The Credibility of Expert Advice for Regulatory Decision-making in the US and EU

Comparative Case Studies on Ambient Air Quality Standards and Regulation of Genetically Modified Crops

Ariane König
Sheila Jasanoff

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Center for Business and Government
John F. Kennedy School of Government
79 John F. Kennedy Street, Weil Hall
Cambridge, MA 02138
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Regulatory Policy Program

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For Further Information

Further information on the Regulatory Policy Program can be obtained from the program’s director, Jennifer Nash, Center for Business and Government, John F. Kennedy School of Government, 79 JFK Street, Cambridge, MA 02138, telephone (617) 384-7325, telefax (617) 496-0063, Email jennifer_nash@ksg.harvard.edu.
1. Introduction

1.1. Background and Context

Concerns about expert advice to governments in decision-making on risk prevail in both the European Union (EU) and the United States (US). In the EU, trust in government decisions and expert advice has been undermined by a series of recent food scares, the most significant of which concerns Bovine Spongiform Encephalopathy (BSE). A consequence of the food scares is criticism and distrust of any government decisions on risk, particularly in openly value-laden contexts such as decision-making on genetically modified crops. In the US, distrust in expert advice is in a sense more routine, with political actors regularly resorting to litigation as a means of challenging governmental decisions that adversely affect them.

Institutional responses to the European crisis of trust in government include the rethinking of the institutional infrastructure and guidelines on how to draw on expert advice and the reshaping of institutions for food safety in many of the Member States, including France, Germany and the United Kingdom (UK). At the European level, the establishment of a central European Food Safety Authority is planned for 2002. A more fundamental analysis of ways to improve the solicitation of expert advice for regulatory decision-making is also underway. The European Commission created the inter-service Group on ‘Democratising Expertise and European Reference Systems’ to make recommendations on ways to improve processes for soliciting expert advice at the European level. The Group’s recommendations are intended for inclusion in the White Paper on Governance. This report has been commissioned by the Secretariat General of the European Commission as a contribution to that work.

Member State governments and the European Parliament have looked to the US in the past for ideas on institutional infrastructures to solicit expert advice. The objective of this report is to complement existing descriptions of the US system for soliciting expert advice with a more careful analysis of the advantages and disadvantages of different approaches to obtaining advice on questions of environmental and health risks in situations of uncertainty.

This report compares the changes in the procedures for use of expert advice in decision-making in the EU and in the US in the recent past by researching official documents and the published literature pertaining to two cases: the setting of ambient air quality standards and the regulation of genetically modified crops. Analytic perspectives are drawn from the fields of law, comparative policy studies, and science and technology studies (STS).

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1.2. The Institutional Setting of Expert Advice in US and EU

The institutional setting in which expertise is used in the US and the EU is broadly similar at both the political and the regulatory levels. Both are federal structures with divided jurisdictions and legal competences, although the role of Member States in the EU system substantially differs from that of states in the US federal union. For example the EU Council provides the infrastructure for pooling the powers of the Member States, whereas the US Congress and President are independently elected and have no comparable function in relation to the states. Further, the principle of subsidiarity confers different and in many ways more sovereign powers on EU Member States than does the Tenth Amendment of the US Constitution on the 50 US states. Both federations are fundamentally committed to science and technology for innovation and economic growth, and both are democratic polities with high levels of public accountability and media scrutiny.

While the broad social and political environments for regulatory policy-making are similar in the US and EU, mechanisms for responding to challenge to government decisions, such as increasing the transparency and inclusiveness of the decision-making process, are conspicuously different. Apart from inherited institutional differences, one fundamental dissimilarity is that regulatory policy-making in the US is more openly adversarial, that is, government regulatory decisions are more prone to be challenged and there are more formal mechanisms for such challenges. The US regulatory process also requires agency officials to take the viewpoints of interested public and private sector actors thoroughly into account in their decision-making. Nevertheless, challenge by actors with a stake is likely,2 and the ability of government to defend decisions in court may be seen as one test of their robustness. An in-depth analysis of the US system is particularly illustrative of processes for the construction of socially robust expert advice. We can therefore consider which, if any, of the more successful mechanisms used in the US context are transferable and could be relevant to EU policy-making.

Both the US and the EU have approached risk-based regulation through a shared understanding of the process of risk analysis that is based largely on a 1983 report of the National Research Council.3 That approach was further elaborated by international expert groups under the auspices of Codex Alimentarius, the Food and Agricultural Organisation, and the World Health Organisation. Decision-making on health and environmental risks is conventionally broken down into the following steps: risk assessment, or ‘the determination of the likelihood of the occurrence and potential magnitude of harm’; risk management, or ‘the process of weighing, selecting and implementing policy alternatives in the light of risk assessment’; and risk communication.4 The remit of expert advisory bodies acting within a regulatory framework is

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2 Even the adoption of consensual procedures, as in negotiated rule making, does not appreciably reduce the probability of lawsuits. See Coglianese, C. 1996. Litigating Within Relationships: Disputes and Disturbance in the Regulatory Process. Law & Society Review.


generally seen as contributing to the validity of agency decisions. Within this envelope remits can be narrow or broad and can include guidance on long-term research or data needs, review of the technical rationale for decisions, identification of gaps or weaknesses in the scientific basis for standards, review of risk assessment methodology, evaluation of new scientific evidence, and peer review of specific studies or risk assessments. In practice expert advisors frequently exercise judgment of a value-laden nature, although their institutional role as scientists helps them to delineate a conceptual boundary between ‘scientific’ risk assessment and ‘political’ risk management.5

Science for policy, and specifically research for the assessment of environmental and health risk, is framed by legislative mandates to which values and stakes are attached. Moreover, scientific investigations conducted to prevent future harm use the results for predictive purposes; these are often associated with large uncertainties because of inherent limitations on the analysis of complex systems. As regulatory research is often conducted at the forefront of scientific knowledge, discoveries tend not to be verified as quickly as action is mandated. Often conflicting hypotheses exist. Furthermore, with increasing scrutiny of the scientific base by non-scientists, the process of obtaining data becomes as important as its informational content, opening the way to procedural challenges. For all these reasons science in the regulatory process is prone to be highly contested.

These factors are reflected in the case studies in this report. In the context of the regulating genetically modified crops, the highly visible, polarized debates can be seen as calls for more consideration of ethical and value-based concerns, and hence for broader participation in decision-making.6 A somewhat different set of problems is encountered in the determination of ambient air quality standards within regulatory frameworks for the improvement of air quality. Here, standards have to be defined by reconciling long-term protection of public health and the environment with immediate economic costs, in a system in which neither costs nor risks are evenly distributed. Moreover, a central value needs to be determined from a continuous concentration-dependent range of pollutant-related health effects and there is significant uncertainty associated with the impacts on different subpopulations at different levels and durations of exposure.

### 1.2.1. Regulatory Policy-Making and Expert Advice in the United States

In the US, the institutional framework for regulatory policy, consists, at the national level, by the three main branches of government: Congress or the legislative branch; the White House or the executive branch; and the courts or the judicial branch. Two additional institutional levels --

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regulatory agencies and their external expert advisory bodies -- are also implicated in the construction of regulatory policy. Hence, there are three levels of decision-making on regulatory policy. Legislation is enacted by Congress, it is interpreted and translated into guidelines and standards by the federal agencies, and these actions are subject to litigation in the courts. At the subnational level, the 50 states also participate in the formulation and implementation of regulatory policy. Under the US Constitution, Congress can pre-empt state and local law unless individual statutes disavow pre-emption. Political forces shaping tensions between the federal system and the states in the US include reluctance on the part of some states to assume regulatory burdens that are seen as disproportionate or unfounded, desire for autonomy in the enactment and implementation of standards, and judicial support for states’ rights. As the case of California demonstrates, however, the dynamics of federalism can lead to more stringent standards at the level of the state. California has for instance instituted a strict organic labelling regime and has more stringent rules on the use of some pesticides, toxic chemicals, and air pollutants.

The US Constitution gives Congress broad powers to regulate health, safety and environment. The enactment of statutes and their amendments is politically arduous and time-consuming. Nevertheless, in the ten-year period between 1968 and 1978 Congress passed more laws than in the 179 years from 1789 to 1968. This flurry of activity was prompted in part by social upheaval and the activist movements of the 1960s. New agencies were created in several instances to implement new legislation for health, safety and environmental protection, and liberal procedural mandates ensured more open and transparent processes of governmental decision-making. Congress continues to exercise oversight over these programmes through the budget process and through committee hearings on aspects of agency performance.

Federal agencies created by federal law, or in the case of US EPA by executive order, are involved in standard-setting, enforcement, and adjudication. The President exerts control over the regulatory agencies mainly by controlling appointments to political posts and through the budget. Further, the White House Office of Management and Budget (OMB) reviews the cost-effectiveness of regulatory decisions under presidential executive order. In particular, since the Reagan administration, costs associated with the implementation of regulation have become a most important criterion in determining a regulation’s acceptability.

Judicial review by the federal courts is provided for under major regulatory statutes, which also specify the procedures by which agencies should carry out their mandates. In addition, the Administrative Procedure Act (APA) specifies general rules for agency rule making and adjudication, and also for the judicial review of administrative decision-making.

The US regulatory system is highly politicised because of the explicit separation of the powers of the three main branches of government and because of the fundamental belief in a pluralist democracy that divergent opinions need to be expressed as prelude to public action. This leaves considerable room for agency discretion in reconciling the competing views of interested and affected parties. There is, however, also a prevailing belief in the rationality of science, and science is used as an important instrument for legitimating government decisions. The reliance on scientific information and technocratic expertise represents an inherent conflict with democratic values; tensions are highlighted in a highly deconstructive, as well as participatory
and adversarial, environment. Yet, decisions made within such a system often capture public confidence, in particular those that have been negotiated and re-negotiated through several rounds of administrative and legal proceedings. The drawbacks of such a system are that the formal adversarial style of decision-making highlights uncertainty, polarises scientific opinion, and prevents efficient resolution of disputes on controversial topics. Litigation, which produces ‘winner take all’ decisions, contributes further delay, uncertainties and inefficiencies.

A distinctive source of expert advice is the National Academy of Sciences (NAS), which was created in 1863 as a private, non-profit, self-governing membership association to investigate, examine, experiment and report on any subject when called upon by a department of the federal government. The National Research Council (NRC) was established in 1916 by the NAS as its principal operating agency. The NRC has a governing board, which approves projects and forms committees to execute and review projects. The members of the governing board are drawn from the NAS, the National Academy of Engineering and the Institute of Medicine, and Committee members are chosen on the basis of special competence and appropriate balance. Review of draft reports is carried out according to procedures approved by a report review committee.

Expert panels under the auspices of the National Academy of Sciences compare most closely to European expert panels by virtue of informal procedures that are consultative rather than adversarial. Over time, however, the protection given to NAS committees in relation to their power and weight in providing policy input have become less acceptable. Protective veils for expert advice under NAS were lifted in a 1997 decision of the D.C. Circuit Court of Appeals overruling an earlier judicial determination that NAS committees were not subject to FACA provisions. The lawsuit by the Animal Legal Defense Fund charged an NAS committee on the use of laboratory animals as not appropriately balanced in accordance with FACA. The NAS tried to defend that its committees were not subject to FACA reasoning that the Academy is independent of government, although largely funded by government, it maintained that it creates its own expert committees and that it has a contractual relationship with government. FACA, it held, is directed specifically at federal agencies and expert committees constituted by the government. This line of defence was only partly successful, as in 1997 the Federal Advisory Committee Act was amended by Congress to include a requirement for NAS committees to observe certain openness procedures that are less stringent than those applying to federal agencies, including rules on balance, conflict of interest, and disclosure of names of candidates to serve on the committee, as well as names of the selected appointees.

Through the NRC, the NAS regularly reviews and provides guidance for decision-making on risk. Often such review is based on requests by Congress. In 1981, Congress asked the NRC to study the institutional means for risk assessment, with a specific remit to assess the merit of institutionally separating risk assessment functions from regulatory policy-making. The resulting report, one of the most influential in the field of risk analysis, advocated the separation of responsibilities of risk assessment from risk management within government agencies to ensure that scientific findings would be clearly distinguished from the political, economic and social considerations that influence the design and choice of regulatory strategies. The NRC

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committee, however, recommended against creating a separate agency for risk assessment. It was noted that organisational separation may have the advantage of creating a firmer conceptual distinction; it may help to shield analysts from policy pressures and may foster consistency between risk assessment approaches. However, it also has the disadvantages of potentially disrupting communication between risk assessors and risk managers and could possibly result in a risk assessment process that is less responsive to the regulatory agency’s mandate.  

Subsequent studies by the NRC on risk analysis gave more importance to early participation of the spectrum of interested parties to ensure that decisions take account of all relevant positions, which in turn is thought to promote more legitimate policies. Furthermore, analysis, that is the assessment of risk and the identification and recommendation of risk management options, is increasingly seen as an iterative process that benefits from maximal information exchange and minimal institutional barriers between experts, publics, and decision-makers. Decision-making is seen as recursive, with periodic evaluation and review of decisions where appropriate in order to create a certain degree of institutional reflexivity over time. Consideration of context and of divergent issue framings at the start of the decision-making process permits analysis not only of the scientific, health and environmental dimensions of the risk but also of social, political and economic factors. Such iteration and reflection in turn allow problem framings to be revisited, with implications for data gathering and establishing appropriate terms of reference for expert committees.

1.2.2. Participatory Mechanisms in the US

Five cross-cutting legal provisions have proved to be most relevant to the solicitation of expert advice in US regulatory decision-making. These general procedural mandates may be overlapping, complementary, or in conflict with administrative provisions in the specific regulatory statutes. In case of conflict, the more specific statute prevails, although this determination lies at the discretion of the courts. The five procedural statutes are as follows:

1. The Administrative Procedure Act (APA) of 1946 provides basic procedures for agency rule making and adjudication, and for judicial review of administrative decision-making. For instance, concerning citizen access and participation, every agency is required to provide interested parties at least notice of proposed rules and the opportunity to comment on them. The APA provides for judicial review in situations where originating statutes are silent on the point. The ‘standing doctrine’ clarifies criteria for eligibility to bring a case to court. Usually an individual must provide evidence of a direct impact to gain standing.

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The ‘exhaustion of administrative remedies’ provides that all intra-agency appeals must be utilised before one can seek judicial review. The ‘ripeness’ doctrine, a constitutional norm, determines that federal courts can only entertain cases that are real and imminent.

2. The Federal Advisory Committee Act (FACA) of 1972 provides rules for the use of outside advisors by federal agencies. Access to advisory committees by the public is ensured by opening up proceedings and records to the public and permitting interested persons to appear before and submit evidence at FACA meetings. Exceptions relating to the protection of confidential information and privacy can be granted. FACA requires membership of committees to be “fairly balanced in terms of the points of view presented and the functions to be performed.” In theory, this rule provides interested parties with some control over the composition of advisory committees, but the extent to which an agency determination based on an “unbalanced” advisory committee may be challenged in court remains to be determined. FACA pertains to almost all formal and informal advisory bodies convened by an agency (for example, any meeting with industry alone that is not fully open to participants can be challenged under FACA).

An example of challenge on the basis of non-compliance with FACA is the court case brought by the Association of American Physicians and Surgeons (AAPS) against Hilary Rodham Clinton. AAPS filed an action in February 1993 alleging that the government had violated FACA by failing to file an advisory committee charter for “the President’s Task Force on National Health Care Reform” (Task Force) and by denying access to both the Task Force and an interdepartmental working group overseen by a Task Force member. The government countered with the ‘wandering horde’ theory, namely, that the working group lacked an organised structure, a fixed membership, and a specific purpose (i.e., work was conducted for the Task Force, not for the President directly) and hence did not meet the definition of a FACA committee. The Court of Appeals, however, concluded that the wandering horde in this case could be seen as a number of advisory committees that did represent a link between government and the public and hence could well qualify as a FACA body.

3. The Freedom of Information Act (FOIA) of 1974 provides that all agency documents must as a general matter be available for disclosure to the public and that agencies have to make all records “promptly available to any person in response to a request” within ten working days. In cases of non-compliance, individuals can take agencies to court. However, FOIA’s general presumption in favour of disclosure is mitigated by several exemptions, including commercial information and certain internal agency documents.

4. The Government in the Sunshine Act (GISA) of 1976 extends provisions of openness to information on decision-making processes. It provides that proceedings of meetings have to be made available to the public and that “every portion of every meeting of an agency shall be open to public observation”. Exceptions exist for example to protect personal privacy and trade secrets.

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5. The Ethics in Government Act of 1978 lays down rules on conflict of interest that form the basis for the implementation of the Federal Advisory Committee Act with respect to such conflicts.

To sum up, US government agencies have recourse to a variety of approaches to procuring expert advice, ranging from more ‘democratic’ advice from FACA-type committees to more ‘technocratic’ advice from NAS expert panels, to match different intended uses of expert opinion. In turn, these advisory panels have recourse to a variety of procedures, from open meetings to well-publicised hearings, to engage interested parties in the advisory process.  

