REGULATING GMO RELEASES : BRITAIN'S PRECAUTIONARY DILEMMAS

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Dans le débat sur l'application du principe de précaution aux organismes génétiquement modifiés, la réglementation anglaise a fait son choix : elle accorde une importance au moins aussi grande aux risques de rejet de ces organismes par la société qu'aux risques proprement écologiques qu'ils pourraient induire.

Résumé en français p. 113

This essay analyses how Britain regulates GMO releases. It serves as a case study of how environmental "precaution" derives its content and limits from wider sources. The analysis refers to theoretical perspectives on regulatory boundary-setting and on national regulatory styles.

SOURCES OF PRECAUTION

The intentional release of genetically modified organisms (GMOs) provoked political controversy prior to any evidence of environmental harm. At issue was not only direct physical harm, but also the biotechnological aim of further industrializing agriculture (*e.g.* Haerlin, 1990). GMOs were variously conceptualized as self-reproducing pollutants or as "environment-friendly products" (Levidow and Tait, 1991). Public protest, along with diverse regulatory responses, potentially obstructed biotechnology R&D and an eventual international market for products (Levidow, 1994a).

In response to the legitimacy problems of biotechnology, the European Community enacted process-based legislation, *i.e.*, regulating all organisms which result from the genetic modification process. The EC Directive 90/220 was called "preventive", though it was precautionary, by virtue of preventing undocumented hazards (Tait and Levidow, 1992). For regulating GMO releases, precaution has had diverse meanings among EU member states[1]. The form of Britain's precaution may be illuminated by various theoretical perspectives.

"The precautionary principle" has been a frequent reference point for environmental policy but has a problematic relation to science. According to an early German proponent of the *Vorsorgeprinzip*, it provides a framework for proposing safety measures « before damage occurs and beyond the current state of knowledge », even for « acting against risks which are not (yet) identifiable » (von Moltke, 1987). This

ABSTRACT : Regulating GMO releases : Britains's precautionary dilemmas

Britain has been developing a precautionary approach for regulating the intentional release of genetically modified organisms (GMOs). The specific form of precaution has non-environmental sources, e.g. in extending a consultative regulatory style, and in accommodating public suspicion. As biotechnology innovation seeks to industrialize agriculture, safety regulation carries the burden of symbolically normalizing a contentious "progress".

Consequently, the regulatory procedure encounters practical dilemmas : how to justify risk-management procedures in terms of a hypothetical risk identification ; how to acknowledge the stigma associated with GMOs, in a way which could eventually overcome it ; how to justify relaxing initial controls, without necessarily claiming to resolve ecological uncertainties ; and how to provide definitive safety assessments, while proceeding as if the R&D agenda were not an issue.

1. International comparaisons lie beyond the scope of this essay. Difficulties in implementing and harmonizing the EC Directive will be analysed in *Science and Public Policy*, June 1996 issue.

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remains contentious in the case of the North Sea, for example : scientists have disputed the potential causes of documented harm to marine fauna, the types of scientific evidence worth seeking, and thus the basis for a policy which would permit or restrict waste dumping (Wynne and Mayer, 1993 ; Wynne, 1992).

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 » (Johnston and Simmonds, 1991). However, those limitations entail difficult questions : What evidence of environmental harm warrants precautionary measures? If there is no direct evidence, or only disputed evidence, then what plausible analogy to other harmful activities warrants shifting the usual burden of evidence? Such questions receive quite different answers in different cases. Thus « it is difficult to speak of a single precautionary principle at all » (Bodansky, 1991).

If such a "principle" exists, then it is not simply applied, but rather interpreted, or even constructed anew. It should be understood as "an expression of environmental value, phrased in the rhetoric of science". Precaution is necessarily a social construct, dependent upon whichever types of uncertainty are emphasized, investigated and managed (Hunt, 1994, pp. 121-22).

Precautionary approaches become more compelling in the face of recent innovations. These have been theorized as bearing "modernization risks", which are relatively more pervasive, elusive and potentially catastrophic. « Dealing with these consequences of modern productive and destructive forces in the normal terms of risk is a false but nevertheless effective way of legitimizing them » (Beck, 1992, pp. 22, 28). Yet this implicit role of risk regulation presents difficulties for demarcating the risk-generating system. A safety judgement can claim an authoritative scientific basis by modelling the bounds more narrowly; but its judgement can be definitive only by evaluating the entire technological system, or by pretending that this is not an issue (Wynne, 1982, p. 172). In regulating GMO releases, what is the extent of causal chains for which regulators develop expertise, seek evidence and take responsibility?

For the case of Britain, its safety regulation has been generally theorized as a "consultative" style. That is, the state flexibly applies broad discretionary powers, so as to guide industry in regulating itself. Through a practice of "responsible co-optation", Britain incorporates relevant interest groups into confidential procedures. Their participation serves to protect the neutral image of regulatory science, while gaining public deference to expert committees (Vogel, 1986, pp. 51-52; Brickman *et al.*, 1985, pp. 310). In this way, regulatory authorities have generally avoided public disputes over the scientific basis of policy, as in regulating hazardous chemicals (Jasanoff, 1986, pp. 73-75, 58-59).

More recently, however, British regulation has undergone pressure to formalize its scientific rationale, *e.g.* by adopting clear statutory rules (O'Riordan and Wynne, 1987, p. 409). In regulating GMO releases, how does a statutory basis extend or alter the British consultative style ?

Those questions inform the following analysis of how Britain constructs "a precautionary approach" for GMO releases. For research materials, this essay draws upon numerous interviews, especially with industry lobbyists, civil servants, and members of Britain's advisory committee. From this material, I constructed a cognitive map which depicts the strategic thinking of each interviewee. Such a map traces perceived cause-effect relations, from means to ends, as links from lower-order to higher-order concepts; the triple dots (...) denote "rather than" (Eden *et al.*, 1983; Huff, 1990, pp. 28-31). This essay includes excerpts from just a few cognitive maps, in Figures 1 to 5.

JUSTIFYING NEW LEGISLATION

In the late 1980s GMO releases came under a voluntary regulation, operated by the Health and Safety Executive (HSE), whose statutory powers covered only human health and safety. The HSE opposed "process-based" legislation, *i.e.* new laws specifically to regulate GMOs, and the UK government took a similar stance in the European Community. Nevertheless the EC enacted the process-based Deliberate Release Directive 90/220, which had to be implemented in all member states. This new EC obligation coincided with growing domestic pressures for the UK to enact process-based legislation, particularly in order to provide an imprimatur for environmental safety.

