principle, the objective of the Directive is to provide a common regulatory framework in the Member States (MSs) to protect human health and the environment when deliberately releasing GMOs into the environment, and when placing on the market GMOs as, or in, products within the Community.[61] MSs must ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from these activities.[62] Before releasing a GMO into the environment a person must carry out an environmental risk assessment (ERA). When carrying out an ERA particular consideration must be given by MSs to GMOs containing genes expressing resistance to antibiotics for medical or veterinary use. By 31 December 2008 MSs should identify and phase out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment.[63] MSs must also ensure that any adverse effects that may occur through gene transfer from GMOs to other organisms are accurately assessed on a case-by-case basis.[64] A competent authority must be designated by MSs to take responsibility for obligations imposed by the Directive,[65] and such authority must organise inspections and measures to ensure compliance with the Directive.[66]

The ERA process is spelt out in Annex II of the Directive.[67] It comprises the following steps:

Step 1: Identify characteristics which may cause adverse effects.
Step 2: Evaluate potential consequences of effects.

60 CONSLEG: 2001L0018 — 07/11/2003. See C. MacMaolain "The New Genetically Modified Food Labelling Requirements: Finally a Lasting Solution" (2003) 28 *European Law Review* 865.
61 Directive 2001/18/EC of the European Parliament and of the Council, note 60, Art. 1.
62 Ibid, Art. 4(1).
63 Ibid, Art. 4(2).
64 Ibid, Art. 4(3).
65 Ibid, Art. 4(4).
66 Ibid, Art. 4(5)
67 See also Commission Decision of 24 July 2002 [OJ L 200/22, 24.7.2002] establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council, note 60, on the deliberate release into the environment of genetically modified organisms, repealing Council Directive 90/220/EEC [OJ L 117/15, 8. 5. 1990].

Step 3: Evaluate likelihood of occurrence of potential adverse effect.
Step 4: Estimate risk posed by each identified characteristic of GMO.
Step 5: Apply management strategy for risks arising from deliberate release of GMO.
Step 6: Determine overall risk of GMO.

The ERA should be carried out in a scientifically sound and transparent manner based on available scientific and technical data. An analysis of "cumulative long-term effects"[68] must also be carried out. If new information on the effects of GMOs becomes available the ERA may need to be re-addressed.[69]

After conducting an ERA, conclusions must be drawn about the potential environmental impacts or the placing on the market of GMOs, with reference to the following: the likelihood of GMOs becoming persistent or invasive in natural habitats; any selective advantage or disadvantage conferred to the GMO becoming realised under conditions of release; the potential for gene transfer to other species; the potential immediate or delayed environmental impact of the direct and indirect interactions between the GMO with target/non-target organisms;[70] human and animal health;[71] and biogeochemical processes.

Having undertaken an ERA, and drawn the necessary conclusions, the person wanting to release the GMO into the environment must notify the competent authority. The person must provide the competent authority with a technical dossier containing information about the GMO as well as the ERA and conclusions drawn. Bibliographic references and indications of methods used may also be supplied.[72] Having acknowledged receipt of the notification, the authority must advise the notifier within 90 days either that the release may proceed in conformity with any conditions, or that the notification does not fulfil the requirements of the Directive and is rejected.[73] If there are any modifications or unintended changes to the release of the GMOs which could impact on human health or the environment, the

68 These are spelt out under the Principles for the ERA in Annex II as effects on human health and the environment including flora and fauna, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics; note 60 at 28.
69 Directive 2001/18/EC of the European Parliament and of the Council, note 60, Annex II, B. General Principles.
70 Here the impacts on population levels of competitors, prey, hosts, symbionts, predators, parasites and pathogens must be considered; ibid, Annex II, D. Conclusions on the Environmental Impact from the Release or the Placing on the Market of GMOs.
71 Here consequences for the feed/food chain resulting from consumption of the GMO must also be considered; ibid.
72 Directive 2001/18/EC of the European Parliament and of the Council, note 60, Art. 6(1) – (3).
73 Ibid, Art. 6 (5) – (8).

competent authority must be informed and measures must be taken by the notifier to protect human health and the environment.[74]

MSs must ensure that the public is consulted on proposed deliberate releases and that all information on such releases within their territory is made publicly available.[75] The information required in such notifications is set out in Annex III of the Directive and includes information relating to: the GMO; the conditions of release and the receiving environment; the interactions between the GMO and the environment; and information on monitoring, control, waste treatment and emergency response plans.

