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

*Diahanna L. POST*  
*Jérôme M. DA ROS*

**Science et participation publique dans la réglementation des aliments génétiquement modifiés : les expériences françaises et américaines**

**Mots-clés :**

sécurité alimentaire, réglementation, organisations, étude sociale des sciences, aliments génétiquement modifiés

**Science and public participation in regulating genetically-engineered food: French and American experiences**

**Key-words:**

food safety, regulation, public organizations, science studies, genetically-engineered food

**Résumé** – Cet article analyse trois expériences menées par le décideur public pour intégrer les différents acteurs concernés dans le processus d'élaboration des politiques publiques en matière d'aliments génétiquement modifiés. Nous étudions les interactions entre les scientifiques, les citoyens et les décideurs publics dans le cadre de ces trois initiatives, ainsi que la manière dont ces derniers ont traité la question complexe des aliments génétiquement modifiés. Ces processus nous apparaissent déficients dans la mesure où la participation publique semble ne pas avoir d'impact substantiel sur la définition des réglementations et des politiques publiques. Nous examinons comment ces processus pourraient être améliorés, en nous appuyant sur les apports de l'analyse sociale des sciences et sur la théorie des organisations. Une meilleure combinaison de ces deux disciplines ouvrirait de nouvelles perspectives à l'étude des sciences et des organisations publiques, spécialement en matière de régulation de systèmes technologiques complexes et incertains.

**Summary** – This paper describes three cases of government-led efforts in France and the United States to bring stakeholders into the regulatory process for genetically-modified food. We analyze how government regulators, scientists, and members of the public interacted in these three different settings, and conclude that public participation is not linked with a regulatory outcome; in other words, for various reasons which we consider, public participation did not have a substantive impact on government policies in this area. We consider how these processes could be improved, by drawing on two distinct literatures — social studies of science and organization theory. A more conscious cross-fertilization of the two literatures would shed some insights broadly on science and public organizations, and particularly on the problem of regulating a complex and uncertain area of technology.

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ONE of the core assumptions behind regulation of genetically-modified food, and other environmental and food safety issues, is that better science will solve conflicts over policy. 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.* strawberries altered with a gene from flounder)? 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 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.

Cross-national studies of the regulation of genetically-engineered food have generally focused on explaining the differences between United States and European regulation<sup>1</sup>. This important and interesting area of study overlooks at least one aspect of remarkable similarity in how genetically-modified foods are considered on either side of the Atlantic: how scientific expertise and public concerns are brought into the regulatory arena.

This article describes three cases of government-led efforts to bring stakeholders into the regulatory process for genetically-modified food<sup>2</sup>. Two cases – the Citizens’ conference and the Commission du génie biomoléculaire (CGB) – took place in France; the third was a public meeting convened by the Food and Drug Administration in the US. We analyze how government regulators, scientists, and members of the public interacted in these three different settings, and conclude that public participation is not linked with a regulatory outcome; in other words, for various reasons which we consider, public participation is not having a substantive impact on government policies in this area.

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<sup>1</sup> See McNichol and Bensedrine, 2001; Pollack and Shaffer, 2001; Ramjoué, 2002; Meins, 2000; Vogel, 2001; Patterson and Josling, 2002.

<sup>2</sup> Terminology is part of the debate between supporters and opponents of genetically-engineered food. For instance, the term “genetically-modified” is prohibited in current FDA draft guidelines on labeling, while that same term is used extensively throughout European Union Commission documents. We use genetic modification, genetic engineering, and bioengineering as interchangeable terms here, reflecting similar usage in the mainstream media.

The next section sets out a framework for analyzing the cases, drawing on two distinct literatures: social studies of science and organization theory. We argue that these two literatures help us better understand why government officials seek to involve the public in decisionmaking, and what the outcome of that is likely to be. Then, we describe the background and process of the French Citizens' conference, the Commission du génie biomoléculaire, and the Food and Drug Administration public hearing in Oakland, California. Following, we analyze those cases in the light of the theoretical expectations set out in the beginning. A final section puts forth some recommendations for regulating a complex and uncertain area of technology. We suggest that what is needed is not only more and better science, but also a reconsideration of how to involve the public in decision making processes on risk.

## SCIENTIFIC UNCERTAINTY AND REGULATION

In the following discussion, we will draw on insights from theory in social studies of science and organization studies to think about what the implications are for involving these three sets of actors – experts, the public, and government officials – in regulating GM foods.

Scholars working in the diverse field of social studies of science attempt to understand both the influence of science on society, as well as social influences on science. A key starting point of many analyses is to question the assumption that more and better science leads to better policy. This assumption, often termed a technocratic approach by its critics, offers greater reliance on expert knowledge as the best path to policy decisions<sup>3</sup>. Those who question whether we should assume that greater involvement of experts necessarily leads to better policy do so from two grounds: the first has to do with scientific uncertainty surrounding particular policy issues, and the second is a deeper criticism focusing on the socially constructed nature of the general scientific enterprise<sup>4</sup>.