The new law was the Environmental Protection Act, Part VI (EPA, 1990, which this essay will call "the 1990 Act"). With this law, responsibility for GMO releases would be transferred from the HSE to the Department of the Environment (DoE). The new system encompassed the dual aims of anticipating environmental hazards and public unease about them, though these aspects remained inseparable, given that regulatory actors could cite different scientific accounts of plausible hazards. (For more detail on the British and EC legislation, see: Levidow and Tait, 1992; Tait and Levidow, 1992.)

Precautionary features

Prior to the 1990 Act, the DoE formulated scientific and political arguments for regulating GMO releases as such. The DoE issued a consultation document which cited the potential for GMOs to become harmful "pests", starting from the earliest trial releases. The document also emphasized that extra costs of GMO regulation would be offset [compensated] by the value to industry from increased public confidence. Without adequate regulation, « A distrust of the industry by the general public could lead, as it apparently has in the USA and Germany, to the development of potentially wealth-creating products being held up by

action on the part of concerned members of the public » (DoE, 1989, pp. 19, 23).

A similar warning came from the Royal Commission on Environmental Pollution, a permanent body which convenes working groups on specific issues. According to its report on GMO releases, biotechnology products offer environmental benefits, yet these « could be frustrated by public opposition motivated by fear of the unknown » (RCEP, 1989, p. 62). As a scientific rationale for strict regulation, their report also reiterated warnings from ecologists who compare GMOs with some non-indigenous organisms which have gained a competitive advantage in a new environment.

As proposed in both the above documents, the 1990 Act introduced a licensing system, which combined a specific consent with a duty of care (see later this section). Industry regarded such a system as essential for making their activities publicly acceptable. Privately, industrialists cited the need "to keep out the cowboys", a metaphorical term for irresponsible people whose behaviour might discredit biotechnology in general. Thus a hypothetical intruder served as a rationale for collective self-discipline, as well as for policing admission to the "club" of GMO releasers.

However, industry lobbyists criticized the stringent language of the Environmental Protection Bill, and Conservative backbench MPs proposed amendments to weaken it. For example, in defining a "GMO" as the product of specific techniques, the Bill list listed not only recombinant DNA but also cell fusion and even mutagenesis – thus apparently regulating a traditional technique, even naturally occurring organisms. The Bill prohibited any GMO release entailing "a risk" of damage to the environment – which could mean that regulators require proof of zero risk for a range of unspecified hazards; amendments would have prohibited only "a significant (or unreasonable) risk". Moreover the Bill defined environmental damage as the mere presence of organisms "capable of" causing harm – which stigmatized GMOs as pollutants; the amendments would have specified only actual harm. On such grounds, the Bill was attacked as "unscientific". However, the government defended and retained its statutory language as essential for a precautionary approach.

These disputes had several sources. It was inherently difficult to legislate against hypothetical hazards, prior to any agreement on risk-identification methods or cause-effect models of potential harm. GMO regulation could achieve its dual anticipatory role only if the 1990 Act established broad enabling powers. Yet its technical-legal language led biotechnologists to fear that they might lose the informal, consultative relation which the HSE had developed with them in the late 1980s. Similar tensions arose in other regulatory areas which the DoE was entering (Weale, 1992, p. 104).

Through the consent system, the state would specify and enforce the conditions for each GMO release. Each consent also imposed a general duty of care upon notifiers (releasers) to protect the environment. In particular, they must report any new information which may indicate that the risk is greater than originally thought. They must also follow the BATNEEC criterion: « best available technology not entailing excessive cost ». For pollution control in general, BATNEEC meant an explicit trade-off between cost and risk reduction; it could impose greater costs in order to force technological improvements. BATNEEC had a more ambiguous meaning when extended to GMO regulation, which lacked any agreed method for deciding which hypothetical hazards warrant preventive measures, much less how to prevent them.

The licensing system provided a basis for both assigning and restricting legal liability. The 1990 Act authorized penalties only against GMO releasers who violate safety procedures, and it authorized the state to remedy damage resulting from such violations; thus the state would act as a last-resort insurer. The 1990 Act allowed releasers to avoid liability for damage by

demonstrating that they had complied with the duty of care.

Protection from/for GMOs

Conflicts around the 1990 Act exemplify more widespread problems of legitimizing hazardous activities through licencing systems. Such systems are intended to facilitate long-term investment decisions by providing clear safety standards; yet they do so by adopting a standard scientific language to encompass diverse types of pollution hazards (O'Riordan and Wynne, 1987, p. 394). In the case of GMO releases, Britain's stringent legislation symbolized a safe control; with such language, regulators could encompass all hypothetical hazards, could request more evidence of safety, and could hold releasers liable for damage. Yet its scientific meaning was vague or problematic ; this precautionary framework strained the "rational" British image of science-based regulation.

Moreover, the 1990 Act reversed the traditional meaning of "sound science". With this familiar slogan, the British government has often deferred preventive measures until more evidence of harm becomes available. Indeed, in the name of science-based regulation, Britain has often resisted EC regulatory proposals as "threats imposed by unreasonable foreigners acting counter to scientific and economic rationality" (Boehmer-Christiansen, 1992, p. 22). For GMO releases, the government again claimed to base its policy upon "sound science" (HMG, 1990, p. 183), yet initially this meant placing the burden of evidence on the applicant.

The 1990 Act emphasized the long-term potential for direct ecological effects of GMOs or their inserted genes. Its statutory language seemed to omit the scenario of GMO products encouraging agricultural practices which pose systemic hazards – an issue which had been highlighted by an EC-funded report (Mantegazzini, 1986, pp. 76-80). Opposition MPs emphasized this regulatory gap when they attempted to broaden the environmental remit of the 1990 Act. For example, they cited the scenario of herbicide-resistant crops which could encourage or force changes in herbicide usage.

Some MPs proposed that the government establish a Public Biotechnology Commission, which would assess GMO products on broader grounds than direct environmental "risk". However, the government speakers rejected the Opposition proposal on several grounds. For example, they warned that obstacles to technological advance would hinder our socio-economic progress – thus equating the two, in both the past and the future. This government response took for granted the R&D agenda of biotechnology, which mainly seeks solutions for the problems of intensive monoculture.

