Experts, Citizens, and Eurocrats – Towards a Policy Shift in the Governance of Biopolitics in the EU

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Keywords

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Abstract

The hypothesis put forward in this paper is that we are currently observing a remarkable policy shift in the European Community concerning the conceptual basis and instruments for the governance of biopolitics. Biopolitics refers to an emerging policy field which involves the societal conflicts over the application of new genetic and reproductive technologies to humans (biomedicine) as well as the application of these new technologies particularly to agriculture and food production (biotechnology). The changes refer to the basic concept of how to govern the relationship between science and society, experts and lay-people, citizens and Eurocrats. The EC is opening up for incorporating ethical concerns into its research, technology and development policy as well as its regulatory biopolicies; furthermore, there is growing openness for "participatory" forms of biopolicy-making, yet the meaning of participation is limited. The reasons for this development are to be found in a more general trend in the transformation of European governance on the one hand aiming at involving civil society actors, and, on the other hand, in the characteristics of the policy field. These visions, spread out in the Commission's White Paper on European Governance and several related policy papers, prove to be challenging for the Union as dynamic and multi-level polity.

Kurzfassung

In diesem Beitrag wird die These vertreten, dass wir gegenwärtige eine bemerkenswerte Veränderungen im Hinblick auf die konzeptionelle und instrumentelle Ausgestaltung der Biopolitik in der EU beobachten können. Biopolitik bezeichnet ein neues Politikfeld, welches sowohl die Anwendung von genetischen und Fortpflanzungstechnologien am Menschen (Biomedizin) umfasst als auch die Anwendung dieser Technologien speziell in der Landwirtschaft und Lebensmittelproduktion (Biotechnologie). Die Veränderungen betreffen die Regulierung der Beziehung (governance) zwischen Wissenschaft und Gesellschaft, zwischen Experten und Laien, zwischen Bürgern und Eurokraten. Die EG öffnet sich für eine Inkorporierung von Ethik in ihre Forschungsförderpolitik und in ihre regulative Biopolitik sowie gegenüber neuen Modi von Governance in Gestalt von „partizipativen" Verfahren, wobei hier ein verengter Partizipationsbegriff zugrunde gelegt wird. Die Gründe hierfür liegen zum einen in dem allgemeinen Trend einer Transformation von europäischen Governance-Strukturen und einer Beteiligung zivilgesellschaftlicher Akteure, zum anderen in den Charakteristika von Biopolitik. Diese Visionen der Europäischen Kommission, die sie sowohl im Weissbuch „Europäisches Regieren" als auch in damit zusammenhängenden Dokumenten ausbreitet, sind eine Herausforderung für die EU als einem dynamischen Mehrebenensystem.

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1 Introduction: Biopolitics in the European Union

The question who should be involved in policy- and decision-making and what is the proper relationship between experts, lay-people and politicians is fundamental to democracies. Due to the strong tradition for deliberation and direct democracy in modern political theory and in public policy, there is a tendency to make policy- and decision-making more open to participation not only by stakeholders, but also by citizens. While this is essentially an old debate dating back to the Greek polis, it has been renewed with regard to advanced technologies in the last decades. Claims for involving a variety of social actors have been raised and the role of science particularly in regulatory policy-making has been widely discussed first in the US since the 1970s and for some years also in Europe. Biotechnology is an outstanding example, because of the alleged social impacts and, partially, unpredictable environmental and health risks which has even enforced the general participatory shift in technology assessment (TA) and policy-making. A variety of procedures has been conceptually and methodologically developed as well as practically tested that turn the focus from the traditional policy advice function of TA to the creation of a public sphere; the aim is to get citizens involved in discourses on science and technology.

For some years biotechnology and biomedicine and their political regulation (biopolicies) have served as a hot issue in all member states of the European Union (EU) so that a dynamic biopolitical arena emerged.(1) For example, Eurobarometer 52.1 on "The Europeans and biotechnology", the fourth survey in a series that cover biotechnology since the 1990s, shows that there is generally a

high acceptance of so-called "red" biotechnology or biomedicine, while there is a far greater and, over time, even growing scepticism against "green" (agricultural) biotechnology in the late 1990s (cf. Durant et al., 1998; Gaskell/Bauer, 2001). Scepticism towards biomedicine and biotechnology focuses mainly not on the technology as such but on particular applications judged against the criteria of usefulness, supposed risks, and moral acceptability: While the vast majority is downright against genetically modified (GM) food, most people assess the detection of hereditary diseases as a good and morally acceptable purpose. However, some biomedical applications are regarded, in fact, as morally difficult, especially cloning and research on human embryos as well as the use of genetic diagnosis for preimplantation genetic diagnosis. The politicisation of green biotechnology does not mean that red biotechnology is immune to public opposition. On the contrary, the possibility of predictive medicine (e.g. genetic testing) has lately become an issue of public debate, for example, in Denmark, France, Germany and the Netherlands. Embryo and embryonic stem cell research are particularly contested matters in most member states and also at the supranational level in the context of the 6th Framework Programme for research, technology, and development (RTD). Not only the members states but also the European Community (EC) has to tackle these questions with regard to its RTD and its regulatory policy. Community competences in both areas have immensely increased. This is primarily an outcome of the common market as *the* central project of European integration. Public support for, in particular of advanced technologies, is thought to be vital for the competitiveness of European economy.

The hypothesis that I want to put forward is that we are observing a remarkable shift particularly in the Commission's position on how to govern biopolitics. "Participation" is the key word – yet reduced to a very limited concept, as I shall illustrate. The proposed "participatory" modes of governance aim at greater *inclusiveness* of social actors, i.e. experts and lay-people, stakeholders and citizens, the public and Eurocrats in supranational policy-making and regulation. The underlying assumption is that the effectiveness and efficiency, i.e. the output-side of policy-making, can be improved by strengthening the input-side and, in so doing, the legitimacy of EU policies will increase. This policy shift is particularly relevant in the area of biopolitics due to the ongoing political struggle especially over genetically modified (GM) food on the one hand and the assumed economic benefits on the other. Yet, it takes place within a fundamental discourse on European governance recently promoted, above all, by the European Commission which goes far beyond biopolitics and which has effects on the concept and limits of participation.

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Since any analysis of societal conflicts over new technologies has to take the very technological characteristics into account, I will first sketch the conflict dimensions involved (section 2). I will then illustrate the historical development of biopolicies in the EU starting with research policy and the development of European TA (section 3) before I turn to the development of regulatory policy-making in this field (section 4). I will then introduce and analyse the relevant documents on governance and, in particular, on science and society published by the Commission over the last two years (section 5). In the final part, I will draw some conclusions for European governance (section 6).