The first set of criticisms of the technocratic approach to policymaking concerns the relationship between science and public policy. Alvin Weinberg, the renowned physicist, addressed the relationship between science and society three decades ago in his seminal article on “Science and Trans-Science” (Weinberg, 1972). Weinberg labeled as trans-scientific those questions “which can be asked of science and yet *which cannot be answered by science*” (*op. cit.*, p. 213). Trans-scientific questions are of three

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<sup>3</sup> National Research Council (1996) is an excellent example of this, as is Breyer (1993).

<sup>4</sup> See Irwin (1995) for a critique of the expert approach to policy, which he calls the enlightenment model.

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<sup>5</sup>; and those where “science is inadequate simply because the issues themselves... deal not with what is true but rather with what is valuable” (*op. cit.*, p. 213).

Funtowicz and Ravetz (1992) similarly address what happens when science reaches into the public realm. 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*” (*op. cit.*, p. 253). 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.

A second set of criticisms delves deeper, beyond just the arena where science and public policy interact, to question 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 – *i.e.*, the type of issue involved – 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*” (Gieryn, 1983, p. 792). 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*” (Gieryn, 1999, p. 15)<sup>6</sup>.

In her study of the scientific advisory process in the United States, Jasanoff (1990) found that 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. Rather than seeing science as surrounded by societal influences but separated from them, science is permeated by society (Latour, 1999).

<sup>5</sup> This is where Weinberg places the social sciences.

<sup>6</sup> Gieryn points out how this constructivist explanation for the epistemic authority of science differs from other explanations (Gieryn, 1999, pp. 14-18). The functionalist explanation, for instance, sees science as formed and developed in reaction to society’s need for it.

The science studies literature leads us to some tentative conclusions regarding expert involvement in regulating highly scientific issues such as genetically-modified foods. First, experts may not have all the knowledge necessary to ask and answer the appropriate questions. Second, those experts themselves engage in social processes of constructing and defining the boundaries of knowledge. If this is the case, then it makes sense to examine other actors involved in those social processes of defining what is and is not appropriate knowledge. In the case of genetically-modified foods, government officials and those who are potential consumers of genetically-modified food – the general public – are two particularly interesting groups to examine.

Organization theory offers insights into the interactions of government officials and the broader public. First, we look at the regulatory officials, who make the policies. The science may be uncertain, but a decision, or a decision not to make a decision, must be taken. Regulators are embedded within regulatory agencies, which structure their decisionmaking processes. J.D. Thompson, in his classic 1967 work, tells us that organizations facing uncertainty, such as how to regulate genetically-engineered food, will deal with it in two ways. First, they will attempt to eliminate any outside interference in the core function of the organization. For the regulatory agency, this means an assertion of complete control over the regulation of the products. Second, the organization attempts to adjust “to constraints and contingencies not controlled by the organization” by attempting to manage those environmental contingencies (Thompson, 1967, p. 67)<sup>7</sup>. Thompson predicts that the agency will try to control the uncertainty of its environment by reaching out to it.

What does this imply about efforts to regulate genetically-modified food? It suggests that when government agencies reach out to their constituencies, their goal is not to solicit advice or information on how to regulate, but rather to protect that core activity of regulation by managing the uncertainty of the constituencies.

This leads us to our third set of actors: the general public. The case studies outlined below describe three efforts to involve the public in decisionmaking over genetically-modified foods in France and the United States. The central questions are: why do regulators choose to involve the public, and what effect does this have on the regulatory outcome? We argue that, if the theory is correct, we will see that involvement of the public had little impact on policies adopted.

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<sup>7</sup> See also Pfeffer and Salancik, 1978.

## INVOLVING THE PUBLIC

### Regulation of genetically-modified food

Genetic modification of plants is not a new practice, but DNA-level manipulation is. 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<sup>8</sup>. 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<sup>9</sup>.

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 make them resistant to weed-killing herbicides (Brown, 2001). Crops that are either still in experimental stages or not yet widely planted include those engineered to produce vitamins (such as “golden” vitamin A-enhanced rice), vaccinations, and other nutritional and/or medical enhancements.

The issue of how to regulate genetic engineering arose in the mid-1970s, when high-level scientists, backed by the famous Asilomar conference<sup>10</sup>, called for a temporary moratorium on research involving genetic engineering. Over the past 25 years, US and European approaches to regulating genetic-engineering have sharply diverged<sup>11</sup>. The US approach considers that regulating the process by which a food is produced (*e.g.* through genetic engineering) is unnecessary. Instead, the government focuses on the safety of the final product (**a product-based approach**). In other words, a genetically-engineered tomato is not subject to special regulations solely because it is genetically-engineered; the FDA instead asks whether the tomato, like any other, is safe to eat. France, like many other European countries and the EU, regulates gene-

<sup>8</sup> *New York Times*, 7 March 2001, “Gene Research Finds New Use in Agricultural Breeding”, by Andrew Pollack.

<sup>9</sup> 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. See Brown, 2001.

