RISK MANAGEMENT AND EXPERTISE: Biotechnology Risk Regulation in Europe: Linking Precaution with Sustainable Development

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Summary: In the risk debate over genetically modified (GM) crops, their status as ''environmentally-friendly products'' has been controversial. The 1990 precautionary legislation of the European Union was designed to anticipate potential harm from GMOs in advance. Yet the acceptability of harm - or even its definition - has been contentious in evaluating commercial products. The legislation has been interpreted in ways which implicitly link concepts of precaution and ''sustainable development''. In the mid-1990s risk regulation, the European Union framed ''risk'' within a commitment to intensive agriculture. Its familiar hazards were accepted as a normal baseline for evaluating the effects of GM crops. The regulatory procedure regarded choices of crop protection measures as irrelevant or interchangeable, and therefore regarded some future options as dispensible, regardless of whether they would be environmentally preferable. At least implicitly, safety claims presupposed environmental advantages of GM crops in reducing agrochemical usage. That risk-framing came under challenge from widespread protest and expert disagreements. In response, some governments applied more precautionary measures. They broadened the definition of the ''adverse effects'' which must be avoided, devised market-stage precautions for such effects, and increased the burden of evidence for demonstrating safety. Soon the EU-wide procedure began to formalize such approaches. In the contested definitions of relevant harm, there are deeper issues about the sort of environment which should be protected, sustained or created. Thus GM crops have become a test case for environmental norms, within a broader debate about how to construct a sustainable agriculture.

Keywords: European Union, biotechnology, genetically modified (GM) crops, risk, environmental protection, precautionary approach, sustainable agriculture.

ARTICLE

In the risk debate over genetically modified (GM) crops, their status as ''environmentally-friendly products'' has been controversial. Arguments continue over whether agricultural biotechnology will mitigate the harmful effects of intensive monoculture, or inadvertently perpetuate such problems. The debate involves conflicting concepts of risks and benefits, not simply different emphases on risks versus benefits.

Proponents emphasize that GM crops offer crucial benefits, e.g. by enhancing economic competitiveness, increasing food production in pace with population growth, and minimizing

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agrochemical usage. Industry R&D programmes diagnose the problem as inefficient agricultural inputs, which can be solved by precise genetic changes. From this perspective, society faces the risk of foregoing the benefits that biotechnology can bring.

Moreover, the biotech industry has adopted the language of environmental sustainability. According to one company, for example, ''Our products create value for our customers by helping them to combine profitability with environmental stewardship. For product impact, this means: more productive agriculture, more soil conservation, less insecticide use, less energy, better habitat protection." For example, "in-built genetic information" helps GM crops to protect themselves from pests and disease [1, 2]. On a similar basis, many companies promote their GM crops as sustainable agriculture.

Critics argue that GM crops impose unknown ecological risks, reduce the biodiversity of plant cultivars, direct R&D according to commercial criteria, generate selection pressure for resistant pests, and promote the further industrialization of agriculture. They warn against a "genetic treadmill", by analogy to the agrochemical treadmill - whereby pests develop resistance to pesticides, companies try to develop alternatives faster than the resistance, and farmers become more dependent upon chemical solutions.

Some critics diagnose the problem as intensive monocultural practices which attract pests and disease. They attack biotechnology for perpetuating the problem, while precluding beneficial alternatives. As a means to sustainable agriculture, they advocate alternative practices which would help farmers to minimize or overcome their technological dependency.

Risk regulation has had the task of translating this debate into risk-assessment criteria and scientific evidence, as arguments for whether (or how) to permit the commercial cultivation of specific GM crops. European Union legislation has precautionary features for anticipating potential harm in advance. Yet the acceptability of harm, or even its definition, has been contentious. The criteria for risk assessment have been changeable, even within each country.

This essay asks: How do the EU's regulatory conflicts relate to various accounts of agricultural problems and solutions ? How is the risk problem framed and reframed ? What links are drawn between environmental precaution and sustainable agriculture ?

To address such questions, this essay first surveys general perspectives on key concepts. Subsequent sections analyse how GM crops gained EU-wide commercial approval, how those decisions came under challenge, and how governments imposed more stringent controls. The final section analyses the links being drawn between environmental precaution and sustainable agriculture.