2 Dimensions of biopolicies

For a long time, EU policy-makers attributed the lack of acceptance of and resistance to biomedicine and biotechnology to people's insufficient knowledge and irrational fears. A good example is the Bangemann report on the promotion of a competitive environment for biotechnology, it states:

> "At the same time, biotechnology suffers from a bad image amongst policy-makers and the general public … Although some of the expressed fears seem exaggerated they are,

> nonetheless, of great political influence. It is imperative therefore that problems of public acceptability, and ethical questions raised, be recognised and dealt with." (Commission, 1991, p. 41)

Policy measures focusing on better public relations and information campaigns are then judged to be major instruments for promoting social acceptability. This 'deficit model' blames the public for its ignorance as to the merits of science. However, Eurobarometer surveys illustrate that there is no linear relationship between knowledge and social acceptability: an increase in knowledge does not go hand in hand with an increase in acceptability.

The public controversy over biomedicine and biotechnology (biopolitics) is strongly influenced by the very policy characteristics; three dimensions are deeply intermingled especially with regard to biomedicine, but also in biotechnology (cf. also Gill/Dreyer, 2001):

Cognitive dimension: How can societies take decisions under the condition of intrinsic cognitive uncertainty, e.g., in relation to health risks associated with gene therapy or environmental hazards resulting from the deliberate release of genetically modified organisms (GMOs)? What does epistemological uncertainty and the knowledge about the inherent limits of scientific knowledge mean for the management of risks? There is a strong, ongoing trend towards a 'scientification of politics', i.e. the inflationary use of scientific expertise in public policy-making. Simultaneously, we observe the 'politicisation of science': the competition between expertise and counter-expertise reveals that science is not an objective and value-free endeavour, but a socially constructed sphere. Science has lost it authority, yet, policymakers still rely on it for advice (cf. Weingart, 1999). Furthermore, risk research, which is so prominent with respect to biotechnology and biomedicine, does have a cognitive bias. This holds also true for the precautionary principle which is regarded as a management instrument to deal with this epistemological problem. Yet, risk research and risk management both assume that the regulation of risks can be encountered by increasing knowledge; they underestimate the fact that the *lack* of knowledge is a basic component and requires new modes in the management of knowledge as well as a higher reflexivity of regulatory law and practices (cf. Bora, 2002).

Interest dimension: Decisions over scientific and technological trajectories always involve conflicts of interest. For example, scientists are interested in doing research, medical doctors aim to help their patients, and industrialists want to sell new products and services; while patients' groups want to benefit from new therapies and demand individual choices, activists of the disability movement fear genetic discrimination or compulsory use of biomedical applications once they are on the market. While environmental groups often want to ban genetically engineered food, industrialists want to use the new technologies in food processing but depend on a reliable regulatory frame that addresses standards and requirements. Policy-makers have to balance these opposing interests and have to keep the common good in mind. They must develop policies which satisfy social needs and do not lead to permanent social conflicts.

Normative dimension: Risks deriving from technological inventions are perceived and judged differently according to social norms and cultural practices. In risk regulation 'objective' scientific values are "intertwined with more normative considerations. The acceptability of risk must therefore be weighed against normative values which are often strongly rooted in national traditions and cultures". (Vos, 1999, p. 30) At the same time, dissent over fundamental normative issues could be a constant source of social conflict. Thus, how do liberal societies respond to such issues? What kind of procedures are suitable for solving the principal dilemma that "the 'law' cannot resolve the cognitive dimension of risks; 'science' cannot provide answer to the normative dimension" (Joerges,

2001, p. 3)? Not only in the members states, but also at the supranational level normative standards have become a problem, for example, for social regulation of biotechnology and also with regard to embryo research in the fifth and particularly the sixth framework programme for RTD.(2)

Governance practices have to take these different dimensions into account and to balance their influence in policy and decision-making. Cognitive approaches that focus solely on (scientific) knowledge and interests while ignoring the normative dimension are insufficient.

3 Biopolitics and the development of European TA

In this paper, I attend to a widespread definition of TA which includes, for example, technological foresight, parliamentary TA institutions, policy advice committees just as well as more deliberative practices. The core of TA is to combine scientific evaluations of (new) technologies with their social assessment. Policy-makers are a primary addressee of (formal) TA; a common goal is to inform them about technological and social options and, thereby, to improve policy-making. This policy advice function is central to the concept of TA from it inception in the late 1960s; however, since the 1990s TA is reorienting towards the public sphere (cf. Joss, 2002; Weale, 2001). Simon Joss and Helge Torgersen (2000, pp. 84f.) proclaim that

> " the European landscape of policy analysis and TA seems to have changed remarkably. While only a decade ago, there were just a small number of institutions actively pursuing participatory initiatives, nowadays there are dozens of organizations and individuals engaging in such activities. To be sure, there are still critical voices, and public participation is by no means fully established in institutional TA; but the issue has certainly moved more centre-stage."

This turn to so-called participatory TA is, in fact, reflected on the supranational level. The brief historical reconstruction of this development and the predominant role biopolicies have played is the focus of this section of my paper.

3.1 Development of European TA

The founding of the Office of TA (OTA) at the US-Congress in 1972 was the starting point for a first wave in the institutionalisation of (parliamentary) TA in many West European countries and at the European level (cf. Vig/Paschen, 2000). The EC gained importance for the institutionalisation of TA in Europe by helping to build up relevant networks and by promoting the cooperation of organisations for TA founded in the member states (cf. Baron, 1995, p. 147). The programme “Forecasting and Assessment in Science and Technology” (FAST), set up in the mid-1970s, was a first attempt to build a community method for planning and forecasting of new technologies. One thematic focus of the FAST activities was the European 'biosociety'. The FAST group tried to formulate “A Community Strategy for European Biotechnology.” The effects of the FAST programme were rather limited because of the lack of strong ties with policy-makers, and of a firm institutionalisation within the community policies, especially RTD policy (Baron, 1995, 144; Weiler, 1995, p. 149). Furthermore, the basic orientation of FAST, stressing societal demands, collided with a general enthusiasm for technology among conservative governments in the 1980s.

For many years, the European Commission was the only institution attending to TA at the European level, even though the European Parliament become interested early on. In the mid-1970 when the parliamentary influence on European policies was still very limited, a proposal was made for a

„European Office of TA“ based on the OTA model which did not find the necessary support from the Commission; all attempts for a firm institutionalisation of TA were blocked (cf. Wennrich, 1999, p. 529). With the rise of counter-movements against nuclear energy and biotechnology in the 1980s and with the growing importance of RTD policy established in the Single European Act in 1986, the European Parliament took the initiative again. In 1987, a pilot project was set up for the establishment of a European parliamentary organisation for TA. In order to fulfil the responsibilities of the European Parliament on issues of socio-technical change and to defy the strong position of the Commission, the “Scientific and Technological Options Assessment Programme” (STOA) was finally set up.(3) STOA became an integral part of the Parliament’s administrative structure in 1992 (Holdsworth, 2000). However, while the idea was to incorporate participation of the public and of stakeholders as well as to create a public sphere, STOA followed in fact a strong expertise and instrumental model of TA.

