

Science and Public Participation in
Regulating Genetically-Modified Food:
French and American Experiences

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This paper sets out a framework for considering how scientists, members of the public, and regulators interact in setting policies to regulate genetically modified food, and examines three areas where government officials have involved the public in discussions. One of the core assumptions behind regulation of genetically modified food, as well as other environmental and food safety issues, is that what we really need is “better” science. By “better” science, we mean science that fully explicates all of the questions raised about the health and safety implications of genetically modified food. For instance, how will genes extracted from known allergens affect those susceptible (e.g. the flounder gene in strawberries)? Will pollen from genetically modified (GM) crops become mixed in with pollen from traditional crops, thereby leading to cross breeding? And what will the effects of cross-breeding be? What about “super-weeds:” will GM crops confer resistance to weeds on the edges of the field? These are just a few of the questions that are being asked about genetically modified crops. Science does play a role in answering these questions. Indeed, the efforts of scientists in many different fields to understand these processes will add to societal understanding, and may lead to better efforts to regulate. But increasingly policymakers have come to recognize that involving the public in regulating GM foods is a critical next step.

The paper is divided into two sections. The first section considers the role of science and policy, contrasting it with understandings of participatory policymaking. It suggests resolving the tension between these two modes by turning to regulatory officials. Regulators are often portrayed as empty vessels reflecting the preferences of either scientists or the public, but in fact can possess considerable discretion in resolving tensions. We then suggest a set of ideal types of policymaking. The second section turns to the analysis of our cases. We consider the the Citizen Conference and the Commission du Génie Biomoléculaire in France, and the Food and Drug Administration public meetings in the United States. We conclude with some reflections on how well these three cases integrate and moderate expert and public participation.

I. Theoretical Framework

A. Science and Policy

The notion that more and better science leads to better policy results in an approach to policy where the expert plays the key role; this is sometimes called a “technocratic” mode of decisionmaking. Here, the expert is supposed to speak truth to power, to produce the facts and then let policymakers decide.¹ But both uncertainties as well as the socially constructed nature of science itself undermine the appeal of this approach.²

Academics have long recognized the difficulties science faces in addressing questions asked of it by public policy. Alvin Weinberg, the renowned physicist, addressed the relationship between science and society almost three decades ago in his seminal article on “Science and Trans-Science.”³ Weinberg labeled as trans-scientific those questions “which can be asked of science and yet *which cannot be answered by*

¹ (National Research Council 1996) is an excellent example of this, as is (Breyer 1993)

² See (Irwin 1995) for a critique of the expert approach to policy.

³ (Weinberg 1972)

science."⁴ Trans-scientific questions are of three types: those that are simply too expensive to get answers to; those where the subject matter is too variable to answer according to the natural sciences;⁵ and those where "science is inadequate simply because the issues themselves...deal not with what is true but rather with what is valuable."⁶

Funtowicz and Ravetz similarly address what happens when science reaches into the public realm.⁷ They identify the emergence of "post-normal science" when decision stakes and system uncertainties are both high. "The problem situations that involve post-normal science are ones where, typically, facts are uncertain, values in dispute, stakes high, and decisions urgent."⁸ These analyses have pointed out that science is not capable of answering all the questions put to it by public policy, primarily because public policy reflects not only facts, but also values. These scholars contend that science is prepared to answer questions of facts, but not ones of values.

Other analysts have questioned whether science is indeed the objective enterprise that the above portrays it as; that is, whether it is indeed even capable of answering the questions of facts. While the above characterize the distinction between science and trans-science or post-normal science as based on external factors, other accounts look to the work of scientists themselves in drawing these boundaries. "The boundaries of science are ambiguous, flexible, historically changing, contextually variable, internally inconsistent, and sometimes disputed."⁹ Scientists try to stake out their own territory in which their competence is not questioned, and juxtapose that to non-scientific intellectual or professional activities. Their interests guide how they present their work to the public. This effort at "boundary work" is the way in which scientists stake out the authority and legitimacy of their work; and this authority is not a permanent feature, but rather "is enacted as people debate (and ultimately decide) where to locate the legitimate jurisdiction over natural facts."¹⁰ In her study of the scientific advisory process in the United States, Sheila Jasanoff found scientific advisory boards produced their science through a process of negotiation—which points to the socially-constructed nature of science—and then gave the result legitimacy through demarcating their scientific work from other non-scientific work.¹¹

Thus, rather than seeing science as surrounded by societal influences but separated from them, science is permeated by society. Bruno Latour suggests five aspects to this connectedness: 1) how science keeps the world engaged through equipment, expeditions, surveys, etc.; 2) how science convinces colleagues and scientific institutions; 3) how science engages groups outside of the sciences that are interested in their work (e.g. military); 4) how science affects public representation, media etc., i.e. how much trust do people place in science; 5) scientific content. When science is

⁴ Ibid., 209 – italics in original.

⁵ This is where Weinberg places the social sciences.

⁶ Ibid., 213.

⁷ (Funtowicz and Ravetz, 1992)

⁸ Ibid., 253.

⁹ (Gieryn 1983: 792)

¹⁰ (Gieryn 1999: 15) Gieryn points out how this constructivist explanation for the epistemic authority of science differs from other explanations (Gieryn 1999: 14 fn 18). The functionalist explanation, for instance, sees science as formed and developed in reaction to society's need for it.

¹¹ (Jasanoff 1990)

connected on all these levels, it is more “sturdy,” or less uncertain.¹² This offers us a way to conceptualize how science influences and is influenced by society.

B. Participatory Policymaking

As a reaction against the “technocratic” mode of policymaking, where scientists possess the authority that speaks truth to power, some have suggested a broadly participatory mode of policymaking, envisioned to give more voice to larger segments of the public. Greater involvement of and reliance on the public will enhance the legitimacy of decisions. But this approach also faces problems.