Perspectives: risk, precaution and sustainability

The term "risk" has acquired many meanings. When debates are phrased in terms of risk, often it denotes a legitimacy problem for an entire technological development. According to Ulrich Beck [3] risk debates express contending visions of how society should be organized. From this perspective, technological options are seen as broad socio-political choices about "how we should live". Risk debates generate conflicts of accountability about how potential harm "can be distributed, averted, controlled and legitimated" [4].

Technical evidence is inseparable from worldviews about nature and society. This feature has been theorized as a "framing" which underlies all risk knowledge. In seeking and organizing more facts about risk, we make socio-political choices - e.g. about what potential harms to prevent and, in so doing, about what opportunities to forego. "We can hardly order, rearrange, or usefully supplement our knowledge about risk without incorporating these issues into a clear, framing vision of the social and natural order that we wish to live in" [5].

For this reason, any claim about scientific "uncertainty" plays several roles. It may be used as a political strategy to delay contentious decisions, to accommodate disagreements, or to gain resources to gather more scientific information. In practice, additional research often leads to further controversy over how to interpret the experimental results, partly because the research is grounded within a particular model of the relevant uncertainty [6].

Moreover, according to Wynne [7], scientific uncertainties cannot be properly described as objective shortfalls of knowledge. Rather, the perceived uncertainty is a subjective function of complex social and cultural factors: scientific uncertainty can be enlarged by social conflict. Moreover, the disputed uncertainties may go beyond different interpretations of the available data: "the body of knowledge itself may change". Research may set new priorities for "what is defined scientifically as problematic or not". In precautionary mode, risk research has generated new facts on broader cause-effect pathways of harm [7].

Scientific uncertainty has served as a link between environmental precaution and sustainability. According to the 1990 Bergen Ministerial Declaration: "In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation." (cited in Haigh, [8]).

Key terms in that statement have been subjects for further debate. As widely defined, sustainability is often understood as "development which meets the needs of the present without compromising the ability of future generations to meet their own needs" [9]. Its interpretation requires judgements about how resources should be conceptualized, valued, managed, preserved or consumed. A precautionary approach requires judgements about what counts as "serious" damage, what protective measures are warranted to avert or manage it, and what further scientific knowledge would clarify the uncertainty.

The meaning of the precautionary principle is flexible, depending on the types of uncertainty which are emphasized, investigated and managed. It can be seen as "an expression of environmental value, phrased in the rhetoric of science" [10]. Likewise, claims for "sound science" entail environmental values too, though in less transparent ways [11, 12].

Since the early 1990s European Community policy has emphasized both "the precautionary approach" and "sustainable development", though without a clear link. For the agricultural sector, environmental problems have been attributed to an "over-intensification", leading to degradation of the natural resources on which agriculture depends. The corresponding solution is to develop cultivation methods which decrease inputs of agrochemicals [13].

According to a proposal for reforming the CAP, Agenda 2000, "The development of genetic engineering, if well controlled, could enhance production but may raise questions of acceptability to consumers." That document emphasized the priority to enhance rural livelihoods and the quality of production, rather than its quantity [14]. For European agricultural policy, then, sustainability denotes environmental and socio-economic effects rather than food security.

The rest of this article will trace how those issues have arisen, at least implicitly, in the European regulation of GM crops. The analysis will emphasize the framing visions of agriculture and society.

Approvals re-opened

As GM crops entered commercial use in the late 1990s, anti-biotechnology activists catalysed a wide-ranging debate on the agro-food chain. Environmental issues were taken up by consumer NGOs as well as environmental ones. New protest linked GM food with environmental risks of cultivating GM crops. Many people boycotted GM food as a way to "vote" against agricultural biotechnology, in the absence of any available democratic procedure for taking such decisions. Consumer protest and boycotts led major retailers to exclude GM ingredients from their own-brand labels.

By the late 1990s GM crops were being evaluated for how their associated agricultural methods might affect biodiversity and sustainable agriculture. In Austria GM crops are widely regarded as a threat to organic agriculture, which the government heavily subsidizes as a model for sustainable development and high-quality products. Austrian regulators evaluated potential environmental effects of GM crops by comparison to methods which use no agrochemicals. The Italian Parliament has foreseen GM crops threatening traditional cultivars and high-quality products, perhaps through economic competition as much as through environmental effects.