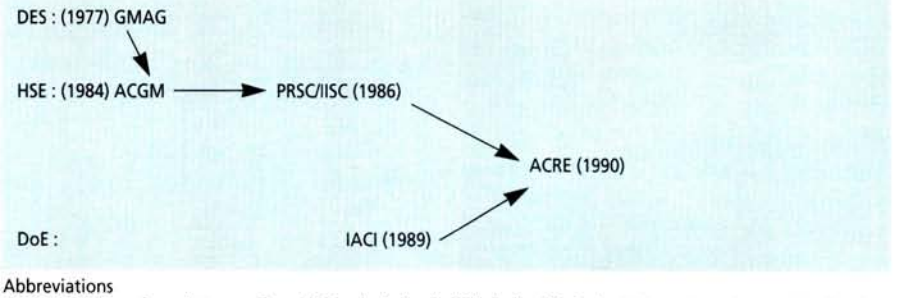
CONSTITUTING THE ADVISORY COMMITTEE

During the 1990 Parliamentary debate on the Environmental Protection Bill, MPs questioned whether safety assessments would remain above commercial pressures. In response, the government emphasized the high reputation of the Advisory Committee on Releases to the Environment. ACRE thereby held a central importance for the social legitimacy of GMO regulation. This section analyses the committee's origins, remit, membership and political role (Levidow and Tait, 1993.)

ACRE's remit for "novel organisms"

When the UK government created ACRE in 1990, it replaced two predecessor committees (see *table 1*). The IISC had been advising the HSE on GMO releases, while IACI had been advising the DoE on the same, as well as non-indigenous organisms. ACRE combined key features of the two committees : *i.e.*, both human and environmental safety; both GMOs and non-indigenous organisms; both the HSE and DoE civil servants. Although regulators justified this new structure in scientific terms, it had political rationales : under a Joint Secretariat, ACRE could continue industry's working relation with the HSE, could complement the DoE's environmental imprimatur, and could reconcile the different safety perspectives of those two departments.

The biotechnology industry had preferred to keep the relevant committee within the HSE. According to one interviewee, the HSE's IISC should continue to deal with GMO releases, rather than have the DoE set up its own committee for GMOs; this way, applicants would get a single post box located within the HSE, rather than have to



Abbreviations
ACGM : Advisory Committee on Genetic Manipulation (which had advised the HSE on GMOs in contained use)
ACRE : Advisory Committee on Releases to the Environment
DES : Department of Education and Science
DoE : Department of the Environment
GMAG : Genetic Manipulation Advisory Group
HSE : Health and Safety Executive
IACI : Interim Advisory Committee on Introductions
IISC : Intentional Introductions Sub-Committee
PRSC : Planned Release Sub-Committee

Table 1 : **ACRE's Precursors.**

notify the DoE as well. As a more substantive reason, this industrialist expected that HSE regulators "would nurture better relations with industry" and minimize regulatory burdens upon industry (see cognitive map, *Figure 1*, left-hand side). Given these apprehensions about the DoE's environmental perspective, ACRE was designed to resolve any conflicts within confidential procedures; this political role guided the restructuring of Ministerial links around the new committee.

ACRE was assigned a remit to advise the DoE on "novel organisms". This new administrative category drew upon a biological analogy, which the government later made explicit: « Since a GMO is regarded as a "novel" organism, parallels have sometimes been drawn with the introduction of non-indigenous or exotic organisms into the environment, some of which have caused harm to the environment in the past » (DoE official quoted in Levidow and Tait, 1993, p. 199).

Such an analogy defined the risk problem in naturalistic terms, more than in agronomic terms ; it also downplayed the significance of the genetic modification technique. Indeed, ACRE members welcomed their combined remit for all "novel organisms" as a truly scientific basis for the committee. They would regulate GMO releases on grounds of genetic novelty, not the genetic modification technique.

British industrialists too favoured constituting ACRE on the basis of "novel organisms". According to one interviewee, industry should « accept that GMOs are novel organisms », so that government can « combine regulation of GMOs with non-indigenous organisms » ; thus industry would obtain a « regulation convenient for companies trading between sites », as well as the advantages of dealing with the HSE for both categories of organism (*Figure 1*, right-hand side). For administrative purposes, industry accepted the conceptual similarity between GMOs and non-indigenous organisms, in order to prove their dissimilarity through the experience of field trials.

Symbolically the category of "novel organisms" acknowledged public fears of GMOs running out of control. The regula-

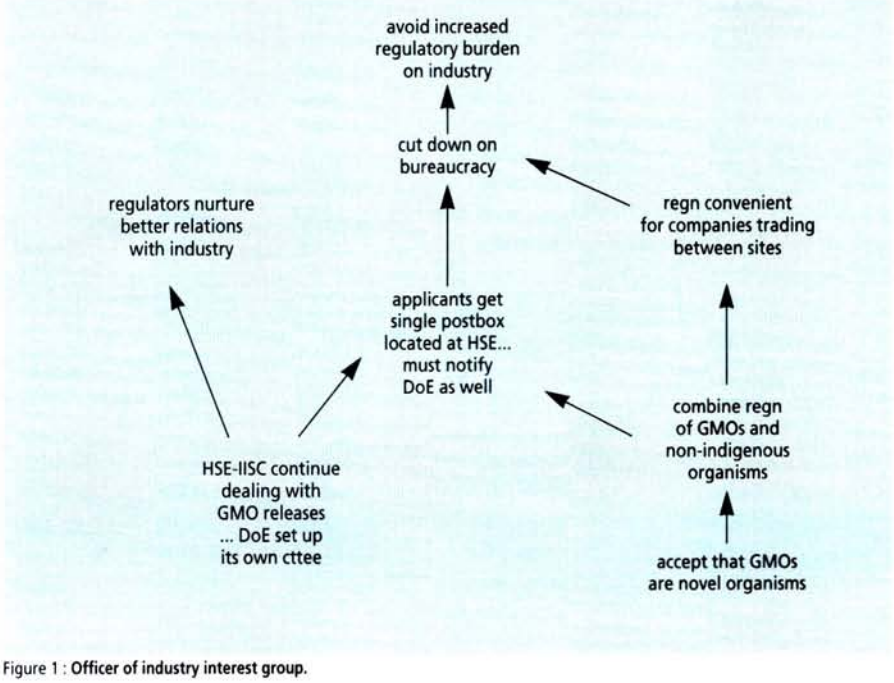


Figure 1 : **Officer of industry interest group.**

tory procedure could translate this scenario into scientific terms, into testable criteria for demonstrating safety. Thus a hypothetical analogy offered an administrative compromise, which could help bypass disputes over whether "process-based regulation" has any scientific basis.