First, very few, if any, instances can be found of participatory approaches to policy that do not involve also relying on experts.¹³ There is not really a “pure” participatory model, as there is a “pure” expert model. Thus the same problems that are inherent in the expert approach to science are also present here. For instance, the public understanding of a particular scientific issue may not be recognized as valid, or the public may be cast as “ignorant.” Thus the difference between the participatory approach and the expert approach is not as large as it might seem: in both, expertise is limited to what scientists have to say.¹⁴ Rutgers and Mentzel recognize this tension, and suggest that “[t]he science-politics relationship needs to be embedded more firmly in the broader social context in which it figures.”¹⁵

Second, the question arises of which publics to involve (See Table 1). Certainly industry is part of the public, yet many non-governmental organizations would question the participatory character of a process that involved industry and government only.¹⁶ Do NGOs represent a broader public interest? Or should public participation mean a wide opening to anyone who wishes to participate in a process?

Table 1. Spectrum from public to expert

Mass public	Concerned public	Non-governmental organizations	Parliamentary representation	Scientists from different fields	Same field specialists but divergent views	Same field specialists
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Third, there is the question of how the participatory procedure is used. It is possible that a participatory forum could be used as “window dressing” for a previously-

¹² (Latour 1999)

¹³ For a definition of participation: “Participation broadly means the active involvement of social actors from outside the specialised expert communities in technology assessment. Participatory technology assessment may include groups that are directly affected by, or particularly concerned about, certain scientific and technological developments and applications, such as patients’ organisations or environment interest groups; or, it may include lay people with no particular interest other than as citizens” (Joss 1998).

¹⁴ (Irwin 1995: 72)

¹⁵ (Rutgers and Mentzel 1999: 150)

¹⁶ Indeed, (Vogel 1986) and (Brickman, Jasanoff, and Ilgen 1985) found that the industry-government model of environmental policymaking was quite prevalent in Britain, Germany, and France, but they (and others) term this a “closed” model of policymaking.

determined policy; in other words, to enhance the legitimacy of a policy but without any real influence on that policy.

Finally, there is the question of whether bringing people around a table to bargain will lead to an agreement.¹⁷ In a passionate issue such as the GMO one, it would be illusory to expect antagonist groups to agree on a definite and common ground on which to debate. As the President of the British Royal Society Robert May affirmed,¹⁸ the problem with settling the GMO controversy results from the fact that the various groups bring their own agenda to the debate. May argues that these groups may work toward their goals by consciously engaging in campaigns of disinformation. He considers that nevertheless, a wide and open consultation is necessary to address the various claims brought on the scene. "We have to acknowledge and address" the different issues rose by these controversies, namely: "what kind of a world do we want?" and hence give a say to non-scientific claims. As to the problem of the anti-science agenda, he proposes to have "mechanisms that seek to investigate the truth."

Would it be enough to calm down everyone? Let aside the problem of "having a mechanism that seek to investigate the truth," his proposal takes for granted that bringing in people to bargain will lead to an agreement, or at least smooth the dispute. Nothing is less certain. If the discourses are dealing with concerns of different nature, how could convening people around a table ease the dispute? Is it easier to deal with an issue solely by convening its actors? On which medium ground, apart from science and ideology, would these people discuss? This theory maybe draws on a very liberal and maybe idealistic mode. This process could even lead to adverse affects, such as formalizing and eventually crystallizing the disputes into even worse ways than they were before.

C. The Role of Policymakers

Both the participatory and expert ideal types share an assumption that policymakers—the government bureaucrats who actually make the decisions—are merely empty vessels reflecting the will of whatever group wins out in the struggle to form policy. This overlooks both the considerable expertise that these policymakers often possess and the interests of these government officials in the policy outcome. A third approach, which Irwin labels "pragmatic," is to give local regulators "maximum discretion" through the use of "reasonably practicable" and "best practicable means."¹⁹ Others have also focused on the staff of regulatory agencies, calling for increased technical expertise and a more flexible decisionmaking process to enable administrators to revise their decisions on the basis of new information.²⁰ Our analysis will now draw on organization theory to help us understand how government agencies and their staff might be expected to behave under these different approaches to policymaking.

The central problem organizations face is how to cope with uncertainties.²¹ These uncertainties stem both from the technologies the organizations deal with—in this case, the uncertain nature of the risk posed by genetic engineering of crops—as well as from

¹⁷ See (Douglas and Wildavsky 1982) for a discussion of the social selection of risks.

¹⁸ (May 2001)

¹⁹ (Irwin 1995: 73-77)

²⁰ See e.g. (Breyer 1993; Ramo 1981; National Research Council 1996).

²¹ This discussion is drawn primarily from (Thompson 1967).

the external environment the organization has to deal with. Organizations attempt to cope with uncertainty in the technical core by sealing off their core technologies from the environment, that is by eliminating or reducing any outside interference in how the core function of the organization is performed. At the same time, organizations cope with uncertainty in the environment by adjusting "to constraints and contingencies not controlled by the organization."²² This is done by increasing the number of people within the organization who deal with the external environment to help manage environmental contingencies.

The question of the external environment is the one we have addressed so far: do regulators face an external environment of experts, or one of a much broader public? The answer to this question has significant implications for the government agency, and for how successfully regulators are able to do their jobs. Increasing public participation may, in fact, limit the discretion of policymakers. Increased public participation implies an increase in the number of people within the organization who will have to interact with that public, with the organizational environment. How does the organization accommodate the increased information it receives from those boundary spanners? It needs greater coordination, and this implies a more formal, hierarchical decision making procedure.²³ Galbraith contends that hierarchy is a necessary response to complexity, to facilitate the flow of information through a vertical information system.²⁴ If, on the other hand, the regulators face an external environment of experts, and the external experts are similarly trained to the staff of the agency, then there is much less conflict and effect on agency structure.

