Precautionary uncertainty: regulating GM crops in Europe

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ABSTRACT Through the precautionary principle, governments acknowledge the limits of science as a basis for policy, while seeking to clarify scientific uncertainty. This tension is exemplified by the European risk regulation of genetically modified (GM) crops. The risk debate has been translated into various precautionary approaches, each with its own cognitive framing of the relevant uncertainties. Early safety claims took for granted intensive agricultural models; normative judgements served to downplay uncertainties which were not readily reducible, thus justifying commercial approval of products. In the late 1990s public protest strengthened broader accounts of uncertainty, for example through more stringent environmental norms and more complex causal pathways of potential harm. Fact-finding methods were debated as a value-laden choice for how best to generate more relevant knowledge.

As risk-assessment research challenged assumptions in safety claims, critics cited the results as evidence of greater uncertainty. Invoking the precautionary principle, regulatory procedures delayed or restricted commercial use of GM crops. They not only increased the burden of evidence for safety, but also stimulated and requested knowledge about more complex uncertainties. Criteria for relevant evidence were implicitly linked with different framing visions for agriculture.

Such value conflicts made scientific uncertainty more important - rather than vice versa. When risk research methods were challenged, fact/value boundaries were blurred, thus increasing `uncertainty' - rather than vice versa. In these ways, the risk controversy was constituted by divergent accounts of the relevant scientific uncertainty. Uncertainty was constitutive, not merely contextual. In general, then, precaution offers a means to justify uncertainty - not simply vice versa.

Keywords Bt insect-protected maize, genetically modified (GM) crops, herbicide-tolerant oilseed rape, Precautionary Principle, risk assessment, scientific evidence

Precautionary Uncertainty:
Regulating GM Crops in Europe

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The Precautionary Principle in Policy Debate

On what scientific basis does risk assessment make predictive claims? For this long-debated question, the precautionary principle offers greater scope to emphasize scientific uncertainty. In this way, regulators can acknowledge the limits of science as a basis for policy, while seeking to clarify uncertainties.

Scientific claims have had an ambiguous rôle in precaution. For example, the precautionary principle was cited by the Montreal Protocol on Substances that Deplete the Ozone Layer, which had the aim of eliminating such substances `on the basis of developments in scientific knowledge'. It was also cited, in a 1987 Inter-Ministerial Declaration, as a basis for protecting the North Sea `from possibly damaging effects of the

most dangerous substances ... even before a causal link has been established by absolutely clear scientific evidence'.[1] As a general principle, the most widely quoted version of the precautionary principle comes from the 1990 Bergen Declaration of European Ministers:

> 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.

When the precautionary principle was adopted by the 1992 Rio UNCED conference, the term `measures' was changed to `cost-effective measures'.[2] Taken together, those criteria are ambiguous or even inconsistent. On the one hand, the `cost-effective' criterion presupposes adequate knowledge to predict the potential damage - or perhaps affordable alternative products which avoid serious hazards. On the other hand, `full scientific certainty' is rarely accepted (or even claimed) for safety judgements, so `lack' thereof could readily justify `uncertainty' as grounds for control measures.

During the 1990s, the precautionary principle became more controversial. As a basis for new controls, it was criticized by many countries, especially the USA. Such conflicts emerged over multilateral environmental agreements - for instance, the Kyoto Protocol on fossil fuel emissions, and the Cartagena Protocol on Biosafety for `living modified organisms' - that is, genetically modified organisms (GMOs). The precautionary principle was also cited by the European Union in justifying its blockage of US beef exports, which led to a World Trade Organization (WTO) ruling against the EU. Under the WTO Sanitary and Phyto-Sanitary (SPS) Agreement, as one critic argues, expert judgements are made in a technocratic world `in which the contingency of scientific knowledge is denied, and in which the values which enter law through science remain obscured'.[3]

Amid such conflicts, the European Commission eventually issued guidelines which reproduced the earlier tensions around science. The guidelines stated that:

> ... application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy.

They acknowledged predictive uncertainties at every stage, while mandating that `these four components should be performed before action is taken' (see Table 1, based on the guidelines).

TABLE 1: Stereotypical Risk-Assessment Sequence

Stage	
Hazard identification	Identifying agents that may have adverse effects
Hazard characterization	Determing the nature and severity of effects
Exposure appraisal	Evaluating probability of exposure or contamination
Risk characterization	Evaluating probability, frequency and/or severity of adverse effects

If risk-management restrictions are imposed, then they must be `proportionate' to the chosen level of protection, thus implying adequate knowledge of cause-effect dynamics. Meanwhile, clear responsibility must be assigned `for producing the scientific evidence necessary for a more comprehensive risk assessment'. Pending such efforts, `the provisional nature is not bound up with a time limit but with the development of scientific knowledge'.[4]

According to these guidelines, then, the precautionary principle informs risk-management responses to an incomplete risk assessment, *vis-à-vis* a level or type of harm which must be prevented. The text offers little guidance for diagnosing the sources of uncertainty - apparently due to inadequate knowledge. Implicitly, it denies the socio-cultural values inherent in risk assessment.[5] Unsurprisingly, arguments have ensued over the practical relevance of uncertainty for regulatory decisions. After the US Food and Drug Administration (FDA) questioned the scientific basis of the precautionary principle, the European Commission issued a long reply with a new concept: `precaution is normally applied by risk managers in case of *established scientific uncertainty* that risk assessors cannot reduce, eliminate or quantify' (emphasis mine).[6] That account emphasizes evidence of uncertainty, rather than evidence of risk.

Arguments have also ensued over whether the precautionary principle allows politics to supersede science, especially in the case of GM crops. Some critics argue that the principle emphasizes conjectural threats, and so `provides neither evidentiary standards for "safety", nor procedural criteria for obtaining regulatory approval...'.[7] Some proponents of the precautionary principle acknowledge that it has become a tool for protest movements, while others emphasize that it helps to scrutinize scientific unknowns about complex interactions.[8] According to a recent survey of risk-assessment research on GM crops, there are `information gaps' - even limitations in our capacity to predict ecological impacts - which in turn `increases the uncertainty associated with a risk assessment'.[9] Yet, in the mid-1990s, US and European regulators had claimed to reduce or resolve any uncertainty.

How should `uncertainty' be conceptualized as more than a scientific matter? How does the precautionary principle relate to uncertainty? Such questions are explored here through a case study: the European risk regulation of genetically modified (GM) crops. The paper has the following sections:

1. Theoretical Perspectives on Scientific Uncertainty;
2. EU Decision Procedure for GM Crops;
3. Regulatory Disputes over Herbicide-Tolerant Oilseed Rape;
4. Regulatory Disputes over Bt Insect-Protected Maize;
5. How Precaution Changes the Criteria for Evidence;
6. How Precaution Justifies Uncertainty.

The analysis draws on research material and interviews from two studies, as explained in the opening paragraph of the Notes section (below: p. ???).

`Uncertainty': Theoretical Perspectives

Regulatory disputes often centre upon `uncertainty' about potential harm. Policymakers may claim that scientific uncertainty warrants deferring regulatory measures - or warrants

imposing them. By seeking additional scientific knowledge, they attempt to overcome the uncertainty and thus overcome the dispute. Such attempts to reduce uncertainty, however, have often intensified methodological disagreements among experts about the appropriate criteria for evidence.[10]

What could explain such difficulties? In social studies of science, risk controversy has been analysed by theorizing scientific uncertainty as value-laden. Among various theoretical perspectives, there is divergence or ambiguity on key questions, namely: Where does uncertainty come from? And what special uncertainty drives precautionary measures? Let us survey perspectives on each question in turn.