Formally open processes, of course, do not necessarily lead to more ‘democratic outcomes.’ Often only those with means, usually industry, can easily mobilise resources to be informed, to appear, and to make informed and professional contributions that are beyond the capacities of other interested and affected parties. Nonetheless, it may matter most that the ‘process’ appears democratic, and that other mechanisms exist to identify a range of normative concerns at the start of a decision-making process when questions on risk and evidence are being defined. These can subsequently be addressed by the ‘most appropriate experts.’

Tensions between the recognition of communal benefits derived from science-based health and safety regulation, individual rights, private sector interests in profit-making, and fundamental democratic values easily rise to the surface through mechanisms for transparency and participation in the US system. Clashes among these values may hinder or delay development and implementation of certain types of regulatory measures. The case study of setting ambient air quality standards under the Clean Air Act particularly illustrates this tendency.

1.2.3. Regulatory Policy-Making and Expert Advice in the European Union

In the EU, the institutional and legislative framework for regulatory policy-making is jointly shaped by the European Commission, Council and Parliament. The European Commission has the right of initiative and drafts first proposals, either of its own accord or following a request from Parliament or Council. Since the Treaty of Amsterdam came into force in May 1999, policy and legislative activities on matters regarding the environment and public health are decided in accordance with the co-decision procedure of Article 251 of the Treaty. In this decision-making procedure, the Parliament has two readings to amend the draft legislation and can veto its acceptance. Based on the Commission initiative and Parliament’s proposed amendments, the Council brings forward a common position of the Member States. After the second reading of Parliament, the Council votes on the proposal; the number of votes a Member State has is largely determined by size, GDP and population. Support from a qualified majority of Member States, that is, at least 63 out of a total of 87 votes, is required to pass the law. Exceptions to this rule are decisions concerning energy use, country planning, and provisions of a fiscal nature, where unanimity is required. If the Council and Parliament cannot agree on amendments proposed in the second reading of Parliament, a conciliation procedure is initiated whereby a consensus position between Council and Parliament has to be agreed upon within six months. If no agreement can be reached, a fresh start to the legislative process is required.
This decision-making process involves close cooperation of Member State representatives in the Council, members of Parliament, and officials of the European Commission. There are therefore only two distinct levels of policy-making in the EU: consensus-driven procedures on policy instruments and guidelines at the level of the European institutions; and the transposition and/or implementation of the legal instruments by the Member States. The European Court of Justice is responsible for the interpretation of EC law.

There are three main types of legal instruments: regulations; directives, which have to be transposed into national law by Member States; and decisions. European directives have direct legal effect. Individuals can file complaints against governments of Member States based on negligence of transposition or implementation of directives, provided they incur direct harm from such negligence. Citizens can claim reparations for Member State failure to comply with Community measures since the ruling of the European Court of Justice on Francovich and Bonifaci v. Italy in 1991\(^\text{12}\) (stating that remedy shall be available for failure by Italy to implement Directive 80/987 on the protection of employees in the event of insolvency of their employers). European citizens’ complaints regarding EC law and its implementation can also be brought to the ombudsman who acts as an institutional link to gather feedback from citizens and pass it on to the European institutions.

Since the ratification of the 1957 Treaty of Rome on the creation of the European Economic Community, the remit of the Community has expanded from a purely economic focus to encompass increasingly political realms. The first links between fostering intra-community trade and impacts on the environment were acknowledged in the Declaration of the Council of the European Communities of 22 November 1973, which calls for the implementation of a European Communities programme of action on the environment. The legal basis for Community environmental policy was only granted later with the Single European Act of July 1987, which added powers to the Treaty providing for community competence in matters of environment and health and safety at work. The 1992 Treaty of Maastricht gave more importance to the environment in Article 2 on the tasks of the European Community:

> The Community shall have as its task, by establishing a common market and an economic and monetary union and by implementing the common policies or activities referred to in Articles 3 and 3a, to promote throughout the community a harmonious balanced development of economic activities, sustainable and non-inflationary growth respecting the environment, a high degree of convergence of economic performance […].

Article 2 of the 1997 Treaty of Amsterdam added even more emphasis on environmental and health concerns by referring to sustainable development as a priority goal in the European Union. The Fifth Environmental Action Programme states: “The ultimate objective … is to strike a new balance between short term benefits of individual persons, companies and administrations and the longer-term benefits of society as a whole.”

The trend toward giving priority to environmental and health concerns over immediate economic considerations, coupled with explicit mention of the precautionary principle in the Treaty of

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\(^{12}\) Cases C-6/90 and C-9/90, Francovich and Bonifaci v. Italy ECR I-5357, [1993] 2 CMLR 66.
Amsterdam, represent the most fundamental distinctions between the regulatory philosophies of the US and the EU. The explicit policy statements in the Treaty and in secondary legislation about the chosen high-level of consumer and environmental protection at EU-level may help to build the confidence of the general public in EU regulatory policies; however, by in effect Europeanising basic value choices affecting states and localities, it can also lead to questions about possible conflicts with the principle of subsidiarity.

Scientific advisory structures for consultation on the definition of policies, strategies and standards by the European Commission were initially developed on an ad hoc basis through secondary legislation pertaining to a wide range of sectors. Until 1997 scientific advisory bodies to the European Commission were usually administered by the Directorates General that were responsible for administering the respective legislative sectors. In 1997, at the peak of the BSE crisis, the then President of the European Commission, Jacques Santer, in a speech to the European Parliament, announced general principles for the management of food safety and consumer health. Among the principles were that responsibility for legislation should be separate from that for scientific consultation, and that there should be greater transparency and more widely available information throughout the decision-making and inspection process.

These guiding principles were the basis for the reorganisation of the scientific advisory system of the European Commission. Until November 1997 scientific advice was provided by six different scientific committees: Food, Veterinary, Animal Nutrition, Cosmetology, Pesticides and toxicity and Ecotoxicology. In addition the Multidisciplinary Scientific Committee (MDSC), established in 1996, addressed the multi-disciplinary aspects of the recent BSE epidemic. The entire system for scientific advice was reformed in the period of June to October 1997. A Scientific Steering Committee (the former MDSC) and eight new scientific committees were created that replace, update and broaden the mandate of the former scientific committees. These include the Scientific Committees on Food; Animal Nutrition; Animal Health and Animal Welfare; Veterinary Measures relating to Public Health; Plants; Cosmetic Products and Non-Food Products intended for Consumers; Medicinal Products and Medicinal Devices; Toxicity, Ecotoxicity and the Environment.

Moreover, all scientific committees were moved from the Directorates with the respective legislative responsibilities to the newly created Directorate General for Consumer Protection in order to separate legislative and policy responsibility from that for scientific consultation. The subsequent European Commission Communication on Consumer Health and Safety announced these changes and, as indicated by the following statement, placed emphasis on the excellence of the Committee members and the independence and transparency of the advice: “Consumer confidence in the legislative activities of the EU is conditioned by the quality and transparency of the scientific advice and its use on the legislative and control process.”13 The Steering Committee was charged with advising the European Commission on selection of members of other committees. The selection process involves an open call for applicants in the Official Journal; in the selection of applicants particular emphasis is placed on ensuring that members of

http://europa.eu.int/comm/food/fs/sc/index_en.html
the Scientific Committees are free from conflicts of interest. The Commission Communication on Consumer Health and Safety also announced the need to investigate whether current voluntary provisions to consult independent experts on regulatory policy need to be formalised across legislative instruments.

Compared to the US, expertise at the EU level is conceived more narrowly in terms of ‘elite’ scientists. Committees are considered multidisciplinary if the main relevant fields of the natural sciences are represented (in some Member States, such as Germany, the notion of expertise is much broader). There are no specific requirements for ‘balanced’ membership comparable to the provisions in the Federal Advisory Committee Act of the United States, and no additional rules concerning transparency or openness, except for a commitment that opinions of committees, and in some cases minutes of committee meetings, are posted on the web. The Commission relies heavily on expert authority and has built a firewall around the scientific committees by stressing members’ exclusivity and ‘eminence’ so as to fend off challenges from other ‘less authoritative’ individuals. Any potential political influences on epistemic positions are denied in this approach.

Expertise, so conceived, may prevail at the cost of democracy, depending on how expert advice is integrated into the general, sectoral and case-specific decision-making procedures on safety standards or product regulation. The basic system is a technocratic one, which looks to scientists as threshold validators of science-based policy. In other words, the acceptability of science-based policy depends on first subjecting the knowledge base to screening by elite scientists. The system has, however, recently been forced to take more account of politics in response to the food scares which climaxed with BSE and genetically modified foods, and in response to the progressive institutionalisation of the precautionary principle in an increasing number of sectors beyond environmental policy.

In response to the loss of trust of citizens in governments after the food scares, and the fraud allegations against the Santer Commission, changes in European administrative and institutional structures, including those for the solicitation of expert advice in risk decision-making, are currently being considered. Commission staff and external experts are focusing on a range of contexts that include the Commission Communication on the Precautionary Principle, the report on the ‘Harmonisation of risk assessment procedures’ by the Scientific Steering Committee, the White Paper on Food Safety and the establishment of the European Food Safety Authority, and the White Paper on Governance.

Increased transparency has also appeared as a priority, both, in the context of the solicitation of expert advice and for the European Institutions in general. Article 1 of the Treaty of the European Union establishes as a general principle that decisions are to be taken as openly as possible and “as closely as possible to the citizen”, and secondary legislation to implement this Treaty provision is at present being negotiated. Parliament has just endorsed a new rule on public access to documents handled by the European Institutions that provides citizens with the right to access official papers under Community law, unless officials can prove that their release would be harmful. In the field of environmental policy provisions for greater transparency were implemented earlier and include the 1997 Commission Decision on Public Access to Documents of the European Environment Agency. The 1997 Council Resolution on Drafting, Implementing
and Enforcing Community Environmental Law, apart from highlighting the need for transparency, also recommends increased participation in the form of stakeholder consultation “at an early stage on concrete legislative proposals.” The conclusions of the March 2000 Lisbon European Council stressed that the European Institutions, national governments and regional and local authorities should pursue their dialogue with business and citizens, in particular in the context of impact and compliance costs of proposed legislation. There are, however, no open and formal procedures comparable to those of the US that ensure public notice, and opportunities to comment or actual face-to-face involvement, of those who wish to participate in rulemaking.

1.3. Strategies for Enhancing the Credibility of Expert Advice

Institutional changes to strengthen or stabilise the public credibility of expert advice, and hence provide a more ‘democratically acceptable’ basis for decisions, can be grouped under four headings:

- Technical peer review and scientific expert analysis
- Broader public review and participation
- Normative analysis and reframing
- Institutional accountability

1.3.1. Technical Peer Review and Scientific Expert Analysis

To be credible, expert judgments need to be accepted, in the first instance, by other experts. In each case, we analyse to what extent and at what stages of decision-making the scientific information base and its interpretations were reviewed by scientists, and how broad a scientific peer community engaged in the review. Research questions asked include: What quality control procedures were in place to assess the quality of both the data and the technical review process? What were the terms of reference for the scientific advisory bodies? Were they called upon merely to conduct a review of the data and/or the risk assessment or were they also consulted on proposed risk management options? What were the mechanisms and criteria for the selection of experts? To whom were the experts accountable? How transparent was the expert consultation process?

1.3.2. Broader Public Review and Participation

The need for participation in decision-making has been stressed in two recent US NRC publications on risk analysis (see section 1.2.1. above). The establishment of expert committees, their terms of reference and membership will shape the framing of questions, determine the approach to analysis, and may bias attention toward certain types of solutions at the expense of others. Bias in problem framing may leave out issues that are of real concern to relevant

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stakeholders, leading to solutions that may be irrelevant or politically unacceptable. Accordingly, the NRC recommended that risk characterization be conceptualized as an analytic-deliberative process, which must include participation by the spectrum of interested parties, decision-makers and specialists. Decisions that take account of all affected parties’ positions are anticipated to be more acceptable and hence easier to implement. Scientific facts used as a basis for decisions may be more credible if affected parties play a role in producing or evaluating them; in this way, participation can actively bridge the gap between scientific expertise and a concerned public, by engaging interested and affected parties in the very production of knowledge. These newer approaches to participation suggest a need to investigate how broadly expertise was defined in the respective expert advisory committees and what role, if any, was played by publics in the construction of data relevant to decisions.

1.3.3. Normative Analysis and Reframing of Questions

Especially in research related to risk assessment, where ineradicable uncertainties persist in a value-laden environment, knowledge of both the factual and the value dimension is required for the determination of an ‘acceptable risk.’ Scientific advice is often accepted if it is deemed consistent with underlying normative accord on the applicable standard of risk or precaution (for instance, children should be protected more than adults or risks should not fall disproportionately on disadvantaged communities). Normative judgments that represent the beliefs of a majority can prevail in a democratic society even if they are not necessarily based on technical rationality. An example is the rejection of nuclear power plants in some countries, like Germany, despite expert assurances that they are safe. The case studies will be analysed in order to identify whether strategies were used to help frame scientific questions and arguments so that they would gain acceptance beyond the community of knowledge-producers. Such strategies may include efforts to ensure that scientific arguments (1) are consistent with prevailing moral values, (2) support generally accepted norms of discourse and reasoning, and (3) are ratified by communities that are concerned with issues of fairness and justice. Each of the case studies also asks whether procedures existed to take into account both scientific expert concerns and normatively different concerns of citizens. As normative values and concerns may change over time, periodic analysis and reframing may be warranted. The case studies consider the availability of mechanisms for doing this.

1.3.4. Institutional Accountability

Citizens’ awareness that decisions are not open to question increases a sense of powerlessness and institutional distrust. Persistent challenge of government decisions, however, may also generate distrust and absorb significant amounts of institutional resources in dispute resolution. The case studies therefore examine what avenues existed for contesting to decisions on risk before, during or after rulemaking, and how they were used.

Grounds on which the credibility of policy-relevant science and advice can be challenged, mainly through the courts or through media, include not only questionable methodology (the standard basis for challenge in scientific settings), but also more overtly social criteria, e.g., lack of peer review or transparency, conflict of interest of those who offer data or advice, uncertainties that were not factored into the assessment of science, lack of fit between expert and lay expectations of relevance, inappropriate standards of proof, and failure to consider vulnerable groups. The case studies illustrate how these social determinants of credibility come into play, and how the institutional design of regulation promotes or deters challenge along these dimensions.

To sum up, it may not be necessary to adopt all of the above strategies at all stages of decision-making for all types of regulatory policy, since each of the strategies presents a trade-off between a more democratic, participatory, and credible decision-making process and one that is also more complex and likely more time- and resource-consuming. Unlimited opportunities for participation and challenge may make little sense in an institutional context with limited resources or relatively low stakes, although some attention to transparency will surely always be warranted. In politically salient and value-laden contexts, however, time and resource investments into carefully designed, inclusive, and reflexive decision-making processes may well be warranted.

2. Case Study on Clean Air

2.1. Background

The first case study relates to the setting of ambient air quality standards for ozone and fine particulate matter. This case study was chosen largely because of a rich history of scientific controversy and institutional response. The first federal National Ambient Air Quality Standards (NAAQS), including an ozone standard were set in the US in 1971; since then the standard for ozone has been revised twice. EPA proposed a standard for fine particulate matter in 1997. The economic impact of these rules has contributed to the intensity of challenge and response. The first EU-level standard for ozone in ambient air was referred to in the 1992 Directive on Ozone. Parliament requested consideration of setting a standard for fine particulate matter in the next round of revisions of the Air Quality Framework Daughter Directives.

Although some of the US contestation reflects particular aspects of that country’s socio-political environment, such as its adversarial character, it is expected that some of this history will be relevant to policy-making by expert advisory bodies in Europe, both in general terms and for the particular case of clean air. Not only do the same scientific and policy questions arise in both regions, but regulators in both political contexts increasingly have drawn on the same scientific studies.

Standard-setting for ozone and fine particulate matter was selected for study, first, because it addresses the key issues of how to reconcile long-term protection of public health and the environment with immediate and unevenly distributed economic costs, and, second, because
significant scientific uncertainty is associated with the establishment of cause-effect relationships between the emitted pollutants and injury to health. The standard-setting process involves the extrapolation of a single value from a continuous, concentration-dependent range of health effects that are associated with the pollutant. These effects may vary across population subgroups and in synergy with other pollutants. Precursors of photochemicals, such as ozone, mainly hydrocarbons and nitrogen oxides, can come from natural sources and from human activities (such as car exhausts). Limits to emissions based on an ambient air quality standard will always have significant cost-implications for some industrial activities and no immediately palpable benefit to identifiable individuals. A decision on a threshold value for a standard will rely on weighting and then allocating financial and health risks to different target groups, based on the fact that individuals in a population have different sensitivities, and different industrial sectors, as well as regions, will encounter different costs and hurdles in attaining the standards.

Moreover, there are significant scientific uncertainties associated with setting air pollution standards. Ambient air quality standards are generally based on three types of scientific evidence: acute health effects shown through controlled exposure studies; epidemiological data based on population studies; and biochemical data on the mechanisms through which the pollutant affects human health. There are, however, methodological limitations in both mechanistic studies and their extrapolation to the human population. In particular, with particulate matter, there are as yet virtually no data about the relations of different particle compositions and health effects. The power of extrapolation from controlled exposure experiments and epidemiological data, in turn, is limited by uncertainties in models of exposure at very low dose levels and by variable sensitivities to the pollutant in different subpopulations.