After release, and at any intervals laid down in the consent, the notifier must send the competent authority the result of the release in respect to any risk to human health or the environment.[76] The Directive also contains provisions for consultation with the relevant Scientific Committee and the European Group on Ethics in Science and New Technologies.[77]

In addition to this sophisticated body of rules for releasing GMOs into the environment, the EU has placed specific liability for environmental damage on those who release the GMOs.

Placing Liability on Developers of GMOs to Prevent and Remedy Environmental Damage

Liability for the prevention and remedy of environmental damage is placed on those who release GMOs into the environment, and is imposed under Directive 2004/35/CE Placing Liability on Developers of GMOs to Prevent and Remedy Environmental Damage.[78] The objective of this Directive is to establish a common framework for the prevention and remedying of environment damage[79] at a reasonable cost to society. Of particular concern are the significant health risks posed by the many contaminated sites in the Community, and also the dramatic acceleration in the loss of biodiversity[80] over recent decades. GMOs are brought within the ambit of the Directive as a result of their specific mention in Annex III.[81]

74 Ibid, Art. 8.

75 Ibid, Art. 9.

76 Ibid, Art. 10. Note also Commission Decision of 29 September 2003 [OJ L 254/21, 8.10.2003] establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council, note 60, a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.

77 Ibid, Arts. 28, 29.

78 OJ L 143/56, 30.4.2004.

79 This includes damage done by airborne elements so far as they cause damage to water, land or protected species or natural habitats.

The Directive refers specifically to the principle of sustainable development and the polluter pays principle. The Directive does not apply to cases of personal injury, to damage to private property or to any economic loss and does not affect any right regarding these types of damages.[82] The liability mechanism will only be effective where there is an identifiable polluter, the damage is concrete and quantifiable, and a causal link between the damage and the polluter can be drawn. The mechanism is thus not particularly well suited to diffuse and widespread environmental effects that cannot be traced back to individual actors.[83] Operators should also be encouraged to lodge appropriate forms of financial security to provide effective cover in the event that they are held liable under the Directive.[84] Operators are required to take remedial[85] or preventive[86] action where environmental damage has, or has not yet occurred, and to bear the costs of such action.[87] Persons affected by environmental damage, with a sufficient interest relating to the damage, or alleging the impairment of a right, can request a competent authority to take action under the Directive.[88]

Regulating GM Foods in the EU

The EU has regulated both the placing of GM food on the market, and the traceability of GMOs through the food chain and the labelling of GM foods. Information on GM products on the market must also be displayed in public registers.

Placing GM Food on the Market

The placement of GM food on the market in the EU is governed by Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed.[89] The Regulation applies

80 The Directive refers to other Council Directives on the conservation of wild birds [OJ L 103, 25.4.1979], the conservation of natural habitats and of wild fauna and flora [OJ L 206, 22.7. 1992] and in the field of water policy [OJ L 327, 22.12. 2000].
81 Directive 2004/35/CE, note 78, Annex III s. 11.
82 Ibid, Preamble section (14).
83 Ibid, s. 13.
84 Ibid, s. 27.
85 Ibid, Art. 6.
86 Ibid, Art. 5.
87 Ibid, Art. 8. Note that where the competent authority has taken preventive or remedial action, the costs of the action can be recovered from the operator. Exceptions apply where the damage was caused by a third party, or the operator was ordered to comply with a compulsory administrative order, or the operator demonstrates that it was not at fault; see ibid, Art. 8(3) (4).
88 Ibid, Art. 12. Note that it is for the MSs to determine what constitutes a "sufficient interest" and an "impairment of a right".
89 OJ L 268/5, 18.10.2003. This Regulation should be read together with Regulation (EC) No 178/2002 [OJ L 31/1, 1.2.2002] laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

to GMOs for food use, food containing or consisting of GMOs and food produced from or containing ingredients produced from GMOs.[90] It also applies to GMOs for feed use, feed containing or consisting of GMOs and feed produced from GMOs.[91] Food must not: have adverse effects on human health, animal health or the environment; mislead the consumer; or differ from the food which it is replacing such that its consumption would be nutritionally disadvantageous to the consumer. No person can place on the market, use or process such food without an authorisation granted under the Regulation.[92]