Increasing the technical competence of agency staff is another approach that has been suggested for improving policymaking in environmental and social risk arenas. Organization theory expects that increasing the technical competence of staff will lead to a less hierarchical, more flexible decisionmaking process, given that all other inputs are equal. For instance, Perrow suggests that as tasks become more technical and less analyzable, decision making must become more decentralized.²⁵ Victor Thompson suggests that as technical content of a task increases, conflict will occur between managers and technicians if decision making is hierarchical.²⁶ As technical experts increase in number, they will also possess greater authority as a result of the organization's dependence on their knowledge. Crozier's classic study locates power in the organization members who control uncertainty.²⁷

But here lies the problem. If both technical capacity and public participation are increased at the same time, a conflict is likely to erupt because the public is not socialized along the same lines as the technical staff.²⁸ How can we enhance the legitimacy of

²² Ibid., 67. See also (Pfeffer and Salancik 1978).

²³ See (Udy 1965): in Proposition 4, he suggests that increased pressure from the external environment leads to an increase in the saliency of administration over membership or group structure. This could imply a more hierarchical decision-making procedure.

²⁴ (Galbraith 1973). This may or may not reduce discretion of decision makers, depending on the degree of coupling between the technical core and the environment (Scott 1992).

²⁵ (Perrow 1970)

²⁶ (Thompson 1961)

²⁷ (Crozier 1964)

²⁸ (Udy 1965)

expertise along with providing the policymaker with a broad range of action? There are two dimensions of importance in considering advisory panels: (1) the degree to which the citizen is associated with the work, and participates in debates over the policy; and (2) the degree to which the panel limits the discretion of policymakers (See Table 2). This limitation can occur both in a formal sense, as through legislation that indicates that an agency must follow the conclusion of a panel, and in an informal sense, through some of the mechanisms described above leading to more hierarchical decision-making procedures.

Table 2. Ideal Types of Advisory Panels

	<i>Open</i>	<i>Closed</i> ²⁹
<i>Decisionmaker discretion is limited</i>	socially deterministic	elitist
<i>Decisionmaker has greater discretion</i>	broadly consultative	instrumental

D. Ideal Types of Advisory Panels

Table 2 maps out systematically the interaction of the composition of an advisory panel with the degree of discretion possessed by the policymaker. A *closed* committee is characterized by its quasi-exclusive scientific composition, often strengthened by a uniform scientific specialization. On the contrary, an *open* panel will allow citizens' views to be more systematically voiced. In other words, the more a panel takes into account different perspectives, the more open this panel can be considered in our sense.

A socially deterministic advisory panel includes popular and democratic representation, which will likely enhance the legitimacy of the advice issued and make it more difficult for the policymakers to bypass the advice. The panel is likely to deter policymakers from carrying out policies at odds with its advice, because the policymakers may fear a loss of popularity.

An elitist advisory panel is made possible by two things. The first factor necessary is the positive behaviour of scientific elites acting to advance a specific agenda, based on their specific group interest, or ideology, or, borrowing from Simon Joss, "the elitist model places technology assessment in the hands of scientific expert bodies, such

²⁹ See (Joss 1998) for the use of the terms "elitist" and "instrumental."

as natural science academies. Here, technology assessment is detached from official decision-making procedures.”³⁰ The second factor that makes possible an elitist advisory panel is the incapacity of the state and the public to challenge the scientific discourse.

A broadly consultative advisory panel is similar to a socially deterministic panel except that the state acts to mitigate the strength of the public in order to preserve its broad range of discretion. Indeed, within the French context during the citizen conference, we saw officials having a whole discourse aimed at stressing that any conclusions issued by the citizen panel would remain only advice and should in no way determine public-policy making.³¹

An instrumental advisory panel will more likely be perceived as non-binding for the politician for its advices does not possess the legitimacy of an open committee. The state is serving instrumental purposes in convening such a panel, because it is less interested in the advice offered by the panel, and more interested in the use of the panel as a legitimating façade for predetermined policymaking. As Millstone puts it: “[S]ome wish to invoke the authority of science, and to conceal their own evaluative stance. In that case they would merely be articulating the model for rhetorical and political purposes to try to foreclose certain types of challenge.”³²

II. Case Studies

A. What is Genetically Modified Food?

Genetic modification of plants is not a new practice. Since the late 19th century, scientists and farmers have been cross-breeding plants that each have desirable characteristics, such as disease resistance, in order to produce a crop that contains the characteristics of both plants. This conventional breeding process usually takes thousands of crossings and up to fifteen years to discover if the breeding successfully imparted the desired characteristics.³³ Genetic engineering of crops bypasses this tedious process by selecting a particular gene with desired characteristics—for instance, a gene from the Bt bacterium (*Bacillus thuringiensis*) that instructs plant cells to produce a toxin poisonous to some insects—and inserting that gene directly into plant cells. In addition, scientists also insert a “marker” gene, by which they are able to tell whether a plant cell has successfully taken up the Bt gene.³⁴

Most genetically modified (GM) crops on the market today, including soy, corn, cotton, and canola, are modified to produce toxins that kill insect pests or to make them resistant to weed-killing herbicides.³⁵ Crops that are either still in experimental stages or not yet widely planted include those engineered to produce vitamins (such as “golden”

³⁰ Ibid.

³¹ For illustrations, see Le Déaut, Jean-Yves. 1998. *Le Monde*, 20 June; and Donnet-Kamel, Dominique. 1998. La conférence de citoyens: une innovation démocratique.