Stretching expertise

In appointing ACRE's membership, the HSE/DoE Joint Secretariat extended the standard composition of health & safety committees, with their tripartite basis – experts from industry, trade unions and scientific research (see *Table 2*). Like the IISC, ACRE included nominees from the Confederation of British Industry and from the Trades Union Congress; representatives from other government-funded bodies, *e.g.* the Nature Conservancy Council and the Association of Metropolitan Authorities, the latter represented by an Environmental Health Officer. It included "assessors" from government departments responsible for industry, agriculture, and health.

The Secretariat also stretched the scientific notion of "expertise". As compared to its predecessor committees, ACRE included not only more ecologists, but also more lay members: *i.e.*, more TUC nominees, a "farmer" and an "environmentalist". The latter member, from the Green Alliance, had lobbied MPs for amendments to the 1990 Act. Reportedly, the DoE wanted her present on ACRE in order to "ask awkward questions" about environmental uncertainties.

The lay members provided an implicit public-interest representation, whose role was double-edged. On the one hand, in concert with the ecologists, they could press applicants for more evidence of safety. On the other hand, their presence could legitimize the regulatory task of translating scientific uncertainty into testable properties of GMOs. In this way, biotechnology regulation extended the customary British mode of "responsible co-optation".

How did British industrialists regard ACRE's membership ? According to one CBI nominee, the tripartite composition would help regulators to "get an industry viewpoint on marketable products", so that the advisory committee could "look at competitiveness" vis-a-vis the Japanese and US biotechnology industries (see cognitive map, *Figure 2*, left-hand side). From this standpoint, they welcomed "reasonable" lay members, especially TUC nominees, who were sympathetic to the practical problems of implementing the safety rules.

However, industrialists privately disagreed on the merits of including other lay members, especially the "environmentalist". Some regarded this move as undermining the scientific authority of the committee. Others expressed approval: for example, lay members would help ACRE to advise the Environment Minister on public fears (see *Figure 2*, right-hand side). According to another industrialist, ACRE should encompass wide-ranging environmental interests, especially an environmentalist from an independent body not under official government control. With this broad composition, ACRE could more easily help regulators to reassure people, to ask questions that would be asked anyway at a later stage, and to overcome public alarm at an early stage (see *Figure 3*, middle).

In general, ACRE members too favoured a broadly based membership (see *Figure 4*, ACRE composite map). They expected that lay members would encourage the committee to think as if they were members of the public, so that scientists would explain their views to non-scientists. Thus the committee could reach a broad consensus and keep all GMO releases publicly acceptable.

While nominally assessing safety, ACRE could accommodate public unease and/or market pressures. By citing ACRE's advice, the government might avoid external challenges to its authority. Yet policy issues remained irreducible to technical criteria.

Moreover, there was some public expectation that the government would regu-

The number of ecologists is shown in brackets. All figures in the table are approximate[1].

Year established	1984	1986	1989	1990
Committee	ACGM	PRSC/IISC	IACI	ACRE[3]
Academics	4 (0)	5 (2)	5 (3)	8 (4)
Govt/research	2 (0)	3 (1)	4 (1)	4 (1)
TUC nominees	6	1	–	3
CBI nominees	4	1	–	3
Other Industry	2	–	–	–
EHO/AMA	1	1	–	1
NCC	–	1 (1)	1 (1)	1 (1)
Environmentalist	–	–	–	1
Farmer	–	–	–	1
Departmental officials[2]				
HSE	1+	1	1+	
DoE	2	1+	1+	
DTI	1	1	1	
MAFF/DAFS	4	2	5	
DH (ex-DHSS)	1	1	1	
Research (e.g. NERC)	1	–	1	
Total ecologists		(4)	(5)	(6)

1. Most figures above should be taken as estimates, for several reasons. "Govt/research" includes diverse government-funded institutions. If members have a background in both academic institutions and government service, the table categorizes them as the latter. The committees' size and composition have changed over time, so the figures above represent the largest size for each one. "Ecologists" are defined as those whose main expertise lies in ecology ; more members are familiar with ecology than the number indicated in the brackets.

2. Many departmental officers attended ACGM meetings, which advised the HSE on GMOs in contained use. These individuals were formally designated as 'assessors' on the IISC and ACRE. The figure "1+" refers to a department which provided a committee secretary and additional secretariat support. For all departments, their attendance partly depends upon the agenda items for a particular meeting.