The following information must accompany the application for authorisation: where applicable, information complying with the Cartagena Protocol; a detailed description of the method of production and manufacturing; a copy of studies, including independent peer-reviewed studies, which demonstrate that the food does not have adverse effects on human health, animal health or the environment; an analysis that the food is not different from its conventional counterpart; a reasoned statement that the food does not give rise to ethical or religious concerns; the conditions for placing the food on the market, including specific conditions for use and handling; a proposal for post-market monitoring; and other information.

In addition, the complete technical dossier of information on a GMO required under Annexes III and IV of Directive 2001/18/EC must be included. Information and conclusions about the ERA carried out under the Directive, as well as any authorisation under Part C of the Directive, must be provided to the competent authority. The monitoring plan for environmental effects prepared under the Directive must also be produced.[93]

Upon receiving an application, the competent authority must notify the European Food Safety Authority (EFSA) and supply it with all relevant information to enable the Authority to formulate an opinion on the safety of the food. EFSA must forward its opinion, within six months, to the Commission, the MSs and the applicant, with a report describing its assessment of the food and stating the reasons for its opinion and the information on which its opinion is based, including the results of any consultation with competent authorities.[94] Within three months of receiving this opinion the Commission shall inform the Standing Committee on the Food Chain on Animal Health[95] of its draft decision. Once a final decision is made, the applicant is notified and the authorisation lasts for ten years, and may be renewed.[96]

90 Ibid, Ch. II.

91 Ibid, Ch. III. Note that although it is clear the feed given to animals may harm human health, these provisions are not discussed in any detail in this article, which focuses on GMO food.

92 Ibid, Art. 16.

93 Ibid, Art. 5.

94 Ibid, Art. 6. See this Article generally for details relating to the formulation by the Authority of its opinion.

95 Established under Art. 58 of Regulation (EC) No 178/2002.

Tracing and Labelling GMOs

Traceablity and labelling provisions are found in Regulation (EC) 1830/2003 Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms.[97] The Regulation provides a harmonised Community framework for the traceability and labelling of GM foods to allow the internal market to function effectively. According to the Regulation, traceability of GMOs facilitates the withdrawal of products if unforeseen adverse impacts on the environment or animal and human health are detected. It also facilitates the implementation of risk management measures in accordance with the precautionary principle.[98] Accurate labelling of GM foods is also enhanced.

The person who places the GM product on the market is required to give the receiver of the product (both parties being known as "operators") both the information that the product contains or consists of GMOs and the unique identifier assigned to the GMOs.[99] This information must be continually transmitted in writing throughout the supply chain. Operators who place GM products on the market and who receive them must have in place systems and standardised procedures for holding the necessary information about the product for a period of five years after each transaction.[100] An operator placing GM food and feed on the market must give the receiver of the product the following: an indication of each of the food ingredients which is produced from GMOs; an indication of each of the feed materials or additives which is produced from GMOs; and in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.[101]

Operators are also required to label pre-packaged products consisting of or containing GMOs with the words "This product contains genetically modified organisms" or "This product contains genetically modified [name of organism(s)]". For non-pre-packaged products offered to the final consumer the same words must appear on, or in connection, with the display of the product.[102] Consistent with

96 Directive 2001/18/EC on the Deliberate Release of GMOs, note 60, Art. 7.

97 OJ L 268/24, 18.10.2003. See, A. MacGregor and E. Brown "EU: GMO Regulation – Progress" (2003) 9 *International Trade Law & Regulation* N17.