³² (Millstone 1996 : 87-8).

³³ (Pollack 2001).

³⁴ This marker gene is often one that shields cells from being killed by an antibiotic or herbicide. The plant is then exposed to an antibiotic, and only cells with the inserted genes will survive the exposure (Brown 2001).

³⁵ (Brown 2001)

vitamin A-enhanced rice), vaccinations, and other nutritional and/or medical enhancements.

B. The French Citizen's Conference

Reversing former prime minister Alain Juppé's decision from the 12th of February 1997 to ban the cultivation of Novartis Bt corn,³⁶ while still allowing its import, the new elected prime minister Lionel Jospin stated: "Public opinion is still undecided and appears insufficiently informed. Although our fellow citizens appear prepared to accept the resort to genetic engineering in drug manufacture, they are reluctant to accept it in their food. Despite great scientific experience in the field of genetic engineering, citizens do not agree that decisions affecting their future are made without allowing all opinions to be aired and debated. A 'consensus conference' will be organized by the Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques." This "conference of citizens," part of a broader reflection carried out by the *Office Parlementaire d'Evaluation des Choix Scientifiques et Technologiques* on "The genes and their application," was shaped on the model designed ten years earlier by Denmark, and followed by the Netherlands, Germany, Great Britain, and Australia. This debate was conducted under the aegis of the above mentioned parliamentary institution, and its president, the representative Jean-Yves Le Déaut.³⁷

In respect to the denomination of this conference, the organizers first thought of calling it a "consensus conference," as Nordic countries did.³⁸ However, it appeared that this qualification should be replaced by "citizen's conference," for "one of the characteristics of the French conference relies in the fact that the research of a consensus between all the members of the citizen's panel, as opposed to Denmark, has been exclusively sought, leaving the possibility to issue divergent or minority opinions."³⁹

The public debate took place Saturday 20 and Sunday, 21 June 1998, within the walls of the National Assembly.⁴⁰ Nonetheless, the preparation of the meeting went through three stages. First was a time of initiation, and then came a period for dialogue, and finally occurred the time to deliberate. Two initiation weekends were held the 25-26th of April, and the 16-17th of May, where 11 scientists discussed the potential benefits and risks embedded in GMOs. A third preparatory weekend was used to draw the five big questions around which the debate would be articulated, and served to finalize the list of experts to be auditioned. These five questions were:

- "According to current research, what are the effects of consuming GMOs on human health?"
- "How can we prevent the unregulated proliferation of GMOs in the environment?"

³⁶ For a thorough account of that episode, see (Marris 2000).

³⁷ Vincent, Catherine. 1998. Un débat public sur les plantes transgéniques va être organisé. *Le Monde*, 14 February.

³⁸ See, for instance, (Bercano 1999; McDonald 1999).

³⁹ (Donnet-Kamel 1998)

⁴⁰ Vincent, Catherine. 1998. Examen de passage populaire pour les plantes transgéniques. *Le Monde*, 20 February.

- “Given the economic stakes that represent information about quality, what is planned concerning the information of consumers about GMOs?”
- “How will the legislator prevent the hypothetical hazards that could be caused by GMOs in the short and long run?”
- “Given the complexity of the interests at stake, what are the different configurations of power and interest that will emerge?”

In the afternoon of Sunday 21st, after two days of intensive hearings and debate, the citizens’ panel retired during 24 hours to write its conclusions.⁴¹ In particular, they requested that “The *commission du génie biomoléculaire* should be open to fields that had previously been poorly represented.” They also called for the strengthening of public research in the particular domain of risks assessment, and urged a “clear, reliable and accountable” labeling policy, including the separation and traceability of GM and non-GM products throughout the food chain.

The representative Le Déaut officially released the report the 30th of June, which the government had said to wait before defining a policy of GMOs. The government took decision that were on stand from a certain time. He notably agreed on the release of two new varieties of corn, declared a moratorium of two years on GMOs like colza, presenting risks of cross-pollination with other crops, strengthened the bio-vigilance dispositif, and put in place separated industries in France.

The experts had a large influence on the debate. It appears that the questions, and auditions carried out by the citizens’ jury were largely directed to experts, so that we have reasons to think that the opinions issued were fundamentally influenced by, and eventually mirrored, experts’ viewpoints.

The real virtue of the citizen’s conference is its role in mediating the debate between supporters and opponents of GMOs, and in alleviating antagonisms. The citizen’s conference can then stand for a useful way, we think, of dispelling emotional debates and revealing the real agendas. If an interest group brings an extremist agenda before a citizen panel, the panel could lose trust in the interest group and could marginalize the interest group’s views. This could eventually lead to a loss of influence for these groups. More than the technical competence of the citizens’ panel, then, it is its function as mediator AND OTHER, made possible by the necessity for experts to frame and modify their discourse in ways understandable for the citizens’ jury that accounts for the success of that institution. The citizen conference, in our mind, remains an efficient way for the people to recapture and restore the legitimacy of the debate.

C. The French Commission du Génie Biomoléculaire

The Commission du Génie Biomoléculaire (CGB) is responsible for “evaluating the risks related to the deliberate release of genetically modified organisms.” Moreover, the CGB contributes “to the evaluation of the hazards related to the release on the market of product entirely or partly made out of genetically modified organisms, and to the

⁴¹ Available: http://www.senat.fr/rap/097-5451/097-5451_mono.html

definition of their condition of use and their presentation.”⁴² In its present form,⁴³ the CGB is the result of the law of July 13th, 1992,⁴⁴ which still constitutes the keystone of biotechnology regulation in France. This law was promulgated in the wake of three European directives, respectively dealing with the contained use of genetically modified micro-organisms,⁴⁵ the deliberate release of genetically modified organisms into the environment,⁴⁶ and the protection of workers from risks related to the exposure to biological agents at work.⁴⁷ The CGB has then a very particular and strategic place within the decision-making process. It is at the junction of the public use of GMOs and scientific research, because its expertise is necessary in the process of releasing a GM crop into the environment and to the market.