The effect of STOA on the work of the European Parliament has been, at best, limited. The reasons are scarce financial and personnel resources, lack of continuity, the complicated institutional and cultural environment, unclear competences, an instrumental and science-driven focus, as well, as inadequate support by the Parliament itself (cf. Baron, 1995, 139ff.; Weiler, 1995, 163ff.; Wennrich, 1999, pp. 532f.). Biotechnology and biomedicine have been areas of major concern for STOA, however with minor influence.(4)

3.2 Biomedicine – a catalyst for the development of European TA

From the very beginning of European TA with the FAST programme, biomedicine was important and centre-stage. In the 1980s, Parliament discussed the rapid development of biotechnology and biomedicine several times, either in response to policy proposals by the Commission or on its own initiative. Yet, it was the European Parliament and its objections to the Human Genome Analysis Programme, originally launched by the Commission under the provocative title “predictive medicine” in 1988, that has incited and challenged the development as well as the function of European TA (Abels, 2000). With support from some member states in the Council, Parliament seriously criticised the proposal for its title and its supposedly eugenic rationale. It demanded, among other things, the establishment of a programme for the study of the ethical, social and legal aspects of human genome analysis (ELSA) and a broad public debate. The concept of accompanying TA became important for approval of the Commission’s proposal in Parliament (and the Council). In the final programme proposal, ELSA became an essential part funded with one Mio. ECU for two years. ELSA’s main task was to win acceptance for the programme and to soothe the interinstitutional and public debate .

This pragmatic ad hoc procedure and the installation of expertise-oriented TA have had long-term effects for the development of European TA. RTD policy, whose first rationale was to improve the competitiveness of European industry in a globalised economy, hitherto neglected normative and non-technical values. Conflicts in RTD policy were conflicts of interest, not of values. This changed dramatically starting with the Human Genome Analysis Programme. In the following RTD framework programmes, ELSA studies covered the whole field of biomedical ethics and of biotechnology. This means that around 1990, EC policymakers became receptive to the idea that technological innovations need to be “socially robust” to be successful. The presidents of the Commission, the Council and the Parliament decided that bioethics should become an integral part of RTD policy. Ethics and economy were no longer seen as opposing orientations, but as interdependent factors. Nevertheless in the beginning an instrumental conception of bioethics prevailed, as illustrated in the so-called Bangemann report on the competitive environment for biotechnology (cf. Commission, 1991, p. 41).

Besides the regulatory and internal market framework as well as funding policies, bioethics was now considered to be of utmost importance for the market success of biotechnology. Interestingly, some years later, the Commission interprets its policy shift as follows:

> " It may seem surprising at first sight that the Commission supported research on bioethics and even fundamental research on bioethics. But these new activities are in fact *logically integrated* into the larger scientific research programmes of the EC … Moreover, research on bioethics does indeed *answer to a political need* as bioethical considerations are playing a growing role in political debate within the European Union." (Biomedical & Health Research Newsletter Nr. 2/1995, p. 10; my emphasis)

The Commission was in a central position to confront these barriers. In the 1990s, it concentrated on the following instruments:

1. The outcome of the Presidents' meeting in 1991 was a Commission communication on the integration of ELSA into all biotechnology and biomedicine related RTD activities. Bioethics and TA were integrated into the regular mechanisms of *European RTD policy*, and funding increased enormously.(5) Bioethical research is expected to fulfil two main tasks: Firstly to develop a set of guidelines for ethically responsible research funding; some research is excluded from the RTD programmes (e.g. germ line interference and human cloning), for some other provisions are set. Secondly, it should contribute to public debate and policy deliberation. Whether the studies are effective, and how to measure their success, is under debate. According to a STOA evaluation, it is quite unclear what role „the issue of public policy relevance plays in the Commission's evaluation of the ethics research. In fact, it is not clear *what* role bioethics research plays in such evaluations at all" (STOA, 1998, p. 50). STOA warns that the Commission perceives "ELSA, Biomedical ethics and public perception funding … as merely a public relations exercise or sop to the concerned" (ibid., p. 51).
2. Along with the reorientation of RTD policy came some *organisational restructuring* in the Directorate-General for research. A special unit for ELSA was founded within the directorate for life sciences.
3. The Commission has revised its *structure for policy advice*. In the course of the 1990s, it established several new groups for such purpose. The first such group was the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB) set up in 1991; it consisted of first six, then nine members from law, philosophy, medicine, biology. Its task was to identify and define new ethical problems with regard to biotechnology, to assess these aspects and their potential influence on society and the individual, as well as advise the Commission. In 1998, GAEIB was suspended and the new European Group on Ethics in Science and New Technologies (EGE, 2001) set up. The groups consists largely of experts from the same scientific disciplines as GAEIB plus informatics; its mandate to assess *all* new technologies is confined by the competences as laid down in the treaties.(6) Yet again, the common-market approach to bioethics is evident:

   > " On the basis of the principles laid down in the European Treaties (which make reference to the fundamental rights defined by the European Convention of Human Rights of the Council of Europe), the EGE endeavours to draw up common rules *to enable the internal market to operate in accordance with Europe's ethical values*." (EGE, 2001; my emphasis)

A further high-ranking policy group, the Life Sciences High Level Group consisting of eleven biologists, was formed in April 2000 by Commissioner Philippe Busquin to inform the Commission on new developments in the so-called life sciences, and to generate proposals on how to further the dialogue between science and society.

3.3 Characteristics of supranational TA and policy-making

Three conclusions can be drawn regarding the development at the supranational level from the 1970s to the late 1990s: Firstly, the European level relies on a *instrumental and science-driven model* of TA; generally, participatory structures have not been developed. The Commission sets up and makes use of scientific advisory committees; it utilizes its organizational resources and experiences to decide who gets access to European policy networks and who doesn't. Policy- and decision-making on issues of science and technology is, above all, a "politics of expertise". Epistemic communities, that is networks of professionals with recognized expertise and an authoritative claim to policy-relevant knowledge, have easy and – above all – privileged access to European-level policymakers (cf. Haas, 1992; Zito, 2001). This has also become obvious in the EC comitology system dealing with these questions (see section 4). Yet, as the sociologist of science Sheila Jasanoff (1990) has forcefully argued: "The naïve vision of neutral advisory bodies 'speaking truth to power' should be renounced." It is this focus on expertise in RTD regulatory and funding policy that has led to the accusation of technocratic governance suffering from a lack of public legitimacy (cf. Peterson, 1995a; Radaelli, 1999; Zito, 2001).