<sup>10</sup> 1975 International Conference on Recombinant DNA Molecule Research, Asilomar Conference Center, California.

<sup>11</sup> For discussions of the history of regulatory divergence, see Bud 1995; Jasanoff 1995; Kraus 1996 and 2001; and Patterson 1997.



tically-engineered food as distinct from traditional food (a **process-based approach**).

As will be seen below, one of the ways in which this divergence manifests itself is that regulatory authority in the US has already been granted to a handful of executive branch agencies, and Congress is no longer involved<sup>12</sup>. In France, by contrast, the issue of regulatory authority has not been fully delegated to the ministries, and Parliament is still heavily involved. Generally, the parliamentary involvement would naturally lead to a greater role for the public than executive branch only. Nevertheless, both countries in the late 1990s embarked on a process of increasing input from the public into the decisionmaking process, due to increasing public controversy over and awareness of genetically-modified food.

### The Citizens' conference

The idea for the French Citizens' conference emerged in 1997 as a way to help resolve inconsistencies in French policy on GMOs<sup>13</sup>. In February 1997, the French government allowed the commercialization of Bt corn, but not its cultivation, a policy criticized from all sides. After the election of a left-green coalition in May, the new government led by Prime Minister Lionel Jospin, although reversing the ban on cultivation, stated in a press release: *"Public opinion is still undecided and appears insufficiently informed. Although our fellow citizens appear prepared to accept the resort to genetic engineering in drug manufacturing, 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 can be made without allowing all opinions to be aired and debated. A 'consensus conference' will be organized by the Parliamentary Office of Evaluation of Scientific and Technological Choices"*<sup>14</sup>. Moreover, insisting on the importance of "participatory democracy" in order to "fully apply the precautionary principle", the prime minister observed that *"in its present state, the debate on biotechnology is reserved to specialists; it is too narrow, too confidential"*. Hence, the strengthening of participatory democracy was needed to *"foster information and an open and adversarial debate on scientific choices by provoking a dialogue between citizens and experts"*.

This "Citizens' conference", part of a broader reflection carried out by the Parliamentary Office of Evaluation of Scientific and Technological

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<sup>12</sup> Several bills were introduced in the House and the Senate in the late 1990s to change how the US regulates genetically-engineered food, but none of them passed and the issue still remains relatively low profile on Capitol Hill.

<sup>13</sup> For a thorough account of that episode, see Roy (2001) and Marris (2001).

<sup>14</sup> 27 November 1997, Prime Minister's Office, *"Les plantes génétiquement modifiées"*.

Choices (*Office parlementaire d'évaluation des choix scientifiques et technologiques* or Parliamentary Office) on "Genes and their application," was shaped on a model designed ten years earlier by Denmark, and followed by The Netherlands, Germany, Great Britain, and Australia (McDonald, 1999; Bereano, 1999). This debate was conducted under the aegis of the Parliamentary Office and its president, Representative Jean-Yves Le Déaut<sup>15</sup>.

The organizers first planned on calling it a "consensus conference", as Nordic countries did. However, it appeared that this qualification should be replaced by "Citizens' conference", for "*one of the characteristics of the French conference lay in the fact that the search for consensus between all the members of the citizens' panel, as opposed to Denmark, has been excluded, leaving the possibility of issuing divergent or minority opinions*" (Donnet-Kamel, 1998).

Fourteen citizens were selected by a polling institute through a random procedure. This selection process was designed to avoid the nomination of candidates from interested parties. At the same time, the Parliamentary Office selected a group of experts for the conference to consult. The participants prepared in three stages. First, over two initiation weekends in April and May, 1998, 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?
- Given the economic stakes that represent information about quality, what is planned to inform 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?

Interest groups criticized this first initiation phase for compromising the neutrality of the panel, since it was carried out under the exclusive control of academic experts. These groups argued that the experts selected by the Parliamentary Office provided the citizens with an incomplete view of the various opinions involved in the debate. Yet keeping interest groups away from this preliminary phase was expected to avoid

<sup>15</sup> *Le Monde*, 14 February 1998, "Un débat public sur les plantes transgéniques va être organisé" by Catherine Vincent.

any attempts at manipulating the panel. In the end, due to this initial exclusion, some major environmental groups such as Ecoropa refused to participate in the event.

The second stage was the public debate, which took place on June 20-21 at the National Assembly<sup>16</sup>. In the afternoon of the second day, after two days of intensive hearings and debate, the citizens' panel retired for 24 hours to write its conclusions, which constituted the third stage of the conference<sup>17</sup>. One important part of their conclusions referred to the Commission du génie biomoléculaire, which will be discussed in the next section. They also called for the strengthening of public research in the domain of risk 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 conclusions of the Citizens' conference formed part of an overall report from the Parliamentary Office on "Genes and their application." The main policy recommendations made by the Citizens' conference are listed in table 1.