What Sources of Uncertainty?

Where does uncertainty come from? Is it merely contextual? According to some early theoretical perspectives, a context of technical uncertainty provides greater opportunity for conflicting interpretations of policy-relevant science.[11] Technical uncertainty lends greater importance to value conflicts over `risk', though this term may really denote a problem of moral responsibility.[12] In a similar vein, it was argued that `Scientific uncertainty also contributes to controversy about risk', that scientific experts may `avoid making definitive statements in areas of real scientific uncertainty...', and that regulatory systems have different ways to handle `uncertainty or incompleteness in the scientific evidence'.[13] In sum, those perspectives analyse uncertainty as a knowledge gap, which in turn provides the context for controversy.

Other perspectives have theorized uncertainty as more fundamental than an external context. According to Brian Wynne, 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 uncertainties in the context of practical interpretation, and it can be reduced by opposite social forces'. From this latter perspective, uncertainty expresses rather than explains conflict.[14] Indeed, `uncertainty' may be constituted by a social context, not simply given by a technical context: it can serve as a strategic argument among experts, not simply as a source of disagreement. In the controversy around a proposed oil pipeline in Canada, favourable experts expressed confidence about managing potential harm, while hostile experts emphasized disastrous consequences which lay beyond any credible management. At issue were the consequences of uncertainty: `the problem of adequate knowledge becomes related to what is reasonable to know for practical purposes'.[15] The pipeline case-study illustrates a more general dynamic: that the terms `risk' and `uncertainty' express unease at loss of control over one's environment, beyond physically measurable harm alone.[16]

Consequently, facts can be framed by values, not simply interpreted by them. As Sheila Jasanoff has argued, `facts and values frequently merge when we deal with issues of high uncertainty'. In seeking and organizing more facts about risk, moreover, we make choices about what potential harms to prevent and 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.[17]

In a similar vein, Brian Wynne argues that risk science is limited by `proactive scientific commitments' to theoretical models and methods, along with assumptions about how to define the issues.[18] From these perspectives, then, fact-finding is framed by particular socio-natural models.

If a fact/value boundary is absent, then does this blurring *result from* uncertainty - or does it, perhaps, *explain* the uncertainty? According to the former accounts, values enter when *interpreting* uncertainty, though not when *investigating* uncertainty: new scientific knowledge may be *used* politically, but is not *formed* politically. But some cultural theorists, such as Michael Schwarz and Michael Thompson, argue that risk controversy entails a structural uncertainty - that is, divergent accounts of the range or type of relevant uncertainty. Values are involved when *generating* facts, not simply when *interpreting* them. Each problem-definition has a `structural interdependence of facts and values'; any fact/value boundary is a construct which needs to be analysed, rather than a natural consequence of low or high `uncertainty'. According to this theoretical perspective, any administrative procedure emphasizes a particular type of uncertainty as the `technical' issues; such a procedure depoliticizes its own problem-definition, while marginalizing other accounts of uncertainty.[19]

Conversely, a particular account of scientific uncertainty may become politicized. Under critical examination, argues Ulrich Beck, scientific facts `are nothing but answers to questions that could have been asked differently'; they are products of rules for gathering and omitting aspects of reality. Different scientific disciplines make competing assumptions about the relevant uncertainty to be investigated or managed. Such inter-disciplinary competition virtually forces regulators to make their own cognitive decisions and commitments: the mobilization of belief becomes a central source for the social enforcement of validity claims about science.[20] To gain policy relevance, then, factual evidence requires a cognitive argument, which may reveal the value-laden framework of fact-finding.

From these diverse perspectives, we may recast the earlier questions as follows: Is uncertainty merely contextual - or also constitutive? Does technical uncertainty lend greater importance to value conflicts - or *vice versa*?

What Uncertainty for Precaution?

Those relate to further questions: What special uncertainty justifies or drives the precautionary principle? How does evidence establish, increase or decrease uncertainty?

Given its epistemic novelty, the precautionary principle cannot simply be interpreted or applied. Rather, it is constructed anew: its content depends upon the types of uncertainty which are emphasized, investigated and managed.[21] Indeed, a meta-uncertainty goes beyond scientific judgements:

> Since there is likely to be uncertainty about when uncertainty disappears, there will also be uncertainty about whether to talk of the principle of precaution rather than of prevention. ... Whether the precautionary principle should be a principle of science is a matter that the scientific community will want to resolve for itself.[22]

In dealing with that matter, there has been a `culture of denial of culture', by, for example, assuming that risk assessment could have an objective basis. As Wynne notes: `This vacuum

is filled substantively instead by an over-inflated scientistic framing of many issues which cannot and should not honestly be defined in scientific terms'.[23] Thus cognitive-cultural differences may generate a recursive debate on `uncertainty about uncertainty', compounded by arguments about whether this is a scientific issue at all.

To avoid such an impasse, the burden of evidence could be assigned to those who make safety claims. As advocated by some environmental scientists, a precautionary approach

> ... shifts the burden of proof so as to give the environment the benefit of the doubt. ... [This approach] actually increases the rigour of the scientific process because it is based on an understanding of the real limitations of science.[24]

However, such a burden encounters problems of scientific rigour. What is the basis for shifting the burden of evidence? If the aim is to prevent serious or irreversible harm, then which activities - and what kinds of evidence - warrant imposing precautionary measures? And what kinds of measures? Each question can receive different answers, so `it is difficult to speak of a single precautionary principle at all'.[25]

As another difficulty for scientific evidence, a precautionary approach more overtly undermines the stereotypical sequence of objective risk assessment followed by risk management. This sequence underlies `the specious divide' between scientists debating the facts and politicians debating the values. Such a boundary has become untenable for many reasons - for example, because scientific evidence often depends upon judgements about control measures.[26] Moreover, even the initial stage of `hazard identification' presupposes some causal theory which can justify risk management and guide fact-finding,[27] and this identification remains more difficult to justify in cases where the causality of harm is disputed. In studying North Sea pollution, for example, there arises a fundamental conflict between two bodies of scientific knowledge, which derive from different methodologies within marine epidemiology. Here the prevalent science perceives `risk' only as a specific measurable harm due to a specific pollutant. By contrast, a precautionary approach would require a `greener science', investigating a more complex range of cause-effect models for potential harm.[28] Such epistemic uncertainty may be an inherent feature of risk science, rather than a special case resulting from inadequate knowledge. A recent report emphasizes the complexity of cause-effect pathways, the multidimensional scope of risk, and the incommensurability of different classes and aspects of risk, as well as scientific ignorance. Each of those issues can have alternative framing assumptions; each issue becomes `a matter of analytical rigour' for scientific evidence. Hence an epistemologically humble precautionary approach is arguably more scientific than the traditional narrow risk approach called `sound science'.[29]

At issue, then, is not simply whether to shift the burden of evidence for risk within the existing science. When risk research operates in precautionary mode, `the body of knowledge itself may change'. Research may set new priorities for `what is defined scientifically as problematic or not';[30] `Ultimately, the precautionary principle does not consist in shifting the burden of proof but in shifting the very notion of scientific proof'.[31]

From these perspectives, we can recast the earlier questions as follows: How does uncertainty justify the precautionary principle - or perhaps *vice versa*? How does precaution

depend on evidence - or perhaps *vice versa*? Let us examine how these issues have arisen for the European risk regulation of GM crops.