Secondly, we can observe the *rise of bioethics*. The responsiveness to and emphasis on bioethics in European TA is clearly rooted in the normative dimension of biopolitics – moreover, bioethics and TA are often thought of as the same. This development is not unique to the supranational level, but ethics has gained prominence in strategic decision-making and public policy in the member states as well (cf. Lindsey et al., 2001; Salter and Jones, 2002). In the 1970s and much of the 1980s, the predominant policy framing centred on risks; controversies were framed as scientific-technical debates. In the 1980s and, particularly, in the 1990s, we can see a fundamental change towards ethical framing of policies. Since 1997, ethics has taken centre stage in public, policy and media discourse. This is also obvious at the European level, if we look at the Council activities. Shortly after the cloning of "Dolly" the sheep, the Amsterdam Council accepted a resolution that prohibits the cloning of human beings. The Council requested that the Commission considers this aspect in the patenting directive, which was still under debate. The position against reproductive (as opposed to so-called therapeutic) cloning was confirmed in the "Charter of Fundamental Rights" first accepted at the Nice Council in December 2000, then acknowledged by the Commission and the European Parliament.(7) In addition, for the first time in EU history, the Stockholm Council in June 2001 called attention to the need for a broad and open ethical debate on biotechnology as one of the most important technologies for Europe's future; bioethics should become an integral part of the innovation process (Swedish Presidency, 2001). With regard to RTD policy, until the end of 2003 the Council has to come up with shared ethical guidelines which regulate the funding of sensible fields such a embryo research. Finally, the outstanding position of ethics is also reflected in the changes introduced in the regulatory framework. For example, the new European Parliament and Council directive 2001/18/EC on the deliberate release of GMOs speaks of the possibility of introducing an ethical expertise into the regulatory procedure (see section 4). However, this turn towards bioethics poses new challenges for Community policy- and decision-making; current governance practices prove inadequate for these issues.

Thirdly, since the days of Commissioner Edith Cresson, the Commission has tried to take the *social prerequisites of technological innovations* into account. John Peterson and Margaret Sharp point out:

> "The diffusion of innovations involves constant change and a reciprocal moulding process between technologies on the one hand and societies on the other. Yet, technology policy is a uniquely technocratic area of policy in which experts are powerful and the general public is not. Efforts by the Commission under Cresson to make EU-funded research more socially relevant and sensitive to the 'needs of society' reflect a new and general enthusiasm for open debates about how technology policy can

serve broad social needs." (Peterson/Sharp, 1998, p. 20)

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Including bioethics and integrating a wide range of scientific disciplines into the structures of policy advice was a way to tackle the growing sensitivity to social innovations. According to Christine Landfried (1997), these changes suggest a transformation of the Community "beyond technocratic governance". However, it took some more years until a deeper policy shift began to mature.

4 Regulatory biopolicies – between science and participation

The historical changes outlined so far with regard to RTD policy influence the approach to regulatory issues. The development and dominance of regulatory policy has been widely discussed by scholars of European integration. Furthermore, the regulation of risks and the role of scientific expertise in decision-making, in particular with regard to food and technical standard-setting, has been a major topic (e.g. Joerges et al., 1997). Recently, outstanding institutional and policy changes have been introduced in EU risk regulation so that David Vogel (2001) speaks of a "new politics of risk regulation". Biopolitics and above all the controversy over GM food has fostered these changes.

Since the 1990s, the EC has become the most important actor for the regulation especially of biotechnology; it has developed a vertical and horizontal, process and product-related regulatory framework focussing on the special risks inherent in these new technologies. However, it is essential to distinguish the Community's regulatory competences with regard to biopolicies. The EC Treaty assigns broad competences to the supranational level for biotechnology, while they are very limited in the area of *biomedicine*.(8) Health policy (of which biomedical policy is part) is still for the most part a national domain. Yet, some Treaty articles allow for measures related to biomedicine, especially in relation to research funding. So far, the main role has been to encourage biomedical RTD, which has become a controversial issue in the context of human genome research and, recently, embryo research. Yet, for one aspect the EC has strong regulatory power and that is pharmaceuticals. Since the early 1960s, the EC has harmonised the marketing authorisation for pharmaceuticals, and in 1995 two new procedures were introduced, one specifically for pharmaceuticals derived from genetic engineering (cf. Feick, 2002). While the new regulatory regime still allows for national authorisation procedures and subsequent mutual recognition, biotech (and all other innovative) pharmaceuticals have to go through a centralised procedure requiring approval by the European Agency for the Evaluation of Medicinal Products (EMEA) and leading to uniform and binding European decisions. Since drug development is a very long-term (and high-risk) process (it takes 10 to 15 years from the laboratory to clinical practice), and since the pharmaceutical sector has only started to invest in this development in the 1990s (this is partially an outcome of the Human Genome Project), more and more pharmaceutical will have to be authorised under this centralised procedure in the future.

In *biotechnology*, distinctive and rigorous regulation has been developed since the 1990s pertaining to agriculture and food. The first two Community directives addressed the contained use of GMOs (Council Directive 90/219/EEC) and their deliberate release (Council Directive 90/220/EEC). The latter directive regulates experimental as well as market release of GMOs; it has become *the* cornerstone of Community regulation and was under massive critique from the very beginning (cf. Cantley, 1995; Gottweis, 1999; Patterson, 2000). Especially the market release of GM food and crops has led to massive conflicts at the supranational level, particularly via the comitology regime, that is, the complicated implementation procedure involving the competent national authorities and the Commission in the regulatory process. Christian Joerges and Jürgen Neyer (1997) claim that comitology committees are usually an efficient means of social regulation by "transforming strategic interaction into deliberative problem-solving". Thereby, according to Joerges and Neyer, they

constitute a special way of legitimising Community policies beyond the dichotomy of input versus output legitimacy. With regard to GMOs, however, rational deliberation and normative reasoning failed: In all cases where a competent authority approved the market release of a GMO, a competent authority in another member state raised objections and in so doing initiated the comitology procedure. “This was because the mutual recognition of risk assessment demanded by the directive did not occur since competent Authorities do not trust the risk-assessment carried out by other Competent Authorities”. (Toeller/Hofmann, 2000, p. 40) Material criteria for risk assessment and management, which are not fixed in the directive itself, were contested among the members of the Article-21 Committee in charge. The situation escalated with Ciba Geigy’s bt-maize in 1996: after having consulted several scientific committees supporting the Commission’s position pro market release, the Commission authorised the bt-maize against the outspoken will of 14 member states.(9) This incidence contributed, firstly, to an institutional reform of the comitology system itself (cf. ibid.), and, secondly, to a policy change: since 1999 there is a *de facto* moratorium for placing GMOs on the market.(10) The moratorium stressed the urgent need for a revision of the deliberate release directive which was finally adopted in early 2001 (EP/Council Directive 2001/18/EC). The new directive, coming into force in October 2002, attends to strong public concern and makes transparency as well as public participation in the national authorisation procedure compulsory.(11) Still, the new directive has not yet led to a lift of the ban on GMOs.