2.2. Standards under the US Clean Air Act

2.2.1. Brief History of the Clean Air Act

The first attempt to federalize air pollution control was the 1967 Air Quality Act, which established the National Air Pollution Control Administration and charged it with helping states to devise pollution control programmes. Under this Act, states established and enforced their own air quality standards based on studies conducted by the federal government. Both, standards and enforcement plans were subject to federal government review and approval. There were no attainment deadlines, and states were responsible for devising plans to meet air quality standards. Judicial review was governed by the Administrative Procedure Act. By 1970, the Air Quality Act had proved ineffective, as not a single state implementation plan had been approved by government. Environmentally concerned critics feared that states would compete for new industries by keeping standards permissive and enforcement lax, although opposition to national standards for emissions and ambient air quality continued, mainly based on limits to federal action under the US Constitution’s commerce clause.¹⁵

The Clean Air Act (CAA) of 1970 sought to remedy these defects. President Nixon had created the US EPA by executive order in the beginning of 1970. Later in 1970, a completely revised Clean Air Act was proposed that responded to criticisms of the earlier statute. The powers of the federal government in matters of regulation for clean air were drastically increased through four main measures: uniform National Ambient Air Quality Standards; limited balancing between health risks and economic costs; rigid deadlines; and emission standards for certain sources and pollutants. An attainment deadline of 1975 or 1977 was set for primary standards. State implementation plans were due in 1972; they had to include enforceable emissions limits and schedules for meeting them. EPA had to either approve these or set alternative standards. Emission limits were now enforceable both by the state and the federal government, with authorisation for criminal penalties and injunctions. The Act provided for citizen suits in case of agency failure and liberalized the provisions for judicial review.

Intermediate legal decisions, followed by the Clean Air Act Amendments of 1977, further strengthened the powers of the federal government. The precautionary nature of standards was affirmed, resulting in more discretion for EPA to act when facing uncertainty. Special provisions for problem sources were added to the implementation plans. In order to facilitate enforcement even further, civil penalties and non-compliance penalties were added, including bans on construction and other sanctions for failing to attain air quality standards. The District Columbia Court of Appeals was identified as the appropriate Circuit court for regulations of national applicability.14 Furthermore, the amendments provided a legal basis for review of the risk assessment of criteria pollutants in the so-called ‘criteria document’ by the Clean Air Scientific Advisory Committee, a sub-committee of the Scientific Advisory Board (SAB) to US EPA. A periodic review (every five years) of the standards set under the Clean Air Act was also foreseen.

In 1990, under the Bush administration, Congress substantially revised the Clean Air Act for the second time, adding among other things further measures to facilitate implementation and enforcement. The previous act required that all areas of the country come into compliance with ozone standards as ‘expeditiously as practicable, but no later than 31 December 1987.’ Many areas had not attained the standard by that date. The response to the continued ozone problem was a new enforcement scheme with requirements for different classifications of non-attainment areas (marginal, moderate, serious, severe), mandatory reporting and control measures, and an attainment date for each class of non-attainment area.16

The 1990 amendments also expanded the remit of CASAC to advise the EPA about ‘any adverse public health, welfare, social, economic, or energy effects which may result from varying strategies of attainment of such measures,’ Art. 109 (d)(2). Again, socio-economic considerations are mentioned only in the context of strategies for implementation, not in the standard-setting exercise.17 To further facilitate implementation, the Clean Air Act Advisory

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17 American Trucking Associations v. Whitman. 175 F.3d 1027 and 195 F.3d 4. (Supreme Court 2001)
Committee was established in November 1990, in addition to CASAC, to provide advice and counsel to the Assistant Administrator, Office of Air and Radiation, on EPA’s proposed rule-making, specifically including advice on potential health, environmental and economic effects associated with the implementation of the 1990 CAA amendments.

Increased harmonisation, both in ambient air quality standards and in research, reporting, and monitoring of implementation was immensely facilitated through these developments, which enhanced levels of federal involvement and coordination between different levels of government.

We turn now to the standard-setting process for national ozone standards in the period between 1970-2000. Changes in procedures for soliciting expert advice are analysed. The grounds for challenge to the standards and institutional responses to the challenges are described using the conceptual framework outlined in section 1.3.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1965</td>
<td>Air Quality Act: National Air Pollution Control Administration charged with helping States to devise pollution control programmes.</td>
</tr>
<tr>
<td>1967</td>
<td>EPA promulgates ozone standard of 0.08 ppm.</td>
</tr>
<tr>
<td>1971</td>
<td>Informal creation of the Science Advisory Board (SAB) by EPA. Congress asks NAS to study standard. Standard confirmed, scientific basis criticised.</td>
</tr>
<tr>
<td>1971</td>
<td>Interagency Task Force on motor vehicle air pollution announces 0.08 ppm ozone standard unattainable, EPA announces review of standard.</td>
</tr>
<tr>
<td>1971</td>
<td>Clean Air Act amendments: Mandates 5 year review of NAAQS; provides legal basis for SAB and establishes CASAC as ‘independent source of review and advice.’ Creation of Regulatory Review and Analysis Group (RARG) by President Carter to assess inflationary cost of regulation. Office of Research and Development (ORD) starts criteria document. EPA requests SAB involvement in drafting criteria document. Creation of a parallel advisory panel chaired by Carl Shy on health effects: draft report on health effects available. Subsequent availability of criteria document, review by SAB.</td>
</tr>
<tr>
<td>1971</td>
<td>Creation of panel on quantitative risk assessment of ozone; Public hearing (30 January) for broader feedback on criteria document. EPA proposes revised standard of 0.10 ppm (June) 4 public hearings on the ozone standard (July &amp; August) - Environmental Defense Fund maintains no reason to relax 0.08 ppm rule, - American Lung Association states effects demonstrated at 0.08 ppm, - Virginia State Air Pollution Board suggests 0.12 ppm, - American Petroleum Industry suggests 0.23 ppm. RARG report recommends higher standard, first based on cost, then on science Publication of Shy Panel report.</td>
</tr>
<tr>
<td>1971</td>
<td>Douglas Costle held a press conference to announce a revised standard for ozone of 0.12 ppm (January)</td>
</tr>
<tr>
<td>1971</td>
<td><em>API v. Costle</em>, D. C. Circuit Court of Appeals Upholds revision of ozone standard, but rules that establishment of the Shy Panel was in violation of Federal Advisory Committee Act.</td>
</tr>
<tr>
<td>1972</td>
<td>Supreme Court declines to hear appeal from <em>API v. Costle</em>.</td>
</tr>
<tr>
<td>1979</td>
<td>Clean Air Act Amendments to provide additional means of enforcement and a new Clean Air Act Advisory Committee (CAAAC) with broad participation to provide recommendations on scientific and socio-economic considerations for devising implementation plans.</td>
</tr>
<tr>
<td>1984</td>
<td>HEI starts peer review of health impact studies of ozone that are drawn upon in the criteria document.</td>
</tr>
</tbody>
</table>
President Clinton announces the decision on new air quality standards, including ozone and particulate matter (June).

EPA announces new standard for:
- ozone of 0.12 ppm with a one-hour averaging time and 0.08 ppm with a one-hour averaging time
- fine particulate matter at 65 µg/m³ averaged over 24 hours

American Trucking Association v. EPA, D.C. Circuit Court of Appeals filed accusing EPA of overstepping the non-delegation doctrine in setting ozone and particulate matter standards.

Shelby Amendment to Circular A-110 of Omnibus Appropriations bill to request public availability of all studies funded by the federal government.

US Court of Appeals for D.C. Circuit blocks the implementation of the 8-hour standard for ozone and all standards for fine particulate matter on the basis that the agency exceeded its discretion (May)

EPA files petition to rehear key aspects of D.C. Circuit case (June)

Supreme Court Decision on American Trucking v. Whitman endorsing EPA’s right to set standards

2.2.2. Technical Peer Review and Scientific Expert Analysis

The role of scientific expert committees and the extent to which data were peer reviewed will be investigated in the procedures used to establish the primary standards for ozone in 1971, 1979 and 1997 and the standards for fine particulate matter in 1997.

US EPA set a primary standard for ozone in 1971 at 0.08 ppm with a one-hour averaging time. This standard was set on the basis of work by US EPA staff, who conducted the research, performed the risk assessment, and took the decision. There was thus no external technical review of data, analysis or recommendations for decision.

In 1974 Congress asked NAS to study the standard. The NAS panel confirmed the standard, but criticised the scientific basis (concluding there was no compelling reason for change, although the technical basis was inadequate and scientific evidence limited). The panel underscored the need for more research and called upon EPA for long-term reassessment of all its standards, but the NRC also confirmed that any threshold concept likely has no purely scientific basis for pollutants for which there is no clear no effect level. In 1976 Interagency Task Force on motor vehicle air pollution declared the 0.08 ppm (157 µg/m³) ozone standard to be unattainable.

In response to this challenge, and to broader changes affecting the legitimacy of regulatory decisions through implementation of the Federal Advisory Committee Act and the Freedom of Information Act, EPA announced a review of the standard. Douglas Costle, then administrator of the EPA, intended to consolidate the agency’s authority by improving the scientific basis of decisions and the level of scientific endorsement of the standard through broader ‘peer review’ or independent expert review.18

EPA informally established the Scientific Advisory Board (SAB) in 1974, for peer review of the technical analysis of the data and proposed standards. A legal base for SAB was subsequently established by statute in the 1978 Environmental Research, Development, and Authorization Act. SAB membership was specified as a ‘body of independent scientists and engineers of sufficient size and diversity to […] assess scientific and technical issues.’ The 1977 law requires appointment of an independent scientific review committee, the Clean Air Scientific Advisory Committee (CASAC), to review criteria and standards and recommend new standards or revision of existing criteria and standards, as appropriate. CASAC is administratively organised as a standing committee of the Science Advisory Board.

In January 1979 Costle announced a revised standard of 0.12 ppm (235 µg/m$^3$). Relevant scientific research was conducted by the EPA Office for Research and Development (ORD) and the standard was recommended by the Office of Air Quality Planning and Standards (OAQPS). Based largely on the resulting data, an air quality criteria document for ozone was developed, henceforth the ‘criteria document.’ The criteria document was reviewed by CASAC. Additionally Costle appointed an ad hoc expert panel on health effects of photochemical oxidants, called the Shy panel after its chair, which produced a report on the health effects of ozone.

The standard was challenged by the media$^{19}$ and through the courts. A lawsuit was filed by the American Petroleum Institute (API). The case was decided in the D.C. Circuit Court of Appeals, which sustained EPA’s standard in spite of noting serious deficiencies in EPA’s interactions with SAB.$^{20}$ EPA had only partially fulfilled its statutory obligations as it had consulted CASAC only on the criteria document, but not on the final standards. The Court did, however, defer to EPA in setting the final standard, based on a Supreme Court judgment that courts should not overturn agency decisions merely on procedural grounds.

This case illustrates the importance of procedural regularity in the adversarial environment in the US, and the degrees of freedom that are permitted in consultations with expert panels. While US courts have become increasingly reluctant to overrule discretionary judgments of agencies, the ozone proceedings of the 1970s show that agencies can suffer harm to their credibility and reputation if they are seen as manipulating expert opinion to suit their short-term needs.$^{21}$ In the 1980s the Scientific Advisory Board became a mini-arena for conflicts between environmentalists pushing for broader membership and others defending a narrower concept of scientific expertise. The appointment procedure for experts on SAB and CASAC was recognised to be of political importance and was therefore rendered more official through the announcement of openings in the Federal Register generally indicating the desired kinds of expertise. Opening up the appointment process helped to enhance the SAB’s credibility.

A further review of the ozone air quality criteria and standards was completed in March 1993, resulting in a decision not to revise the then existing standards.

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In 1997 EPA announced a revised standards for six criteria pollutants, including a new primary standard for ozone of 0.12 ppm with a one-hour averaging time and 0.08 ppm with an eight-hour averaging time. Together with the announcement of the revised standard for ozone, the EPA defined a new category of pollutant - fine particulate matter of a diameter less than 2.5 microns - the ambient air quality standard for which was set at 65 µg/m$^3$ averaged over 24 hours.

For these decisions, CASAC reviewed both the criteria document that summarised pertinent scientific information and the staff document that evaluates policy implications and presents staff recommendations for options. CASAC held public meetings to discuss both the criteria and the staff documents that described the basis for the decisions on standards for ozone and particulate matter; public comments were documented and considered.

Whereas in the 1980’s most controversies on clean air standards related to the establishment of ozone standards, in the 1990’s the focus of the debate shifted to standards on fine particulate matter. This decision was heavily disputed for lack of conclusive data and for lack of access by parties to primary data on health effects. Resulting litigation had to be resolved at the level of the Supreme Court.

Of the three lines of evidence for potential human health effects of air pollutants – short-term experimental studies of the health impacts of controlled exposure, long-term epidemiological studies, and studies of mechanisms for potential toxicological effects – only one played a role for particulates. Limited epidemiological data were available from two sources: the so-called Six Cities Study of the Harvard School of Public Health$^{22}$ and a study by the American Cancer Society,$^{23}$ in which higher ambient sulphate levels were associated with increased mortality. Following the proposed decision in 1997, both studies came under intense scrutiny by Congress, industry, and the scientific community and others interested in air regulation. Significantly, several parties tried to access the primary data for the Six Cities Study, which had not been published, and they soon received assistance from an unexpected quarter.

Senator Richard Shelby (Republican-Alabama) inserted an amendment into the Omnibus Appropriations Bill, requesting the OMB to amend circular A-110, which sets standards of consistency and uniformity in the administration of grants and agreements with public and non-profit institutions. The ‘Shelby amendment’ required quite simply that all data produced through federal funding should be made available through procedures established under the Freedom of Information Act. The OMB filed an implementing provision for public comment in the Federal Register of February 1999. This proposal narrowed the amendment’s original scope to “research findings used by the federal government in developing policy or rules.”$^{24}$

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24 The circular A-110 now reads that “ _53 (f) _Unless required by statute, no Federal awarding agency shall place restrictions on recipients that limit public access to the records that are pertinent to an award, except when it can be demonstrated that such record would have been exempted from disclosure under the FOIA if the records had
community feared nevertheless that sensitive research data could be compromised and that the Freedom of Information Act was not the correct mechanism for release. The Shelby requirement was perceived as potentially hindering public/private cooperation, fostering misinterpretation of research, and posing additional administrative and financial burdens on the conduct of research. Further, it was feared that data accessible to the public would not fulfil the ‘novelty criterion’ required for publication in leading scientific journals. In the case of epidemiological studies, many researchers believe that the privacy of individuals who participated in the study should be protected; the disclosure rule triggered a wider debate on ‘the right to know’ as opposed to the right to privacy.

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<thead>
<tr>
<th>Committee</th>
<th>Acronym</th>
<th>Function</th>
<th>Mandate</th>
<th>Institutionalisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Advisory Body</td>
<td>SAB</td>
<td>Scientific Advice to EPA</td>
<td>Clean Air Act</td>
<td>1977/ Permanent</td>
</tr>
<tr>
<td>Clean Air Scientific Advisory Committee</td>
<td>CASAC</td>
<td>Scientific Advice on Air Quality Standards</td>
<td>Clean Air Act</td>
<td>1977/ Permanent</td>
</tr>
<tr>
<td>Ad hoc expert panel on ozone</td>
<td>Shy panel (name of chair)</td>
<td>Scientific advice on 1979 standards</td>
<td>EPA decision</td>
<td>1977/ Ad Hoc</td>
</tr>
<tr>
<td>Health Effects Institute</td>
<td>HEI</td>
<td>Peer Review Research Strategy</td>
<td>EPA/Private charter Funded by EPA and industry (50/50)</td>
<td>1980/ Permanent</td>
</tr>
<tr>
<td>Clean Air Act Advisory Committee/subcommittee on ozone, particulate matter</td>
<td>CAAAC</td>
<td>Advice on Implementation Plan</td>
<td>Clean Air Act</td>
<td>1990/1995/ Permanent</td>
</tr>
</tbody>
</table>

The EPA standard was challenged in court by the American Trucking Association. An initial decision against EPA by the D. C. Circuit Court of Appeals was overturned by the Supreme

belonged to the Federal Awarding Agency.” The narrower interpretation of the OMB to restrict access to data used for regulatory decision-making is still being contested.
Court, which unanimously ruled in February 2001 that EPA had acted within its discretion in issuing the fine particulates standard.\textsuperscript{25}

Congress since then has again intervened in the data gathering process by requesting a National Academy of Sciences to both study in general terms to help ‘strengthen science at US EPA’ and, more specifically, to ‘help determine the research priorities on particulate matter.’ As the Shelby amendment was not retroactive, and challenges to the study on fine particulate matter continued, Congress also appropriated more funds than EPA had requested (US $10 million) for the agency’s research on the health effects of particulate matter and assigned part of the amount for involvement by the Health Effects Institute (HEI).