In the UK the government's own nature conservation advisors warned that broad-spectrum herbicides, for which herbicide-tolerant crops are designed, could harm wildlife habitats near agricultural fields. Similar warnings had already come from various NGOs, which also criticized chemical-intensive agricultural methods. Some promoted organic methods - as a future model, and as a baseline for judging the environmental effects of GM crops. As they are designed for an "increasingly intensive monoculture", GM crops became a focus of public pressure for environmental improvement: they should be evaluated in a wider debate about sustainable agriculture, "not just relative to today's substantially less-than-sustainable norm" [19].

In France numerous scientists joined calls for a moratorium on gm crops. INRA abandoned its innovation research on herbicide-tolerant oilseed rape. According to the then-President, "extreme caution is necessary in the face of a major innovation which has, as yet, unknown effects" [20].

Some large-scale farmers initially sought access to GM crops to enhance their economic competitiveness, though others have regarded such products as a threat. French peasants' leaders emphasized biotechnological risks to democracy, to consumer choice, to their economic independence and to high-quality French products. As an alternative future, they argued, "Today, more and more farmers lay claim to a farmer's agriculture, which is more autonomous, economic, and which integrates problems associated with the environment, employment, and regional planning" [21].

In these ways, public debate and scientific disagreements opened up new ways of interpreting the precautionary principle. Arguments tended to link environmental effects, agricultural methods and/or socio-economic concerns - in different ways than safety claims had done in the mid-1990s. New pressures highlighted weaknesses in the official risk assessments and strengthened objections that had previously been over-ruled.

Risk-assessment judgements can be analysed as three related elements *(figure)*:

* a normative baseline for defining the "adverse effects" that should be evaluated and avoided;

* the predictability of effects, given new scientific knowledge which may decrease or increase uncertainty; and

* the burden of scientific evidence for safety or risk, as well as relevant types of evidence.

In the original safety claims, the normative baseline was the familiar hazards of intensive agricultural methods. In the original objections from some member states, and in the later public debate, the normative baseline was more stringent. "Adverse effects" were defined more broadly, e.g. including the implications for agrochemical options. This shift opened up more cause-effect pathways to arguments about predictability, e.g. gene flow and persistence.

In response to new protest and debate, government and industry devised further precautions for the cultivation of GM crops, as means to address public and scientific concerns. These measures were intended to detect and/or avoid undesirable effects whose acceptability was in dispute [22]. In so doing, extra precautions can also fulfill other important purposes, for example, to allow time for further discussion about risk-assessment criteria, and to provide public accountability for the test methods.

These measures are being formalized in the revision of Directive 90/220. As well as adopting the precautionary principle, it provides for time-limited registrations and market-stage monitoring, which shift the burden of evidence further towards demonstrating safety [23]. Links with sustainable agriculture can be illustrated by two main products.

Herbicide-tolerant oilseed rape

Oilseed rape has been genetically modified for tolerance to broad-spectrum herbicides, e.g. glufosinate or glyphosate. When a glufosinate-tolerant oilseed rape was first proposed for market approval in 1994, conflicts emerged over two main risks. (For a more detailed account, see références [16-18]).

Oilseed rape has considerable pollen flow and weedy relatives in Europe, so the inadvertent development of glufosinate-tolerant weeds could jeopardize the use of glufosinate as a future weed-control option. Among other member states, Denmark and Austria wanted the risk assessment to evaluate the overall implications for herbicide usage. Denmark had a policy to reduce agrochemical usage, so that ground water could be used safely for drinking purposes. As in all its environmental legislation, Denmark's 1986 biotechnology law affirmed the general aim of "sustainable development".

As rapporteurs for glufosinate-tolerant oilseed rape, the UK and France conceptualized the prospect of herbicide-tolerant weeds as "an agricultural problem". This concept allowed them to argue that widespread tolerance would be acceptable on several grounds, e.g. because other weed-control methods would still be available if necessary. Such an argument provided the official basis for EU-wide market approval [24, 25]. As one UK advisor commented, "A weed is not a problem if you can control it", as if the choice of control methods made no difference. Thus the safety claim was framed by an intensive agricultural model.

Eventually the policy changed in France, in response to public protest. Rather than sign the final authorization, as required for the EU-wide consent to take effect, France declared a two-year moratorium in November 1998. Citing its own field studies on hybridization with weedy relatives [26], the government argued that further research was needed before deciding on commercial use. Thus approval was blocked by broadening the regulatory definition of "adverse effects".