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GM food has proved to be most controversial. Especially due to the BSE crisis and its mobilising effect on domestic publics, food safety has become the prominent policy frame. Vogel (2001, p. 13) states that “… mad-cow disease has shaped the way Europeans have framed the potentials risks associated with GMOs”.(12) The principle of mutual recognition applied also to GM food until the so-called novel food regulation (Regulation 258/97) was adopted in 1997 – again after years of intense debate (for a detailed reconstruction cf. Rückert, 2000). It introduced a harmonised, two-step procedure involving national food agencies and the Commission; accompanying regulations concerned, above all, labelling standards (cf. also European Commission, 2002b). Nevertheless, the regulation proved insufficient and some member states used the safety clause to ban the import of GM food. Finally, in 2000 the Commission proposed a new regulatory regime for food in its *White Paper on Food Safety* (European Commission, 2000e; cf. also European Commission, 2000d). At the heart of this new regime is the independent European Food Safety Authority (EFSA) formally adopted on 28th January, 2002. EFSA is of chief importance for the GMO debate, because it will provide scientific opinions on any issue related to GMOs (European Commission, 2001h, p. 2). The crucial aim is to win back public *trust* in the Community’s ability to effectively manage the risks posed to the environment and human health.

In addition, the Commission proposed two new regulations in 2001 focussing on the traceability and labelling of food (ingredients) and feed that consist of, contain, or are derived from GMOs (European Commission, 2001f; European Commission, 2001g). It suggests establishing a 'one door – one key' principle for the authorisation procedure of food and feed involving EFSA along with traceability and labelling of GMOs “from the farm to the fork”. As Commissioner David Byrne comments on the first reading in the European Parliament, the proposals “provide the right approach to foster public confidence and social acceptance of the application of biotechnology in agri-food production. They will also give legal certainty for business operators as well as facilitating trade”. (European Commission, 2002c)(13)

The emerging food regime deserves some further consideration, particularly in comparison to other countries such as the US, where regulatory agencies have been introduced as a response to the regulatory crisis of the 1960s and 1970s. A characteristic feature of the EU food regime is that it distinguishes between *risk assessment* and *risk communication*, which is the duty of EFSA, and *risk*

management, which is a privilege of the policy-makers. This distinction has ambiguous and even counter-productive effects as, for example, Giandomenico Majone, Ed Randall, and David Vogel argue in their critique of the new regime.

Majone is certainly one of the most important and outspoken advocates of regulatory policy and strong regulatory agencies in the EU (cf. Majone, 1996). In a recent article he has criticised the emerging European food safety regime. According to him, the EFSA structure reflects the changing meaning and the ambiguity of the precautionary principle. First introduced in the Maastricht Treaty in the chapter on environmental policy, the precautionary principle has been broadened to cover all human, animal and plant health. In its Communication on the precautionary principle (European Commission, 2000a), the Commission assigns it “the status of a 'central plank' of Community policy and, more ambitiously, the status of a general principle of international economic and environmental law” (Majone, 2002, p. 90). Majone claims that this principle has many theoretical as well as practical weaknesses, above all the lack of a clear definition besides the unclear effects on regulatory science, on integration and diversity as well as on free trade. He argues that the emphasis on the precautionary principle and the key status assigned to it “could be interpreted as a strategy to avoid or at least delay difficult institutional choices” (ibid., p. 107). He suggests establishing strong regulatory agencies with powers of rule-making *and* rule enforcement based on the US model of federal agencies.

Majone reasons that the distinction between scientific risk assessment and political risk management leads to a politicisation of food safety which restricts the credibility of the new regulatory institution. This is, of course, of paramount importance in an already highly politicised policy area such as biotechnology and GMO where public opinion is highly divided and where some member states have an outspoken anti-biotech position due to the public controversy (resulting, for example, in an imposition of national bans on GMO products). This politicisation argument is supported by Ed Randall, who asserts that it brings about the real danger of secrecy and intergovernmental pork-barrel politics.

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> "The real concern of those who believe that a sharp distinction between risk assessment and communication and risk management is unsound is a well founded fear that the squabbles and national rivalries and suspicions that have characterised EU decision making and risk management in the recent past will undermine the authority of both the EFA (European Food Authority; G.A.) and the Commissioner for Health and Consumer Protection in the future." (Randall, 2001).

Yet, credibility of the new regime is an important issue. Vogel contributes an historical argument; he states that the current style in EC risk regulation resembles the risk-averse US approach during the 1960s and through the mid 1980s. In the US, strong regulatory agencies helped to reconstitute citizen’s trust in the state’s capacity for successful risk management. Vogel implicitly assumes that this is a viable course for the Community as well, since the EC and US polity share important similarities such as a division of power in a multi-level system (Vogel, 2001, p. 18; cf. also Randall, 2001).

While these critical analyses certainly shed light on some most important aspects of the current debate, in my opinion, they do misjudge to some extent the nature of the problem and its institutional context. Firstly, the current regulatory crisis is not limited to the EU and its member states alone.(14) The resistance to GMOs has influenced biopolitics far beyond the EU, for example with regard to world trade (cf. Skogstad, 2001), but also international food aid.(15) Martin Bauer and George Gasekell (2002) speak of “the making of a global controversy” which is, to some extent, induced by

the critical European public; the EU debate does have impacts on the US debate. Jasanoff (2000) observes, in fact, a "crisis of expertise" in the US just as in Europe. However, the political responses differ: The debate in the US focuses on the role of experts, on policies, and on specific issues such as biotechnology. The European debate, in contrast, is about the status of science in general, new forms of governance, institutional reform and the need for changing the relationship between science and society. Yet, participation is considered an adequate response in the EU as well as in the US.(16)

The EU focus on governance and institutional change is linked to a second aspect: the state of its *polity* and fundamental differences to the US. The establishment of strong regulatory agencies in the US was, of course, a major and, according to Vogel, also successful institutional intervention. However, they were introduced into a historically grown political system with well established means for securing legitimacy, e.g. by introducing a system of notice and comment which allows for transparency and responsiveness of the regulatory system. These agencies work, in general, quite well in the field of biotechnology so that opinion polls show that the level of trust in the regulatory agencies is higher in the US than in the EU (cf. Gaskell et al., 2002). Yet, the conditions for choosing such institutional solutions are different in the EU: it is an evolving, dynamic and hotly disputed political system of intergovernmental and supranational character which poses new challenges for the problem of democratic legitimacy. It cannot rely as much on generalised public trust and support since it still has to develop ways to channel public opinion into supranational policy-making. The history of the biotech controversy shows that the existing institutions do have the capacity to channel public opinion, but it is limited and so far it has not been successful in terms of resolving the conflict.