HEI was established in 1980 with joint funding from EPA and the automobile industry to build a neutral, reliable scientific knowledge base for use in regulating air pollution. HEI was seen as a new model for a public-private partnership to secure the legitimacy of regulatory science by taking important elements of research funding, design, and interpretation out of the adversarial regulatory process. The HEI has a Board of Directors of independent scientists who appoint two expert committees and manage the budget of the institute.\textsuperscript{26} The two committees are the Health Research Committee, which sets research strategies, writes calls for proposals and selects applicants, and the Health Review Committee, whose objectives include the critical and impartial evaluation of HEI-funded research, ensuring the credibility of research findings, placing results into scientific and regulatory context, and identification of future research opportunities.\textsuperscript{27} Transparency and communication are major purposes of HEI involvement; thus results of all HEI-funded research, once peer reviewed, are available to the public, and workshops are often organised to disseminate and discuss results.

HEI played an important role in the reanalysis of particulate matter epidemiology. In 1997, to address the public controversy, Harvard University and the American Cancer Society requested that HEI organise an independent reanalysis of the data from these studies. Both institutions agreed to provide access to their data to a team of analysts selected by HEI through a competitive process.\textsuperscript{28} HEI’s Health Research Committee selected a reanalysis team led by an academic scientist. The first step in the reanalysis was a public meeting to raise concerns about the existing data from as broad a range of interested parties as possible and to frame questions to the reanalysis team so as to capture and address the broadest range of concerns. An Advisory Board

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{26} Members of the Board shall not be employed or receive regular compensation from government agencies working on the protection of the environment or the regulation of motor vehicles, or a corporation deriving profits from motor vehicles, or have a demonstrated lack of objectivity relating to health effects of air pollution. Charter of the Health Effects Institute.
\item \textsuperscript{27} Members of the research committees shall not be employed by above specified government agencies or corporations, or have a lack of objectivity. Members can only serve on one Committee or the Board.
\item \textsuperscript{28} HEI. 2000. Special Report. Reanalysis of the six cities study and the American Cancer Society study of particulate air pollution and mortality. www.healtheffects.org
\end{itemize}
\end{footnotesize}
of knowledgeable scientists and stakeholders was also set up to provide additional advice to the expert panel. The final results of the reanalysis team were peer reviewed by an independent specialist panel of the HEI Review Committee, again chaired by an academic. Reanalysis included quality assurance by replication of a sample of the original data and by validation of the original numerical results. Previous results and interpretations of the data were confirmed. The robustness of the original results was also tested using alternative risk models and analytic approaches.

Figure 1. HEI Process for Reanalysis of Data on Health Effects of Particulate Matter

Over time, then, there were three noteworthy developments in the process of soliciting expert advice on US air pollution standards. 

First, a fairly rigid institutional framework and procedures evolved for soliciting expert advice. Failure to respect these procedures led to legal and political challenges. These disputes showed that process is considered at least as important for the credibility and legitimacy of scientific advice in the US as are the content of advice and the nature of expertise. Highly specified procedures, however, may excessively curtail an agency’s discretion to consult specific expertise on an ad hoc basis or on short notice.

Second, CASAC’s remit increased from considering the science and the risk assessment to reviewing recommendations for decision options. The terms of reference of CASAC hence were broader than is consistent with a strict separation of risk assessment and risk management. The committee’s remit acknowledged the close intertwining of science and judgement in risk assessment.

Third, public scrutiny focused not only on the decision-making process, but also on
the construction of the information base itself. The Shelby amendment demanded transparency of the data used for policy purposes, and Congress provided a budget for HEI to become involved in an additional reanalysis, peer review, and broader dissemination of the disputed data that was the basis for the controversial regulatory decision.

2.2.3. Broader Public Review and Participation

Mechanisms for participation and review potentially play a major role in the framing and perception of uncertainties associated with regulation and the legitimacy of regulatory outcomes. In particular, the establishment of advisory committees, their terms of reference and their membership shape the questions they ask, their styles of analysis, and the attention they pay to particular types of solutions in policy-making. For instance, a focus on technical uncertainties may override the extent to which social uncertainties are taken into account. To secure more robust forms of knowledge for regulation, new processes may be required to guard against such avoidable biases. This section explores whether institutional changes in response to controversy affected the breadth of participation in decision-making.29

Basic provisions of the Clean Air Act concerning public participation and review require that notices of proposed rulemaking be published in the Federal Register. Not only are all assumptions and technical justifications for the proposed rules disclosed and open to public comment, but also all significant criticism has to be addressed by the agency. These provisions for more widespread citizen participation have been generously implemented by EPA in order to help broaden the debate within the scientific community and to prevent EPA from making mistakes. The D.C. Circuit Court of appeals enforced these provisions in 1973.30

For the revision of the ozone standards in 1979, the CASAC review process was complemented by increased participation through four public hearings convened by the EPA. Organisations invited to voice their opinions included the Environmental Defense Fund, the American Lung Association, the Virginia State Air Pollution Board and the American Petroleum Industry. Furthermore, the White House under Presidents Nixon and Ford added review processes for EPA rulemaking by the Office for Management and Budget (OMB). President Carter established the Regulatory Analysis Review Group (RARG) to conduct cost benefit analyses of EPA rule-making. President Reagan reinstated and reinforced the OMB’s role in this process.

To further facilitate implementation, the Clean Air Act Advisory Committee was established in November 1990, in addition to CASAC, to provide advice and counsel to the Assistant Administrator, Office of Air and Radiation, on the technical and policy content of proposed EPA rule-making, including specifically advice on the potential health, environmental and economic effects associated with the implementation of the CAA amendments of 1990. A subcommittee on ozone, particulate matter, and regional haze was created in September 1995, as a mechanism for obtaining advice and recommendations on proposed regulations from a balanced group of persons with a variety of perspectives and professional qualifications. The subcommittee is

30 Portland Cement Assoc. v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973)
composed of members representing state and local agencies, Native American tribes, business, industry and environmental groups, other federal agencies, and academic/scientific institutions. Meetings of advisory committees and subcommittees are open to the public and announced in the Federal Register 15 days prior to the meeting. Any member of the public may submit written statements to the committee and speak at committee meetings.31

It should be noted, however, that the setting of NAAQS at the federal level is based by law exclusively on scientific facts and information pertaining to public health. No additional factors, such as economic cost considerations, should be taken into account. The Supreme Court in American Trucking Association v. EPA has recently confirmed this interpretation of the Clean Air Act. Agency advisory committees should, however, provide advice to state and local governments on socio-economic factors to design cost-effective, flexible and least burdensome implementation plans, with an appropriate mixture of national, regional and local measures that are market-based and contain some positive incentives.

Unprecedented steps were taken to ensure the broadest possible public participation for setting the final NAAQS for ozone in 1997. The EPA established a national toll-free telephone hotline and special Internet and e-mail systems to facilitate public comment on the proposed revisions. The criteria document, the staff paper, and other related technical documents could be accessed via the Internet. Federal and regional EPA offices also conducted a series of public hearings across the country to provide direct opportunities for public comment and to disseminate information on the decision. As evidence of the effectiveness of this public consultation, EPA announces at its web site that over 14,000 calls and 4,000 e-mail messages were received, over 400 citizens and organisations testified in public hearings, and over 50,000 written opinions were received.

In conclusion, public participation in scientific meetings can not only broaden the questions considered by experts but also convey a more immediate sense of public accountability. Consultation to the extent practiced by EPA for the 1997 rule, however, is very resource intensive and may not always be warranted. Moreover, one drawback of stringent rules and requirements for inclusiveness and participation is that such rules, including FACA, may be frivolously used to undermine the proceedings and conclusions of advisory committees by challenging a committee for insubstantial or alleged procedural errors, such as the ‘lack of balance of committee membership’.

2.2.4. Normative Analysis and Reframing

The legislative process offers perhaps the most formally democratic, but cumbersome and uncertain (because subject to interest group pressure and political bargaining), approach to normative reframing. Examples in the case of the CAA include the institutionalisation of a periodic review of decisions, as happened in the 1977 CAA amendments, and the substitution of technology-based rather than risk-based standard-setting for toxic air pollutants, as occurred in the 1990 CAA amendments.

Discussions within the broader Clean Air Act Advisory Committee, which has participation of NGOs, state representatives and other stakeholders, although not officially drawn upon for standard-setting, are likely to be another avenue by which broader normative concerns are documented and can be unofficially considered in a subsequent review and in drafts of both the criteria document and the staff document.

HEI started its reanalysis of the contested epidemiological studies of health effects related to particulate matter by holding a public workshop with broad participation to generate questions about the study results. A summary of workshop comments provided the starting point for addressing the range of normative concerns on this issue.

Apart from these explicit or ad hoc processes, there are no administrative routine practices that allow the framing and re-framing over time of normative questions concerning the basic goals and instruments of air pollution control. Indeed, arguably, the courts act as a brake against radical reformulations by holding agency action to the perceived intent of the legislature, even when relevant provisions may have been enacted under significantly different social and scientific conditions a generation or so ago.

### 2.2.5. Institutional Accountability

For US regulatory decisions, the main mechanism by which the public challenges state decisions is the courts. The CAA of 1970 authorised three types of suits: challenges to EPA rules and regulations; citizens seeking performance of non-discretionary duties by EPA; and enforcement suits against polluters. Nationally applicable issues must be brought to the District of Columbia Circuit Court. Challengers do not need to be adversely affected by agency action. The citizen suit provisions were seen as a tool for pushing EPA to be more vigorous in its enforcement actions against polluters.

Judicial review, according to one early analyst of the CAA, had an impact on policy implementation, leading to more stringent standards than was strictly required by law. Generally, the court decisions of the 1970s allowed EPA to relax the standards of scientific proof, thereby favouring more a precautionary than a risk-based approach to regulation (see for example *Ethyl Corp v. EPA*). The courts also reinforced the view that costs were not to be taken into account in setting primary NAAQS.

In cases not related to ozone, courts played a role in settling procedural rather than scientific controversy. To facilitate agency action and increase public participation, the courts have required EPA to adopt rule-making procedures more elaborate than those required by APA. In *Kennecott Copper Corp. v. EPA* and *Portland Cement Association v. Ruckelshaus*, a secondary

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33 *Ethyl Corp. v. EPA*, 541 F.2d I (D.C. Cir. 1976)
standard for sulphur dioxide and a new source performance standard were, respectively, invalidated, because Clean Air Act provisions on public participation and review that were more elaborate than the APA had not been respected by EPA. More recently, in the case brought against EPA by American Trucking Association, the EPA was accused of misleadingly using science as the sole justification for decisions that in fact were based on additional criteria of feasibility and cost. Opponents of the ozone and particulates standard further argued that there are no coherent principles set out in the CAA to make judgements under uncertainty. However, the Supreme Court unanimously upheld the principle that courts should defer to agencies in the interpretation of ambiguous statutes and ambiguous science.

The Supreme Court ruling of 27 February 2001 addressed four questions:

1. Does the Clean Air Act delegate legislative power to the EPA administrator in an unconstitutional manner?
2. May the administrator consider costs in implementing an NAAQS?
3. Does the Court of Appeals have jurisdiction to review EPA's interpretation of the CAA with respect to implementing the revised ozone standard?
4. If so, was EPA's interpretation permissible?

In its judgment, the Court essentially upheld the constitutionality of the CAA, and therewith also EPA’s discretionary right to set health-based standards under conditions of pronounced scientific uncertainty.

Additional mechanisms for challenging agency action include the Congress, which as we have seen has massively intervened in EPA's strategy on research, review, and data collection. Congress can conduct hearings on EPA actions and has control over the budget, while the White House has control over political appointments to the EPA.

2.3. Ambient Air Quality Standards under the EU Air Quality Framework Directive

In contrast to the US case, policy-making on clean air in the EU has always been closely, but informally, intertwined with international efforts in the field, such as the Convention on Long-Range Transboundary Air Pollution (LRTAP) and WHO activities on the definition of air quality standards. LRTAP is an intergovernmental forum, in which the EU Member States participate as full sovereign countries in the context of international law. Environmental policy-making in the European Community by contrast involves a pooling of sovereignty, with many decisions being taken by qualified majority vote following procedures as laid down in EC law. Expert deliberations to establish the scientific basis and guidelines for ambient air quality standards are conducted under the auspices of WHO.

Of the three European institutions involved in the legislative decision-making to improve ambient air quality in Europe, the European Commission draws most extensively and broadly on expert advice for decision-making from ‘independent scientists,’ Member State representatives, and stakeholders. The European Council Working Group on the Environment advises COREPER, the Committee of Permanent Representatives to the Council, which in turn prepares files for decisions in the meeting of the Council of Ministers. The Working Group is made up of the environmental attaches from the permanent representations of the Member States, who
sometimes bring experts to meetings but usually act based on instructions from the respective Member State governments. The Parliament also has an Environmental Committee composed of Members of the European Parliament.

This section focuses on expert advice solicited by the European Commission to bring forward proposals for a new ‘Daughter Directive’ on ozone that is being drafted under the Air Quality Framework Directive. The first EU-wide standard on ozone was included in the 1992 Council Directive 92/72/EEC on air pollution by ozone, which came into force in March 1994. The Directive established procedures for harmonised monitoring of ozone concentrations, exchange of information, communication with and alerting of populations regarding ozone, and optimising action needed to reduce ozone formation. The ozone standard in the Directive and emission reduction targets for ozone precursors were set in accordance with the WHO guidelines, as had been specified in the Fifth Environmental Action Programme of 1992.\textsuperscript{35} The Directive contained no provisions for consultation with experts.

The 1996 Air Quality Framework Directive requested the establishment of a co-ordinated framework on ambient air quality that consists of individual Daughter Directives for each of the major categories of air pollutants. The Daughter Directive on ozone, drafted by the Ad Hoc Working Group on ozone is currently in the conciliation procedure between Council and Parliament. We will use the conceptual framework outlined above in section 1.2 to analyse the use of expert advice in drafting the Daughter Directive on Ozone.

\subsection*{2.2.1. Technical Review and Expert Analysis}

Three levels of expert advice were drawn upon in setting the ozone standard for the Daughter Directive on Ozone. The Framework Directive specifies that guidelines on ambient air quality established by WHO are to be taken as the starting point for the development of EU standards. The European Commission Ad Hoc Working Group on Ozone uses the WHO guidelines and any additional relevant scientific information, consults the Scientific Committee on Toxicology, Ecotoxicology and the Environment (SCTEE) on specific scientific questions before sending the draft Daughter Directive that includes a proposed standard for review at the political level of the European Commission, by Council and by Parliament.

The WHO expert group on ambient air quality establishes guidelines on threshold values for the major air pollutants, including ozone. The process is managed by the WHO’s European Centre for Environment and Health in close cooperation with the International Programme on Chemical Safety and the European Commission. The deliberations on guidance levels for ozone under the auspices of WHO seem to be largely based on published and peer-reviewed data on potential health effects and additional data from monitoring ambient ozone levels across Europe and on integrated assessment modelling conducted by International Institute for Applied Systems Analysis (IIASA) and funded

by the Commission. The US EPA criteria document is apparently also an important information source for the setting of WHO guidelines. Based on this information the WHO determined that acute effects on public health are likely to be small at ozone levels of 120 µg/m³ in ambient air for a maximum period of 8 hours/day. The detailed analysis of decision-making at the international level and its implications for EU and US decision-making are beyond the scope of this report.

To obtain advice for the implementation of the Air Quality Framework Directive, the Commission spontaneously and informally created the Ambient Quality Steering Group, which includes expert representatives of all Member States and stakeholders. The Ambient Quality Steering Group in turn informally appointed Working Groups to draft the Daughter Directives on the main categories of pollutants. The Ad Hoc Working Group on Ozone, which consists of expert representatives from Member States and stakeholders, draws up the proposal for the EU ozone standard. The Working Group, like the Steering Group, is funded and overseen by the European Commission Directorate General on the Environment. National representatives usually chair the Working Groups. Not all Member States are represented. Participants are volunteers and include UN/ECE, industry associations and environmental NGO’s including the European Environmental Buero, the Environment Network, and Acid Rain, a Swedish group. The Working Group used the WHO standard as a basis and subsequently looked at supplemental evidence to produce a position paper on ozone, which, similarly to the US EPA staff document, lays out the reasoning behind the proposed interim target values and alert threshold levels for ozone. Only health effects and environmental impacts are considered in this position paper.

The Directorate for Consumer Protection requested an ad hoc review of the position paper on ozone by the SCTEE. The terms of reference for the SCTEE, defined by DG Environment, included very specific questions about the underlying science, ranging from whether clear no-effect levels exist for ozone to whether the Committee agreed with the proposed critical level, longer-term objectives, interim values and information and alert thresholds. The Committee was also asked whether it agreed with the ranking of effects based on uncertainty and relevance in the cost-benefit analysis. Interestingly, the minutes of the SCTEE meeting on tropospheric ozone refer to a discussion on “the issue of the boundaries of science and management” in the context of the terms of reference given by DG Environment. Judging from the minutes, questions were raised as to whether there is a scientific basis for distinguishing between limit values and alert thresholds, which represent two different risk management measures whose values are based on the same data. The SCTEE confirmed the standards that had been proposed by the Working Group.