Table 1. Policy recommendations from the Citizens' conference

Health	<ul style="list-style-type: none"> <li>• prohibition of antibiotic resistant genes</li> <li>• reform of the CGB (composition, working methods)</li> </ul>
Economics	<ul style="list-style-type: none"> <li>• creation of separate food chains (with/without GMOs)</li> <li>• clear and reliable labeling</li> <li>• preservation of European competitiveness in genetics</li> <li>• debates in the 'biovigilance' committee</li> </ul>
Environment	<ul style="list-style-type: none"> <li>• creation of an international consultative commission at the United Nations (to authorize GMO field cultivations)</li> <li>• creation of world data bank of modified genetic sequences</li> </ul>
Law	<ul style="list-style-type: none"> <li>• specific and precise protection for consumers and farmers</li> <li>• questions of liability</li> </ul>
Politics	<ul style="list-style-type: none"> <li>• increase funds for public research in France</li> </ul>

The Parliamentary Office released the final report, including the Citizens' conference conclusions, on June 30. One month later, the executive branch issued several decisions that had been on hold for some time. Most notably, it agreed to allow the cultivation of two new varieties of corn. This was despite the conclusions of the Citizens' conference to the contrary, but in keeping with the advice of the Parliamentary Office report, which overall was in favor of approving cultivation<sup>18</sup>. The

<sup>16</sup> *Le Monde*, 20 February 1998, "Examen de passage populaire pour les plantes transgéniques" by Catherine Vincent.

<sup>17</sup> Available at [http://www.senat.fr/rap/097-5451/097-5451\\_mono.html](http://www.senat.fr/rap/097-5451/097-5451_mono.html), (accessed October 4, 2001).

<sup>18</sup> Environmental organizations took the government to court over this approval, but lost their appeal. Nevertheless, the uncertain regulatory climate kept many farmers from sowing GM crops. See Marris, 2001.

government's decision regarding the CGB was also contrary to the Citizens' conference recommendations, and is discussed in the next section. In other decisions, however, the government followed the panel's recommendation to create separate food chains, promote transparency (primarily through labeling), create an agency responsible for long-term impacts of GMOs, and strengthen bio-vigilance measures.

While citizens were clearly the main component of the Citizens' conference, the role of government and experts is instructive here. First, the panel was organized at the behest of a government institution, and the head of the Citizens' conference was an elected representative, not someone entirely outside of government. Second, before the Citizens' conference began its debate, experts were brought in to educate for several days. Citizen knowledge on its own was not seen to be useful unless it was refracted through expert knowledge. This is particularly evident in the way the final report for the conference was constructed. Although the citizens issued their own conclusions, the official report for the conference was that written by Le Déaut under the auspices of the Parliamentary Office.

It is unclear what, if any, effect the Citizens' conference report had on government policy. It appears that it did not particularly change the course of policy, which had already undergone some retooling as a result of the change from a center-right to a left-green coalition with the May 1997 parliamentary elections. Rather, the results of the Citizens' conference may have served to affirm the direction policy was headed in (Maris and Joly, 1999).

### The *Commission du génie biomoléculaire*

The *Commission du génie biomoléculaire* (CGB) [Commission for Biomolecular Engineering] is a consultative scientific panel created by legislative mandate in 1992<sup>19</sup>. It is responsible for "*evaluating the risks related to the deliberate release of genetically-modified organisms... {and contributing} to the evaluation of the hazards related to the release on the market of products entirely or partly made out of genetically-modified organisms, and to the definition of their condition of use and their presentation*"<sup>20</sup>. As such, it is supposed to

<sup>19</sup> Loi n° 92-654 du 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.

<sup>20</sup> *Ibid.*, Article 3-II. 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.

provide non-binding scientific advice to the French government, specifically the Ministry of Agriculture. The CGB was established in the context of three European Council (EC) directives, which concern the contained use of genetically-modified micro-organisms<sup>21</sup>, the deliberate release of genetically-modified organisms into the environment<sup>22</sup>, and the protection of workers from risks related to the exposure to biological agents at work<sup>23</sup>.

On paper, the CGB is designed as primarily an expert body and not an issuer of policy advice. The composition of the CGB is weighted toward experts. According to the law, "*at least half the members of the Commission are persons competent in scientific matters, and a member of the Parliamentary Office of Evaluation of Scientific and Technological Choices; it includes representatives of environmental protection associations, consumer organizations, employee organizations and relevant professional organizations*"<sup>24</sup>. Yet the inclusion of more overtly political groups, such as the environmental and consumer organizations, and the particular mandate of the CGB in determining whether a GM crop may be released into the environment and to market, indicate that the Commission is not free of political, economic, social, and other considerations. Some observers view the establishment of the CGB as an effort to channel and ultimately overcome "irrational" public fears and reticence by resorting to an expert body (Hermitte, 1994). At the least, the CGB occupies a niche where the public use of GMOs and scientific research overlap.

In 1997, a loud public debate erupted over the role and composition of the CGB. The controversy stemmed from a decision that year by the Ministry of Agriculture, supported by the CGB, to approve the commercialization of genetically-modified corn. The tense public atmosphere was further exacerbated by the arrival of shipments of genetically-engineered crops from the United States. The debate hinged on the consensual functioning of the CGB and the representation of non-governmental organizations on the Commission.