The limited capacity has to do, so I believe, with the nature of the conflict and its strong normative foundation. The argument that risk assessment and management are inseparable and should be in one hand, that is, the regulatory agency, is after all based on a *cognitive and positivist premise* that doesn't sufficiently take the normative (and sometimes even ethical) dimension of technological conflicts into account. It underestimates the influence of norms in regulatory science and considers science-based knowledge as the only legitimate source of regulatory knowledge production and decision-making. However, a normative dimension is inherent in all social regulation, but it is of particular importance with regard to biopolicy. In her discussion of European agencies Ellen Vos points out that – at least in situations of scientific uncertainty – the "non-majoritarian governance model based on independent technocratic agencies clearly fails to recognise the value-laden nature of health and safety and environmental regulation" (Vos, 2000, p. 19; cf. also Neyer 2000; Joerges 2001). Moreover, normative premises are often, indeed, part of the assessment procedure itself; therefore, there has to be a political debate. The dominant public view of the EU is already that of technocratic decision-making. Efforts to depoliticise a debate that is inherently political will not solve the basic problem.

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This is also the official Commission's position; it claims that the separation of risk assessment and management allows the necessary inclusion of other factors than science.

> "It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk-management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, ethical and environmental factors and the feasibility of controls". (European Commission, 2000d, p. 28) (17)

The EFSA structure in my opinion tries to reflect some of these aspects by establishing a corporatist structure integration stakeholders and policy networks with national authorities, as well as by

communicating risks to the public.(18) The Commission states that the work of the EFSA shall be transparent for the public (European Commission, 2000d, article 37); furthermore, it "shall develop appropriate contacts with consumer representatives and any other interested parties" (ibid., article 41) and the management board shall include representatives of consumers and industry (ibid., article 24). However, so far it practically not clear who should be involved in the production of regulatory knowledge, in which way and to what ends; the Commission's statements are still very vague. This is not to say that there should not be regulatory bodies, there is of course an urgent need. The normative and the science-based assessment are complementary; the normative assessment does require a science input. Yet, both modes of assessment of technological risks do operate under the Damocles sword of uncertainty and the intrinsic lack of knowledge (cf. Bora, 2002). Whether or not the EFSA will be efficient in solving or channelling the biopolitical debate is still an open question. If it is to be successful, it is important to consider how it fits into the overall governance design and the ongoing "participatory" shift in the EU.

5 Contextualising the "participatory" shift: Reforming European governance

The reform of European governance has held top priority on the agenda since early 2000. The current crisis to which the Community is attempting to respond is not limited to risk regulation only, but is essentially part of the deep "democratic deficit" of the EU and its legitimacy crisis. This is the reason for the prominent place of risk regulation and biopolitics in the White Paper on Governance and related policy papers the Commission has published in the last two years. One of the most striking features these policy papers share is their "participatory" speech: They emphasise the need for input legitimacy and take this as a means for strengthening output legitimacy. They are all concerned with new institutional and procedural mechanisms for more "participation" by creating a public sphere and including stakeholders, the general public and citizens in Community policy-making. Science and technology – in particular, biotechnology – assume a prominent place; it is in this context that the Commission speaks of the need for a "new societal contract". While this focus on participation is itself very remarkable, a closer analysis of what participation means in this context and how it is operationalised reveals that the Commission basically applies a very limited concept that can be characterised as "participation via consultation" rather than participation as used in theories of, for example, participatory democracy.

5.1 Challenges and principles of European governance: the White Paper

The long awaited *White Paper on European Governance* (European Commission, 2001a) addressed to the Member States, public authorities, and civil society provides the most general outline of the Commission's view of the problem.(19) For the Commission, the starting point is that "people increasingly distrust institutions and politics"; this is "particularly acute at the level of the European Union" (ibid., p. 3). The goal of the *White Paper* is "to open up policy-making to make it more inclusive and accountable. A better use of powers should connect the EU more closely to its citizens and lead to more effective policies." (Ibid., p. 8) For the Commission there is a very strong link between input and output legitimacy. Key principles of "good governance" referring to input legitimacy are openness, participation, and accountability. In the Commission's vision, consultation of and dialogue with civil society, that is a wide range of interest groups, associations and grass-roots organisations, enjoys a prominent role, because "civil society plays an important role in giving voice to the concerns of citizens and delivering services that meet people's needs" (ibid., p. 14).

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At first sight, it seems striking that the Commission is adopting such an input approach. Scholars of

the 'democratic deficit', such as Fritz W. Scharpf (1999), raise serious doubts that the EU fulfils the necessary systemic prerequisites for input legitimacy; according to Scharpf, the EU can only rely on output legitimacy. The options laid out in the *White Paper* raise the question as to why the Commission is advocating a participatory governance model. In the past, the Commission has proved a very successful architect of policy networks. These networks allow the formal and informal interaction of public and private actors from a heterogeneous background. The networks are sometimes very open, inclusive and bottom-up but often very elitist, exclusive, and top-down (Kassim, 1994; Peterson, 1995b). Experts, i.e., scientific experts as well as representatives of interest groups(20), do take a central position in these policy networks, because the Commission depends heavily on external expertise. The remarkable committee system is the main route via which expertise is integrated (cf. Pedler and Schaefer, 1996; van Schendelen, 1998; Christiansen/Kirchner, 2000).

Bearing this in mind, the Commission's commitment to a participatory approach is less amazing, since it puts the Commission in a central position as a policy-broker. In this sense, the interinstitutional battle for policy-making power as well as shifting weights in favour of the European Parliament (due to the co-decision procedure) are the background for the Commission's vision of European governance (cf. Héritier, 2001; Laffan, 2002; Wincott 2001). The Commision attempts to gain back lost ground by promoting a concept that puts itself in a key position.

In the *White Paper*, the Commission considers the relation between science and society a crucial area for European governance (cf. European Commission, 2001b), explicitly mentioning biotechnology. Policy-making and regulation rely very much on expert advice, but biotechnology has illustrated that advice beyond 'pure' science is necessary, and that there is need for public confidence in expert-based policy-making (cf. ibid., p. 19). The Commission suggests a multi-disciplinary expert system and the creation of a European scientific reference system to support community policy-making, in order to democratise expertise. In so doing, it can handle the "challenges, risks and ethical questions thrown up by science and technology" (ibid., p. 33). In the final analysis, a lack of public confidence is *the* fundamental problem for the Commission. Hence, the task of the Community institutions, above all the Commission, and of experts is to rebuild this confidence by integrating the citizenry. The next question is: How is this 'trust model' further elaborated in the sectoral policy papers on science and society?

5.2 Science and society – sectoral visions for European governance

In addition to the *White Paper*, the Commission has published several sectoral papers, for instance the *Communication on the European Research Area* (ERA) that address general questions of governance in RTD policy. It has furthermore published papers on the relation between science and society. Les Levidow and Claire Marris (2001, p. 348) claim that these papers indicate a change in the Commission's own view of the science/society relation "from public ignorance to loss of trust". So far, the Commission has attributed societal opposition and resistance to biotechnology to a lack of public understanding, to people's fear and ignorance (cf. Commission, 1991), now trust is the new catchword. This 'trust model' already mentioned in the *White Paper* requires a new tools: better communication between researchers, industry, policymakers and citizens – and participation.