As to its composition, the law provides that: “at least half the members of the commission are persons competent in scientific matters, and a member of the Office Parlementaire d’Evaluation des Choix Scientifiques et Technologiques; it includes representatives of environmental protection associations..., consumer organizations, employee organizations and relevant professional organizations.” The composition reveals that the philosophy underlying the creation of the expert panel was not only a response to scientific claims, but partly arose from political concerns: the European and French desire to control and prevent what they perceived of as “irrational” public fears.⁴⁸ The CGB then embodies elements of science and politics. Government officials and representatives hoped to avoid possible reticence toward GM technologies by resorting to an expert body.

The discussion over the status and the organization of the CGB emerged in 1997, when the CGB gave the French government its approval for releasing the first GM crops on the market. At this point, interest groups opposed to GMOs entered the debate, bringing their own experts who opposed the CGB on various points. The opposition to, and eventually the revision of the CGB must be seen in light of the emergence of this competing group of non-governmental experts.

⁴² The CGB has performed an intense activity. Between 1987 and 1997, this commission has reviewed 593 petitions for release of GMOs according to the Ministry of Agriculture. Among them, 510 dealt with crops. They resulted in 120 experimental releases of canola, 117 of corn, 64 of tobacco, 59 of beets, 14 of potatoes, 11 of melon, and 10 of tomatoes. Most of these crops were genetically engineered to resist herbicides. In April 1991, the first genetically modified corn was released at Colmar, in Alsace, by the firm Ciba-Geigy, which later became Novartis

⁴³ The roots of the CGB go back to the Asilomar conference and the Berg letter, but was created in 1986, and started working in 1987.

⁴⁴ Loi n° 92-654 of 13 juillet 1992 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés et modifiant la loi n° 76-663 du 19 juillet 1976 relative aux installations classées pour la protection de l'environnement.

⁴⁵ Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms, Official Journal of the European Communities - 8.5.90 - Page No L 117/1

⁴⁶ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, Official Journal of the European Communities - 8.5.90 - Page No L 117/15.

⁴⁷ Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work, Official Journal of the European Communities - 31.12.90 - Page No L 374/1.

⁴⁸ (Hermitte 1994)

Interest groups had several criticisms of the CGB. First, interest groups doubted the legitimacy of the CGB's advice because the commission functioned largely on the basis of consensus. The scientific community more broadly was debating the merits and limits of GMOs. Yet the commission continued to issue consensual advice. Although there is an option in each annual report for members of the CGB to issue a separate additional report—where it would be possible for them to dissent from the majority opinion—this possibility was never used until 1998. Then, Dr. Serallini complained about the shortcomings of the scientific debates, especially the lack of contradiction, occurring in that commission.⁴⁹

Another criticism concerned whether the debate taking place within the CGB adequately voiced the concerns of civil society. The answer was definitely negative: although the commission included representatives from civil society, they did not take part in the debates of the commission or challenge any of the commission's reports. In his report on the citizen conference, to be discussed below, J.Y. Le Déaut reports: "the citizen conference has clearly put into question the way the CGB works, especially the fact that civil society is not well associated with the work of this commission."⁵⁰ Finally, interest groups also criticized the scientific representativeness of the CGB. Indeed, it appeared that the commission before 1998 was mainly composed of specialists of molecular biology, with few specialists on weeds, and environment ecologists.

Another problem, ensuing from the ones above mentioned, was that the functioning of the CGB ended up giving little room for policymakers to maneuver in. "It is obvious that the advice of the CGB has been, with time, less and less advisory, and more and more a determinant of policy. Thus it happened at the political level to defer *de facto* to the advice of that commission, which, understandably, could not evaluate the proper political consequences of its advice."⁵¹

The criticisms of too much consensus, not enough attention to broader societal concerns, and lack of meaningful public representation on the commission, among others, provoked a public debate regarding the CGB. The debate took place during the citizens' conference, discussed above. Experts presenting at the conference proposed a more adversarial mode for the CGB as the means to overcome some of the CGB's problems.⁵²

The question was how to achieve a more adversarial mode. The experts at the citizens' conference considered broadening the composition of the CGB to integrate different views. Hence, during the citizens' conference, Millereau called for a "transdisciplinary" approach: "Along with biochemists and molecular biologists we should have ecologists, environment lawyers, weed specialists... The approach must really be transdisciplinary."⁵³ In the same vein, the former minister for the environment Corinne Lepage declared that "the composition of the commissions should be reviewed in the way to ensure the diversity of scientific expression, and of the general interests that

⁴⁹ (Rapport d'activité 1998)

⁵⁰ [Le Déaut, 1998 #254

⁵¹ (Le Déaut 1998)

⁵² (Hermitte 1994; Lepage 1999). Cf. (Brickman, Jasanoff, and Ilgen 1985; Vogel 1986), which consider the adversarial mode of policymaking less cost-effective.