3. When ACRE's membership was reappointed in 1993, the numbers fell by about half.

Table 2 : **Membership of advisory committees for GMOs regulation.**

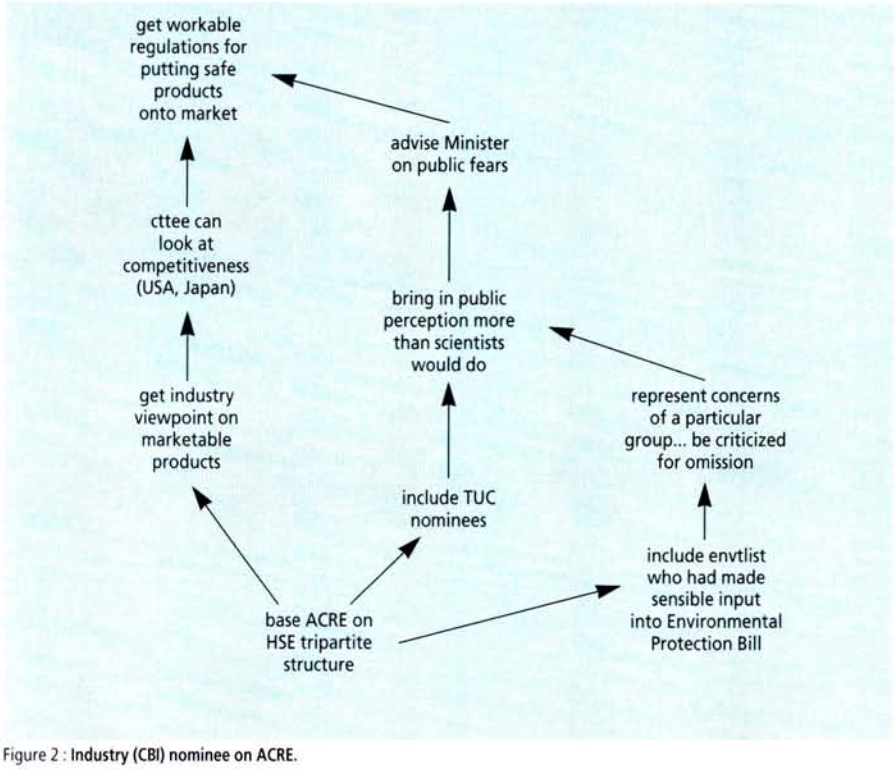


Figure 2 : **Industry (CBI) nominee on ACRE.**

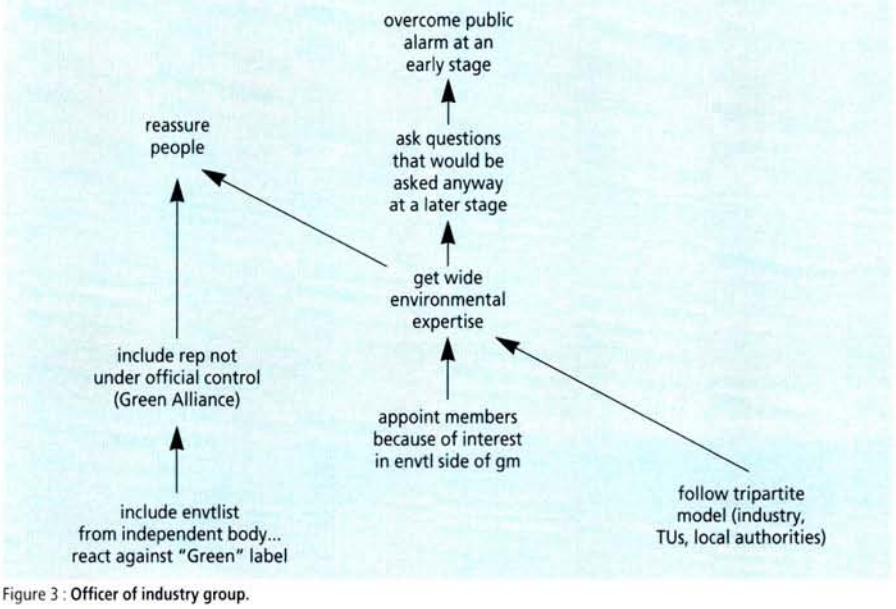


Figure 3 : **Officer of industry group.**

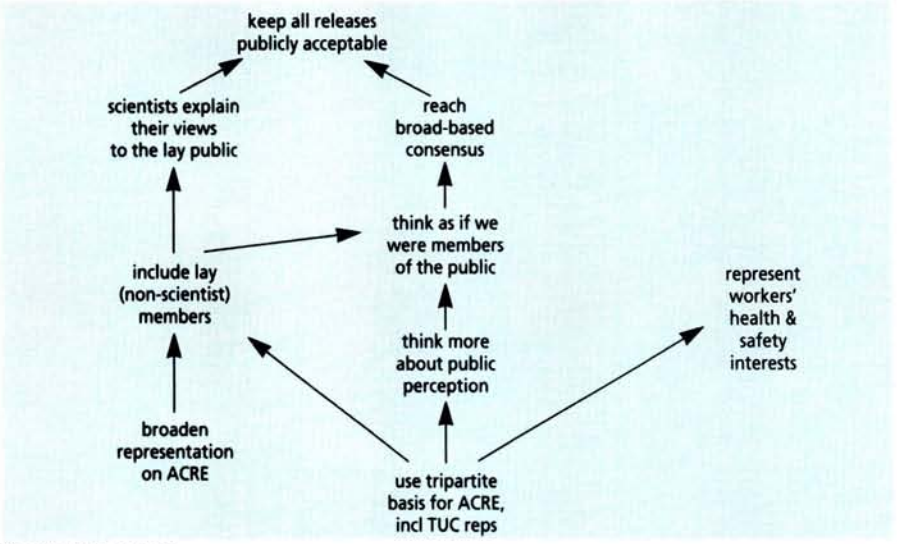


Figure 4 : **ACRE members.**

late products according to broader criteria than technical safety. Understandably, one journalist described ACRE as « clerk-of-works to the New Creation... punching out ticket to the future » (quoted in Levidow and Tait, 1992, p. 103). Yet ACRE operated within a naturalistic account of the risk problem; apparently its remit excluded, for example, the herbicide implications of herbicide-resistant crops.

EVALUATING SCIENTIFIC UNCERTAINTIES

When the DoE established a precautionary framework, even the most stringent language could not specify how ecological uncertainties matter for environmental harm. Regulators faced not simply a pre-