Also controversial were the wider environmental effects of spraying a broad-spectrum herbicide such as glufosinate. Among other countries, Denmark originally demanded that the risk assessment should encompass the overall environmental implications of cultivating the crop. However, the rapporteur argued that any "secondary effects" would be caused not by the crop, but rather by the herbicide, which is regulated under the EC Pesticide Directive [27]. In practice, however, this legislation offers no clear means to evaluate the overall effects of herbicide usage. In the UK no regulators had clear responsibility for evaluating potential harm from the broad-spectrum herbicides which would be spray-ed on herbicide-tolerant crops.

Again, in response to public protest, some member states changed their stance. In 1998 the UK Environment Ministry re-interpreted Directive 90/220 to encompass the effects of agricultural practices. This move linked GM crops with the Ministry's previous efforts at encouraging farmers to reduce herbicide usage in ways which would benefit wildlife habitats and biodiversity. Like the UK, France too re-interpreted the Directive so as to encompass the herbicide effects. Eventually the Council of Ministers undertook to evaluate all "indirect effects", widely understood to encompass ''secondary effects'' of cultivation practices [23].

In addition, the UK funded farm-scale trials of herbicide-tolerant crops to monitor the effects of broad-spectrum herbicides on the biodiversity of farmed land. The experimental design was overseen by a steering committee whose members included environmental NGOs. The UK also expanded its main advisory committee to include expertise in agro-ecology, thus overcoming its previous demarcation between the "agricultural" and "non-agricultural" environments.

Insecticidal maize

Among other crops, maize has been genetically modified to express an insect toxin from the micro-organism Bt, for self-protection from the European corn borer. When a Bt maize was first proposed for market approval by Novartis in 1995, conflicts emerged over two main risks. (For a more detailed account, see [16, 18].

The constant expression of Bt could intensify selection pressure for resistant insects, thus undermining the efficacy of the product, as well as that of Bt sprays which have been used for several decades by organic farmers. Among other member states, Austria and Belgium criticized the company's risk assessment for failing to evaluate this risk. As the rapporteur, France adopted the company's argument: that such a scenario would not be an "adverse effect", on grounds that other insect-control methods would still be available.

Such an argument provided the official basis for EU-wide market approval [25]. Thus a natural resource was officially regarded as dispensible and ultimately replaceable by chemical insecticides. Since then, the resistance issue has been taken up by more member states, even those where the relevant insect pest is no problem.

Also controversial was potential harm to beneficial insects. From the start, Austria queried the experimental method which showed no evidence of such harm. When later laboratory experiments provided evidence of potential harm [28], more member states challenged the safety claim. After further evidence of harm came from US research [29], the European Commission delayed approval of a Bt maize from Pioneer Hi-Bred.

Controversy continues over the normative baseline for acceptable harm. According to safety claims, Bt maize would cause less harm than present chemical insecticide treatments. This argument assumes that conventional maize is sprayed with chemical insecticides, but in practice such sprays are little used, partly because they cannot reach the corn borer inside the stalk. Thus the safety argument takes the most chemical-intensive methods as a normative baseline for all maize fields.

As the rapporteur for the Novartis maize, France eventually signed the EU authorization. Austria and Luxembourg soon banned the product under Directive 90/220 Article 16. The Italian government too banned the product, temporarily, until the company presented a plan to delay insect resistance [30]. When the European Commission demanded that Austria and Luxembourg withdraw their bans, this demand drew little support from other member states; some implicitly used the impasse to pressurize the European Commission to accept responsibility for managing the insect-resistance problem.

Soon France and Spain imposed stringent conditions on commercial use under Plant Variety Registration, legislation which was designed mainly to ensure product quality [31]. The Novartis maize was granted a time-limited registration, requiring field monitoring for all the risks that had been debated in the Directive 90/220 procedure. These risks included: insect resistance, non-target harm and spread of the ampicillin-resistance gene which had been inserted as a marker [33, 34]. The French Environment Ministry established a new, broadly-based advisory committee for biovigilance to evaluate the monitoring efforts [34].

CONCLUSION

precaution and sustainability

Genetically modified products have become a difficult case for interpreting and implementing the precautionary principle. In identifying "serious" risks, environmental norms have been linked with diverse accounts of sustainable agriculture. Across Europe the risk debate emphasizes various agro-environmental concerns about the effects of GM crops, such as herbicide usage, pest-control options, wildlife habitats, biodiversity, and water quality.