98 Ibid, Preamble (3), (4).

99 The Commission must establish a system for the development and assignment of unique identifiers to GMOs; ibid, Art. 8.

100 Ibid, Art. 4 A. Traceability.

101 Ibid, Art. 5.

102 Ibid, Art. 4 B. Labelling.

Directive 2001/18/EC,[103] exemptions apply to the traceability and labelling of products which contain traces of GMOs below thresholds established under the Directive.[104] MSs have the obligation of ensuring that inspection and monitoring systems are put in place to ensure compliance with the Regulation in accordance with a technical guidance developed by the Commission. MSs must also lay down rules on penalties for infringements of the Regulation.[105] Also, the Commission must ensure that a central register is available at the Community level containing all available sequencing information and references for GMOs that are authorised. Information should also be included about GMOs that are not authorised.[106]

Recording Information about GMOs on Public Registers

In addition to the requirements for making information publicly available under Directive 2001/18/EC, detailed arrangements are in place for the operation of GMO registers. This is done under the Commission Decision 2004/204/EC Providing for Public Registers to Record Information on GMOs.[107] The following information must be included in the registers: details of the notifier and persons responsible for placing GM products on the market (where they are different from the notifier); general information concerning the GMO; information on the nucleotide sequence of the insert; information concerning detection and identification methods; and information on the lodging, storage and supply of samples.[108] Registers must be publicly available, although confidential data on the registers will only be accessible to the MSs, the Commission and EFSA.[109] Competent national authorities are responsible for extracting all of the information they receive in notifications and submitting this to the Commission either at the time of submitting the assessment report, or within two weeks thereafter. Links to other registers and databases such as the opinion of the EFSA, the assessment report of the competent authority, and the Biosafety Clearing-House, may also be provided.[110] The registers must be updated.[111]

103 Note 60, Art. 21.
104 Note 97, Art. 4 C. Exemptions.
105 Ibid, Art. 11.
106 Ibid, Art. 9.
107 OJ L 65/20, 3.3.2004.
108 Ibid, Art. 3.
109 Ibid, Art. 4.
110 Ibid, Art. 5.
111 Ibid, Art. 6.

Regulating the Transboundary Movement of GMOs

Clearly, European states have an interest in being informed about the transboundary movement of GMOs. This is provided for under Regulation (EC) 1946/2003 on Transboundary Movement of GMOs between European States.[112] This Regulation is expressly intended to adopt the Cartagena Protocol into EU law.[113] Hence, the advance informed agreement procedure contained in the Protocol is replicated in the Regulation. The definition of "transboundary movement" excludes the intentional movement of GMOs between Parties within the Community. The Regulation deals with GMOs intended for deliberate release into the environment,[114] GMOs intended for direct use as food or feed, or for processing,[115] and GMOs intended for contained use.[116] The Regulation does not cover GMOs intended for deliberate release if the Conference of the Parties to the Convention on Biological Diversity has already decided that the GMO is not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health.[117] MSs are required to take appropriate measures to prevent unintentional transboundary movements of GMOs.[118] MSs are also required to inform the Biosafety Clearing-House and the Commission of all national legislation and guidelines that implement the Protocol.[119]

The Centrality of the Precautionary Principle in the EU Context

As already mentioned, the precautionary principle is a fundamental principle of sustainable development. Analysis of EU regulation governing GMOs indicates that the EU recognises that the precautionary principle has a crucial role to play in assessing the risks relating to GMOs, and in the making of decisions based on that assessment.[120] Reference to the precautionary principle in all the EU law mentioned above should be read together with the Communication from the Commission on the Precautionary Principle[121] in order to understand how the precautionary

112 OJ L 287/3, 5, 5.11.2003.
113 Ibid, Art. 1.
114 Ibid, Ch. II, s. 1.
115 Ibid, s. 2.
116 Ibid, s. 3.
117 Ibid, Art. 8(1).
118 Ibid, Ch. III, Art. 14.
119 Ibid, Ch. IV, Art. 15.
120 See N. Salmon "A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO" (2002) 27 *European Law Review* 138. See also, A. Nucara "Precautionary Principle and GMOs: Protection or Protectionism" (2003) 9 *International Trade Law & Regulation* 47.
121 Brussels, 02.02.2000, COM (2000) 1.

principle will be applied in the context of GMO decision-making. What is most notable is that the EU believes that an assessment of the risks associated with GMOs should be made not only in accordance with the precautionary principle, but that the assessment should be politically determined.