Public interest groups opposed to commercialization of GMOs doubted the legitimacy of the CGB's advice because the Commission functioned largely on the basis of consensus. The broader scientific community in France, according to these groups, was debating the merits and limits of GMOs, and did not appear to have a consensus opinion on whether

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<sup>21</sup> 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.

<sup>22</sup> 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.

<sup>23</sup> 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.

<sup>24</sup> *Loi n° 92-654 du 13 juillet 1992, Article 3-II.*

these crops should be released for commercialization. Yet this diversity of opinion did not appear to be reflected in the CGB's deliberations. Against the background of scientific controversy, the Commission continued to issue consensus opinions. These groups were concerned that the CGB was too narrow in its scientific base. They pointed out that the 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 — was not used until 1998. In that instance, Dr. Séralini<sup>25</sup> complained about the shortcomings of the scientific debates, especially the lack of contradiction, occurring in the Commission (*Commission du génie biomoléculaire*, 1998)<sup>26</sup>.

The consensus problem spilled over into the policymaking arena, illustrating the political role the CGB was accused of playing. Le Déaut observed that “*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*” (Le Déaut, 1998). In other words, the Ministry of Agriculture was not left with a range of options from which to choose, but rather, because of the consensus, was essentially bound by the CGB's decisions. This is despite the fact that on paper, the CGB's advice is supposed to be non-binding. Thus this lack of discretion for the policymakers at the Agriculture Ministry posed a significant concern for many observers.

NGOs also criticized how civil society concerns were taken into account within the CGB. 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. These concerns were echoed by the Parliamentary Representative Le Déaut, who stated that “*the Citizens' 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*” (Le Déaut, 1998). Finally, interest groups also criticized the scientific representativeness of the CGB. Indeed, it appeared that the Commission before 1998 was mainly composed of specialists in molecular biology, with few plant specialists or environmental ecologists.

<sup>25</sup> Dr. Gilles-Eric Séralini is a member of the CGB and a professor of molecular biology at the University of Caen. He chairs the scientific board of the Crie-Gen, a French environmentalist association, and has actively campaigned for a commercial moratorium on GMOs in agriculture.

<sup>26</sup> This criticism of “too much consensus” hints at a striking difference between American and French conceptions of science in public policymaking. From the French perspective, the goal is to provide policymakers with different views. If there is too much consensus, then the experts are not doing their job adequately. From the American perspective, expert panels are supposed to achieve consensus, and often go to great lengths to conceal differences (see Jasanoff, 1990). See also Brickman *et al.* (1985) and Vogel (1986) for admiring accounts of consensus in European policymaking.

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 (Hermitte, 1994; Lepage, 1999)<sup>27</sup>.

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. For instance, during the Citizens' conference, Millereau<sup>28</sup> called for a "transdisciplinary" approach: "*Along with biochemists and molecular biologists we should have ecologists, environmental lawyers, weed specialists... The approach must really be transdisciplinary*" (Le Déaut, 1998, pp. 84-85). In the same vein, the former minister for the environment Corinne Lepage declared that "*the composition of the Commission should be reviewed in a way to ensure the diversity of scientific expression, and of the general interests that are to be taken into account*" (*op. cit.*, p. 88). 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 CGB, allowed the representatives of the community of different sensibilities to be heard. Maybe it is necessary for these sensibilities to be heard more clearly*". He added, "*it should be necessary to increase the scientific competence {of the CGB} by including weed specialists, gene flux specialists, {and} scientific ecologists. This is particularly important*" (*op. cit.*, pp. 91-105).

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 Le Déaut expressed his fears that the first proposition would lead to perpetual confrontation, paralyzing and eventually undermining the efficiency of the CGB. Thus, he expressed his favor for the second option. Questioning the presence of representatives of the civil society in scientific commission<sup>29</sup>, he called for enlarging the CGB to include scientists from other fields (*op. cit.*, pp. 46-49).

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<sup>27</sup> Cf. Brickman *et al.* (1985) and Vogel (1986), who consider the adversarial mode of policymaking less cost-effective.

<sup>28</sup> Marc-William Millereau is a director of the environmentalist association France Nature Environnement. This association called for a general moratorium on the cultivation of GMOs.

<sup>29</sup> See Kahn (1996), who stresses that the "*duality between citizens leads to two reactions in such a scientific matter. These reactions consist for the non-scientist either to believe in its ignorance of the field, or to ask questions that have only a remote relation with the reality of the issue*".

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 representatives of civil society who possessed a more pro-active stance on GMOs. Linking these changes to a particular regulatory outcome is difficult; however, French policy on GMOs did change significantly after 1998, and became much more cautious than it had been previously (Maris, 2001). Arguably, both the shift in regulatory policy and institutional changes in the CGB appear to be the result of pressure from the public and strict regulation of GM crops at the level of the European Union.