⁵³ (Le Déaut 1998: 84-5).

are to be taken into account.”⁵⁴ Axel Kahn, former president of the CGB, stressed that “the CGB, whose composition has in no way been decided by its members or its president, was and wanted to be a commission that, on the contrary of the CGG, allowed the representative of the community of different sensibilities to be heard. Maybe is it necessary for these sensibilities to be more heard.” He added, “It should be necessary to increase the scientific competence [of the CGB] by including weed specialists, gene flux’s specialists, scientific ecologists. This is particularly important.”⁵⁵

The citizens’ conference concluded, however, that an adversarial mode of debate within the CGB could be promoted through more formal institutional changes. One suggestion was to divide the CGB into two commissions, dealing with scientific and societal issues. This would allow a confrontation of opinions within the commission. The other suggestion the citizens’ conference offered would have given the role of scientific expertise to the CGB, and the role of a more general commission to another institution. But J.Y. Le Déaut expressed his fears that the first proposition would lead to perpetual confrontation, paralyzing and eventually undermining the efficiency of the CGB. Thus, the president of the citizen conference expressed his favor for the second option. Questioning the presence of representatives of the civil society in scientific commission,⁵⁶ he called for the enlargement of the CGB to scientists from other fields.⁵⁷

In the end, no institutional changes were made with respect to the CGB. Instead, the government broadened the commission’s composition by appointing scientists from different areas along with nominating more activist representatives of civil society.

The analysis of the CGB illustrates a participatory approach based on the inclusion of scientists from different fields. This had two consequences. First, the CGB has seen its legitimacy enhanced since scientific contradiction has been rendered possible and acknowledged within that commission. A debate deemed representative of the one taking place in the civil society is trying to be introduced in the CGB. Second, the broadening of the composition, referring to the larger concept of transparency, along with the refusal to create a citizen college, has provided the policy-maker with a broader room of maneuver, since he is now provided with a array of different competing, and hence for him alternative ways of interpreting a problem and then carry out its policy.

D. US Regulation of Biotechnology

The United States federal government regulates genetically modified food under the 1986 *Coordinated Framework for the Regulation of Biotechnology*,⁵⁸ which remains the major US government document on biotechnology. This framework identifies the US Department of Agriculture (USDA) as responsible for overseeing the safety of growing transgenic plants; the Environmental Protection Agency (EPA) as responsible for microbial and plant pesticides; and the Food and Drug Administration (FDA) as

⁵⁴ (Le Déaut 1998: 88).

⁵⁵ (Le Déaut 1998: 91, 105).

⁵⁶ Kahn, A. (1996), *La dissémination d'organismes génétiquement modifiés (OGM) la prudence est-elle possible?* stressing that the “duality between citizen leads to two reactions in such a scientific matter. These reactions consists for the non-scientist either to believe in its ignorance of the field, either to ask questions that have only a remote relation with the reality of the issue.”

⁵⁷ (Le Déaut 1998: 46-9).

⁵⁸ “Coordinated Framework for Regulation of Biotechnology,” 51 FR 23302, June 26, 1986.

responsible for the safety of human consumption of biotechnologically-derived food products. The major difference between the regulatory approach of the US and the French governments is that the former decided that it was not necessary to regulate the process by which a food is produced (e.g. through genetic engineering), but rather to focus on the safety of the end product. France, like other European countries and the EU, decided on a process-based approach to regulation.

Here we will briefly review FDA, USDA and EPA regulations. The primary document guiding FDA in regulating GM foods is their 1992 "Statement of Policy."⁵⁹ This document outlines procedures by which companies can voluntarily consult with and notify FDA before bringing foods to market. According to the FDA, all of the companies currently marketing genetically engineered food in the United States have completed the voluntary consultation process. The 1992 statement also calls for labeling only if food "differs significantly from its conventional counterpart." In May 1994, the FDA determined that Calgene, Inc.'s FLAVR SAVRTM tomato was "as safe as tomatoes bred by conventional means,"⁶⁰ and thus did not require labeling. Recently, the FDA has proposed regulations for mandatory consultations and voluntary guidelines for labeling. These will be discussed in more detail in the next section.

The USDA has worked actively to ease regulation of GMOs. In 1997, the USDA Animal and Plant Health Inspection Service (APHIS) simplified the notification procedure for importing, releasing into the environment (as in field tests), or moving GMOs across state lines.⁶¹ These simplified procedures were intended to cover eighty to ninety percent of GMOs. In addition, APHIS also allowed petitions to remove from its oversight genetically engineered plants which it determined no longer presented a risk to the environment. The FLAVR SAVRTM tomato, for example, was exempted from APHIS oversight under this petition process.⁶²

In contrast to the USDA and the FDA, the EPA has adopted a stricter regulatory approach to genetically engineered plants. EPA has proposed relatively strict regulations for the introduction of plants genetically engineered to resist pests, such as the Bt varieties. On November 23, 1994, EPA issued a set of proposed regulations which regulated plants genetically engineered to resist pesticides. The proposed rules separated "low-risk" from "high-risk" plant categories, based on their potential to damage the environment and/or human health, with a broad category of "low-risk" plants excepted from these regulation.⁶³ In its last days in office, the Clinton administration published a final ruling formalizing this policy, but the ruling was quickly withdrawn by the incoming Bush administration and remains under review. EPA has also asked farmers

⁵⁹ 57 FR 22984, "Statement of Policy: Foods Derived from New Plant Varieties," May 29, 1992.

⁶⁰ Biotechnology of Food, FDA Backgrounder, May 18, 1994, cited in (Beach 1998)

⁶¹ "Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms," 62 FR 23945, May 2, 1997.

⁶² (Beach 1998)

⁶³ "Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA)," 59 FR 60535, November 23, 1994.

planting corn that produces Bt toxin to also plant a buffer zone of traditional corn as a protection for monarch butterflies.⁶⁴

More recently, EPA announced that it would not approve GM crops for feed if they were not already approved for human consumption. This decision was made in response to the Starlink corn controversy that exploded in the fall of 2000. Starlink corn, manufactured by Aventis, was supposed to be used only in animal feed, but was found in taco shells and other corn-based human food products. The corn was modified with a protein, Cry9C, that does not normally appear in the human food supply, leading to concerns that it might create severe allergies in humans. Aventis withdrew the corn from the market, but not before making a fevered and unsuccessful pitch to EPA to temporarily allow the corn to be sold for human use.