EU Decision Procedure on GM Crops

Directive under Pressure

The European Communities' Deliberate Release Directive 90/220 was designed to manage scientific and political uncertainty about hazards of genetically modified organisms (GMOs) which are intentionally released into the environment. It governs the approval process for all GMO releases in the European Community (later expanded into the European Union). Directorate-General XI for Environmental Protection acted as *chef de file* for promoting and implementing it. The 1990 Directive was officially justified by linking environmental protection with European market integration. It aimed to `establish harmonized procedures and criteria' for assessing GMO releases, especially for EU-wide approval of commercial products.[32] Implicitly, the Directive was precautionary by regulating *a priori* entire categories of products for which there was no prior evidence of harm.[33] In that regard, it had several precautionary features. The applicant must submit a risk assessment for evaluation by the national Competent Authority, which in turn must take all appropriate measures `to avoid adverse effects' from GMO releases. According to the `step-by-step' principle, the scale of release is increased gradually, `but only if the evaluation of the earlier steps ... indicates that the next step can be taken' safely.[34] The Directive set no standards, for (e.g.) assigning the burden of evidence, or defining the `adverse effects' which must be prevented by member states.

As a scientific basis for such a Directive, its proponents emphasized uncertainties about hazard identification. According to an earlier report on risks of GMOs, `agriculture and other human-created systems' are particularly vulnerable to disruption. This vulnerability was conceptualized in two ways: by analogy to introduced non-indigenous organisms; and by analogy to agricultural products whose usage had caused problems - for example, reduced biodiversity, pathogen invasions, pest resistance, herbicide resistance.[35] Some environmentalists called the latter scenarios a `genetic treadmill', by analogy to agrochemical usage which had generated a `pesticide treadmill' of resistant pests. According to some members of the European Parliament, GMOs pose `social and economic risks, as well as risks to our world view and culture'; they warned that `this step forward can never be reversed'.[36]

Echoing the precautionary principle, the Directive itself cited the potential for living organisms to cause `irreversible' environmental effects, as a rationale for applying the principle of `preventive action' to GMOs.[37] That phrase was widely interpreted to mean `precautionary' - for example, for regulating hazards not yet demonstrated. In justifying the Directive, the European Commission later emphasized the prospect of ecological imbalances:

> ... there are concerns that this new technology might entail potential risks not only related to human health, but also for the total environment. There could be a risk that the widespread use and release of novel GMOs could upset the delicate balance existing in nature or even have evolutionary impacts.[38]

Conflicts would ensue over how the regulatory procedure should evaluate various risk scenarios mooted in the 1980s.

Shortly after its enactment, Directive 90/220 came under attack by agrochemical multinational companies which were heavily investing in plant biotechnology. According to them, it lacked a scientific basis, stigmatized GMOs and thus disadvantaged `European' biotechnology.[39] Industry-wide lobby groups warned government that companies would shift R&D investment to North America if it were unduly hindered by regulation. Echoing those complaints, the Commission asserted that the Directive `is unfavourably perceived by scientists and industry', in terms of hindering biotechnology investment and economic competitiveness. It sought to ensure that `advances in scientific knowledge are constantly taken into account and that regulatory control is based on potential risks'.[40] Such language presumed adequate knowledge to identify and evaluate all risks. Soon the EU regulatory procedure came under greater political pressure to approve GM products for commercial use.

Although such a decision applies EU-wide, it depends upon member states at two stages. In order to place a GM product on the market, the `notification' must be filed in the member state where marketing is expected to begin. If that member state recommends approval, then its Competent Authority becomes the rapporteur for the Europe-wide procedure. Along with the notifier's dossier, the rapporteur circulates its favourable opinion to all the other member states, which then have the opportunity to request additional information or raise objections. If necessary, a vote is taken by the regulatory committee of Competent Authorities and the Council of Ministers. If the European Commission grants approval, then the rapporteur signs the authorization, which becomes valid for all member states. Under Article 16, known as the safeguard clause, a member state may restrict such a product, though the valid grounds have been disputed.

Approval Decisions in Dispute

In the mid-1990s, some GM crops were proposed for EU-wide commercial approval under Directive 90/220, without any further conditions. For each product, the company provided scientific evidence to argue that any adverse effects would be unlikely. These arguments were elaborated by the UK and France, acting as rapporteurs for such products in the EU-wide approval procedure.

The risk assessments downplayed or accepted uncertainties which could not readily be reduced by the available science (for example, scenarios of a genetic treadmill). As even the companies acknowledged, GM herbicide-tolerance genes could spread among weeds, and GM insecticides could generate resistance among insects. The safety claims regarded such effects as acceptable, on grounds that other pest-control methods would be available if necessary. Thus specific pest-control options were treated as interchangeable and therefore dispensible. More generally, undesirable effects were deemed acceptable if they caused no greater environmental harm than the most chemical-intensive practices. The UK defended its safety claims as `precautionary' - for example, by evaluating any potential harm to the wider `non-agricultural environment'.

Before and after GM crops were granted approval, several EU member states dissented. They demanded a delay, so that the risk assessment could consider a broader range of plausible effects relevant to crop-protection methods. Ultimately the European

Commission granted approval, without any further conditions, thus marginalizing the objections from Denmark, Austria and Sweden.[41] As GM crops approached the commercial stage in the late 1990s, however, public debate and scientific disagreements re-opened the original basis for approval decisions. Many scientists raised doubts or presented evidence challenging safety assumptions. New protest linked GM food with environmental risks of cultivating GM crops, even of intensive agricultural methods in general. Various NGOs emphasized unpredictable effects as grounds for a moratorium on commercial use of GM crops.[42] In response, after mid-1998, the EU-wide committee of national Competent Authorities delayed any further decisions on commercial approval. Some regulators cited new evidence of risk and/or demanded more evidence of safety. In June 1999, Environment Ministers mentioned the precautionary principle when declaring that they would not vote to approve any additional GM crops until various conditions were met - for example, a broader risk assessment, traceability of GM crops through the agro-food chain, and rules for liability. Controversy also intensified over the prospect of GM crops contaminating other ones, thus jeopardizing commercial claims for non-GM or organic food (though such arguments lie beyond the scope of this paper).

As a parallel development during that impasse, the European Commission attempted to separate risk assessment from risk management - that is, from statutory responsibility for product approvals. Partly as a response to the BSE crisis, the Commission restructured all its scientific committees. In mid-1997, DGXXIV for Consumer Affairs took over responsibility for committees which were formerly based in other Directorates-General. The reorganization aimed to render the committees independent of the legislative DGs, of the member states, and of material interests. Such independence took on a special significance for GM crops. From November 1997 onwards, the Scientific Committtee on Plants (SCP) was asked to comment on product dossiers which had been stalled under the Directive 90/220 procedure. Officially, the SCP was asked to resolve risk issues which had been raised by some member states. Unofficially, some SCP members saw themselves as protecting scientific risk assessment from political bias - by contrast to national regulatory procedures, which had been influenced by anti-biotechnology pressure groups.[43]

In its advice on marketing notifications for GM crops, the SCP has made implicit judgements about which potential effects would be unacceptable, and would therefore count as an `adverse effect'. According to the chair of its environment subcommittee:

> We are asked only scientific questions. The definition of `adverse effects' is not a political question - only a scientific question.[44]

On the contrary, the question necessarily goes beyond science. According to an official of the Directorate-General for Environmental Protection:

> All three types of judgement - scientific, legal, and political - are involved in any judgement on defining `adverse effects'. It involves considerations broader than science, e.g. by interpreting the law, and taking on board public concerns.[45]

As the latter comment suggests, hazard-identification depends upon normative judgements beyond science as such. The next two sections examine how all these issues arose in regulatory disputes over two main GM crops: herbicide-tolerant oilseed rape, and Bt insect-protected maize. The next section also describes new public protest, though it was directed

against both categories of product. After I have presented this evidence, I will summarize, in Table 2 (below: p. ???), how uncertainties were reframed, thereby shifting the criteria for evidence.