Subsequently the Working Group assessed whether the determined limit value is achievable when factoring in socio-economic costs. Based on these considerations the draft Directive on Ozone proposed an interim target value of 120 µg/m³, averaged over a period of eight hours, which corresponds to the WHO guideline.
Interestingly, the question of the need for additional peer review of data used as a base for decision-making was raised at Member State level, when the French National Institute for Public Health Surveillance, the Institut de Veille Sanitaire (InVS), asked the US-based HEI in 1999 to carry out an independent reassessment of their recent epidemiological study in 9 French cities. This was in response to questions about the study by some French scientists and other critics. HEI began reanalysis of the data but the review had to be interrupted because of allegations of budget mismanagement and financial problems in the InVS.

Criticisms of the standard setting process by industry, who feel the values are too stringent, mainly relate to the closed nature of the process for the establishment of the WHO guidelines, as WHO expert panels decide on guidelines *in camera*, with little if any provision for transparency and participation.\(^36\)

### 2.3.2. Broader Public Review and Participation

Since the implementation of the 1992 Council Directive 92/72/EEC on Air Pollution by Ozone, which contained no provisions for expert advice at EU level, there has been a definite trend toward broadening the definition of expertise, and hence participation in the decision-making process, first, through the creation of ad hoc advisory structures to facilitate the implementation of the Air Quality Framework Directive, and subsequently through the newly proposed multi-level advisory system of the Clean Air for Europe Programme.

As described above, in order to obtain advice on the implementation of the Air Quality Framework Directive, DG Environment informally appointed the Ambient Quality Steering Group; there is no legal basis for this body. The Steering Group is open to expert representatives of all Member States and stakeholders. Invitations to meetings are sent to a list of recipients initially established by recommendations from Permanent Representations and industry and other stakeholder groups – an informal process.

Review by the Council and Parliamentary groups on the environment can also be seen as part of a broader, political review process. The draft Directive on Ozone proposes an interim target value of 120 $\mu g/m^3$, averaged over a period of eight hours. The Member States in Council were mainly concerned about the feasibility of implementation, but did not criticise the value *per se*, or its scientific basis. Instead, they proposed to change the maximum number of days of exceedence that are specified in the Directive or to take the higher limit value only as a target value. Parliament, however, took the moral high-ground of environmental protection; hence, no agreement had been obtained on this value between Council and Parliament at the time of writing this report.

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\(^36\) The authors can confirm this, as preliminary attempts to get information on WHO decision-making processes, mainly via the internet, but also in conversations with interviewees, failed.]
A reorganisation of structures for the implementation of the Air Quality Framework Directive has recently been proposed by DG Environment. The new programme on Clean Air for Europe (CAFE) proposes revised structures for solicitation of expert advice, for setting a strategy, and for developing individual standards for pollutants. Proposed elements of the CAFE programme include technical evaluation, policy recommendations, and defence of these in the political arena. There will be a (intra-Commission) group to coordinate between CAFE and other Directorates General involved in sectoral implementation of air pollution control measures. Decision-making on policy and standards will have broader participation; for example, European Parliamentarians will be invited to participate in the Steering Group. A periodic review of decisions is also foreseen.

CAFE has three proposed levels of expert advisory committees:

1. The Steering Group, with broad participation of Member State experts, stakeholders and, built on learning from the AQSG, Members of the European Parliament (MEPs). The Steering Group would give advice on strategy and would meet 2-3 times per year.

2. The Technical Analysis Group (TAG), with exclusive participation of leaders or representatives of projects at European or international level, that is, from intergovernmental organisations (the European Commission, WHO and UN/ECE). TAG would coordinate the technical analysis work.

3. Structural working groups would be formed around cross-cutting themes rather than individual pollutants, and ad hoc working groups would be convened for specific tasks and policy measures, with broader participation, including stakeholders who can provide significant technical contributions. The exact structure and remits of these bodies are still being discussed.

In this scheme, stakeholder involvement would be included at two levels: the level of strategy-setting by the steering group and the level of individual working groups. The CAFE proposal will be sent to Council and Parliament once the inter-service consultation process is complete.

2.3.3. Normative Analysis and Reframing

Social and political norms relating to environmental pollution and abatement policies have significantly changed in the EU over the last decade (see section 1.2.2. of this report), as environmental concerns, integrated approaches to sustainable development, improved management of natural resources, and precautionary approaches to risks have increasingly gained in importance. Environmental policy decisions have concomitantly been reframed through legislative changes, institutional changes in expert advisory structures and changes in fundamental policy documents.
Legislative changes relevant to ambient air quality standard-setting occurred both at the level of the Treaty on the EU and in secondary legislation, including the Air Quality Framework Directive. Changes in the structure and operation of expert advisory bodies that have been proposed as part of the programme on Clean Air for Europe, described in section 2.3.2. above, include provisions for both broader participation and periodic review of decisions, which will in turn facilitate continued normative analysis and reframing of policy, and hence add a degree of institutional reflexivity.

The overall policy-making process, and in particular discussions on the Environmental Action Programmes, in which the European Parliament, the Commission and Council are involved, also represent opportunities to reframe questions according to changing political and societal norms. Interestingly, the Sixth Environmental Action Programme not only gives priority to environmental policy concerns, but also to the need to improve processes for procuring expert advice for environmental standard-setting. In the context of air pollution, three models are being discussed within the Commission:

1. Leaving CAFE as proposed at present mainly in the hands of the Commission, with the majority of effort devoted to improving coordination between existing structures like WHO and UN/ECE and the Commission. This model is apparently mainly supported by middle-level Commission officials who consider it the most pragmatic. HEI was felt to have a useful function and a place around the CAFE table, but several Commission officials also felt that it should not play too dominant a role in Europe, as it is American-based.

2. An agency that serves the European Commission (the remit would have to be coordinated with that of the European Environmental Agency). Germany is among the proponents of this approach, which was considered in a draft of the Programme, but was removed from the final version.

3. An independent, HEI-like, joint government-industry -funded organization with a base in Europe. Proponents are mainly Commission-internal and external Anglo-Saxon members.

Consensus norms on environmental concerns at EU level may yet again experience a shift with the imminent accession of Eastern European countries. New geopolitical and cultural influences will contribute to shaping EU-level environmental policies. It is therefore likely that legislation and institutional structures will remain sufficiently flexible to address changing normative concerns, as will be required for politically workable decision-making at EU-level. Questions may however be raised as to whether mechanisms to systematically identify and address broader concerns are routinely required for the standard setting processes, or whether such resource and time intensive processes are only worthwhile in especially value-laden contexts or in times of intense controversy.

2.3.4. Institutional Accountability

In theory there are at least three ways for citizens to challenge the decisions of EU institutions or their implementation at Member State level (see also section 1.2.2.). Citizens can claim reparations from negligence of implementation of EU directives and regulations by Member States and can voice concerns on EC law and its implementation to the European Ombudsman.
In practice, however, these mechanisms are rarely used in regulatory proceedings, and the authors are not aware of any uses in the context of setting EU ambient air quality standards. Public accountability is mainly secured at the inter-institutional level, through negotiations between Council and Parliament, with the latter often acting as the voice for the Green lobby and other grassroots forces. Industry, by contrast, mainly resorts to lobbying at EU and Member State levels during the standard-setting process and experts its influence importantly through participation in the Air Quality Steering Group.

2.4. Conclusions on Expert Advice for Setting Ambient Air Quality Standards in the US and EU

In both the US and the EU increasingly formal legal and institutional structures have evolved to guide the solicitation of expert advice on ambient air quality standards.

Beginning with the implementation of the Clean Air Act in 1970, expert advice in the US has been drawn from a combination of institutionalised forms of expertise such as CASAC and more ad hoc consultations, for instance, with expert committees assembled by the NAS to address specific questions of policy relevance. Based on the recommendations of the 1983 Red Book on risk assessment in the federal government, expert committees are administratively distinct from decision-makers; they are not, however, institutionally separated, as the linking of expert advice and decision-making is considered essential for ensuring the relevance of the scientific assessment.

In response to the activism of the late 1960s and 1970s, the US instituted formal legal provisions for transparency and public participation, those of the Clean Air Act being particularly stringent. On one hand, the immediate exposure to the public gaze likely increases experts’ awareness of their accountability to the public, and the public’s perception of an open process may in turn enhance trust. On the other hand, the openness of processes does not necessarily democratise decisions, as those with means (often industry), will likely have more resources to participate than those without.

The grounds for challenges to standards, often initiated through the courts, have included both procedural matters and complaints about the scientific basis of decisions. Submitting science policy processes to adversarial dispute can usefully reveal the values at stake in regulation, but it can also create unhelpful deconstruction of scientific judgment. Formats that are least likely to bring a durable consensus are those that lead to confrontation between alternative polarized constructions of uncertain scientific data. Judicial review in addition to scientific review appears justified in cases where: the advisory body and agency differ on assessment of evidence; the agency acts contrary to recommendations of the peer review panel; or there is evidence of procedural impropriety of the peer review process. Courts at their most effective may serve to increase the political legitimacy of decisions through public airing and closure of competing positions on risk.37

It appears that closure of debates over regulatory science is now more frequently achieved through peer review than through judicial review in the US. Diverse scientific review mechanisms are used to reconcile different viewpoints, discuss new facts, and build consensus. At the same time, the scientific review process itself has become more contested and new demands for representation, transparency, and accountability have arisen both in the provision of review and in the production of data for policy-making. In response, measures were adopted to foster closer coordination between EPA and the scientific expert community, such as increasing use of NAS and the establishment of HEI for independent scientific peer review.

In the EU, at present expert committees for advice on ambient air standards, including ozone, are all formed or consulted on an ad hoc basis. There are no formal requirements for openness of meetings and public participation comparable to the requirements for openness and transparency under the Clean Air Act. Since 1997, more attention has been paid to transparency, as for instance minutes of expert meetings usually have to be published on the Internet. The latest proposal for regulatory decision-making on ambient air quality standards emphasises both the need for transparency and ‘controlled’ participation, which corresponds to an increased awareness of the need for balance and representation of stakeholders’ views in expert committees. The proposal diverges slightly from the mainstream EU policy on expert advisory structures in that the advisory system is likely to be institutionally integrated into the Directorate General Environment, which that has the legislative and administrative responsibilities for clean air, rather than adhering to the institutional separation of legislative and advisory capacities. The rapidly evolving and ever-changing institutional structure at the EU-level -- currently under pressure to adapt to a fundamentally altered (in particular, enlarged) social, political and geographical environment -- will likely be forced to be more responsive and flexible to changing normative concerns than the present US system.

The WHO Centre for Environment and Health will announce revised standards for ozone in 2002, the US EPA in 2003, the European Commission in 2004, and a review of the Long-Range Transboundary Air Pollution (LRTAP) protocol is also planned in the same time frame. All four bodies will increasingly draw on the same data for decision-making, because of the progressive globalisation of research, resulting from enhanced efforts between research groups to coordinate protocols and compare results across national borders. Drivers of the transnational connectivity of research on air pollution include the recognition that local contributions to air pollution can have global implications, as well as the increasing involvement of multinational industrial players that significantly contribute to air pollution through their products and processes (e.g. the car industry, with its worldwide manufacturing and marketing). Transnational convergence is also fostered by bodies that aim to coordinate research so as to recognise and address knowledge gaps relevant to policy-making, such as the European Framework Research Programmes and bodies such as HEI.

The EU and international standard-setting processes at WHO and LRTAP will be increasingly well co-ordinated, as plans for CAFE foresee closer co-operation between experts, in particular at the technical level. This was called for mainly to prevent waste of resources, as many EU experts are also implicated in international expert committees, and to add value to policy-making. At the political level, the EU will continue to put forward Community positions in
these international fora. The strategies of LRTAP and EU will therefore likely not always be aligned.

Interestingly, conclusions on standards by WHO and EU experts are fairly closely aligned, but the conclusions of the US EPA are markedly different, in spite of being based largely on the same data. The US EPA has a standard of 157 µg/m$^3$ measured over 8 hours and a standard of 235 µg/m$^3$ measured over one hour, whereas the draft proposal of the EU Framework Directive specifies a standard of 120 µg/m$^3$ measured over 8 hours. Moreover, the literature on setting ambient air quality standards under the US Clean Air Act, contrary to documents from European institutions, makes little mention of related efforts in the international arena, such as the 1979 LRTAP Convention and the WHO guidelines and standards for ozone and other criteria pollutants. This omission is striking in view of the increasingly interconnected global research arena.

The significant differences between the US and the WHO and EU standards result from socio-cultural and political economy factors that affect decision-making differently in the two world areas. This observation represents a direct challenge to the notion of science as an instrument that fosters a uniform approach to political action in a multi-level system. Closer comparison of the uses of expert advice and decision-making at the international, regional, and local levels – probing the epistemological and normative consequences of different advisory arrangements – is beyond the scope of this report, but would make for a rewarding project on the global governance of risk.

3. Case Study on Genetically Modified Crops

3.1. Background

The second case study focuses on the solicitation of expert advice in response to public concerns about genetically modified (GM) crops, using the conceptual framework outlined in section 1.3. An increasingly polarised and value-laden debate on the commercialisation of GM crops in the period 1997 - 2001 challenged governmental assessments of the health and environmental risks posed by this technology. These developments, however, produced contrasting approaches to maintaining expert credibility in the US and EU.

In both the US and the EU the basic standard for the environmental and food safety assessment of products derived from modern biotechnology is that of ‘substantial equivalence.’ According to this test, the novel product is compared to a closely related product that is accepted as being safe. The term ‘substantial equivalence’ was first coined by the Office of Device Evaluation (ODE) of US FDA in the context of the evaluation of new medical devices that have a comparable function to existing medical devices.

The approach of comparing a genetically modified crop to a non-modified ‘conventional’ counterpart largely defines the type of data included in risk assessment of GM crops and
considered by the experts. This assessment framework was initially defined through negotiations between industry, experts, and staff in US government agencies. It was subsequently discussed in international fora under the auspices of WHO and OECD and was adopted as the basis for international principles for the safety assessment of GM crops.\textsuperscript{38} An international scientific expert body set up by the World Health Organisation (WHO) translated the concept of ‘substantial equivalence’ into procedures for the safety assessment of GM crops.\textsuperscript{39} The international guidelines are constantly being adapted and refined in joint expert consultations under the auspices of United Nations Food and Agricultural Organisation (FAO) and the WHO, and by Working Groups and Task Forces of the Organisation for Economic Co-operation and Development (OECD).\textsuperscript{40} Participants in the international expert groups are usually government officials or academics appointed by Member States of the international organisations.

The assessment of substantial equivalence of GM crops to their conventional counterparts occurs in two steps. First, agronomic characteristics and the composition of the novel product and the traditional counterpart are compared to assess equivalence within the limits of natural variation. Second, the introduced change is examined to ensure that it is well characterised and poses no harm to human health and the environment. This process takes into consideration the donor organism and involves a molecular characterisation and safety assessment of the introduced proteins.

In all regulatory schemes for GM crops, it is the industrial applicant wishing to place a product on the market, who usually bears the burden of proof and provides all relevant data for the product’s safety evaluation.

\subsection*{3.2. The US Coordinated Framework on Biotechnology}

Regulation of biotechnological products occurs in the US under pre-existing regulatory legislation developed for similar classes of products produced through conventional technological means (e.g. foods, drugs, pesticides, and agricultural products). In 1985, the US Office of Science and Technology Policy (OSTP) elaborated the ‘Coordinated Framework for Regulation of Biotechnology,’\textsuperscript{41} which rationalized approaches under


several different laws. Based on these guidelines, science-based assessments of risks to human health and the environment are conducted by three principal regulatory agencies: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). These three agencies differ significantly in their approaches to soliciting expert advice, in accordance with their particular authorising statutes.

The USDA regulates the import, interstate movement, field trial release, and commercial release of genetically modified plants under the Federal Plant Pest Act and the Plant Quarantine Act, which are administered by the Animal and Plant Health Inspection Service (APHIS). Prior to approval for unrestricted release, as in commercialisation, the USDA/APHIS must determine that the genetically modified plant is not a plant pest. There are no explicit rules for soliciting expert advice on individual applications for releases of GM crops in the Federal Plant Pest Act. The basic data and the risk assessment are provided by the applicant, usually industrial companies, and are reviewed by agency staff. Staff scientists then draft a proposed final rule that is signed off by the head of APHIS. Publication of a final rule ensues after a period for public comment.

The EPA has regulatory oversight for all genetically modified plants that produce a plant pesticide. This authority derives from the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and plant-integrated pesticides are regulated according to the same procedures as other pesticides. EPA has provided guidance for data requirements to support registration and tolerance exemption under its 1994 proposed policy. The basic data and the risk assessment are provided by the applicant, usually industrial companies, and are reviewed by agency staff. SAP is not routinely consulted on individual applications to deregulate plant-integrated pesticides; ‘independent’ expert advice is sought only on the more difficult issues such as insect-resistance management. This is based on the FIFRA provision, that the EPA administrator should only seek advice from the Scientific Advisory Panel (SAP) for pesticides, if s/he decides that the end-use pesticide is not substantially similar to a registered pesticide, as mere amendments of the existing registration do not require further scientific review.