E. FDA Public Meetings

In November and December 1999, the FDA held three public meetings in Washington DC, Chicago, and Oakland, California to reexamine whether GM foods should be considered an additive, thus requiring mandatory labeling, as well as to explore the need for further testing to ensure consumer safety. First, we will briefly analyze the structure of the FDA Oakland meeting.⁶⁵ Then we will discuss some of the controversies that arose during panel and public presentations, including labeling, the relationship of genetically modified food to traditional cross-breeding, and the process versus product distinction in regulating GMOs. We will conclude with the outcomes of the meeting.

In announcing the public meetings, the agency described their purpose as threefold: "to share [the FDA's] current approach and experience over the past five years regarding safety, evaluation, and labeling of food products derived from bioengineered plant varieties, to solicit views on whether FDA's policies or procedures should be modified, and to gather information to be used to assess the most appropriate means of providing information to the public about bioengineered products in the food supply."⁶⁶ Discussion at the meeting was limited to issues of science, safety, and public information. Science and safety issues included whether the current voluntary consultation process should be made mandatory or otherwise changed or discontinued; newly emerging scientific issues regarding the safety of GMOs; and what future foods were planned that could pose safety concerns. Issues concerning public information included whether changes in labeling should be made, who should have responsibility for communicating additional information to the public, and how any new information should be made available.

⁶⁴ Carol Kacsuk Yoon, "E.P.A. Announces New Rules on Genetically Altered Corn," *New York Times*, January 17, 2000. This policy was announced in part as a response to a report from the National Academy of Sciences. The NAS endorsed the central principle underlying the American government's existing biotech regulations, namely that genetically engineered foods pose no special risk simply because they are produced by a new process. At the same time, it called for more careful regulation and long-term studies of health effects of GM foods.

⁶⁵ "Public Meeting: Biotechnology in the Year 2000 and Beyond," December 13, 1999, Oakland, California. Transcript is available from <http://www.fda.gov/oc/biotech/default.htm> [accessed May 10, 2001].

⁶⁶ 64 FR 57470, "Biotechnology in the Year 2000 and Beyond: Public Meetings," October 25, 1999; 57470.

The Oakland meeting, held on December 13, 1999, was presided over by five FDA commissioners who questioned panelists but did not otherwise present. The meeting consisted of five sessions. At the first session, the FDA Biotechnology Coordinator, Dr. James Maryanski, presented an overview of FDA policy. He was followed by a panel of university and industry scientists who focused on scientific and safety issues. The panel was then questioned by the five FDA commissioners. In session three, an FDA official presented the current FDA policy on labeling. Session four was devoted to a panel presentation on public information and labeling. The panel was composed of representatives from academia, non-governmental organizations, and industry groups, both organic and conventional. The final session consisted of scheduled public presentations.⁶⁷ There were a total of 23 panelists and 140 scheduled public presentations at the meeting; in addition, over 1000 people attended.

One issue raised was whether genetically modified food should be seen as new and unique, or whether it is simply an extension of traditional hybrid breeding. One scientist described GM food as "food we've eaten all our lives...it's all been genetically modified just by various kinds of techniques."⁶⁸ But others questioned this. A panelist from the labeling session noted that "[t]he transference of genetic traits between species not varieties but species, does not occur in nature....It is not comparable to hybridization and traditional breeding practices."⁶⁹ A scientist pointed to new risks such as the disruption of biochemical pathways.⁷⁰

Panelists at the meeting also disagreed over responsibility for labeling GM food. The majority at the meeting, including the FDA and major industry representatives, favored settling on a threshold level (for example 1%), and allowing manufacturers to label food as free of genetic modifications. The burden would fall on organic producers and others who wanted to demonstrate that their foods were "GM-free." Advocates of this approach caution that there is "no zero risk" and that "everything we eat contains some sort of risk."⁷¹ Moreover, some advocates also called for an additional statement on such a label which pointed out that there are no differences in safety between GM and non-GM food.⁷² Consumer safety advocates and organic producers, on the other hand, questioned the assumption that they should bear the burden for labeling. "But I think that, again, the burden of dealing with this labeling, and informing the consumers where these [genetically modified] products are present, should be on the foods that are genetically modified."⁷³ Moreover, "if the confidence is there in the safety of these products, why is there so much objection to labeling?"⁷⁴

Finally, there was the issue of distinction between process and product. This concern reaches back to the early 1980s, when there was controversy over whether regulations of genetically modified products should govern the *process* by which they

⁶⁷ According to the FDA announcement, any person registering at least fifteen days in advance to make a presentation was allowed to present.

⁶⁸ Susanne L. Huttner, "Public Meeting": 65.

⁶⁹ Diane Joy Goodman, "Public Meeting": 156.

⁷⁰ Regal, "Public Meeting": 87.

⁷¹ Thomas J. Hoban, "Public Meeting": 182.

⁷² Rhona S. Applebaum, "Public Meeting": 187.

⁷³ Susan E. Haeger, "Public Meeting": 189.