Herbicide-Tolerant Oilseed Rape: Regulatory Disputes

Among other crops, oilseed rape has been genetically modified for tolerance to broad-spectrum herbicides - for example, glufosinate or glyphosate. Conflicts have emerged over several related risks - spread of the herbicide-tolerance trait, long-term implications for herbicide usage, and effects of broad-spectrum herbicides. In the case of glufosinate-tolerant oilseed rape, for example, genes could spread through hybridization or `volunteer' seeds which germinate in later seasons, thus jeopardizing the use of glufosinate as a future weed-control option. Safety claims rested somewhat upon analogies with non-GM plants, though these analogies were challenged, thus generating new uncertainties.

Uncertainties Downplayed

In 1994, Plant Genetic Systems submitted an EU marketing application for glufosinate-tolerant oilseed rape. Its risk assessment considered the prospect that the glufosinate-tolerance trait might be transferred to related species, and thus persist in a weedy form. As evidence, it cited a literature survey of hybridization studies.[46] On that basis, claimed the company, the likelihood of transfer was `extremely low' and the consequences were `negligible'. Any problems would be manageable, if necessary:

> If, in contrast to the expectations, adverse effects would be identified, it may be decided to remove plants either mechanically or by chemical control.[47]

By judging glufosinate-tolerant weeds to be acceptable, the risk assessment made its predictability less important.

Among other member states, Denmark and Austria wanted the risk assessment to evaluate the overall implications for herbicide usage and future options; they requested more evidence of the hybridization capacity. Austria's concern derived from its commitment to organic agriculture as a future model. Denmark's concern derived from its policy to use groundwater for drinking purposes. From both standpoints, it was not necessarily acceptable for a crop technology to encourage further herbicide usage or to jeopardize future options which may be environmentally preferable. But those uncertainties were downplayed in the EU-wide procedure. As the first rapporteur for glufosinate-tolerant oilseed rape, the UK conceptualized the prospect of herbicide-tolerant weeds as `an agricultural problem' rather than an environmental risk. Echoing the company's argument, regulators argued that widespread glufosinate-tolerance would be acceptable on several grounds - for example, because farmers could, if necessary, use other agrochemicals. Such an argument provided a rationale for EU-wide market approval: `any spread of transfer of the herbicide-tolerance gene could be controlled by using existing management strategies'.[48]

The manageability judgement was framed by an intensive agricultural model. As one UK advisor commented then, `A weed is not a problem if you can control it', as if the type of control method was irrelevant.[49] Moreover, UK regulators conceptually divided up the environment. In the `agricultural environment', any plausible effects were deemed

acceptable, on the latter grounds. In the `non-agricultural environment', any harm was deemed implausible - for instance, on the grounds that a herbicide-tolerance gene would confer no selective advantage in the absence of herbicide sprays. Likewise, France treated the uncertainty as unimportant. Its advisory committee classified the prospect of herbicide-tolerance weeds as `socio-economic consequences'.[50] The committee regarded these as serious enough to advocate only a provisional five-year approval for commercial use; it also opposed any field trials which might inadvertently result in multi-tolerant hybrids of oilseed rape. Nevertheless, the French government advocated commercial approval with no further controls.

Regulatory Controls Strengthened

During 1997-98, public protest mounted against GM crops in France. Environmental NGOs there advocated a moratorium on commercial use; many scientists signed a petition along these lines. The Environment Ministry gained more influence over safety regulation, which was previously dominated by the Agriculture Ministry as the main Competent Authority. Leading staff at the Institut National de la Recherche Agronomique (INRA) emphasized environmental unknowns. According to the then-President, `extreme caution is necessary in the face of a major innovation which has, as yet, unknown effects'. INRA singled out herbicide-tolerant oilseed rape for special criticism, as (for example) a threat to weed control and to organic agriculture. Regarding herbicide-tolerant weeds, `The management of new (self-generating) seedlings would require the use of other herbicides in order to facilitate their control...'.[51] INRA previously had contracts with companies to conduct R&D on herbicide-tolerant crops, but it now discontinued such arrangements.

After the European Commission agreed to approve glufosinate-tolerant oilseed rape, in November 1997 the French government announced a delay in signing the EU-wide approval which it had originally advocated: `No authorization for commercial use of plant species other than maize (notably rapeseed and beets) will be given until scientific studies show there is no risk to the environment and until a public debate has been conducted'.[52] It cited new information on hybridization with weedy relatives as grounds to await further research (see next section). Implicitly, it justified delay by broadening the regulatory definition of environmental harm to encompass herbicide-tolerant weeds, while emphasizing their unknowns as relevant to a decision. In the UK too, public protest mounted during 1997-98. Under such pressure, the Agriculture Ministry issued a consultation document on herbicide-tolerant crops. It declared that `there is no suggestion that [such] crops pose any new hazard' to human health or the environment. Reiterating its previous policy, the document classified many environmentalist concerns as `agricultural problems' or as `disadvantages', rather than as environmental harm.[53] By contrast, a long-term moratorium was advocated by the government-funded conservation agencies, as well as by environmental NGOs. A wide range of respondents challenged the government's narrow definition of environment harm. Even a biotechnology company suggested that any potential disadvantage to agriculture `is a potential environmental impact' which should be addressed in the risk assessment, under the official criterion of interactions with the environment.[54]

Given that herbicide-tolerant weeds could jeopardize the efficacy of the product, the UK agricultural supply industry was preparing its own further controls. Voluntary guidelines were aimed mainly at preventing the spread of herbicide-tolerant volunteers and pollen; preventive measures included labelling, segregation of seeds, spatial separation of crops,

monitoring, and the like. Moreover, `Failure to comply will result in sanctions...' by supply companies.[55] However, conservation agencies expressed doubt that such voluntary guidelines could be enforced, especially given that some farmer-contractors had violated the terms of statutory consents for R&D trials under Directive 90/220.[56] The UK government eventually endorsed the industry's voluntary guidelines to minimize pollen flow, though this endorsement did not lead to commercial use. Arguments intensified over how broad-spectrum herbicides may harm wildlife habitats, and therefore how such effects could be reliably predicted. The government emphasized that specific approval would be required for spraying them on additional crops. For such a purpose, each herbicide must go `from the beginning right through the pesticide regulatory process ... because we are applying the precautionary principle', declared the Agriculture Minister.[57] These issues warrant an article in their own right.[58]

Other European countries offer similar stories. For instance, since the early 1990s, German society had been polarized over GM herbicide-tolerant crops.[59] Eventually its national Competent Authority advocated market-stage monitoring as an opportunity to detect readily measurable effects of a single-gene trait; in this way, argued a regulatory official, commercial use would facilitate `learning for the future'.[60] An AgrEvo oilseed rape was aimed at the German market, and the company expressed interest in monitoring its commercial use there. While NGOs cited inadvertent hybridization as an unacceptable risk, the German Competent Authority welcomed such an effect as useful for advancing scientific knowledge.[61]

New Knowledge Sought

For these various uncertainties, new scientific knowledge has been sought by regulators and research institutes. For the persistence of the herbicide-tolerance trait, the most plausible scenario has been volunteer crops. If herbicide-tolerant seeds survive in the soil and germinate in a following crop on the same farm, then they complicate use of the corresponding herbicide there. A key factor is how long such seeds remain viable. For potential effects beyond a particular farm, an important factor is pollen flow. Research ascertained that some viable pollen travels up to 2km.[62].