The FDA has authority over human food and animal feed safety and the wholesomeness of all plant products, including those produced via genetic modification, under the Federal Food Drug and Cosmetic (FD&C) Act. The FDA has concluded that food and feed derived from genetically modified plants pose no unique safety concerns and, therefore, that the food and feed products derived from these plants should be regulated no differently than comparable products derived from traditional plant breeding or any other genetic modification approach. Informal consultation between producers and FDA scientists is encouraged to “ensure that safety concerns are resolved.” Usually the consultation begins early in the product development stage, long before the product can reach market. Company scientists and other officials meet FDA scientists to describe the product and the agency provides advice on what tests would be appropriate to assess its

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safety. The threshold decision as to whether a product requires prior consultation is left with the manufacturer, although some checks are in place through FDA’s broad authority to initiate regulatory action if a product fails to meet the standards of the FD&C Act. FDA to date has consulted with industry on foods derived from 45 GM crops, which cover all GM-derived foods currently on the market.

Since the hereditary material DNA by itself is seen to have no inherent risks, a scientific review of consultations with agency staff is required only when, as stated in the Statement of Policy on Foods derived from New Plant Varieties, new expression products differ significantly in structure, function and composition from substances currently found in food. This voluntary consultation and review process was used, for instance, to make a determination on the NPTII protein present in several genetically modified crops, including the FLAVR-SAVR tomato, which confers resistance to an antibiotic and which was used as a marker to select transformed plant cells. In cases like this the Food Advisory Committee is implicated in the scientific review. This process has been criticised on the grounds that the regulated industry in effect has the ability to self-determine market entry decisions.

Following increased media coverage, particularly in Europe, on the safety and desirability of GM crops, the Clinton administration on 3 May 2000 announced initiatives for strengthening the science-based regulation of food and agricultural biotechnology, the transparency of the process, and consumer access to information. Overarching and agency-specific measures that were adopted are described in the following sections.

3.2.1. Technical Peer Review and Scientific Expert Analysis

The statutory provisions and agency traditions for the solicitation of expert advice are very different among the three agencies FDA, USDA and EPA. None of the agency consults independent experts on a case-by-case basis for regulatory decisions on individual products, rather, experts are usually consulted on critical issues that may be of relevance to a range of similar products.

At USDA, there is no routine expert review of applications to deregulate GM crops. APHIS staff scientists review the risk assessment data that is submitted by industry, and only consult experts on questions where they deem their own expertise is exceeded. There are no rules concerning when or how to solicit expert advice, except rules concerning remuneration. Expert consultations are more the exception than the rule, and often relate to specific questions on risks – as opposed to individual products. Experts were consulted on issues including virus resistant squash and cassava, and the use of viral coat proteins in GM crops. APHIS staff selects the experts for these consultations based on criteria of excellence and recommendations by peer scientists. There are not considered real ‘committees,’ hence the process is not subject to FACA.
In addition to such expert consultations, USDA has organized several workshops on salient issues. Independent scientists were given a budget to organize the workshop and were asked to identify the most pertinent questions in a risk assessment of a novel product concept. Examples of such USDA-funded workshops include a workshop on GM potatoes in Scotland and one on insect-protected corn in the US. The Head of APHIS determined topics for such workshops.

USDA’s responses to the controversies on GM crops included the announcement on 13 July 2000 of the formation of the Secretary’s Advisory Committee on Agricultural Biotechnology (ACAB). This body is composed of 38 individuals from government, academia, production agriculture, agri-business, ethics, and environmental and consumer groups. The committee will bring a broad range of perspectives to the complex challenges of biotechnology in the changing agricultural economy. The committee is subject to FACA. Decision-making occurs by consensus. Oral public comments may be excluded, but members of the public may always comment in writing. ACAB will advise the Secretary on issues concerning the impacts of agricultural biotechnology on farmers, consumers, growers and producers, and trade disputes.

EPA, like USDA, has no provisions for scientific expert review of staff recommendations on individual applications. Agency staff has, however, worked closely with the SAP to review particularly controversial issues, including insect resistance management and the potential allergenicity of the insecticidal CRY9C protein included in the Bt maize product Starlink from Aventis. SAP can select scientists to form sub-panels to address specific questions. FIFRA also specifies that the administrator can request scientific peer review of any major studies and study protocols conducted or funded by EPA and used for decision-making. SAP consists of seven members selected for staggered terms by the EPA administrator from a list of twelve nominees (six by the National Institutes of Health and six by the National Science Foundation). Members are chosen on the basis of their professional and disciplinary qualifications, so as to obtain the multi-disciplinarity required to assess the health and environmental impacts of pesticides. SAP can consult as needed with the agency’s Science Advisory Board (SAB) (see section 2.2.) and can draw on the Science Review Board of 60 members that is established to provide additional support for the scientific reviews that SAP is requested to conduct.

The FDA’s Science Board provides advice on technically complicated issues of regulatory importance and on keeping pace with evolutions in regulatory science. It also provides for the critical review of agency-sponsored intra- and extra-mural scientific research programmes. The Board consists of twelve core members who are selected by the FDA Commissioner from among authorities in relevant scientific disciplines. Members represent academia and industry and may include a technically qualified member with consumer interests recommended by a consumer-oriented organisation. Members serve for overlapping four-year terms. Meetings are open to the public.

For more specific questions on product-regulatory decisions, the Food Advisory Committee (FAC) may be charged with reviewing and evaluating available data and making recommendations on matters including the safety of new foods and food
ingredients, the labelling of foods, nutrient needs and nutritional adequacy, and safe exposure limits for food contaminants. The FAC’s charter specifies that the committee primarily provides advice to the Director of FDA’s Center for Food Safety and Applied Nutrition. Members and chairs are selected by the Commissioner from authorities in the relevant scientific fields and from many different sectors including medical professionals, scientists, researchers, industry leaders, and consumer representatives. The committee comprises thirty-three standing voting members and two non-voting members who represent industry and consumer interests. FAC members also serve for overlapping four-year terms. Meetings are open to the public unless determined otherwise by the Commissioner and are announced in advance. Meetings are conducted and records of the proceedings kept as required by applicable laws and regulations.

In response to demonstrations by activists against GM crops in Seattle, Washington in 1999, the FDA decided to adopt measures to strengthen the scientific basis and transparency of its decision-making process. The changes were announced in January 2001. Expertise specifically relevant to the safety evaluation of GM crops was added to the food and veterinary medicine advisory committees. These two committees are used to provide overarching advice on scientific questions. The Food Advisory Committee was restructured so as to include several special-focus subcommittees, one of which will concern itself specifically with foods derived from genetically modified organisms. Committee meetings are subject to FACA and hence are open to the public. Minutes and proceedings can be publicly disclosed unless specifically exempted according to FOIA.

To further strengthen the credibility of expert advice FDA has also recently published information on policies and procedures for handling conflicts of interest involving advisory committee members, consultants and experts. The agency noted that it is critical for advice to be free from conflict of interest or bias, but also pointed out that researchers on the cutting edge of science are increasingly approached and funded by industry to help in product development, in particular in biomedical research. In this context, the FDA announcement highlighted that in 1989, during the first Bush administration, the President’s Commission on Federal Ethics Law Reform addressed this issue: it stated that “the government is needlessly handicapped in obtaining advice and information from individuals with expertise located in the private sector.” Existing requirements for disqualification had “the effect of eliminating a class of talented and skilled individuals.” The Commission recommended legislation that would authorise the official who appoints members of scientific advisory committees to determine whether expertise outweighs conflict of interest. Reference is also made to the FACA requirements that committee membership be ‘balanced,’ that meetings are open to the public, and that committee recommendations are not binding, all of which ensures that agency staff can judiciously discriminate against advice that appears biased. Thus, under the Ethics Reform Act of 1989 agencies must balance the need for scientific expertise with the need to protect against the possibility that the members will be in a position to advance their financial interests. In 1996, the Office of Government Ethics issued final

regulations that provide guidance to agencies on factors to consider when handling conflicts of interest and granting waivers to experts.

In response to concerns of members of Congress and certain professional organisations, and in recognition of the need to periodically review public oversight and regulation of transgenic plants due to the rapid advances in plant biotechnology, an NAS committee was appointed to conduct an investigation of the risks and benefits of genetically modified pest-protected plants and the Coordinated Framework for Regulation of Biotechnology. The study was initiated in March 1999, and concluded and published in 2000. It contained recommendations on further research, in particular on methodologies to assess the potential allergenicity of stable proteins, and that provisions for transparency and participation in regulatory decision-making to enhance the credibility of decisions.  

In addition, Agriculture Secretary Dan Glickman also asked the NAS to establish the Standing Committee on Biotechnology Food and Fiber Production, and the Environment. This body was charged with review of the agricultural biotechnology approval process and held its first meeting on May 4, 2000. USDA, EPA and FDA will work closely with this Committee; FDA, in particular, resolved to work with the Committee to explore the potential for unknown long-term health effects resulting from the consumption of bio-engineered food.

The Clinton administration also called for closer cooperation between agencies USDA, EPA, and FDA in awarding competitive grants for peer-reviewed research on current and future safety issues, in order to improve the quality of the information base for regulatory decision-making.

3.2.2. Broader Public Review and Participation

Pursuant to provisions of US administrative law, public input is solicited at the level of proposed rulemaking, and agencies have to consider this input in issuing final rules. Within this general framework, however, procedures for public input on GM crops differ significantly among the three principal US agencies, as have their responses to recent controversies surrounding these products.

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USDA gives and advance notice of proposed rulemaking, with a period for public comment. Public comments have to be taken into account in the final rule; specifically how this is done is, however, at the discretion of the agency staff. Provisions to achieve transparency include reports on expert consultations on specific issues that are accessible to the public, and the use of the Internet to provide readily accessible information on pending and past decisions on field releases and deregulations of GM crops in the USDA’s Biotechnology Permits Database and the Biotechnology Index. USDA also requests the applicant to submit one copy of the applications for deregulation in which all confidential information has been deleted. These files are accessible for review by state regulators and are available to the general public on request.

USDA also published in the Federal Register in November 2000 an Advanced Notice of Proposed Rulemaking (ANPR) with an invitation for public comment on “how USDA should help facilitate the marketing of biotech crops, and help to segregate these products from non-biotech products.” USDA will seek to develop input from consumers, industry and scientists on how to meet the needs of the evolving markets and on the feasibility and desirability of a quality assurance programme.

EPA has used the Internet to provide access to pesticide fact sheets, which summarise the types of data and risk issues evaluated for each individual active ingredient. The fact sheets have been criticised as lacking in clarity and factual information. More detailed evaluations of submitted data can, however, be requested under the Freedom of Information Act. EPA has also been criticised for not providing any information on the types of data that are considered for regulatory approvals and of lacking clear and transparent guidelines on which plant-pesticides can be exempted under FIFRA.

The FDA website includes information on the consultation process and a list of completed consultations; details of these consultations are, however, not available for public scrutiny. Opportunities for interested parties to partake in the framing or reframing of regulatory questions include public meetings and hearings that are announced in the Federal Register and are often staged to discuss issues informally before rulemaking begins. Testimony can usually be presented orally or in writing. FDA has posted information sheets addressed to the public on how to participate in agency decision-making on the web, including invitations to provide written or oral testimony and to apply for positions on public advisory panels.

Under the Food and Drug Modernization Act of 1997 (FDAMA), Congress recognized that stakeholders can play an important role in helping the agency determine how best to

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46 Transparency at EPA was heavily criticised in the 2000 NRC report on Genetically Modified Pest–Protected Plants.

meet its responsibilities. The issues of strengthening science and increasing consumer information emerged from the first round of stakeholder consultation to implement FDAMA. In a gesture toward reflection on its own practices, FDA in 1999 invited the public to comment on how to improve the implementation of FDAMA.

Observing the lack of public acceptance of the EU decision-making process on these products, FDA recognized the need for more public outreach on GM crops. The agency organised three regional public hearings in November - December 1999 in Chicago, Washington and Oakland, California, the purpose of which was to provide information on current approaches to safety evaluation and labelling of food products derived from bioengineered plant varieties, as well as to solicit views on whether FDA's policies or procedures should be modified. FDA also wished to explore the most appropriate means of providing information to the public about bio-engineered products in the food supply. These meetings were seen by FDA as affording consumers, industry, and academia an opportunity to provide focused comment in a manner that would assist the agency in evaluating and refining its existing policies and procedures. Written comments were invited in preparation for the meetings.

While broadening its outreach, however, FDA continued to operate with narrow models of expertise and communication. The questions for these regional consultations were very specific: “What actions do you propose the agency take to expand FDA’s capability to incorporate state-of-the-art science into its risk-based decision-making? What actions do you propose to educate the public about the concept of balancing risk against benefits in public health decision-making?” By casting the problem in terms of improving the scientific base, these questions display little sensitivity either to issues of framing or to forms of expertise other than science. Further, communication is conceived as taking place from government to consumers rather than as a two-way process that might elicit and address consumer concerns as recommended by the 1996 NRC report. This approach offered relatively little opportunity for the identification of relevant normative differences between experts and laypeople.

### 3.2.3. Normative Analysis and Reframing

FDA has made significant changes in its approach to regulation of biotech foods based on feedback obtained in the consultation process. Partly in response to the three public hearings mentioned above, FDA modified its voluntary process so as to establish mandatory pre-market notification and to make its decision process more transparent. The agency also developed guidance for food manufacturers who wished to label their foods voluntarily. FDA will take steps to ensure that it is informed at least 120 days before new agricultural biotechnology crops or products are introduced into the food supply and will propose that the submitted information and the agency’s conclusion be made available to the public. The new notification procedure will replace the older voluntary, though widely adhered to, consultation process. FDA will also develop guidelines for voluntary efforts to label products.
In addition to processes initiated by the individual agencies, the NAS Standing Committee on Biotechnology is reviewing the adequacy of the existing regulatory framework for the Council on Environmental Quality. The Office of Science and Technology Policy is also conducting a six-month interagency assessment of federal environmental regulations pertaining to agricultural biotechnology, and will if necessary make recommendations to improve them. Results of these various inquiries will likely provide opportunities for normative analysis and reframing which may or may not result in further legislative change.

3.2.3. Institutional Accountability

Two main avenues have been pursued by critics of GM crops to challenge agency decisions and decision-making procedures: agency petitions and litigation.

In September 1997, Greenpeace International, the International Federation of Organic Agriculture Movements, the International Center for Technology Assessment, and other parties filed a petition for review of the registration and use of genetically engineered plants expressing *Bacillus thuringiensis* endotoxins. Used for many years as the active ingredient in microbial sprays, the *Bt* bacterium produces a type of protein that attacks the digestive systems of target insect pests. Today the *Bt* "plant-pesticide" is produced by adding the gene for the *Bt* pesticidal protein to a plant's own genetic material, so that the plant can manufacture the protein that destroys the target pest. EPA registered certain *Bt* plant-pesticides for use in varieties of corn, cotton, and potatoes in the mid-1990s. After reviewing the issues raised by the petitioners, EPA affirmed the scientific and legal foundation for its current regulatory approach and denied the petition. EPA reiterated that it is undertaking a comprehensive evaluation, using sound science, an open and transparent process, stakeholder involvement, and consultations with other government agencies, to ensure that sound decisions are made on the continued use of *Bt* corn and *Bt* cotton.

On September 29, 2000, the United States District Court for the District of Columbia dismissed a challenge to the Food and Drug Administration's regulatory policies concerning genetically engineered foods. The Alliance for Bio-Integrity and other public interest and religious groups had questioned the procedural legality of FDA's 1992 Policy Statement, ‘Foods Derived from New Plant Varieties.’

The court agreed with FDA that the policy statement was not a rule requiring notice and comment rulemaking. The court deferred to FDA's view that genetically engineered foods as a class do not require pre-market review and approval. The court also accepted FDA's view that special labelling for genetically engineered foods as a class is not required solely because of consumer demand or because of the process used to develop these foods.

In cases like this the courts can be seen to play an ambiguous role. On the one hand, they permit public airing and closure of competing positions, thereby contributing towards increased political legitimacy of contested decisions. On the other hand, by reaffirming
agency discretion – in accordance with the philosophy of judicial restraint -- they arguably cement the status quo and impede deeper reflection, learning and policy change.

3.3. Regulation and Expert Advice on GM crops in the EU

The framework for solicitation of expert advice on the marketing of genetically modified crops in the EU is provided by Directive 90/220/EEC on the deliberate release and the placing on the market of genetically modified organisms (GMOs), and by Regulation (EC) No. 258/97 on Novel Foods and Food Ingredients. This section will provide a more detailed account of the evolution of procedures to solicit scientific expert advice on individual products on a case-by-case basis for product approvals under Directive 90/220/EEC at EU level.