It is not surprising that the EU has taken this stance given that the precautionary principle is specifically mentioned in the Treaty Establishing the European Community,[122] where it is stated that:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay. Environmental protection requirements must be integrated into the definition and implementation of other Community policies.[123]

Nowhere in the Treaty, nor the documents mentioned above, is the precautionary principle specifically defined. However, reference may be made to a well-known definition of the precautionary principle:

> Where there are threats of serious or irretrievable damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[124]

The Court of Justice of the European Community and the Court of First Instance have had occasion recently to develop case law relevant to the precautionary principle and GMOs. In *Monsanto Italia SpA and Others* v. *Presidenza del Consiglio dei Ministri*,[125] the Court stated that the precautionary principle allows protective measures to be taken without having to wait until the reality and seriousness of risks become fully apparent, even if a full risk assessment proves impossible because of the inadequate nature of the scientific data available.[126] In this case, Monsanto notified the Commission of its intention to place cornflour derived from genetically modified maize grain (Bt–11 and MON 810) on the market. It relied on an

122 OJ C 325/33, 24.12.2002.
123 Ibid, Art. 130r.
124 Rio Declaration, note 7, Principle 15.
125 *Monsanto Italia SpA and Others* v. *Presidenza del Consiglio dei Ministri* (C–236/01) [2003] ECR I–8105.
126 Regulation (EC) No 258/1997 Concerning Novel Foods and Novel Food Ingredients [OJ L 253, 16.09.1997] provided that foods which are produced from genetically modified organisms *but no longer contain them* may be placed on the market within the Community under a "simplified procedure". This procedure requires the person to notify the Commission that it intends to place a product on the market. A competent national authority must have already concluded that the GMOs are *substantially equivalent* to comparable traditional foods.

assessment of substantial equivalence by the competent authority in the United Kingdom. The Commission subsequently notified the Member States. In 2000, the presence of residues of transgenic protein (expressed by the inserted gene) in the cornflour were noted by an Italian scientific institute. However, opinion as to whether or not they posed any risk to human health was divided. Italy subsequently adopted a decree on 4 August 2000 providing for the precautionary suspension of the trade in and use of products derived from those maize lines. Monsanto and Others subsequently challenged the Italian decree, which they considered to be in breach of Community law. The Court found that where use of the "simplified procedure" is not warranted, a Member State can, as a preventive measure, temporarily restrict or suspend the marketing of those foods in its territory without first being required to challenge the lawfulness of the procedure.

Despite the lack of definition of the precautionary principle, the Communication states that applying the precautionary principle is a key tenet of its policy that it has the right to establish a level of environmental, human, animal and plant health that it deems appropriate.[127] Further, that the principle should be considered within a structured approach to the analysis of risk which comprises risk assessment, risk management and risk communication, with the principle having particular relevance to risk management. However, the Communication goes on to say that "judging what is an 'acceptable' level of risk for society is an eminently *political* [sic] responsibility". It also emphasises that the precautionary principle is not concerned simply with short- or medium-term risks but with long-term risks and the well-being of future generations.[128] As a result, the decision-making procedure should be transparent and involve all interested parties as early as possible, and to the extent reasonably possible.[129] As well,

> ... all interested parties should be involved to the fullest extent possible in the study of various risk management options that may be envisaged once the results of the scientific evaluation and/or risk assessment are available and the procedure be as transparent as possible.[130]

It is clear that the EU believes that the assessment of risk relating to the release of GMOs must be done in accordance with the precautionary principle and that its application, in practice, must be politically determined.