In the *ERA papers* (European Commission, 2000b; European Commission, 2000c), the Commission starts with a negative diagnosis of the current situation for research in Europe. The Community is at risk of losing the race for growth and competitiveness in a global economy, "Europe might not successfully achieve the transition to a knowledge-based economy" (European Commission, 2000b, p. 4). Science and technology, and particularly biotechnology, are vital for such transition. However, the public image of science is "less positive than it was. Scientific progress seems to inspire as much anguish as hope " (ibid., p. 5). It is this context, when the Commission suggests new modes for governing RTD, particularly a harmonisation of (so far) complementary and often competing research policies between member states and the Union. I do not want to address the problems this

brings along for the adjustment of national RTD policies. Instead, I am interested in how the Commission perceives the relationship between science and society. In the *ERA Communication*, the Commission attends to this problem in the final (!) chapter, "An area of shared values". It recommends developing "new and sustained forms of dialogue between researchers and other social operators" (ibid., p. 20). The Commission refers to consensus conferences, an instrument of TA known for its radical participatory approach, "organised at European level on issues emerging at that level" as a means for "ordinary citizens" to express their opinions and concern on issues of science and technology (ibid.) – "at least experimentally" (European Commission, 2000f, p. 16).(21) Furthermore, the ethical dimension "especially in fields such as life sciences" regarding issues such as cloning or embryonic tissue could be strengthened by establishing closer links between ethics committees set up at the national and European levels (European Commission, 2000b, pp. 20f.).

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In the policy paper on science and society as well as in the action plan, the Commission further elaborates this concept (European Commission, 2000f; European Commission, 2001d). It repeatedly confirms the need for a "new partnership" (European Commission, 2001d, p. 4) by promoting open dialogue between researchers, industrialists, policymakers, interest groups and the public (European Commission, 2000f, pp. 6, 16) especially at the European level, but also at the national, regional and local levels (European Commission, 2001d, pp. 12f.). The Commission denounces a simplistic and linear model of technological innovation from scientific invention to useful application; technological innovations are recognised as outcomes of social networks that incorporate a wide range of social actors, including users (ibid., p. 8). People should be involved, "particularly in defining the priorities of publicly-funded research" via consultative and advisory bodies (ibid., pp. 8f.) in order to "bring science policy closer to the citizens" (European Commission, 2001d, pp. 5, 14). The experiences with participatory research policy-making – a supplement to formal decision-making –, "now need to be widened and deepened to systematically include other sectors of civil society at all stages" (ibid., p. 14).

Levidow and Marris welcome the Commission's initiative, but they are most critical about the way the science/society issue is dealt with. According to them, this new rhetoric of openness is double-edged and contradictory, because participatory talk often just covers the former 'deficit model':

> "the new focus on a crisis of 'confidence' has not entirely abandoned preconceptions about misplaced fears or public ignorance. … On the one hand, official proposals for 'stakeholder dialogue' are put forward as a novel approach, developed from lessons learnt from past paternalistic institutional behaviour. On the other hand, they continue to frame the problem as a gap between scientific knowledge and public anxiety – presumably a gap between rational judgements and irrational concerns. 'Public debate' and 'input from society' are sought mainly as a means to restore the legitimacy of science and technology, not as a means to reconsider innovation processes." (Levidow/Carr, 2001, p. 348)

They continue that

> "thus, in these official discourses, public distrust is often still attributed to deficient public knowledge of science. Consequently, better communication is still seen as a key solution" (ibid.).

While ethical concerns are now taken into consideration, they are believed to be "extra-scientific". Scientific and other arguments are characterised as separable. While the first are still perceived to be objective, the last one is attributed to the subjective realm and are, therefore, of secondary

importance only (ibid., p. 349). This keeps the notion of value-free science and scientists alive; expert advice is too often simply equated with science. In so doing, the public is still the source of the problem; but in accordance with Levidow and Marris, this is a fundamental misdiagnosis.(22) The authors conclude that the perception of science and technology as "objective basis for policy" (ibid., pp. 356f.), in fact, does create the legitimacy crisis. Yet, if the aim is to relegitimise decision-making, government will need to 'un-learn' many institutional assumptions and to redefine the problem at stake. Rather than seeking ways to change the public, it is necessary to change the institutions responsible for promoting innovation and regulating risks. (ibid., pp. 357f.)

To them, wider participation of lay-people should not be restricted to the assessment of innovations once there are near to the market, but to trajectories in research policy in general.

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5.3 Visions for the governance of biopolitics

I presume that biopolitics puts models for European governance in the field of science and technology to the test. As declared by the Commission, "GMOs, and more specifically transgenic plants, have come to symbolise all that is wrong in the relationship between science and society" (European Commission, 2001e). In order to "break the deadlock" (ibid.), it has recently published a document "Life sciences and biotechnology – A strategy for Europe" (European Commission, 2002a). The *Strategy Paper* is the outcome of a consultation process the Commission initiated with its *Consultation Document* "Towards a strategic vision of life sciences and biotechnology" (European Commission, 2001c). This document is an expression of the new governance strategy. The Commission invited "comments from citizens, consumers, as well as organised civil society, scientists, public authorities and operators with economic interests in industry, agriculture of services to contribute to the Commission's reflections" (ibid., p. 5). In the *Consultation Document,* the Commission outlines basic problems and questions on a range of issues related to biotechnology, from ethical implication, to regulation, public involvement to trade, international collaboration and development policy.

The document starts from the assumption that the life sciences have a vast potential for ensuring the competitiveness of European industry (ibid., p. 3f.). The challenge is to transform research into new products and services; the successful transformation requires a society fully committed to technological innovation.

Most importantly, this potential can only be realised if there is broad public support. Consequently, there is increasingly a need for awareness and enlightened policy decisions on the societal priorities, and in particular on the *societal framework* and the *ethical basis* for development and applications of the new sciences and technologies. (Ibid., p. 4)

Ethics as well as social or economic implications biotechnology are perceived to be of "key importance" for public perception and, therefore, they have to be properly dealt with. "The key to success lies with all stakeholders in Europe – public authorities, science, economic operators and consumers as well as the general public." (Ibid.) In short, the issue of science and society is thought to have a direct effect on Europe's economic future. The Commission concludes that the life sciences are of "strategic importance for Europe's quest to become a leading knowledge-based economy" – an opportunity Europe "cannot afford to miss" (ibid., p. 27). The broad public debate has demonstrated the challenge to find "socially acceptable solutions". Therefore, the "key to resolve the apparent dilemmas lies with Europe's citizens", and that is why the Commission invites comments to its policy proposal.