For volunteer persistence and pollen flow, the possible consequences depend upon many other factors. More complex scenarios have been investigated by asking different scientific questions than before. For example, one model has emphasized more complex uncertainties about the causal pathways and fitness of inadvertent hybrids, as well as dynamic links between the crop, volunteers and feral populations (see Figure 1).[63] A shift in questions can be seen from the following survey.

FIGURE 1

A: material flow:

B: mechanisms:

A: Relationship between the two phases of introgression (gene flow, establishment) and the vectors involved (seed, pollen).
B: Brief summary of the most important mechanisms for ecological biosafety matters (network display after Van Raamsdonk [1993]).
Source: see note 63.

- Volunteer/feral dynamics?

Early risk-assessment discussions conceptually separated volunteer rapeseeds within the agriculture field from feral rape outside. These populations had been administratively separated in research funding too, at least in Britain. Volunteers competing with crops are primarily relevant to farming, so research was funded by the Agriculture Ministry. Ferals competing with wild flora are potentially relevant to conservation, so research was funded by the Environment Ministry. Eventually that conceptual separation was tested rather than simply presumed. As a result, new research found that volunteer rape has a constant flux with feral rape outside the field, via flow of pollen and of alternate generations.[64] Consequently, argued the researchers:

> The introduction of genetically modified, herbicide-tolerant, oilseed rape into the agricultural environment will have ramifications beyond weed control of the crop. Herbicide-tolerant rape will undoubtedly become part of established volunteer weed populations that occur in many cereal rotations, but its longevity in these populations and its impact as a weed and contaminant of future oilseed rape crops is uncertain.[65]

Taken together with the gene-flow data, the empirical results suggest that herbicide-tolerance could be readily spread to the wider environment, to feral rape plants and back again to subsequent crops or volunteers. These causal links opened up further uncertainties about the environmental persistence of the trait.

- Hybridization and back-cross fertility?

For predicting the trans-species hybridization and persistence of the herbicide-tolerance trait, previous scientific knowledge was generally drawn from the experience of selective breeding. This selected weedy relatives for desirable traits, crossed them with a crop variety, and then back-crossed the initial F1 hybrid with the crop. In its risk assessment, Plant Genetic Systems had cited such experience of oilseed rape and other *Brassicas*. According to a literature survey:

> Even where there is a possibility of hybridization between *B.napus* [oilseed rape] and a related species growing in the vicinity of a release, poor vigour and high sterility in the hybrids will generally mean that hybrids and their progeny will not survive in either an agricultural or natural habitat.[66]

In a three-year study of simulated agricultural conditions in the UK, no hybrids with weedy relatives could be found;[67] and in a survey of weed populations near agricultural fields, little or no hybridization was seen. The researchers concluded that, assuming that only 2% of hybrid seedlings could survive, any spread of the herbicide-tolerance gene would be `slow and uncertain unless the transgene confers a significant selective advantage'.[68]

For the long-term environmental persistence of the herbicide-tolerance trait, however, an important factor is the viability of back-crosses with the weed, so experiments were designed to simulate this. According to the empirical results, European regions have various types of prevalent weeds with different hybridization behaviours - even for weeds with the same species name, for example *B.campestris*. By contrast to the UK experience, oilseed rape has produced numerous fertile hybrids with some weedy relatives in field trials in some other countries. In hybridization experiments between male-sterile GM oilseed rape and those weedy relatives, the initial F1 progeny always had a lower fitness than the parents. In subsequent back-crosses with the weed, however, the fertility level increased from that of the F1, approaching that of the weed; this pattern was found for *B.campestris* in Denmark and *R.Raphanistrum* in France.[69] Similar results were obtained from field trials in normal agricultural conditions in France.[70]

Another potential variable is the precise chromosomal position where the new gene is inserted by the genetic modification process in the laboratory. Experiments tested whether the insertional position influences subsequent hybridization and fertility of back-crosses between the same F1 hybrid and wild radish. The transmission rate of oilseed rape genes did vary according to the insertional position.[71] And many scientists had warned that different herbicide-tolerances might become inadvertently `stacked' in the same crop. To test this uncertainty, male-sterile GM oilseed rape with tolerance to different herbicides was cultivated in close proximity. As a result, some progeny had double tolerance.[72] Those results were cited as evidence of greater risk or uncertainty about weed control and future options.

In its advice to the European Commission, the EU-level advisory committee focused on a first-stage uncertainty. It concluded: `Potential transgenic exchange is unlikely to lead to establishment, as a result of reduced viability, of any hybrid plants and competition'.[73] With this statement, the Committee emphasized the lower viability of the F1 hybrid, rather than the increasing viability of successive back-crosses with weeds.

- Selective neutrality?

For many years, some scientists had claimed that the inadvertent environmental spread of herbicide-tolerance genes would not matter. According to their scenario, the gene expression would impose a metabolic cost on the herbicide-tolerant weed, thus conferring a selective disadvantage, except where that herbicide is sprayed. They drew analogies to some naturally occurring examples of herbicide resistance.

In a more subtle way, the EU-level advisory committee assumed that the GM trait would not be maintained outside agricultural areas, despite any inadvertent hybrids: `Any viable progeny will have no competitive advantage in the absence of selection by herbicide containing glufosinate-ammonium'.[74] The chair of the environment subcommittee further explained the rationale:

> Environmental harm might occur if the glufosinate-tolerance gene spreads into related weeds in non-crop areas where you would not normally expect to use agricultural practice to eliminate any hybrid. Of course it should be pointed out that such non-crop areas would not normally be exposed to the herbicide needed to maintain the selective advantage of the hybrid.[75]

When evaluating a similar product two years later, the Committee strengthened its earlier claim: `Potential transgenic exchange is unlikely to lead to establishment, as a result of reduced viability and competition'.[76] This statement implied that the gene could not persist without a competitive advantage, or even that it confers a disadvantage. Eventually the latter assumption was tested empirically. When field tests compared GM herbicide tolerant oilseed rape with its non-GM counterpart, the herbicide tolerance was found to be selectively neutral.[77] As some scientists have speculated, naturally occurring herbicide tolerance may be a multi-gene trait, thus imposing a metabolic cost, by contrast to the single-gene basis of GM herbicide tolerance. Thanks to a precise genetic change, the GM trait may be relatively more persistent. Some critics argued that its long-term effects may be less predictable than for a naturally occurring herbicide-tolerant plant.

Uncertainties Manageable?

According to the Scientific Committee on Plants, there was no evidence to indicate that commercial use of the GM oilseed rape - `with the purpose to be used as any other' - is likely to cause adverse effects. The SCP acknowledged that gene transfer to wild *Brassica* relatives `is a new issue in Europe'. As cited earlier, however, it downplayed uncertainties about the viability and persistence of inadvertent hybrids. On that basis, it concluded that any herbicide-tolerant volunteers would not be wild *Brassica* relatives. Rather, they would be the crop plants, `which could be controlled in subsequent crops by conventional agricultural methods', for example, an alternative broad-spectrum herbicide.[78]

Although the Committee did not regard herbicide-tolerant volunteers as an adverse environmental effect, it recommended the following measures:

> i) an agreed code of practice for the particular modified crop involving the active participation of the notifier to promote best practice by farmers; and
>
> ii) a monitoring programme with an agreed design and implementation plan to detect the occurrence and the establishment of herbicide-tolerant volunteers and weeds under field conditions in the EU.[79]

Thus the Committee recommended systematic monitoring to detect effects which were supposedly acceptable and/or implausible, as well as special cultivation protocols to prevent them. Implicitly, the risk-assessment advice presumed the manageability of gene flow and the acceptability of losing the glufosinate option, which was the main current convention. The alternative `conventional agricultural method' would be glyphosate, yet this herbicide was coming under official criticism for environmental risks, and was not recommended for re-registration under the pesticides directive.[80]

In sum, the debate featured links between the framing of uncertainties and their manageability. Early safety claims depended upon various assumptions - for example, reproductive isolation between feral and volunteer plants, negligible hybridization capacity, analogies between GM and naturally occurring herbicide tolerance, and so on. When such assumptions were challenged by new scientific knowledge, they underwent divergent interpretations for decision-making. Predictive uncertainties were downplayed by those who regarded any plausible effects as merely agricultural problems, amenable to routine management through a genetic treadmill, in a manner indifferent to choices or options of weed-control methods. Uncertainties were emphasized by those who sought a delay or ban on various grounds - for instance, because society should preserve future options for agrochemical treatments, or because the risks are unmanageable, or because such products perpetuate intensive monoculture and farmer dependence on a genetic-pesticide treadmill.