127 Note 121 at 3.
128 Ibid at 8.
129 Ibid at 4.
130 Ibid at 17.

Conclusions about the Sustainability of GMO Regulations in the EU

It is clear from the preceding discussion of EU law governing the deliberate release of GMOs into the environment and the placing of GM food and feed on the market that the precautionary principle is a central tenet of the regulatory scheme. This is in direct contrast with the US regulatory scheme where the principle is not mentioned, even once, in all the legal and policy documents regulating GMOs. Purely from this perspective, one could affirm that the EU scheme is more closely aligned with the principles of sustainable development enunciated earlier. Of course this is true for a number of other reasons, not least of which is the detailed body of law which attempts to cover all the elements of a sustainable regulatory framework for GMOs: rigorous risk assessment procedures; reference to expert panels; opportunities for public submissions; access to information; provisions which attribute liability to those who cause harm; and proper labelling requirements. As a result of all of these provisions, we might conclude that the EU framework is likely to present fewer risks for present and future generations and to biodiversity than the US scheme.

Exposing the Regulatory Dilemma: the Relationship Between Regulation and Public Acceptance of GMOs

Despite the extensive regulation of GMOs in the EU, there is still considerable concern amongst NGOs and the public about the safety of GMOs. There is a de facto ban on the commercial development and planting of GM crops in the EU, as well as a ban on the importation of GMOs.

In comparison, in the US 99 per cent of releases of GMOs into the environment are authorised using a streamlined process of "notification", the deficiencies of which have been described above. Of particular concern from a sustainability point of view is that the only risk assessment done prior to the release of a GMO is that done by the proponent of the release. APHIS does not itself assess the risk to the environment and human health before permission is given to undertake field-tests and there is no independent scientific review of APHIS decisions. In addition, there is virtually no public participation. GM foods do not need to be labelled. Only in 2004 did APHIS decide to review its policies and procedures and introduce a more rigorous assessment process. Yet there has been a ready uptake of GMOs and GM foods in the US.

Why is this so? How do we explain the paradox of a US public which is so accepting of food derived under a relatively lax regulatory framework, and a fearful

EU public protected by extensive regulation and risk assessment processes? Is it that the safety of GMOs has not been scientifically proved to the satisfaction of the EU community (and many other communities across the globe), whereas the US public seems to be relatively unconcerned about their safety?

More importantly for present purposes, is this in fact a puzzle which lawyers and regulators can attempt to answer? What this article has probably shown is that law, and agency decision-making that is consistent with that law, will not of itself resolve the public's fear about GMOs, especially when there is still considerable scientific uncertainty, and relatively little experience of them. Not even the application of the most sophisticated legal system for regulating GMOs, such as the EU's, will encourage an unwilling public to accept GMOs.

This makes the task of regulators extremely difficult. Regulators act within a framework of law which vests in them powers and responsibilities. The law requires administrative agencies to act consistently with the law, to reach the "correct" decision, and to act in a way that provides certainty to those affected by their decisions. It must be remembered that the certainty of law, and decisions made consistently with the law, are a fundamental requirement of the Rule of Law. Yet decisions about the release of GMOs into the environment, or the placing of GM foods on the market, must be made on data provided by scientists and even economists, and is surely plagued by uncertainty.

Essentially, decision-makers must decide whether the threshold of scientific uncertainty has been reached, such that they should not allow various dealings with GMOs. Decisions are also likely to be made based on a cost-benefit assessment of such dealings. It must be remembered, however, that scientists and economists are used to dealing with "margins of error" in their respective disciplines. Few scientists will argue that their experiments deliver 100 per cent certainty, whilst economists accept that the results of their modelling are dependent on the data used in the first place. The certainty of scientific and economic data is rendered all the more problematic in the postmodern age where the "truth" of their data may be challenged from a myriad of perspectives.

These challenges provide a background for some fundamental questions about whether the scientific uncertainty inherent in the precautionary principle and the regulation of GMOs can be politically negotiated as suggested by the European Commission in its Communication from the Commission on the Precautionary Principle. How does such negotiation assist the regulator?

Can the Safety of GMOs be Politically Negotiated?