## US regulation of biotechnology and FDA public meetings

Although it is widely agreed – and we will not dispute this – that regulation of genetically-engineered food in the United States has been much less controversial than in most European countries, nevertheless growing public awareness and media coverage of genetically-engineered food prompted the FDA in 1999 to hold several public meetings. In this section, we will first overview US government regulations in the field of biotechnology, and then turn to the FDA public meetings. The federal government regulates genetically-modified food under the 1986 *Coordinated Framework for the Regulation of Biotechnology*<sup>30</sup>. This framework splits major regulatory responsibility among three agencies: the US Department of Agriculture (USDA) oversees the safety of growing transgenic plants; the Environmental Protection Agency (EPA) handles microbial and plant pesticides; and the Food and Drug Administration (FDA) controls the safety of human consumption of biotechnologically-derived food products.

The primary document for FDA in regulating genetically-modified foods is their 1992 “Statement of Policy”<sup>31</sup>. This document outlines procedures for companies to voluntarily consult with and notify FDA before bringing foods to market. According to the FDA, the voluntary consultation process has been completed by all of the companies currently marketing genetically-engineered food in the United States. The 1992 Statement of Policy also addresses food labeling, calling for it only if food “differs significantly from its conventional counterpart”<sup>32</sup>. In

<sup>30</sup> “Coordinated Framework for Regulation of Biotechnology”, 51 FR 23302, June 26, 1986.

<sup>31</sup> “Statement of Policy: Foods Derived from New Plant Varieties”, 57 FR 22984, May 29, 1992.

<sup>32</sup> The only genetically-engineered food to be labeled under this 1992 statement of policy was a canola oil commercialized by Calgene containing lauric acid, which does not naturally occur in significant amounts in non-modified canola oil. Under FDA regulations, Calgene was required to label the product “laurate canola oil”. We are grateful to Dr. Keith Redenbaugh of Seminis Vegetable Seeds for this information.



May 1994, the FDA determined that Calgene, Inc.'s FLAVR SAVRTM tomato was "as safe as tomatoes bred by conventional means"<sup>33</sup>, and thus did not require labeling. Recently, the FDA has proposed regulations to change both of these guidelines for consultations and labeling. Their proposal will be discussed in more details at the end of this section.

In November and December 1999, the FDA held three public meetings across the country 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 meeting in Oakland, California<sup>34</sup>. 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 its purpose as threefold:

*{T}o 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<sup>35</sup>.*

Thus the meeting was initiated at the agency-level of the government as a guide to policymaking, but without the formal requirements that a public hearing would entail. Concerning government involvement, the FDA selected panelists, and FDA officials gave two brief presentations at the panel hearing. Although the panelists were not from government, only FDA commissioners were allowed to ask questions following each panel presentation. No questions from the audience were permitted.

The core of the meeting was the two expert panels, which, in conjunction with the two FDA presentations, took up five of the eight hours allotted. The first panel focused on scientific and safety issues, and

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<sup>33</sup> Biotechnology of Food, FDA Backgrounder, May 18, 1994, cited in Beach (1998).

<sup>34</sup> "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]. There is no reason to expect that the content of the Oakland meeting differed substantially from the other two meetings, held in Washington, DC and Chicago. First, many of the panelists were academics and scientists from around the country. Second, members of the public who presented were not necessarily only from California; some flew in from Texas and other places to make their case.

<sup>35</sup> "Biotechnology in the year 2000 and beyond: public meetings", 64 FR 57470, October 25, 1999.

consisted of university and industry scientists. The second panel presented on public information and labeling. The panel was composed of representatives from academia, non-governmental organizations, and industry groups representing both organic and conventional farming. There were a total of 23 panelists.

Public attendance at the meeting was open to anyone who registered in advance, and according to the FDA announcement, anyone who registered at least fifteen days in advance was allowed to present<sup>36</sup>. Public presentations were limited to two minutes each, which is not unusual in such a setting. Notices went out on the Internet. The number of people wishing to attend and speak, however, appeared to end up limiting the speakers' list. At least one speaker said she knew of others who wished to speak but were denied permission<sup>37</sup>. In order to accommodate the numbers wishing to attend the meeting, the FDA had to provide overflow rooms where the hearing was broadcast on television. Approximately 140 people were scheduled to present at the meeting, and attendance was over 1000.

The FDA limited discussion at the meeting to issues of science, safety, and public information (still a fairly broad agenda). One issue panelists 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"<sup>38</sup>. 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*"<sup>39</sup>. A scientist pointed to new risks such as the disruption of biochemical pathways<sup>40</sup>.

Panelists at the meeting also disagreed over responsibility for labeling GM foods. The majority of panelists 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 if it fell below these levels. The burden to test and label would then fall on those who wished to demonstrate that their foods were "GM-free," such as organic producers. Advocates of this approach caution that there is "no zero risk" and that "everything we eat contains some sort of risk"<sup>41</sup>. 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<sup>42</sup>. Consumer safety

<sup>36</sup> *Ibid.*

<sup>37</sup> Arielle Levine, personal communication with Diahanna L. Post, May 11, 2001.