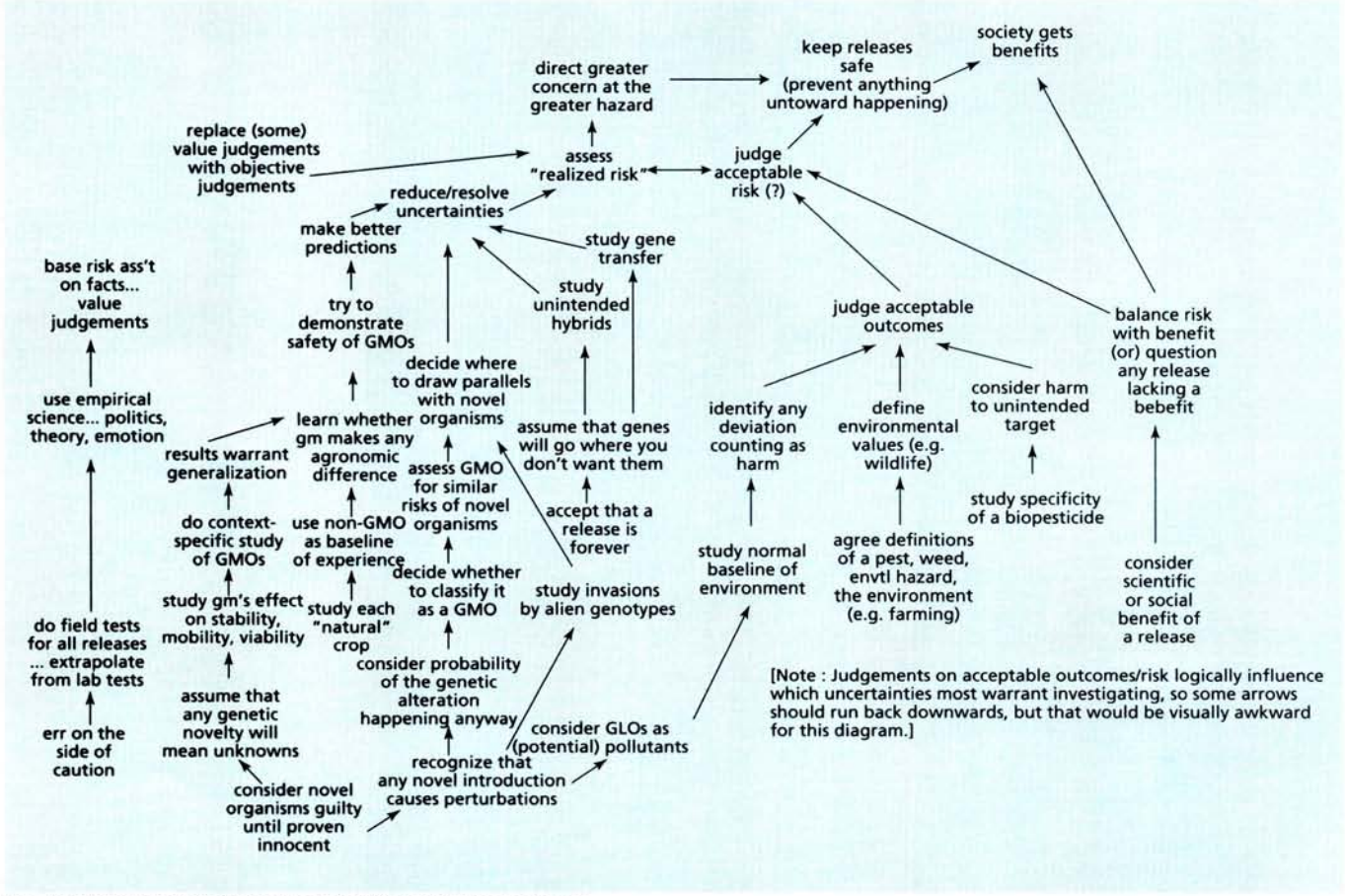


Figure 5 : **Value judgements in risk assessment : Regulatory advisors' composite map.**

dictive uncertainty, but also a normative uncertainty about the acceptability of hypothetical effects.

Pervasive value judgements

Where do value judgements arise in assessing GMO releases? From interviews with many ACRE members in 1990-91, I integrated their comments into a composite cognitive map (*Figure* 5; from Levidow, 1994b, p. 176). As their shared aims, shown at the top, regulators should « prevent anything untoward happening », in order to « keep releases safe », so that « society gets the benefits ». Towards achieving these aims, regulatory advisors expressed diverse views on how or where to make value judgements in risk assessment. Some sought to "reduce uncertainty" and so replace subjective judgements with objective ones (*Figure* 5, upper left-hand side). Others doubted that additional scientific knowledge would overcome the need for acceptability judgements, which should therefore be made accessible to public debate (middle right-hand side).

At least initially, members felt that a risk-assessment procedure was warranted for all GMO releases: « we consider all novel organisms as guilty until proven innocent ». Novel introductions often cause environmental perturbations, which could be harmful (*Figure* 5, near lower left). Thus the process-based regulatory procedure started by treating hypothetical effects as unacceptable.

For clarifying potential effects, members advocated further tests in the laboratory and field (middle left-hand side). For evaluating hazards, some members emphasized the need to assess "realized risk", *i.e.* the ultimate consequences (upper middle). In this regard, some members asked "so what ?", implying that unintended effects may be acceptable, especially if limited to agriculture. By contrast, other members defined environmental harm more broadly, *e.g.*, as including agriculture. Some conceptualized the environment as relatively more fragile; they advocated more extensive testing of ecological and agronomic complexities.

Such differences were manifest at a major biosafety conference, Regem 2. Some ecologists proposed additional research which would ascertain the "normal ecological baseline". With this knowledge, efforts at monitoring GMO releases could better detect any perturbation. By contrast, some laboratory scientists advocated restricting research to identifiable hazards; they even regarded some kinds of harm as acceptable, *e.g.*, eliminating an entire species (reported in Levidow, 1992a, 1992b).

As these debates illustrate, GMO regulation undermines the "rational" stereotype of risk assessment. According to the stereotypical sequence, judgements on acceptability arise only in the latter stages, *e.g.* at "risk evaluation" (see *Figure* 6, left-hand side; based on Whyte and Burton, 1980, pp. 10-12). For GMO releases, however, the "so what ?" question takes priority over the "how likely?" question (see *Figure* 6, right-hand side).

A similar sequence appeared in the proposal for a risk-identification method, "Genhaz" (see *Figure* 6, middle). This was adapted from the "Hazard and Operability" method, which was already being used for anticipating hazards in the chemical industry. Hazop starts by considering realistic causes of any deviations from the design intention; by contrast, Genhaz would first generate possible unintended consequences, then evaluate them to decide which are unacceptable, and then seek realistic causes for any unacceptable consequences (RCEP, 1991, pp. 11-12). Thus an acceptability judgement may influence the efforts at ascertaining the likelihood of unintended effects.