Prevailing social and political values are generally discovered by decision-makers (or lawmakers) when they engage in processes of public participation to receive input from interested and affected stakeholders regarding the decisions (or law) they intend making. The EU's Communication suggests that the problems faced by regulators in making tough decisions about GMOs can somehow be resolved by engaging the public in a determination of whether, by applying the precautionary principle, dealings in GMOs should be permitted. It is not clear that political resolution of this question assists with the dilemma which regulators face.

One of the most extensive GMO public participation exercises to date is the United Kingdom's "GM Nation?" public debate, which was undertaken to inform public policy on the GMOs. The debate emanated from the recommendation the Agriculture and Environment Biotechnology Commission (AEBC) made in its 2001 report *Crops on Trial.*[131] The Commission stressed the importance of encouraging a broader national debate, stating that:

> It will be crucial for the public to be involved in the important decisions which need to be taken. We have to find a way to foster informed public discussion of the development and application of new technologies.[132]

The debate was extensive, involving 675 local meetings, 3.9 million hits on the "GM Nation?" website and 1,200 letters and emails. The findings of the public debate were that: there is a general unease about GMOs; the more people engage with GMOs the harder their attitudes become; there is little support for early commercialisation; there is a desire for more information and further research; and there is a deep mistrust of government and multi-national companies.[133]

With respect to the sense of unease among those people who took an active part in the debate about GM crops, their attitudes of caution, doubt, suspicion, scepticism, hostility or rejection far outweighed any degree of support or enthusiasm for GMOs. The majority rejected any suggested benefits from GMOs. Just over half of active participants never want GM crops to be grown in the UK under any circumstances. The remainder seeks varying periods of delay so that new research can identify, eliminate or reduce to an acceptable level any risks to the environment or human health.

131 For an explanation see <http://www.gmnation.org.uk/ut_09/ut_9_1.htm> (18 November 2004).

132 AEBC *Crops on Trial* at <http://www.aebc.gov.uk/aebc/pdf/crops.pdf> at para 68.

133 "GM Nation? Findings" at <http://www.gmnation.org.uk/ut_09/ut_9_6.htm>. See also M. Grekos "GM Public Debate — Findings Published" [2003] *Journal of Planning & Environment Law* 1530.

The mistrust of government was caused by the suspicion that government has already taken a decision to promote GMOs while using the debate to camouflage its decision. This seemed to link in with a general mistrust of modern governments, which are perceived to pursue secret agendas and ignore the public's views. There is also a lack of trust in the government's ability or will to defend the public interest, especially as they may be too closely aligned with the interests of multinational corporations. The public was suspicious of information about GMOs disseminated by multinational corporations which are regarded as pursuing profit rather than meeting society's needs. Overwhelmingly, people wanted to be provided with information which was independent and which they could trust. Essentially, they were looking for an agreed set of "facts" acceptable to all interested and affected stakeholders.

How Should Agencies Respond to Political Expressions of "Fear", "Unease" and "Deep Mistrust"?

It seems that when agencies exercise their legislative mandates to make decisions about GMOs they inevitably end up in a bind. Typically, developers of the GMOs make applications under the legislation for permission to release GMOs into the environment, or to place GM foods on the market. The agencies attempt to make decisions as they would in the normal course of events, ensuring that they are acting consistently with all laws, delegated legislation and departmental policy. They would base their decisions on the best evidence made available by in-house or external expertise. Ideally, they would seek submissions from the public and base their decisions on the precautionary principle. In other words, they would be exercising their powers in accordance with the highest standards required of administrative decision-making. Yet having done so, can they really be satisfied that they have reached the correct decision, and that their decisions will be accepted not only by those affected by them, but by other interested and affected stakeholders?