⁷⁴ Goodman, "Public Meeting": 191.

were produced, rather than the *products* of biotechnology.⁷⁵ Currently, the FDA does not consider the process by which a product was produced, but instead examines the end product (e.g. a genetically engineered tomato) and decides if it is safe. Many in the proceedings supported this approach. One scientist affirmed that “[t]his is an issue of the safety...and I think any discussions about regulating the process...are misguided and that we must continue to look at the products that are produced and how safe they are.”⁷⁶ But other scientists questioned the procedures by which FDA determines the safety:

“There’s a huge loophole as [the system] now exists. It says that, if a novel protein from a known allergen is used, or a gene from a new allergen...you must test for allergenicity. But if there is no history of...use as a food, we have no evidence as to whether it’s allergenic or not. And according to the current guidelines that [FDA] gives to developers, they actually are not required to assess that.”⁷⁷

After the panel discussions, at which the above issues were raised, the FDA allotted time for public presentations. Yet while the meeting was called a “Public Meeting,” the public was limited to slightly under three hours at the end of the day, whereas the panel presentations took place for five hours. Several present who had registered to present public comments complained about this, calling it a “mockery of our democratic process” and pointing out that most of the press had left by the time the public comment period began.⁷⁸ Public comments were divided between those supportive of and opposed to FDA policies, with a majority on the side of those opposed to current and proposed regulations.

Slightly over a year after the public meetings, on January 18, 2001, the FDA proposed new regulations of GM foods and voluntary labeling guidelines. The regulations, if finalized, will require manufacturers to submit food to safety tests before marketing it. Previously such reviews were voluntary, although most companies abided by them. The labeling guidelines are concerned mainly with how to label food that is not genetically modified: FDA encouraged labels saying that a product is not made using biotechnology, rather than those stating that a product is free of genetically engineered food, since the latter is virtually impossible to verify. Terms such as “GM free” and “modified” are not permitted in the draft guidelines; “derived through biotechnology” and “bioengineered” are acceptable.⁷⁹

This overview of the FDA Oakland meeting leads to a few conclusions. The first thing that is striking about the meeting is that the simple ideal types of “expert” versus “public” quickly fall away. Both panels on safety and labeling were composed of supporters and opponents of FDA current and proposed policies. Experts sparred with experts, some members of the public gushed in support of the FDA, while others chastised the agency for not being more cautious. For instance, a scientist who heads a company called Genetic ID pointed to a “lack of clear consensus” about the safety of

⁷⁵ See (Lynch and Vogel 2000)

⁷⁶ Calvin O. Qualset, “Public Meeting”: 51.

⁷⁷ Fagan, “Public Meeting”: 85.

⁷⁸ Peter M. Rossett, “Public Meeting”: 227.

⁷⁹ 66 FR 4706, “Premarket Notice Concerning Bioengineered Foods,” January 18, 2001; and “Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering,” January 2001, available from <http://www.cfsan.fda.gov/~dms/biolabgu.html> [accessed May 10, 2001].

genetically engineered food, and called for more rigorous safety testing. He also contended that labeling can be done, and that the threshold for labeling should be lower than the 1% threshold that many countries have enacted.⁸⁰ Another scientist on the panel echoed his concerns: there is a "tendency to try to minimize the risks, and to try to deal with the incredible problems that genetic engineering presents with slogans and simplifications."⁸¹

The 2001 proposed rulings that emerged after the meeting, however, appear to reflect viewpoints only of those who sided with the FDA during the meeting. The discussions during the meeting indicated that very few opposed the idea of mandatory consultations. But other concerns raised about labeling and safety issues are not reflected in the proposed rulings. Certainly the FDA was able to keep its discretion in this meeting by not making it a formal public hearing. The question of the extent of public involvement revolves around what kinds of publics. The concerned public was present in the audience, but not given much of an opportunity to discuss or interact with FDA officials or other experts. Their presence appears to have been a device to legitimize the policy that subsequently emerged. The FDA did, however, include scientists from different fields with divergent views, and some representatives of non-governmental organizations. In that sense, then, the meeting was open. We would place it on the border line, in our Table 2, between "broadly consultative" and "instrumental" policymaking.

III. Conclusion

The changing nature of public participation in the regulation of genetically engineered foods has been the subject of recent study. Levidow has noted the effects of biotechnology on public participation even before the public outcry beginning in 1996-97. Public debate can have different roles: in some cases it has affected public policy, as in Denmark, but in others potential for influencing policy has been limited. More broadly, "[s]ome regulatory approaches acknowledge the value-laden nature of technical judgments....[h]owever, the dominant approach accepts and reinforces" a technological fix approach to biotechnology regulation.⁸² Roy and Joly found that the widening of public debate in France to include more members of the citizenry led to a more precautionary approach to regulating GMOs. "The technocratic model of expertise, where public decision making is exclusively based on scientific knowledge, has been challenged and replaced....[and m]ore participatory modes of evaluation, involving a wide variety of stakeholders, are being tried out."⁸³

There exist several modes of involving the citizen in GM food policymaking. We have tried to demonstrate that the adoption of one or another model is likely to influence a policymaker's discretion. The choice of model to be used is highly strategic, and illustrates the degree to which public officials are committed to giving voice to the

⁸⁰ John Fagan, "Public Meeting": 51-57.

⁸¹ Philip J. Regal, "Public Meeting": 58.

⁸² (Levidow 1998: 223)

⁸³ (Roy and Joly 2000: 253)

public's interests. Some participatory models can be used as "window dressing" to legitimate a pre-determined policy, while others can have substantive influence on policy outcomes. One question for future research is the conditions under which one model is selected over another: for instance, to what extent is that choice path-dependent, i.e. conditioned upon previous decisions of a governmental agency or regulatory process. Does the choice depend on the type of agency in charge, or is the question a broader one of national style of policymaking?

We distinguish between instrumental and democratic styles of advisory panels, and conclude that the French system falls into the democratic style, while the US is more instrumental. Indeed, the citizens' conference and the CGB illustrate how conditions of uncertainty have changed the classical ways to conceive of expertise. The authority of expertise has been reinvigorated, not so much by including lay people within expert committees, but rather by including new categories of experts. It remains to be seen if this portends a future trend in policymaking under conditions of uncertainty.

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