"Risk-based" policy

Through the early 1990s, all GMO releases were designed with some confinement measures. According to a DoE official, "risk-management measures have tended to be applied as a contingency measure to manage extreme uncertainty" (Gillespie, 1994a, p. 63). Indeed, the regulatory pro-

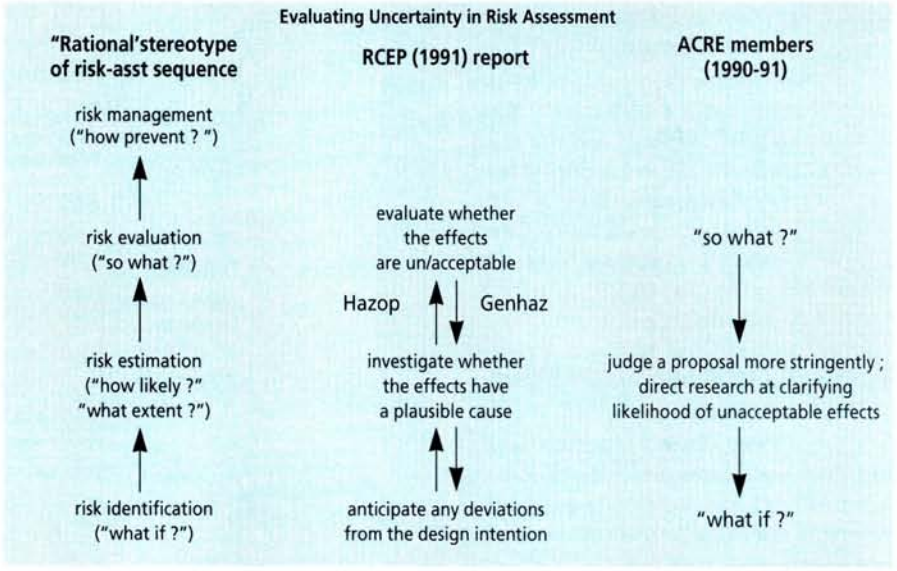


Figure 6 : **Evaluating the Consequences of Uncertainty.**

cedure served to defer the issue of how to define environmental harm, as well as prevent it.

In 1993, when the 1990 Act was formally implemented, the DoE began to describe its GMO procedure as "risk-based"[2]. The DoE formalized a "framework approach" to risk assessment, which starts by identifying the "harm-causing capabilities" of a GMO, in order to judge whether the proposed release is adequately designed to prevent damage. The schema classified potential effects on an ordinal scale of environmental "harm", ranging from negligible to severe. For example, "a change in population densities" as such would be "low harm"; a change in the genetic composition of a species was not mentioned, and so was implicitly classified as "negligible harm" (DoE/ACRE, 1993, p. 61-65).

A year later, the DoE built upon that risk-assessment schema by introducing a Fast-Track procedure. This accelerated the approval of specified plants which were deemed to be "low-hazard GMOs" or "low-risk releases". Its criterion for "low hazard" was "GMOs that do not possess inherent characteristics that pose a risk of damage to the environment". For "low-risk releases", confinement measures could adequately prevent the realization of any hazard (DoE/ACRE, 1994). The DoE also cited previous experience: « a repeat application will qualify for fast-track procedures if previous releases have not shown that there is a risk of damage to the environment ».

In practice, "risk-based regulation" meant helping applicants to design and justify their releases as "low risk", *e.g.* by maintaining the transgenic material in reproductive isolation. Such measures helped to defer uncertainties about whether the GMO is "low hazard" – *i.e.* whether its escape could plausibly cause harm. This ultimate judgement would depend upon how regulators define "harm".

The "risk-based" rationale apparently influenced the DoE's response to Genhaz, which the RCEP (1991) had originally proposed for all types of GMO releases. Two years later, the DoE argued that such a requirement would inflexibly impose a quantitative risk-assessment method – even though Genhaz was only a qualitative method. By contrast, « Flexibility will ensure that no-[risk] or low-risk releases of GMOs are not subjected to unnecessarily heavy burdens, but nevertheless will permit the extensive scrutiny of more novel applications » (DoE, 1993). Thus the DoE expressed a self-confidence which Genhaz was intended to challenge.

When the DoE funded a trial run of the Genhaz procedure, the participants simply wrote down unintended outcomes and means of preventing them; they focused upon early events in chains of consequences. The exercise anticipated "operability" problems, *e.g.* in confining the GMO, but it was « less effective in identifying the ultimate potential environmental consequences » of GMO releases, according to the rapporteur (DoE, 1994, p. 88). Thus, like the official DoE response to Genhaz, the trial run ignored its features which would open up public access to the value judgements on un/acceptable outcomes.

Such judgements can be illustrated by a much-debated scenario: If a herbicide-resistant crop transfers its resistance gene to a weedy relative, then the unintended hybrid could become an environmental problem. ACRE members have evaluated this hypothetical outcome in divergent ways (according to my interviews in 1990-91). Some members foresaw herbicide-resistant weeds affecting only agriculture, where they would be readily controlled by using a different herbicide. By contrast, others defined the environment to include agriculture ; in imagining cause-effect models of harm, they presumed no boundary between agriculture and the managed "semi-natural environment" outside it. One member even characterized the spread of herbicide-resistance genes as "genetic pollution".

For large-scale releases of herbicide-resistant crops, regulators publicly asked the "so what?" question, rather than pretend to resolve the uncertainty about potential effects. The DoE sought methods for how to quantify the money costs of remedying herbicide-resistant weeds, *e.g.* by switching to a different herbicide (Gillespie, 1994b). The agricultural scenarios were translated into cost-benefit analysis, thus implying that

such effects would not be environmental harm. Meanwhile, risk-assessment research attempted to clarify the likelihood that gene flow would inadvertently generate herbicide-resistant hybrids.

All these issues were sharpened in early 1994, when the DoE received a marketing application for herbicide-resistant oilseed rape. According to the applicant, transfer of the herbicide-resistance genes is unlikely, and anyway « the consequence of the transfer is confirmed to be negligible » (PGS, 1994). In response, ACRE and then the DoE recommended that the European Community grant market approval. As a rationale, the DoE's advisors judged that flow of the herbicide-resistance gene could not cause environmental harm – at most, only "agricultural problems", which could be handled with existing herbicide methods. On this basis, they could regard the hybridization potential of the crop as irrelevant to safety. However, this judgement provoked open dissent from the "environmentalist" member of ACRE, and attacks from NGOs. The market approval was opposed by some EU member states, which interpreted the EC Directive 90/220 to encompass the weed-control implications (Levidow *et al.* 1996).

CONCLUSION : PRECAUTIONARY DILEMMAS

In regulating GMO releases, the British state constructed anew "a precautionary approach"; it did not simply apply some *a priori* "principle". The content of precaution, and its practical dilemmas, derived partly from the legitimizing role of safety regulation.