<sup>38</sup> Huttner, FDA (1999b), p. 65.

<sup>39</sup> Goodman, FDA (1999b), p. 156.

<sup>40</sup> Regal, FDA (1999b), p. 87.

<sup>41</sup> Hoban, FDA (1999b), p. 182.

<sup>42</sup> Applebaum, FDA (1999b), p. 187.

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 when these {genetically-modified} products are present, should be on the foods that are genetically-modified*”<sup>43</sup>. Moreover, “*if the confidence is there in the safety of these products, why is there so much objection to labeling?*”<sup>44</sup>.

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 were produced, rather than the *products* of biotechnology. 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*”<sup>45</sup>. 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*<sup>46</sup>.

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 of the attendees 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<sup>47</sup>. 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.

There was a substantial blurring at the meeting of the ideal types of “expert” *versus* “public”. For instance, a scientist who heads a company called Genetic ID pointed to a “lack of clear consensus” about the safety of genetically-engineered food, and called for more rigorous safety tes-

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<sup>43</sup> Haeger, FDA (1999b), p. 189.

<sup>44</sup> Goodman, FDA (1999b), p. 191.

<sup>45</sup> Qualset, FDA (1999b), p. 51.

<sup>46</sup> Fagan, FDA (1999b), p. 85.

<sup>47</sup> Rossett, FDA (1999b), p. 227.

ting. 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<sup>48</sup>. 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*”<sup>49</sup>.

Slightly over a year after the public meetings, on January 18, 2001, the FDA proposed new regulations for GM foods and voluntary labeling guidelines. The rules appear to reflect mainly the viewpoint of those who sided with FDA during the public meetings. 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<sup>50</sup>. These proposed regulations, while somewhat hardening the current system, are still product-based in their approach. As such, they still differ markedly from French and EU regulations.

## THE RHETORIC AND ACTION OF PUBLIC INVOLVEMENT

The regulation of genetically-engineered food is a subject of much scrutiny and controversy in both the United States and France, as elsewhere around the globe<sup>51</sup>. We have outlined these case studies to show how governments have attempted to bring in the public and experts to the regulatory process. Table 2 summarizes the elements of each of the cases. But in none of the cases does the government appear to have changed its policies as a result of public input. Instead, to varying degrees, public input appears to have been at the least not particularly relevant, and at most to legitimate already-determined government policies.

<sup>48</sup> Fagan, FDA (1999b), pp. 51-57. Others present pointed out Fagan’s self-interest in promoting labeling, since his company has developed a system to identify genetically-engineered foods.

<sup>49</sup> Regal, FDA (1999b), p. 58.

<sup>50</sup> “Pre-market Notice Concerning Bioengineered Foods”, 66 FR 4706, 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).

<sup>51</sup> For an account of the GMO controversy in France, see Joly *et al.*, 2000. Paarlberg (2001) examines GMO regulation in developing countries.

Table 2. Summary of cases

Cases	Citizens' involvement	Experts' involvement	Governments' involvement	Regulatory outcome
Citizens' conference (France)	Fourteen citizens were selected at random by a polling institute. Their deliberations constituted the main portion of the conference.	Scientists with a wide range of specializations made presentations to the citizens prior to deliberation of the conference.	Parliament organized the conference, selected the experts, and issued a final report incorporating the citizens' recommendations.	Some contradicted conference recommendations, others followed the recommendations. New policies issued shortly after the conclusion of the conference.
CGB Advisory Panel (France)	Initially, environmental and consumer organizations. After reform, more activist members of these organizations.	Expert deliberation is the primary function of the CGB. Initially, the range of experts was narrow. After the reform, a wider range of scientists were named to the committee.	Government appoints members of panel, but panel conducts inquiries without government input.	Before reforms of CGB, government allowed import of GMOs. After reforms, no import. But causal linkage is hard to make.
FDA Public Meeting (US)	Open to all; public presentations by those who registered in advance; more than half of meeting devoted to listening to panel presenters.	Scientists with a range of specializations and opinions comprised the bulk of presentations at the meeting.	FDA officials selected the experts involved, made two presentations and questioned the expert panelists.	One year later, new regulations were proposed which reflected the views of those at the meeting who supported the FDA's policies. Regulations are still in proposed form.

Underlying many efforts to involve the public in decisionmaking on issues of health and environmental risks, including the cases presented here, is a top-down model of risk communication. This model assumes that once the public is more well-informed, their opposition will taper off. This assumption is clearly seen in the European Commission draft strategic vision statement, which states that public perception is a "challenge," and stresses the "*importance of informing people about what is known and where uncertainty persists*" (European Commission, 2001, p. 16).

In the three cases discussed here, officials were engaged in a top-down process of informing the public. This was most prominent in the FDA public meetings, which involved a panel speaking to the public, followed by public presentations. But the same dynamic was present in the Citizens' conference, where the citizens were educated over several sessions before beginning their debates, and in the CGB, where citizen representatives were selected by the government.