Directive 90/220/EEC, administered by DG Environment regulates the deliberate release of all live GMOs, regardless of their field of application. Only GMOs with medical uses, such as live vaccines, are exempt as regulated elsewhere. The Directive 90/220/EEC is divided into three parts: Part A outlines general principles including objectives and definitions, Part B applies to uncontained research and development work, and Part C applies to the approval to place a genetically modified product on the market. Under Directive 90/220/EEC each EU country has to appoint a national competent authority for the implementation of the law at the national level. Approvals for field trials under Part B of the Directive are issued by the national authorities of the country in which the trial is to be conducted. Approval for commercialisation of products under Part C of Directive 90/220/EEC is gained in a complex authorisation procedure in which all EU Member States participate.

The ‘Novel Foods Regulation’ administered by DG Enterprise provides the regulatory framework for all novel foods, that is foods that have not hitherto been consumed to a

48 Questions on labelling and traceability, although also important in overcoming the current paralysis of the decision-making system, will not be addressed in any detail in this report, so as not to detract from the focus on obtaining expert advice.

49 Directive 90/220/EEC and the ‘Novel Foods’ Regulation require each Member State to appoint national competent authorities for the implementation of the respective laws at the national level. Most competent authorities, usually Ministries, appoint experts to provide opinions to decision-makers. Experts can reside in an agency, as for example in Germany, where the competent authority for the implementation of Directive 90/220/EEC seeks advice from the governmentally operated Robert Koch Institute. Alternatively, advice can be sought from a panel of independent experts that is administered by the competent authority as in France or Britain. Expert committees can also comprise a mixture of ministry representatives and some independent experts, as in Greece and Spain. The Danish authority relies on a network of about 40 experts with complementary expertise to whom it sends relevant parts of the risk dossiers on an ad hoc basis. An analysis of the solicitation of expert advice at national level is, however, beyond the scope of this report.
significant degree in the EU, including foods derived from GM crops. The Regulation describes two alternative decision-making procedures for foods derived from GM crops. One is the complex authorisation procedure for placing on the market of live GMOs or GMOs that are not substantially equivalent (this is comparable to the authorisation procedure under 90/220/EEC). The alternative procedure is one in which a product can be approved at EU-level based on a positive opinion of the rapporteur Member State on the substantial equivalence of the ‘novel food’ to an existing product. The second procedure simply requires notification by the rapporteur Member State. This has triggered some controversy. A number of Member States did not agree with the possibility of merely notifying GM foods and insisted that every Member State should be able to contribute to the decision-making process at EU-level. These discussions are still in progress, but it is likely that in future all GM foods will need to undergo the more elaborate authorisation procedure.

A simplified schematic overview of the authorisation procedure under Directive 90/220/EEC is outlined in Figure 2 below. In order to apply for marketing a GM crop under one of the laws, the applicant first has to select a rapporteur Member State, which conducts an in-depth evaluation of the risk assessment data submitted by the applicant. The rapporteur has ninety days to forward an opinion on the application to the European Commission, plus any time the applicant requires to address questions. For the authorisation procedure, the European Commission forwards the dossiers to the other 14 Member States, whose competent authorities have sixty days to raise objections. If no objections are raised, the product is approved based on the positive rapporteur country opinion. This has occurred to date for one type of GM plant: genetically modified carnations.

If, however, Member States raise objections, as is usually the case, a complex procedure starts in which the European Commission administers the decision-making process between the fifteen EU Member States. The first step in the authorisation procedure is that the European Commission writes a proposal on the application to market the GM crop, based on the rapporteur country opinion and the objections voiced by Member States. Since the restructuring of Scientific Advice under the Commission Directorate General for Consumer Health and Protection (DG SANCO) in the fall of 1997, the Commission has added an additional scientific review step by the Scientific Committee on Plants at the EU-level to the authorization procedure under Directive 90/220/EEC. The Scientific Committee opinion provides an additional basis for the Commission proposal on the product that is the basis for the Article 21 Committee vote. This is described in more detail in the subsequent section 3.3.1.\textsuperscript{50}

Directive 90/220/EEC delegates decision-making on the Commission proposal to a committee of representatives of the competent authorities, the so-called ‘Article 21 Committee.’ The Commission proposal is approved provided that a qualified majority of country representatives endorse it in a vote. If the proposal is not accepted, the decision

\textsuperscript{50} Similarly, the Scientific Committee on Foods reviews data on the food safety of GM crops under the Novel Foods Regulation.
is deferred, according to the principle of subsidiarity, to the next higher entity in the decision-making hierarchy, the Council of Ministers. Under the rules for regulatory committees of the 1992 Treaty of Maastricht, which define the process of sharing power for regulatory decisions between the Commission and the Council of Ministers, unanimity in Council was required to reject Commission proposals. The comitology rules were, however, revised in the Treaty of Amsterdam. Since the implementation of the Amsterdam Treaty in March 1999, Council can reject a Commission proposal if a qualified majority votes against the proposal.

If the Council does not react, or does not take a decision within 90 days following referral, the European Commission College of Commissioners has to make the decision. An approval at EU-level, once published in the Official Journal, still has to be officially endorsed by the rapporteur country, and varieties have to be registered in the respective national variety catalogues, before the product can be marketed in any one country.

1. Rapporteur Review/Approval (90 + days)
2. Member State Review (60 days)
3. Scientific Committee on Plants*
4. Commission Proposal
5. Article 21 Committee Vote
6. Council of Ministers of Environment
7. Commission

*The review by the Scientific Committee of Plants was only added in December 1997 to the 90/220/EEC approval procedure.

**Before the implementation of the Treaty of Amsterdam with revised rules for regulatory committees, unanimity in Council was required in order to reject a Commission proposal.

Because of the similarity of procedures for soliciting expert advice between the Novel Food Regulation and Directive 90/220/EEC, and because the latter has a longer and richer history of operation, this case study focuses on the solicitation of expert advice at the EU-level for decision-making on several individual products under Directive 90/220/EEC. We attempt to identify and interpret the ad hoc and legislative changes over time in the nature and the procedures for expert advice. One of the most fundamental changes was the revision of Directive 90/220/EEC, which has now been published as Directive 2001/18/EEC.

3.3.1. Technical Peer Review and Scientific Expert Analysis

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When Directive 90/220/EEC was first implemented in the early 1990’s, expert input to decision-making was only foreseen at the level of the Member States. There were no provisions for scientific expert advice at EU-level in Directive 90/220/EEC (the Article 21 Committee is not considered a ‘scientific advisory’ committee, as it has decision-making powers and as its members are agency staff). Over time two different types of expert advisory structures were developed under Directive 90/220/EEC to advise on decisions concerning GM crops at EU-level: the Scientific Committee on Plants, housed in DG SANCO, which reviews dossiers submitted under Directive 90/220/EEC on a case-by-case basis; and the Working Group on Insect-resistance management, an issue-specific advisory committee, which was established on an ad hoc basis by DG Environment to develop EU guidelines on this topic. (The establishment of an EU-level Committee on another cross-cutting issue, the management of herbicide-tolerant crops, is also being considered.) The operation of the two different types of advisory structure is described in more detail below.

The need for EU-level expert advice on the safety of individual products was first recognised with the application under Directive 90/220/EEC for placing on the market insect-protected maize CG176 developed by Ciba-Geigy (the company’s name was changed to Novartis after a merger). See Table 4 for an overview on the decision-making procedure. The company chose France as rapporteur, which referred a positive rapporteur proposal to place the product on the market to the European Commission. Discussion of the application was highly controversial as the product contains a gene that confers resistance to ampicillin, a clinically used antibiotic. Most of the other 14 Members States raised questions or objections during the 60 day Member State review period. The Article 21 vote outcome was 34 votes in favour of the Commission proposal to market, 21 against, and 27 abstentions. At Council level, only France and the European Commission supported placing the product on the market, while other Member States voted against the marketing proposal or abstained. In 1996, under the rules for regulatory committee of the Maastricht Treaty, unanimity among Member States would have been required to reject the Commission proposal to market the product. Since Council failed to take a decision, as it neither accepted, nor rejected the proposal, the decision was referred to the European Commission.

So as not to determine marketability of the controversial insect-protected maize CG176 without expert assistance, the European Commission consulted three scientific committees in 1996 on an \textit{ad hoc} basis: the Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Pesticides (SCP) and the Scientific Committee on Foods (SCF). Committee members had been appointed as leading authorities in the field and were not representing the Member States. They were asked to what extent an ampicillin resistance marker in a commercially cultivated GM crop that is also used as animal feed might contribute to the problem of ampicillin resistance in human pathogens, and therefore possibly undermine the treatment value of the antibiotic. All three committees deemed the risk negligible. The opinions were published on the Internet. The European Commission proceeded to publish the approval at EU-level in the Official Journal in 1997.
Table 4. Overview on Decision-making on CIBA Maize CG176

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tbody>
<tr>
<td>March 1995</td>
<td>The French expert committee ‘Commission du Genie Biomoleculaire’ (CGB) endorses the application.</td>
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<td></td>
<td>The French Ministry of Agriculture sends the recommendation to place CG176 on the market to the European Commission.</td>
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<tr>
<td>May 1995</td>
<td>Seven Member States, including Austria, Italy, and Luxembourg file objections to the rapporteur recommendation. The main ground for objection is the presence of the ampicillin resistance gene.</td>
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<tr>
<td>April 1996</td>
<td>Article 21 Committee vote. 34 votes in favour, 21 against, 27 abstentions.</td>
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<tr>
<td>July 1996</td>
<td>The Commission services consult 3 Scientific Committees:</td>
</tr>
<tr>
<td></td>
<td>Scientific Committee on Foods</td>
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<td></td>
<td>Scientific Committee on Animal Health and Nutrition</td>
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<tr>
<td></td>
<td>Scientific Committee on Pesticides</td>
</tr>
<tr>
<td>December 1996</td>
<td>The 3 Scientific Committees have no safety concerns.</td>
</tr>
<tr>
<td>January 1997</td>
<td>The European Commission adopts a favourable decision to place CG176 and its progeny on the market (Decision 97/98/EC).</td>
</tr>
<tr>
<td></td>
<td>The Ministry of Environment, through endorsement by the Juppe government, blocks the addition of CG176 to the Official Catalogue of Maize Varieties, necessary for marketing the product in France.</td>
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<td></td>
<td>The president of the CGB resigns.</td>
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<tr>
<td>March-May 1997</td>
<td>The 3 Scientific Committees publish further opinions in response to the Austrian invocation of Article 16 to confirm their original risk assessment.</td>
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<tr>
<td>February 1998</td>
<td>The Jospin government endorses the decision of the Ministry of Agriculture to add CG176 to the French national variety catalogue.</td>
</tr>
<tr>
<td>February 1998</td>
<td>Greenpeace, Friends of the Earth, Ecoropa and others file a lawsuit against the registration of CG176 in the variety catalogue based on arguments of neglectful safety assessment and flawed approval procedure.</td>
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</table>
December 1998 | The Conseil d’Etat refers to the European Court of Justice the question as to whether France, as rapporteur, has to endorse a Community level decision and advocates suspension of CG176 varieties whilst the decision is pending.

June 1999 | Council of Ministers of the Environment meeting at which 5 Member States, including Denmark, Italy, Greece, France, and Luxembourg decide to block all further product decisions under Directive 90/220/EEC until the revised Directive is implemented.

March 2000 | The European Court of Justice rules that a Member State, whose competent authority forwarded the application with a favourable opinion to the European Commission, given a favourable Commission decision, must issue a consent in writing allowing the product on the market, unless new information on risks to human health and the environment has been received.

March 2000 | Germany invokes Article 16, mainly based on a report from the Ecoinstitute on risks of the ampicillin resistance gene and unintended effects of the Bt protein.

November 2000 | The Scientific Committee on Plants reconfirms previous risk assessments.

The Commission decision to market CG176 was much challenged, not the least by the rapporteur France itself, which, under the Juppe government refused to endorse the Commission decision, by blocking the addition of CG176 to the French Official Catalogue of Maize varieties, necessary for marketing the product in France. Several other countries, including Austria, Luxembourg and Italy, invoked Article 16 of Directive 90/220/EEC to suspend the approval on their territory.

After the reorganisation of all Scientific Committees under the auspices of DG SANCO in the fall of 1997 (see section 1.3. of this report), starting with the review of the assessment of another insect-protected maize product MON 810 in December 1997, the Commission routinely consults the Scientific Committee on Plants (SCP), the successor to the Scientific Committee on Pesticides, on each application under Directive 90/220/EEC, in order to increase the legitimacy of the Commission proposals that serve as a basis for the Article 21 Committee vote. This scientific review step at EU-level has become integral to the approval procedure. The terms of reference for the SCP are defined by staff of the Directorate General Environment and are usually broadly conceived. The SCP is nearly always asked to provide an opinion as to whether there are any potential risks to human health or the environment from the commercialisation of the GM crop.

To date the SCP has only once decided not to voice an opinion on the risk assessment of a product. The data and information pertaining to risk assessment of a potato with an improved starch profile that contains a gene conferring tolerance to the important second generation antibiotic amikacin was deemed insufficient by the SCP to reach a conclusion on the importance of the risk.\(^2\)

\(^2\) Opinion of the Scientific Committee on Plants regarding submission for placing on the market of genetically modified high Amylopectin potato cultivars apriori and apropos
The Scientific Advisory structures under DG SANCO were further elaborated, to ensure some coordination of expert advice on products regulated under Directive 90/220/EEC and under the Novel Foods Regulation. A joint committee on biotechnology was established as a platform for joint deliberations on individual products and efforts to improve risk assessment guidelines. The official opinions on environmental or food safety that are made available to the public are, however, brought forward by the SCP and the SCF, respectively.

In addition to multidisciplinary scientific expert committees that review data on individual product applications under Directive 90/220/EEC, DG Environment has also established, at Commission initiative, a scientific expert committee on insect resistance management. This committee was formed to address recurring questions from Member States that often were cited as a reason for abstaining or voting negatively on proposals from the European Commission to market insect-protected maize. Committee members were selected on the basis of their relevant expertise and geographical distribution across the EU, largely for purposes of representing the geo-biological variation of crop-pest complexes, as well as to ensure political representation, in particular of those countries that had to that date voted against insect-resistant crops citing concerns about the development of resistance in the target pests. This committee has elaborated proposals for EU-coordinated monitoring of the potential development of insects that are resistant to the plant-integrated pesticide in insect-protected crops.

The EU advisory system, complex and ever-evolving, is not highly transparent from the standpoint of the public. The primary effort towards transparency to citizens consists of publishing the minutes of scientific advisory committee meetings and the expert opinions on the Internet. These documents, however, are posted on the web site of DG SANCO without any additional information on the context to the product, its potential uses, the regulatory approval procedure or the role that the various different types of advisory structures described above play in the overall approval process.

One important recurrent concern related to the present system is that data used for the risk assessment of GM crops are usually generated by industry and often not published or peer reviewed, sometimes for reasons of confidentiality, other times because priorities other than writing scientific publications may rank higher in the private sector. Efforts to generate risk assessment data by third parties may be jeopardised, as companies are reluctant to hand over products to be tested by third parties whose records they are not familiar with. Even if companies accept product testing by third parties, the issue of funding for such research has to be resolved.

The credibility of information used by experts in turn affects the credibility of the advice to the general public. In Norway, for instance, a citizens’ panel consulted in 1996

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pointed out the need for more risk assessment data than were being officially submitted; this was one important basis for that country’s moratorium on imports of GM crops. In 1999 the same panel was consulted again, and the verdict again was that the additional data from companies was not sufficient. Peer reviewed data by ‘independent academics’, they held, would be a sounder basis for decisions – with the result that the moratorium was continued.

In the UK, government-led and funded farm-scale field trials of selected GM crops have been initiated; similar concerted efforts are taking place in France and Germany. It is, however, difficult to conceive that government could fund and coordinate the compilation of data required for risk assessment on a product-by-product basis.

To address this problem, new forms of peer review and/or oversight of research by independent experts may also be required to satisfy demands for accountability. Such services could be established in the form of ‘hybrid institutes’ that are partially government funded and partially industry funded, that provide ‘independent’ expertise, and rely as needed on stakeholder advisory boards. The Health Effects Institute created by the US EPA and the auto industry in the 1980’s to generate and review data for setting air pollution standards could serve as a prototype for further discussion.

### 3.3.2. Broader Public Review and Participation

The breadth of review and participation in decision-making at Member State level will vary with each Member State, depending on the institutional infrastructure for solicitation of expert advice, the breadth of expertise, the level of involvement of higher-level political decision-makers at times of controversy, and the culturally and institutionally determined propensity to organise citizens’ conferences, as has been done on the issue of agricultural biotechnology in Denmark, France, Greece, Ireland and other EU Member States. Expert risk analyses that are produced in regulatory processes are increasingly being made public to increase the transparency of the decision-making process, both at national and at EU-level.

As discussed earlier in the report (section 2.3.), there is no clear separation of powers between the executive, legislative and enforcing branches of government for decision-making at EU-level as there is in the US. Rather, the system is one in which the powers and knowledges of sovereign states and European institutions are pooled. Hence participation in decision-making tends to be differently defined in the two systems, with issues of Member State participation and subsidiarity assuming particular prominence in the EU.