GMO regulation both extended and strained the British "consultative" style (cf. O'Riordan & Wynne, 1987). Under pressure of the EC Directive 90/220 and a national risk debate, the UK's voluntary procedure was given a statutory basis. The new process-based legislation was to be implemented by the Dept of the Environment, which thereby took over the authority from the Health & Safety Executive. Industry accepted the political need for the new licensing system, which established legal liability and offered the DoE's imprimatur to safety claims. The DoE's public credibility was enhanced by the stringent legal language – which biotechnologists attacked, *e.g.*, for having no clear scientific basis or meaning. When the DoE established a new advisory committee, ACRE, its broad composition stretched the usual criteria for "expert" members; this provided a basis for reconciling diverse risk perceptions within a confidential procedure, thus maintaining the neutral image of regulatory science.

Eventually the DoE issued "risk-based" guidelines, somewhat clarifying the "risk of harm" which the new legislation had absolutely prohibited. By answering the "so what?" question, the DoE provided a clearer basis for arguing that a release (or a GMO itself) is safe. In effect, regulators initiated a formal "hazard identification", which might justify retaining or relaxing the previous risk-management measures.

GMO regulation had the implicit role of destigmatizing biotechnology. In this regard, the DoE-ACRE remit for "novel organisms" had a double-edged potential: this naturalistic analogy could accommodate fears about GMOs running out of control, but it delinked potential harm from the intensive monocultural practices for which GMOs were being designed. The statutory language implied a long timescale for anticipating harm, but it was interpreted to exclude some potential effects – which were defined as not really harm, or attributed to agricultural practices rather than the GMO as such.

In all those ways, the regulatory procedure encounters practical dilemmas : how to justify risk-management procedures in terms of a hypothetical risk identification ; how to acknowledge the stigma associated with GMOs, in a way which could eventually overcome it; how to justify relaxing initial controls, without necessarily claiming

2. In the USA, "risk-based regulation" became a synonym for "product-based regulation". With these slogans, the US government limited the authority of Federal agencies (EPA, USDA) to regulate GMO releases. The agencies had to cite some biological characteristic of a GMO in order to impose any "additional regulation" on its release – even in order to request data from the releaser. By contrast, the DoE used the term "risk-based regulation" after Britain put its voluntary controls on a statutory basis ; UK applicants had the burden of evidence to demonstrate that any release was safe.

to resolve ecological uncertainties ; and how to provide definitive safety assessments, while proceeding as if the biotechnological R&D agenda were not an issue (cf. Wynne, 1982, p. 172).

These dilemmas arise partly from regulating GMO releases prior to any evidence of harm from them. At the same time, the precaution itself responded to a legitimacy problem of the biotechnological R&D agenda. More fundamentally, then, the practical dilemmas arise because GMO regulation carries the implicit burden of symbolically normalizing a contentious "progress".

Acknowledgements

This essay arises from two related studies funded by the UK's Economic and Social Research Council : "Regulating the Risks of Biotechnology" (1989-91, project number R000 23 1611) ; and "From Precautionary to Risk-Based Regulation : the Case of GMO Releases" (1995-96, project number L211 25 2032). I would like to thank an anonymous referee of *Natures, Sciences, Sociétés, Dialogues* for helpful editorial suggestions. ■

(Received September 29, 1994).

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RÉSUMÉ : Réglementation des dissémination d'OGM : les dilemmes du principe de précaution en Grande-Bretagne

C'est en 1990 que le Royaume-Uni choisit de promulguer une loi relative aux dissémination d'organismes génétiquement modifiés (OGM). À l'encadrement non contraignant issu, de la collaboration entre le *Health and Safety Executive* (HSE) et l'industrie, succède alors une réglementation obligatoire, spécifique, qui soumet ces dissémination à une évaluation préalable, alors même que le risque écologique lié à ces organismes n'a jamais pu être prouvé. Aussi a-t-on pu dire de cette loi, tout comme de la directive communautaire 90/220 qui visait à étendre un modèle identique à tous les États de l'Union européenne, qu'elle procédait d'une "approche de précaution" : au seul motif que les OGM sont nouveaux, ils sont présumés être sources d'un risque potentiel et leur dissémination ne peut avoir lieu qu'une fois leur sécuritÈ démontrée.

Mais au-delà de son originalité, ce qui est remarquable dans ce choix politique, c'est qu'il n'a pas comme seule raison le souci de prévenir sur les éventuels risques écologiques liés aux OGM : un régime de contrôle préalable strict est également vu comme un moyen de légitimer les OGM dans l'opinion publique et d'éviter que les craintes qu'ils y suscitent ne soient néfastes à l'avenir commercial des biotechnologies. Cette dimension politique de la précaution est invoquée dès la fin des années quatre-vingt par de nombreuses administrations ou institutions.

Plus nuancée, l'industrie se rallie bientôt à la même idée. Si réglementer *a priori* les OGM est à ses yeux dénué de fondement scientifique et stigmatise ces organismes, elle accepte néanmoins de se soumettre à une telle discipline, qu'elle présente comme un investissement nécessaire.

La nouvelle loi britannique a interdit les OGM dont l'utilisation implique un risque environnemental, y compris à travers des effets à long terme.

Dans cette politique de légitimation, l'*Advisory Committee on releases to the Environment* (ACRE), comité avisant l'administration des risques présentés par chaque projet de dissémination, joue un rôle pivot. Parce que ce comité d'experts est en partie maîtrisé par le Département de l'Environnement, ses décisions sont censées accroître la légitimité des travaux de recherche et de développement en biotechnologie. Le comité ne regroupe pas seulement des scientifiques de spécialités diverses, mais aussi des représentants supposés du public, censés à la fois jouer le rôle de porte-parole de l'opinion et assurer celle-ci du sérieux du contrôle. En outre, loin de se cantonner dans le contrôle des OGM, le comité est chargé d'évaluer les risques de tous les organismes jugés nouveaux, parmi lesquels les organismes exotiques. Là encore ce choix s'explique par des raisons plus politiques que scientifiques. Évaluer les OGM et les organismes exotiques au sein de la même institution est l'occasion de mettre en relief la dissemblance entre ces deux catégories d'organismes souvent assimilés – à tort aux yeux d'une grande majorité de scientifiques et d'industriels – pour leurs effets sur l'environnement.