In the mid-1990s EU risk regulation framed "risk" within a commitment to intensive agriculture. Its familiar hazards were accepted as a normal baseline for evaluating the effects of GM crops, e.g. a "genetic treadmill" which could preclude particular crop-protection measures. The regulatory procedure regarded such choices as irrelevant or interchangeable, and therefore regarded some future options as dispensible, regardless of whether they would be environmentally preferable. Undesirable effects were deemed acceptable if they caused no greater environmental harm than the worst current practices. Some member states demanded that the risk assessment evaluate a wider range of adverse effects, but they were marginalized in the EU-wide procedure.

Thus the original safety claims rested on a concept of sustainable agriculture which emphasizes reduction in agrochemical usage. The regulatory procedure implicitly accepted the industry's own account of their products as benign. The "precautionary approach" was applied only to specific uncertainties beyond the agricultural context.

That risk-framing came under wider challenge from public protest and expert disagreements in the late 1990s. Protest groups targeted GM crops and food as exemplifying their concerns about intensive agriculture. Consumer protest and boycotts led major retailers and some food processors to exclude GM ingredients from their own-brand products. This commercial barrier, along with widespread demands for a moratorium, strengthened proposals for greater precaution.

Moreover, new scientific information was cited as demonstrating greater risk or unpredictability of GM crops. Risk research shifted towards testing broader cause-effect uncertainties, thus creating new bodies of knowledge, such as harm to non-target insects. In this controversy, scientific "uncertainty" expresses social conflict over the technoscientific development itself, rather than explaining the conflict. At issue are environmental norms for an acceptable baseline, not just a predictive uncertainty.

Previously the UK and France had led EU-wide approval of GM crops, but they changed their stance in response to public protest. They developed a more stringent risk assessment, evaluating a broader range of potential effects, including the familiar hazards of intensive monoculture. Soon the EU-wide procedure too began to formalize such approaches.

Although more stringent norms are not inherent in the precautionary principle, they can be more meaningfully applied by such an approach. Broader "adverse effects" depend upon the agricultural context, so they pose greater difficulty for predictive claims and warrant large-scale testing. For these reasons, commercial use became conditional upon special measures to avoid and detect harm, while the burden of evidence shifted towards those who make safety claims.

These extra precautions have served to manage not only risks but also regulatory conflicts. More social actors are gaining opportunities to be involved in regulatory norms. New evaluation procedures can enhance public accountability for a technological choice and its potential effects.

In retrospect, the 1990 EC legislation did not explicitly mandate a "precautionary approach", nor was it intended to promote "sustainable development". Nevertheless it has been interpreted in ways which link the two concepts in various ways. Such links remain unavoidable. They are evident in the original safety claims of the mid-1990s, as well as in the risk claims of the late 1990s.

In sum, European public protest challenged the assumptions underlying the official risk assessments, as regards the predictability and acceptability of undesirable effects. In the contested definitions of relevant harm, there are deeper issues about the sort of environment which should be protected, sustained or created. Thus GM crops have become a test case for environmental norms, within a broader debate about how to construct a sustainable agriculture.

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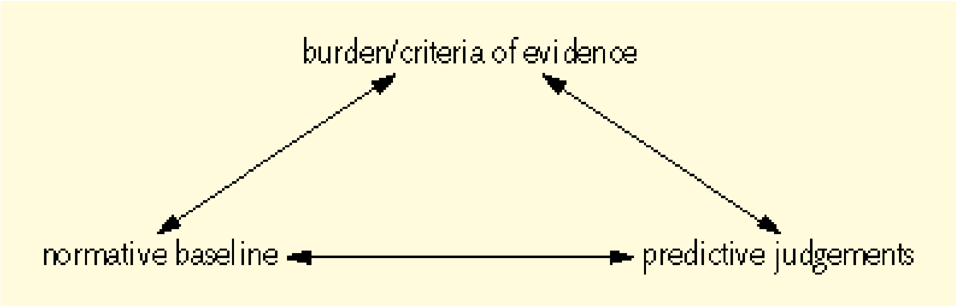
Pictures



Comparaison de la conversion en fonction de la nature du diluant pour une température de 600 °C.