Under Directive 90/220/EEC, the Article 21 Committee, with representatives of all Member State competent authorities, exercises delegated power for decision-making on individual products. Positive proposals are referred to this Committee by the Commission. Only if the Article 21 committee does not take a decision (i.e., if a qualified majority of Member State representatives does not vote in favour of the
Commission proposal), does the decision get referred, according to the principle of subsidiarity, to the next higher decision-making entity, the Council. In the Council, the question is reviewed both by the Council Working Group on the Environment and at the meeting of the Ministers of the Environment of the fifteen Member States. This process constitutes a further review of problematic decisions at the highest political level.

Weaknesses of this process were revealed in the case of insect-protected maize, CG 176, by Novartis, as discussed above. Absence of unanimity in Council in this case, under the comitology rules of the Treaty of Maastricht, constituted the formal basis on which the Commission proposal was approved. Even though the Commission took the extraordinary step of consulting three Scientific Committees on an ad hoc basis (see section 3.2.2.), the episode severely tested the credibility of the application process. Since then, Commission proposals to market four other products have failed to obtain support by a qualified majority of the Article 21 Committee (insect-protected maize, MON 809; insect-protected cotton; herbicide-tolerant cotton; and the delayed ripening tomato). These products, however, have not as yet been sent to the Council.

At EU-level, there are no formal provisions for transparency or public participation other than the general requirement that risk assessments of GM crops of the European Commission Scientific Committee on Plants (SCP) be posted on the Internet. The SCP is developing detailed guidelines on data required for regulatory submissions. Early drafts of this document were open for comments by stakeholders and other interested parties.

DG Environment has held sporadic consultations with an appointed group of stakeholders, including representatives of the larger companies and NGOs, on general issues concerning the regulatory framework, in particular the revision of Directive 90/220, labelling, and now traceability.

At present, official Commission statements on transparency relate largely to the information content of risk assessments and to the minutes of the scientific committee meetings. Comparisons with the US case suggest that numerous steps could be taken to improve the transparency of the process for obtaining expert advice on product-approvals. These could include providing more information to the public about the overall approval process, procedural details of the appointment of experts, how the terms of reference were defined, the rules by which the expert committee operated regarding decision-making, declarations of interest, and minority opinions, if any. Participants at the meeting and their backgrounds and expertise could be described. Access could be provided, on request, to non-confidential data considered by the experts and the sources of the data could be acknowledged.

Important questions remain, however, about the relevance or appropriateness of particular mechanisms to expand participatory opportunities in any of these ways. The need for new forms of participation will have to be evaluated in the light of resource constraints and possible negative consequences of blending expert debate with wider forms of political deliberation.
3.3.3. Normative Analysis and Reframing

Risks identified by molecular biologists or agronomists, be they experts in academia, industry or in government, may differ from the main concerns of citizens, and expert opinions that address these questions may therefore not address issues that the public deems important. For instance, for GM crops on the market in the US, experts did not consider it necessary to assess the potential long-term health or environmental impacts from the consumption of GM crops; they were persuaded by evidence that GM crops are as safe as their non-modified, “substantially equivalent” counterparts in all relevant aspects. The question of long-term effects, however, is repeatedly raised in the public arena.

The issue of whether to address socio-economic concerns through risk regulation had been vigorously debated between Parliament and Commission just before 1990, but in the end the then strong Jacques Delors Commission retained the upper hand. Stated decision criteria in Directive 90/220/EEC remained purely environmental and health risk-based, implying acceptance of a narrower interpretation of risks and of the expertise required for their evaluation.

Guidelines for data requirements in risk assessments are, however, slowly changing to reflect more normative concerns. The Scientific Committee on Plants has recently published draft guidelines on data for the risk assessment of GM crops that require addressing broader concerns than previous practices. Some committee members have emphasised the importance of regularly attending and open meetings on GM crops and conferences on risk assessment in order to remain in tune with broader concerns of citizens. These concerns may not look like real or imminent risks to health or the environment from the standpoint of expert scientists, but many recognise that it is essential to address them in order to have a more democratic basis for decisions.

At the Environment Council in June 1999, five Member States declared the suspension of further authorisations until a more rigorous and transparent regulatory framework was adopted that also addressed monitoring for potential long-term impacts. In response, the revised Directive 90/220/EEC now includes the evaluation of potential long-term effects linked to monitoring as appropriate; the evaluation of socio-economic effects through publication of reports every three years by the Commission; the phasing out of antibiotic resistance markers that confer resistance to clinically used antibiotics by the year 2004; and traceability requirements that are linked to labelling provisions.

Furthermore, measures were taken to improve the political acceptability of the decision-making process: a legal basis was established for the Commission to consult Scientific Expert Committees\(^5\); Member States are required to inform the public on the science and

\(^5\) Directive 2001/18/EC Article 28 on the consultation of Scientific Committees states that scientific committees should be consulted “in cases where an objection is raised as regards the risks of GMOs […] or where the assessment report [by the rapporteur] indicates that the GMO should not be placed on the market, the relevant Scientific
to hold public consultation before releases; decisions are periodically reviewed; and the comitology procedure was altered by the Treaty of Amsterdam to give the Council the power to reject a Commission proposal by a qualified majority, instead of by unanimous agreement.

An additional provision that allows direct interaction between the Commissioners, selected staff and experts and the public, that will inform decision-makers of normative public concerns are ‘Internet chat days’ during which citizens can ask questions on selected topics such as food safety or GM crops to the Commissioners in charge of the respective portfolio. This was instituted by Commissioner Emma Bonino in 1999. Also relevant to normative analysis is the establishment of Ethics Advisory Committees by the European Commission and several Member States.

More routine procedures could be established, however, to take into account scientific expert concerns and normatively different risk-related concerns of citizens so as to periodically reframe the debate on risk. Public meetings and/or other mechanisms for broader participation for new GM product categories could be considered. Summaries of outcomes from such deliberations could be taken into account at expert committee meetings on individual products, or when defining the membership and terms of reference for the committees. They could also be considered in connection with data requirements for the risk assessment of different product categories established at EU-level or by international organisations.

### 3.3.4. Institutional Accountability

The decision on Novartis’ insect-protected maize CG176 has been much challenged through various official channels. The general halt of decision-making by Member States on applications to market GM crops under Directive 90/220/EEC, which followed the Environment Council meeting in June 1999, is regarded by some as in part a consequence of the lack of democratic support for the approval of this product.

Several Member States, including Austria and Germany, have invoked their right to unilaterally ban CG176 based on the Article 16 that states that “where a Member State has justifiable reasons to consider that a product […] constitutes a risk […] it may provisionally restrict or prohibit its use on its territory.” The SCP, however, charged with reviewing the stated reasons for Member State concerns on risk, did not agree with the validity of these concerns as a basis for a national moratorium on imports of CG176.44

Committee(s) should be consulted by the Commission on its own initiative or at the request of a Member State, on the objection.” and “on any matter under this Directive which may have adverse effect on human health and the environment.”

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In France, Greenpeace and Friends of the Earth filed suit against the decision of the government to approve CG 176. The case was referred to the European Court of Justice by the Conseil d’Etat, with questions concerning the approval procedure (specifically, whether a rapporteur country had to endorse a final Commission approval that was published in the Official Journal by default). The European Court of Justice ruled that a Member State, whose competent authority forwarded the application with a favourable opinion to the European Commission, given a favourable Commission decision, must issue a consent in writing allowing the product on the market, unless new information on risks to human health and the environment has been received.

These examples of controversy and framed legal challenge suggest that public scrutiny of decision-making now pertains as much to the process as to the content of decisions even at EU-level. In a value-laden context, improvement of mechanisms to ensure the credibility of the process of expert consultation therefore should have higher priority. As noted above, the revised Directive 90/220/EEC will provide a legal basis for consultation with scientific committees at EU-level on a case-by-case basis. However, to enhance the transparency of the overall decision-making process, and in particular the process of soliciting expert advice, more detailed general guidelines on scientific advice and policy-making (similar to the UK guidelines) could be adopted at EU-level.

3.4. Conclusions of Relevance to the EU

In the US, consistent with longstanding traditions of transparency and public participation, each of the principal agencies (FDA, EPA, USDA) took steps in the late 1990’s to engage more broadly with the public on the technical basis for decisions on GMOs. FDA’s regional public hearings are the most prominent example of this approach. However, none of the agencies backed away from their insistence on sound science and risk assessment as the primary basis for decisions. None accordingly have shown high sensitivity to issues of framing, uncertainty, and normative disagreement in the regulation of GM crops and foods.

An important development of the late 1980s was to recognise that experts may participate in decisions in spite of financial ties to industry, although recent administrative reforms, particularly at FDA, recognise that conflict of interest remains a hindrance to the credibility of decisions.

Limited reframing and normative analysis have occurred in the US, largely through agency uptake of comments generated through hearings and other consultation processes. Ongoing review by the NAS, Council for Environmental Quality, and other bodies may lead to new proposals, but there are no signs that major legislative changes are in the
offing. The record to date of the Bush administration suggests that the White House Office of Science and Technology Policy is unlikely to take the lead on these issues. In marked contrast with the early history of US environmentalism, courts have generally supported agency decisions on GM products and have induced few if any frame shifts in regulation.

In the EU, reforms have served to strengthen and diversify the advisory structure, clarify its legal basis, and routinise its input into decisions involving GM products. Early experimentation with ad hoc bodies (reminiscent of US EPAs efforts in the 1970’s) have led to greater streamlining of consultation processes, although some room remains for constitution of issue-specific and ad hoc advisory committees on an as need basis. Changes in the comitology rules that define the division of powers between the Commission and the Council of Ministers, by incorporation of a qualified majority for rejection of proposals (Treaty of Amsterdam) and the likely abandonment of the notification procedure (Novel Foods Regulation), signal the tendency toward according all Member States a recognised voice in decision-making.

Expert independence and the reliability of risk assessment of data have become matters of concern, in partial contrast with the US. These aspects of EU decision-making suggest a commitment to separating science from legislation, as was also observed in the context of air quality standard-setting. While it is too early to evaluate this development, it appears at first glance to be inconsistent with both the 1983 United States National Research Council report (recommending greater institutional connection between risk assessment and risk management) and the 1996 NRC report on risk characterisation (recommending greater integration of analysis and deliberation). Compared to the US, EU procedures for soliciting expert advice on GM crops and foods are substantially less transparent for citizens, although measures such as posting expert opinions on the Internet make some moves toward greater openness.

4. Overall Conclusions

Procedures for soliciting expert advice with respect to air quality standards and GM products have evolved under substantially different political circumstances in the US and EU. In the US, pressures for change have emanated primarily from domestic politics, with interested actors focusing some of their attacks on the substance as well as the process of expert advice. The separation of powers within the federal government opens up numerous avenues for challenge in the US, both by offering multiple entry points for potential challengers and by permitting competition among the branches of government. Many of the salient reforms in advisory processes have originated in perceptions of over-regulation or (less commonly) under-regulation by federal agencies. Only in the GMO case was US policy affected by unexpected international opposition originating in EU countries; domestically, protests against the WTO and other global institutions also raised the salience of the issue.
In the EU, changes in advisory processes have occurred in tandem with wider structural and political transformations in EU institutions. These comprise, at the political level, EU-enlargement and new obligations under the successive EU treaties, notably the Treaty of Amsterdam, and at the administrative level, reforms responding to the 1999 findings of mismanagement within the Commission. The most fundamental of changes to the scientific advisory structure to date, that is the transfer of Scientific Committees to DG SANCO, has occurred in 1997 and was triggered by a combination of the aforementioned drivers and the loss of public trust in government decision-making on risk in response to the BSE crisis. EU decision-making also occurs with more explicit attention to international treaties and organizations than US regulatory proceedings. These background differences account for some of the major differences of emphasis in the processes for obtaining expert advice that have been noted in this report.

**Similarities between the US and EU**

Looking at expert advisory processes for ambient air quality standards and GM crops over time, one can observe several broadly similar developments in the US and EU:

- Growth in the number and forms of expert advisory structures.
- Increase in the formality and legal specificity of expert consultation requirements, including both the need for consultation and the procedures for doing so.
- Increased attention to representation on expert committees, particularly to ensure multidisciplinarity, but also balance of other kinds.
- Specialization of expert advice to fit particular regulatory sectors and issues.
- Increased use of the Internet to facilitate public communication of expert decisions and (less systematically) the content of expert deliberations.
- Continued adherence to paradigm of separating risk assessment (seen as science and expert judgment) from risk management (seen as economics, politics, and values). This is reflected above all in the rhetoric of “sound science” in the US GMO case and in the insistence on the “excellence” of experts in the EU.
- Periodic review of decisions

**Differences between the US and EU**

Differences between the two political regions may be organized under three subheadings:

*Characteristics of Expert Advice Specific to the US*

- Highly formal legal apparatus, comprising several major pieces of legislation, for ensuring public access to expert committees and agency documentation.
- Diverse opportunities for direct interactions between expert advisers and the public through written comments, hearings, and, lately, Internet communications. Procedures are often highly specified by the soliciting agency (e.g., FDA’s Web posting of information sheets for participants).
Repeated court challenges to process and substance of expert advice, especially in early years of Clean Air Act case, although courts recently have been more reluctant to reopen agency decisions.

Possibility of referring problematic issues to the National Academy of Sciences and National Research Council, which as non-governmental bodies, contributed on principles of scientific merit, are seen as standing somewhat above political fray.

Rising scepticism about the neutrality of basic scientific research, as reflected in the Shelby amendment’s requirement for disclosure of primary research data generated with federal funds.

Characteristics of Expert Advice Specific to the EU

- Organization of expert advice in separate administrative structures from those with legislative responsibility.
- Relative absence of transparency of expert bodies vis-à-vis the general public.
- Rising uneasiness about dependence on industry-generated data as basis for regulatory decisions. Use of expert advice at EU-level to foster consensus on difficult technical issues and strengthen Commission decisions in the light of objections from Member States.
- Concern for subsidiarity reflected in the change of comitology rules in the Treaty of Amsterdam, reflecting altered perceptions of legitimacy of EU decision-making.

Contrasting Trends between the US and EU

- Increased insistence on ‘sound science,’ implying higher standards of proof, in US environmental decisions. Moves to incorporate precautionary orientation in EU environmental policy.
- Institutional dispersal of risk assessment, and accompanying expert advice, across regulatory sectors in the US, in accordance with 1983 NAS Red Book recommendation. Institutional consolidation of expert advice and risk assessment under the aegis of Committee on Consumer Protection in EU; separation of scientific advice from legislative process.
- Incorporation of industry concerns through relaxation of conflict of interest rules and legally compelled disclosure of federally-funded basic science in US. Increasing uneasiness concerning quality of industry-generated data and provisions for ensuring expert independence in EU.
- Continued attention to processes of soliciting advice, with provision for direct public submissions to and comment on expert deliberations in US. Relative insulation of expert committees from direct public review in EU.

Lessons from Comparison
The US case is particularly instructive in the richness of the procedural mechanisms available for engaging interested and affected members of the public in expert advisory processes with respect to both clean air and GM crops and foods. The adoption of particular procedures in the EU has to be carefully considered in the light of resource constraints and also in view of US experience showing that openness increases the attacks on scientific judgment, delaying and perhaps undermining the possibility for building expert or political consensus. Nevertheless, provisions such as those offering more information on the mandate, duties, constitution, operation, and reasoning of advisory committees could be easily adopted without undue expense and with increases in transparency and democratic accountability.

A paradoxical, but diagnostic, trend in the US is toward insistence on improving the scientific information base for regulation. This movement, evident in both case studies, translates into stiffer requirements for agencies to consult with outside experts. This development indicates considerable scepticism about the scientific capacity and expert judgment of regulatory agencies. The cases suggest that EPA has suffered more from this erosion of credibility than FDA. Scepticism toward EPA is surprising considering the many mechanisms that agency has developed over the years for generating knowledge (e.g., HEI), for seeking advice (e.g., the early, non-statutory advisory bodies), and for making its process open to public review. The cases bear out the observation in social studies of science that more openness leads to more unravelling of the basis for technical judgment. Insulating experts from public review may provide a short-term solution to such problems, but this strategy is unlikely to survive crises (as indicated by the GM controversy in the EU). Nor is insulation consistent with the broad goals of democratising expertise.

Finally, the idea of recursive phases of analysis and deliberation, which has been recommended by numerous policy analytic bodies, has yet to be fully implemented in either regulatory culture. Yet, this alternation between expert judgment within contained limits and open-ended public deliberation offers the best prospect for achieving closure on complex risk issues while keeping open possibilities for normative analysis and reframing. The US process, with its emphasis on case-by-case contestation and tendency to translate normative differences into technical ones, may impede such systematic reflective processes. Exceptions, such as the full-scale overhaul of the Clean Air Act in 1977 and 1990, are infrequent, costly, and uncertain. In the EU, subsidiarity principles make it perhaps even more difficult to create engagements between expert decision-making at the EU-level and the normative concerns of the publics of various Member States. Yet, in the attempt to find solutions, the EU may well end up providing innovative models for the US.