Bt Insecticidal Maize: Regulatory Disputes

Among other crops, maize has been genetically modified to express an insect toxin from the micro-organism *Bacillus thuringiensis* (Bt), in order to protect itself from the European corn borer. In Europe the first Bt maize was proposed for market approval in 1994 by Ciba-Geigy, a company later merged into Novartis. Regulatory conflicts emerged over potential effects of the three inserted genes: the Bt gene, a herbicide-tolerance gene, and an antibiotic-resistance marker. The next year another insect-protected maize with a similar Bt gene was proposed for market approval by Monsanto.

The account here first traces regulatory developments; then it analyses arguments over scientific evidence regarding the two main risks of the Bt gene: insect resistance and non-target harm. Bt foliar sprays have been used on crops for several decades, with no evidence of either risk. Safety claims rested somewhat upon analogies with non-GM products, though such arguments came under challenge.

Regulatory Controls Strengthened

Early on, the EU regulatory procedure debated scientists' warnings about insect resistance. That is, constant expression of Bt could intensify selection pressure for resistant insects, thus undermining the efficacy of the GM crop; likewise that of microbial Bt sprays, which provide an option for organic farming. On those grounds, as the Austrian Competent Authority argued: `Extreme care should be taken not to lose an insect management practice which is environmentally sound compared to most chemical insecticides'.[81] Together with other member states, Austria and Belgium criticized the company's risk assessment for providing inadequate information or plans regarding insect resistance.[82] However, as the rapporteur, France accepted the company's argument: if necessary, farmers could revert to other insect-control methods (for example, chemical sprays). Such an argument provided the official basis for EU-wide market approval of the Ciba maize: insect resistance `cannot be considered an adverse environmental effect, as existing agricultural means of controlling such resistant species of insects will still be available'.[83] Thus a natural resource was officially regarded as dispensible, replaceable by chemical insecticides.

After the European Commission agreed to approve the Ciba maize, France signed the EU authorization in February 1997. Austria and Luxembourg soon banned the product, while citing the precautionary principle and the safeguard clause, Directive 90/220 Article

16. The Italian government also banned the product, temporarily, until the company presented a plan to delay insect resistance there. Indeed, DGXI came under considerable pressure to accept and impose some responsibility for the insect-resistance problem.

These pressures focused upon Monsanto's marketing application for Bt maize. For example, the Agriculture DG argued that any marketing authorization must require the company to submit annual reports on environmental monitoring for resistant insects.[84] The German Competent Authority advocated a similar requirement, and proposed that a marketing consent be granted only for a five-year period.[85] In response, companies now made stronger commitments to devise market-stage precautions for their Bt products. Monsanto submitted such an undertaking for its Bt maize, as part of its original notification, followed by a more detailed plan. The EU approval decision mentioned that undertaking, though without stating whether or not it was necessary in order to avoid adverse effects.[86]

Controversy soon emerged over another risk - potential harm to beneficial insects. When laboratory experiments demonstrated such harm, more member states and NGOs questioned the original safety claim. This influenced the next regulatory decision on Bt maize. All novel seeds for food crops require approval under Plant Variety Registration, rules designed mainly to ensure product quality.[87] France and Spain used that legislation to impose stringent conditions on GM Bt maize. Varieties derived from the Ciba maize were 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 antibiotic-resistance gene which had been inserted as a marker.[88] In addition, the French Environment Ministry established a *biovigilance* advisory committee, including environmental NGOs. It had the task to evaluate the monitoring design and results for Bt maize. France also expanded its main advisory committee to include scientists who had publicly criticized GM crops.[89]

Insect Resistance: New Evidence Sought

In 1997, DGXI took responsibility for evaluating company strategies for insect resistance management (IRM). Under the `high-dose/refuge' strategy, the Bt crop is designed to produce enough of the toxin to kill nearly all resistant insects, while a nearby area of non-Bt plants allows susceptible insects to survive and then breed with any resistant ones, thus diluting the resistance gene in the next generation. In case pests nevertheless acquire resistance, companies were developing alternative Bt genes - that is, a genetic treadmill strategy.

The high-dose/refuge strategy depends upon the prevalent theoretical model of insect resistance as a semi-recessive trait, whose expression varies with the number of resistance alleles in each individual. Most individuals in an insect population are homozygously susceptible to Bt toxins: they have two normal alleles, and thus cannot survive exposure to Bt. The few individuals that are homozygously resistant have two resistance alleles, and so can survive a large dose of Bt. Heterozygously resistant individuals have an intermediate character: they can survive only minimal exposure to Bt.

Nevertheless, heterozygous individuals may survive a large dose and thus transmit their resistance alleles, for several reasons. They may avoid the Bt crops, as acknowledged by Ciba; for this scenario, more ecological information was requested early on by Belgium.[90]

As another possible reason for survival, the Bt levels may decline at the end of the growing season. Ciba acknowledged that weakness for its product, given that expression levels `were markedly lower in late-season, senescing plants'.[91] In response to criticism, the company sent DGXI an undertaking to monitor commercial use for insect resistance. The low-dose problem later became an issue for farmers. According to the French maize producers' association, AGPM, the Bt gene may not successfully protect the plant in southern France, where second-generation larvae attack maize towards the end of the crop cycle.[92]

To defend its ban on Bt maize, Austria cited new evidence on the limits of manageability. According to US entomologists, some insect pests were found to have single genes that confer resistance to four different types of Bt.[93] In view of this cross-resistance, experts questioned the utility of substituting alternative Bt genes if the insects developed resistance to the initial one. Companies had already undertaken to monitor fields for any resistant insects. As the simplest method, farmers could look for any surviving insects, which would then be tested in the laboratory. However, some member states demanded `active monitoring' by entomologists, on the grounds (for example) that farmers' efforts may not detect resistance early enough. By the time any homozygously resistant insects survive, resistance genes may have spread considerably in the population. Partial (heterozygous) resistance could proliferate to a great extent before homozygously resistant insects are noticed, so IRM faces the challenge of detecting early signs before then. According to a regulatory officer of Monsanto, `There is a difficulty in finding test insects whose antecedents have been exposed to Bt, survived and reproduced'.[94] Thus an IRM plan needed a reliable method to sample the insect population for any heterozygously resistant insects.