What, for example, has the UK government learnt from "GM Nation?" and what will it do with the information? When people say they want more research, and an agreed set of facts, can government deliver? Surely the fact that the precautionary principle plays such a prominent role in EU decision-making demonstrates that there is still an appreciable level of scientific uncertainty regarding GMOs. Can government ever deliver an "agreed" set of facts in light of this? Even if it could, to what extent do sizeable segments of society understand, and interpret correctly, the scientific evidence and economic modelling that they are shown? How many different interpretations of the same data are possible? One of the problems may be that no matter how much data is presented to the public, its opposition is based not

so much on science as "intuition" that GMOs are dangerous. How can regulators deal with this? Can they, as civic republicanism suggests, mediate conflicting views and reach a decision that equates to the "common good"? Can they do this alone, or what more do they need to understand about the paradoxes of regulating GMOs?

What can be done to overcome the significant levels of mistrust and suspicion with which the government and multinational corporations are regarded? Are regulators adequately equipped to understand and address this serious deficit? Who, and which sources of information, will the public trust?

In the author's view, the attitudes of mistrust, suspicion, fear, hostility, and rejection that permeate the GMO debate require a far broader and very different type of interrogation. What the case studies of EU and US regulation have shown is that the utility of the law is very limited. In fact, the analysis has succeeded in illuminating an essential paradox: there seems to be an inverse relationship between the quality of the law regulating GMOs, and the public's attitudes towards them.

Perhaps there is no paradox. Perhaps lawmakers and regulatory agencies in the EU and the US have been responding to preexisting perceptions in the community. Perhaps where there are no concerns the law is lax; and where GMOs are regarded with scepticism the law is extensive. Yet, even so, the EU case study indicates that even where a body of law is developed with the specific goal of achieving the most sustainable GMO outcome possible, lawmakers have failed in their project to convince an unwilling public of its legitimacy.

Conclusion

It seems fair to say that at present, in the many developed and developing countries around the world, GMOs elicit a very strong reaction. Mostly, the reaction is negative at worst and tentative at best. The result is that lawmakers and agency decision-makers are placed in an unenviable position as they try to navigate a course through the maelstrom created by GMOs. The multinational companies that develop GMOs seem mystified by the public's response to them. To date, there is no science which proves that GMOs are harmful to the environment and human health. Certainly, there is enough science to show that certain problems could arise where GMOs are utilised, but none of this has been conclusively proved. There are many who extol the environmental benefits of GM crops which require fewer fertilisers, herbicides and pesticides. Others point to the fact that there will be nine billion people by 2050 concentrated in developing countries. Their food security is tenuous given the

shrinkage of available farmland and decreasing productivity caused by housing, infrastructure, and climate change. Not even this persuades the detractors.

So what is the way forward on GMOs? It is the author's view that new questions need to be asked about GMOs and the public's attitudes towards them. Without a novel approach to discovering what is at the heart of these feelings of "mistrust", "fear" and "unease", regulators, developers of GMOs, and multiple publics, in both developed and developing countries, will remain deadlocked. Science can only take the debate so far. Public participation procedures seem to deliver a circularity of arguments which go something like this: "Regulators should consult us on GMOs because we don't think we like them, and we are fearful about what they might do to us and the environment. And when regulators do consult us we will tell them that we are fearful and that we don't trust GMOs, or the regulators, or the multinational companies that develop GMOs, for that matter."

The information we have so far about GMOs must have limited utility. If an individual, as opposed to large swathes of the public, were to consult a general practitioner displaying symptoms of fear, mistrust and unease without really knowing why, the practitioner would recommend that the individual consult with a psychologist, trained to infiltrate the intricacies of human thought and understand the source of the symptoms. So too does the GM psyche of nations need to be interrogated from a new and different multidisciplinary perspective. Then society can either move forward on GMOs, or decide once and for all to close the door on their utilisation and development. Alternatively, perhaps a *via media* could be achieved where public trust in agencies is restored. Then agencies could be relied upon to create administrative procedures to firmly regulate and control GMOs, continually monitor their impacts on the environment and human health, and commit to withdrawing their consent to GMOs at the first scientific proof of harm, while penalising those who caused the harm.

At present, the EU has done all of this, but it has failed to prove to the EU community that agencies will adequately assess the possible risks relating to GMOs. It must be because the right questions are not being asked, and satisfactory answers are not being given. Perhaps it is time to do so. Only then can a truly sustainable framework for dealing with GMOs emerge.