This action of top-down communication contrasts with the rhetoric surrounding at least two of the cases. The FDA couched its public meetings in the language of “a new initiative to engage the public about foods made using bioengineering” (Food and Drug Administration, 1999a). The Citizens’ conference was intended to “provoke a dialogue between citizens and experts”<sup>52</sup>. And although not the focus of the studies here, the European Commission conducted a wide-ranging public consultation in the fall of 2001, highlighting that public authorities have an “obligation to consult and listen to the views of stakeholders” (European Commission, 2001, p. 16).

This contrast between rhetoric and action is not to say that the officials running the process are intentionally disregarding public input. Instead, this fits in with what organization theory leads us to expect about how organizations function: that the interaction with the public is a way to manage and control an uncertain external environment. The core regulatory activity – regulating genetically-modified food – is less open to public input than the rhetoric surrounding the public hearings, meetings, and conferences would suggest. Rather, such activities involving the public appear as more of an attempt to manage and shape the environment in which those regulatory agencies are found (Pfeffer and Salancik, 1978), and less of an effort to let that environment into the organization.

Other studies have also examined the nature of the public debate over genetic engineering of food. “*Some regulatory approaches acknowledge the value-laden nature of technical judgments... However, the dominant approach accepts and reinforces a technological fix approach to biotechnology regulation*” (Levidow, 1998, p. 223). 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 more participatory modes of evaluation, involving a wide variety of stakeholders, are being tried out*” (Roy and Joly, 2000, p. 253).

The difficulty is that a tension arises from the disjuncture between protecting the core regulatory function from outside interference and the uncertainty among the external environment – the public – about how the regulators are doing their job. How is it possible to share knowledge emanating from the environment? Can the agencies engage in a real dialogue with citizens and recognize the value of local knowledges (Irwin, 1995; Martello, 2001)?

<sup>52</sup> Prime Minister’s Office, 27 November 1997, «*Les plantes génétiquement modifiées*».

## CONCLUSION: POLICY RECOMMENDATIONS

Once regulators move away from the technocratic model that only better science can lead to better solutions, and acknowledge the need to accommodate multiple knowledge in policymaking, they must involve the public in a meaningful way. How is this possible? We suggest two pathways.

The first, at the level of the individual, is to increase the discretion of policymakers. Discretion – the capacity to say ‘yes’ definitively<sup>53</sup> – becomes ever more important as the environment becomes more heterogeneous (multiple actors) and conflictual; the capacity for flexibility on the part of the regulator is essential to responding. But this goes against the grain of legislation in recent years, at least in the United States, which seeks to impose very detailed requirements and circumvent the judgment of agency officials. And while discretion is power (Crozier, 1964), it is also a way to increase information processing-capabilities, by reducing the number of decisions referred upward (Galbraith, 1977). Increasing discretion would help in bringing the multiple knowledge from the environment into the organization.

Although discretion contributes to a less hierarchical mode of organization, because policymakers are allowed to decide more issues on their own without kicking them back up to superiors, yet another pathway would help officials contend with the tension between the core regulatory function and the external environment. This is to reconceptualize the organization as one node in a network. The increasingly important role of knowledge is one of the factors contributing to the rise of networks (Powell, 1990). Conceptualizing the agency as one part of a network, part of lateral relations rather than vertical, moves us away from the one-way, top-down model of communication with the public<sup>54</sup>. Networks may be both more flexible and more effective than hierarchies. And while accountability and legitimacy are raised as concerns when public organizations share their functions with other non-governmental organizations (Milward and Provan, 2000; Agranoff and McGuire, 2001), in the field of risk regulation we must also consider the loss of legitimacy due to an inability to regulate controversial issues<sup>55</sup>.

One important question the regulatory agency will have to tackle in seeking to involve the public is: who constitutes the public? Industry, for example, is part of the public, yet many non-governmental organiza-

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<sup>53</sup> We are grateful to Todd LaPorte for this definition.

<sup>54</sup> Irwin (1995) labels this the cognitive deficit model of public understanding of science.

<sup>55</sup> See Hood and Rothstein (2001) for an interesting discussion of how organizations regulating risk tend to respond to public pressures for change.

tions (and others) would question the participatory character of a process that involved industry and government only<sup>56</sup>. Do NGOs represent a broader public interest? Or should public participation mean a wide opening to anyone who wishes to participate in a process?

How can regulators and agencies begin to move down these two pathways? First, awareness must be raised of the existence of multiple knowledge. Second, we must understand the conditions under which networks arise. Third, we should ask whether network forms of organization are amenable to interaction with individual members of the public, not just citizens' groups and industry.

Regulation of genetically-engineered foods is an excellent arena in which to study the changing nature of public participation. Moreover, as the trade stakes and conflicts over GM food increase, solutions are being sought. We suggest that re-examining how policy is made, by examining who participates in policymaking and whether their views are taken into account, can offer a way forward.

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<sup>56</sup> Indeed, Vogel (1986) and Brickman *et al.* (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.



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