Moreover, for field monitoring to be meaningful, it must compare the effects of Bt exposure with a normal baseline - that is, with the pre-existing levels of Bt resistance among insect pests. DGXI convened an Expert Group to evaluate methods for ascertaining the baseline susceptibility of insects to Bt. Initially the discussion focused on the European Corn Borer, also the main target of Bt crops in the USA.[95] Greek members emphasized uncertainties about another pest, the pink stem borer, prevalent in Mediterranean areas; the method was adapted slightly for that pest.[96] The test methods were approved for the two main pests of maize.[97] For Monsanto's Bt maize, DGXI sent the product dossier to be evaluated by the Scientific Committee on Plants. Even before any empirical results were available, the SCP judged that the IRM plan would be `an adequate framework to delay the onset of such resistance'.[98] The term `delay' left ambiguous whether the Bt toxin would be ultimately dispensible.

The adequacy of IRM strategies was complicated by further evidence from the USA. Such strategies presumed that any heterozygously resistant individuals would be killed by a high dose, because any Bt resistance would be a semi-recessive trait, by analogy to pesticide resistance already familiar in other pests. According to new research, however, Bt resistance may not always be a semi-recessive trait.[99] If dominant, then resistance alleles could spread more rapidly in target insects than previously thought.

As critics cited these new results, companies came under pressure to provide more evidence for the scientific basis and efficacy of their IRM strategies. More stringent criteria for evidence encompassed more cause-effect uncertainties. These criteria in turn expressed a normative viewpoint about the potential consequences and their manageability: namely, that Bt should be preserved as a future alternative to agrochemical treatments.

Non-Target Harm: Evidence Disputed

After Ciba's Bt maize gained EU-wide approval, potential harm to non-target insects became more controversial. The debate included several related issues: the appropriate design of safety tests to yield meaningful results; cause-effect models of harm to non-target insects; and the acceptibility of such harm, given the beneficial rôle of predators in controlling the insect pest. The ensuing disputes over relevant evidence involved methodological and normative issues.

Some safety arguments drew analogies to the long, safe experience of spraying Bt microbes. According to company evidence, the Bt protein in their GM maize products was identical to the naturally occurring protein in microbes. However, the microbes have a low persistence on the leaf, and the crystalline Bt toxin remains inactive until converted into its truncated active form in the pest's gut. By contrast, most Bt plants express the toxin continuously and in the truncated form, which therefore could affect insects differently than a foliar Bt spray would do.[100] That difference was cited to request extra tests.

When originally requesting EU approval for Bt maize, company applications cited field surveys of potential harm to beneficial insects. No fewer beneficial insects were found in Bt-crop fields than in non-Bt fields. Companies also cited laboratory tests of microbial Bt on several insect species, which had showed no evidence of harm.[101] However, Ciba's tests found that the plant Bt toxin was chemically more active than expected. On those grounds, the Austrian CA asked the company to repeat some `tests giving surprising results which cannot be explained convincingly'.[102] Moreover, the original tests were criticized for using Bt produced by the microbe *E.coli*, on the grounds that this may differ from the toxin in the Bt plant. Citing a scientific paper, the Austrian CA emphasized methodological `shortcomings in using the recombinant *E.coli* Bt protein product instead of the plant for toxicity and digestion studies...'.[103] In a similar vein, the German CA questioned whether *E.coli* Bt protein has `complete correspondence' with the active Bt formed in the maize.[104]

On these grounds, critics proposed that the applicant repeat the tests by using Bt derived from the GM plant, and with more species of beneficial insects.[105] However, according to Monsanto, enormous quantities of plants would be needed in order to extract a high dose.[106] Later tests used microbe-derived Bt of the same type which is inserted into crops,[107] or plant-produced Bt-containing pollen, in a three-day study.[108] These laboratory tests included carnivorous insects further along the food chain (for example, the lacewing, a beneficial predator insect commonly found in maize fields). As a method to simulate predation of live prey, lacewing were fed moth eggs coated with a Bt concentration for seven days; afterwards they showed no adverse effects.[109] However, lacewing in the field normally suck out the contents of eggs, rather than ingest the eggshells, so the insects may not have ingested much toxin. Also, the seven-day test contrasts with a 30-day generation time in the field. Nevertheless the test method was not challenged at the time.

Another method is a tri-trophic test - that is, involving the plant, a pest and predator. In a Swiss study, lacewing larvae ate cornborers which had been fed Bt or non-Bt leaves; the former larvae had a lower survival rate. Similar results were obtained when testing lacewing on alternative prey. That extra test was done partly because lacewing larvae could not survive in agricultural fields by feeding only on prey which is eradicated by the Bt crop, as

the researchers acknowledged. According to their analysis, the reduced fitness was directly associated with the Bt toxin, while the prolonged development time was caused by both the Bt exposure and a nutritional deficiency from eating sick prey. If predators were harmed in Bt maize fields, they argued, then farmers would lose a useful means of controlling Bt-resistant insects.[110]

That Swiss study provoked further debate over the appropriate methods for testing cause-effect scenarios along the insect-food chain. The study was criticized as unrealistic, for example, because lacewing normally eat aphids rather than cornborers. According to a company officer, the Swiss study used `conditions which are far from mimicking the natural exposure of the lacewing to the corn borer in fields'.[111] However, an aphid study would entail more uncertainties about its agricultural relevance. Aphids feed on the phloem in maize stems, where Bt expression was not reliably known. Consequently, Bt-fed aphids would not necessarily provide a more realistic test than other prey.

After Austria cited the Swiss study to justify its ban, DGXI asked the EU-level Scientific Committee on Plants to evaluate it. SCP members raised methodological doubts about the Swiss study, especially the high mortality of the control insects.

> There is little information available on the food chain implications, e.g. at the tri-trophic level of predators. We were aware of some data which is incomplete and questionable. The Swiss study has not been replicated in the field; and there is a question about why the controls had such a high mortality rate (37%, as compared to 62% for the Bt-fed insects). Non-target harm warrants further research, especially in the field, which would be the acid test.[112]

Thus the Swiss study attracted criticism for methodological limits and statistical anomalies - unlike other studies which equally warranted such criticisms. Control insects had even higher mortality in other lab studies where the researcher reported that the experiment yielded no evidence of non-target harm.[113] Yet its scientific validity was not challenged at the time. Earlier test methods were no more `realistic' than the Swiss study (for instance, regarding the duration time and ingestion pathway), yet their safety conclusions were not criticized. Indeed, the Committee later reiterated that a series of lab studies `have not recorded adverse effects'; when acknowledging problems of `experimental rigour' as weak grounds for extrapolating to field conditions, however, it singled out the Swiss study.[114]

Alongside its methodological criticism, the Committee softened its predictive judgement about potential harm. When earlier assessing Monsanto's maize, the SCP had stated that `no risk is identified to non-target herbivores'.[115] After seeing the Swiss study, the Committee assessed Pioneer's Bt maize: it stated that any harm to non-target arthropod insects `will be less than that from the use of conventional insecticides'.[116] Even though few maize fields are sprayed with such agrochemicals, the Committee accepted the most chemical-intensive methods as a normative baseline for the potential effects of Bt maize. Thus its lax environmental norm served to avoid uncertainties about whether Bt maize would cause more harm than the prevalent conventional practices.

Meanwhile, a scientific consultancy group was systematically examining the lab tests which had been cited as evidence of safety. According to its report, the prevalent methods were derived from pesticide testing, and therefore were inadequate for predicting the effects

of genetically-modified Bt toxins, which have different methods of expression and of exposure to non-target insects. In many tests, the methods did not ensure sufficient Bt exposure to provide meaningful results.[117] With such arguments, the report cast doubt on the putative evidence of safety. Not coincidentally, the lead author of this report had previously emphasized the importance of beneficial predators for insect-resistance management.[118]

In sum, there were implicit links between risk-assessment and acceptability judgements: uncertainties were selectively emphasized according to one's normative standpoint. Within an intensive agricultural model, EU-level experts implied that any plausible harm would be acceptable. Applying double standards, they raised methodological uncertainties about the experiments which yielded evidence of risk, but not about those which were cited as evidence of safety. By contrast, NGOs and some member states challenged those judgements - for example, by raising methodological uncertainties about experiments demonstrating no harm, and by requesting evidence for a broader range of cause-effect pathways. At least implicitly, their demands expressed different normative standpoints for the potential consequences - for instance, a non-agrochemical baseline.

Precaution Changes the Criteria for Evidence

For GM crops in Europe, the precautionary principle was constructed anew, not simply applied. Throughout the 1990s, regulators had variously invoked precaution, whose meaning was contentious and changeable. Claims for uncertainty tended to challenge or change the criteria for evidence.

Early risk assessment was framed by an EU biotechnology policy committed to an internal market, international competitiveness and productive efficiency. Safety claims took for granted intensive agricultural models and accepted their familiar hazards. Normative judgements served to marginalize or downplay agro-environmental uncertainties which were not readily reducible, thus justifying commercial approval of products. When public protest and scientific disagreements intensified in the late 1990s, regulatory procedures broadened the relevant uncertainties. They now encompassed scenarios of indirect non-target harm, a genetic treadmill, changes in agricultural practices, as well as ultimate effects of agrochemicals on (for example) wildlife habitats, biodiversity and water pollution. Put in official language, risk assessment adopted a `higher level of protection', which in turn generated new uncertainties about predictability and manageability. Invoking the precautionary principle, some national regulators banned, restricted or delayed commercial use of GM crops.

Rather than providing a final definitive step, commercial use was re-designed as yet another experimental step. Under new pressures, industry devised cultivation protocols to avoid the development of resistant weeds or insect pests. Commercialization became conditional upon special measures to avoid and detect harm, defined more stringently than before. Although more stringent accounts of harm are not inherent in the precautionary principle, they can be more meaningfully investigated by such an approach (for example, through market-stage measures). `Genetic treadmill' or biodiversity effects, for instance, depend upon the agricultural context, so they pose greater difficulty for predictive claims and warrant large-scale or modelling experiments.

TABLE 2: Risk Research: Asking Scientific Questions Differently than Before

	presume familiar analogy	**test or supersede analogy**
HAZARD		
Bt insect resistance		
replaceability? (genetic treadmill)	identify alternative Bt genes, in case insects develop resistance	test pests for cross-resistance
causal pathway?	plan IRM as if Bt resistance were a semi-recessive trait	test whether trait is semi-recessive or dominant
monitoring method?	look for surviving insects (homozyously resistant)	ascertain baseline susceptibility and screen insects for higher resistance
Bt non-target harm		
source of toxin	test insects on microbial Bt	test insects on plant-type Bt
causal pathway	test direct harm, as if a pesticide	test tri-trophic system
herbicide-tolerant *Brassica* weeds		
gene flow?	study volunteers and ferals separately	study volunteer-feral interactions
hybrid viability?	cite familiar data from F1 and back-crosses with crop	test also F1 back-crosses with weed
hybrid persistence?	cite metabolic cost of familiar herbicide-tolerant plants	test selective disadvantage of GM crop in the field

Even for the same type of risk, scientific questions were asked differently than before. Risk research was shifted towards testing more complex cause-effect pathways, thus creating new bodies of scientific knowledge, as outlined in Table 2. Early risk-assessment research generally operated within analogies to familiar non-GM crops or pesticides, for example by testing whether the genetic modification would cause any unintended effects. Later research went beyond such analogies in several respects; it tested, for instance, back-crosses with weeds, the metabolic cost of GM herbicide tolerance, the genetic basis of Bt resistance, and tri-trophic harm to non-target insects. These test designs challenged scientific ignorance in safety claims. From such research, moreover, new scientific information was cited as demonstrating greater unpredictability than previously acknowledged. The criteria for scientific evidence became more contentious, as protagonists selectively emphasized or downplayed different uncertainties (for example, the epistemic limits of research methods). Fact-finding was debated as a value-laden choice for how best to generate more relevant knowledge. There ensued disputes about how to simulate realistic conditions of commercial use, while also optimizing the conditions to detect harmful effects.

The European Commission had sought to separate risk-assessment advice from risk-management decisions, yet these rôles were implicitly linked in practice. According to the official EU-level expert committee, when advising on specific GM crops, there was no evidence to indicate that commercial usage would cause adverse effects to the environment. Such claims rested on extra-scientific judgements about agro-environmental norms, about the adequacy of available knowledge, and about management measures. For example, the Committee advised that IRM measures would delay insect resistance, rather than compare the

effects which would result with and without such measures. For non-target harm, it advised that the Bt crop would be safer than agrochemical usage, thus adopting a particular environmental norm of acceptable harm. For the spread of herbicide-tolerance genes, it advised that any wider environmental persistence was implausible, while also recommending measures to avoid herbicide-tolerant weeds, thus assuming that such an effect would be manageable.

In such ways, criteria for evidence depended on judgements about the predictability, acceptability and manageability of potential harm. Such judgements were linked differently by critics of GM crops. In response to the conflicts, regulatory procedures not only increased the burden of evidence for safety, but also stimulated and requested new knowledge about more complex uncertainties. Sometimes these efforts challenged the assumptions of regulatory science. Thus precaution changed the criteria for evidence - for example, by emphasizing different uncertainties than did the safety claims. Although governments were accommodating political pressures to delay decisions, politics did not simply supersede science. Rather, the implicit politics of regulatory science was undergoing change, in ways less favourable to safety claims.

Precaution Justifies Uncertainty

Overall, this case study clarifies some of the ambiguities or differences among theoretical perspectives that I outlined in my introduction. In the European risk debate on GM crops, disputes over uncertainty cannot be explained by incomplete scientific information. Rather, social conflict increased and reframed uncertainty. Indeed, uncertainty increased in the late 1990s as more information became available, and was cited to re-open earlier approval decisions. At issue was the range of predictive uncertainties which must be clarified, their potential consequences and their institutional manageability.

Through the 1990s, the risk debate was translated into various `precautionary' approaches. Each had its own cognitive framing of the relevant uncertainties. Initially the European regulatory procedure favoured a particular account of uncertainty as the technical problem for fact-finding efforts, while marginalizing other accounts. Public protest strengthened more open-ended accounts of uncertainty, in at least three respects: more stringent agro-environmental norms; greater scrutiny of safety evidence or assumptions; and more complex causal pathways of potential harm.

At least implicitly, conflicts over evidence expressed different framing visions for future agriculture. Such value conflicts made scientific uncertainty more important - rather than *vice versa*. When risk research methods were challenged, fact/value boundaries were broken down, thus increasing `uncertainty' - rather than *vice versa*. In these ways, the risk controversy was constituted by divergent accounts of the relevant scientific uncertainty. Greater uncertainty expressed social conflict and scientific-cognitive disputes, rather than simply facilitating them. Uncertainty was constitutive as well as contextual.

From that deeper perspective, precaution offers a means to justify uncertainty - not simply *vice versa*. Conventional risk assessment generally acknowledges only reducible uncertainties, while obscuring or denying the socio-cultural values in regulatory science. As a critical response, limits of science are cited so as to emphasize uncertainty, and thus to justify precaution. Implicitly, however, a converse logic also operates. By changing the

criteria for evidence, precaution reframes uncertainty, while making the constituent value judgements more socially accountable.

Notes

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