In the *Strategy Paper* and the attached action plan, the Commission takes up the somewhat deterministic vision for biopolitics: the choices for Europe are "either a passive and re-active role, and bear the implications of the development of these technologies elsewhere, or develop pro-active policies" (European Commission, 2002a, p. 3). The Commission holds "uncertainty about societal acceptance" responsible for the lack of attention to biotechnology in Europe, which, in turn, has had negative effects on economic performance. The basis question is: "How can Europe deliver effective, credible and responsible policies which enjoy the *confidence and support* of its citizens?" (ibid., p. 5; my emphasis). Ethical and societal implications are important to consider. Yet, the choice for the Community is "not whether, but how to deal with the challenges posed" (ibid., p. 3).

Chapter 4 of the *Strategy Paper* deals with the science/society issue; here the Commission refers to its *Action Plan* discussed above (European Commission, 2001d). Governance of biotechnology, that is "the way public authorities prepare, decide, implement and explain policies and actions" (ibid., p. 11), is called a "key element for responsible policy". For the Community, five lines of action are important: societal dialogue, a development "in harmony with ethical values and societal good", demand-driven applications, public confidence through science-based regulation, and respect for Community and international regulatory principles and legal obligations. The Commission stresses the need for "constructive" and "meaningful" dialogue open to all stakeholders, which has to be "balanced and rational" (ibid., p. 12). It distinguishes between "real issues" and "false claims", without explaining how to draw this distinction. Who is to decide which is which? The key significance of the dialogue is "to help the public and stakeholders better understand and appreciate" (ibid., p. 13) the complex issues raised by biomedicine and biotechnology. Yet, the Community should actively pursue this dialogue; it should be on-going, and not restricted to product regulation only. In the action plan annexed, the Commission announces its intention to take the initiative for establishing a "broadly based Stakeholders' Forum" and for encouraging public debates (Action 13). The Commission wants to strengthen research into socio-economic and ethical issues (Action 14). Furthermore, it aims to help identify areas for possible consensus on ethical principles, above all in relation to biomedical applications (e.g. stem cell research, genetic testing); it proposes, where appropriate, to set up self-regulatory guidelines for scientists and industry (Action 16).

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The Commission stresses the role of the *bourgeois* rather than the *citoyen* or *citoyenne* in science policy: the consumer should decide what products to buy on the basis of informed choice, and thereby influence the technological trajectory (cf. ibid., p. 14). For regulation based on scientific assessments, "building public confidence and understanding must be a permanent concern" (ibid.; cf. also ibid., p. 16). The scientific community has to take a central position in this dialogue, since it has to explain the scientific background to the public (while industry needs to explain the benefits of products).

6 Conclusions

The Commission has recently turned to the issue of European governance and introduced some proposals for changes in the way, the EU can enhance its policy performance. The Commission has operationalised some of its ideas for the field of biopolitics; its proposals are dressed in a remarkable "participatory talk". At the same time, it has tried to implement some of the changes is suggests; the new food safety regime takes a prominent place.(23) However, the Commission proposals are based, firstly, on a narrow concept of participation and, secondly, the shift from a deficit to a trust-based model in the field of biopolitics does have its pitfalls. Participation, according to the Commission, implies getting all kinds of social actors involved in supranational policy-networks; indeed, this basically means top-down consultation of sectoral stakeholders. Some scholars question, if this is

actually a shift at all; Paul Magnette, for example, criticises that the Commission does neither “break with the classical methods, nor with the philosophy which underpins it … Participation can only be initiated by the institutions, it is limited to non-decision and mainly directed towards sectoral actors”. (Magnette, 2001, p. 5) The various governance papers, particularly the White Paper, do not sufficiently – if at all – address the question of the practical realisation of this participatory shift, especially with relation to policy issues involving risks. Scharpf (2001, p. 7) even argues that “since not a word is lost on the practicalities of Europe-wide participation, one might wonder about the seriousness of the invitation itself”. One of the few concrete instruments mentioned for citizen’s participation are consensus conferences; however, they are practically very difficult to conduct on the supranational level. The advantage of this instrument is that it would allow deliberation between experts, citizens and Eurocrats and help to create a sectoral European sphere.

Furthermore, this shift from deficit to trust is not per se a positive development because it does not sufficiently address the relationship between trust and knowledge in risk regulation. First of all, the trust model covers up what is, at least partially, the 'deficit model': confidence and understanding are mentioned in concert. Yet, understanding can be a major source of distrust. The Commission’s policy is not coherent: While it argues for a separation between risk assessment and management with regard to the food safety regime, in the policy papers on biotechnology it distinguishes between “real” scientific and “false” non-scientific claims. However, who should draw the line? This model assumes that trust in the authorities (e.g. regulators, policy-makers, science) is a better source for creating legitimacy than knowledge. Yet, trust and knowledge are closely interlinked in many ways. How much knowledge and how many control mechanisms does trust require, if we do not want to stick to a model of 'blind trust' and fall back on a paternalistic view of the Commission as “a benevolent dictator” (Scharpf 2001, p. 7)? What does trust imply in a policy field where diverse normative orientations – and even ethical considerations – are as important as opposing interests as well as intrinsic limits to knowledge? How much trust is required in the regulators ability to deal with the lack of knowledge and the omnipresence of uncertainty? And how much “authority” over the dimension of “true science” v. “value-loaded conflicts” does transnational decision-making require in order to be effective (Joerges, 2001, p. 15)? Finally, does participation help to build trust or could it even diminish the trust in authorities? The Commission does not attend to these issues any further.

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The relationship between input and output-oriented legitimacy is essential for the debate on European governance. The choice is not either input or output, since the deficits are on both sides with regard to biopolitics. There are surely options for improving the output side in science-based policies without considering participatory means via established (or new) political institutions, for example, by transparent and coherent policies within the comitology regime or by regulatory agencies. Nevertheless, participatory means may help to improve the legitimacy. However, the relation between participation and legitimacy – claiming that more participation leads to better policies and thereby to more legitimacy – is, in fact, much more complex than the Commission assumes in its various policy papers. Participation guarantees neither legitimacy nor trust. Participatory structures do have their own restrictions. Who can participate when and where, under which conditions, and in what? Moreover, an emphasis on input-oriented methods can even have counterproductive and delegitimising effects given the complexity of the EU and the various sources of its legitimacy (cf. Höreth, 1999). Inefficient outcomes of participatory processes can have a delegitimising effect on the procedure itself. Participation can, at best, serve as a *complement* to other means of representative democracy, especially in a political system such as the EU where participatory procedures are very hard to develop given the multi-level nature of the system and the absence of a European public sphere. The lack of this broader contextualisation of the legitimacy problem and of its practical difficulties is a major blind spot in the Commission’s vision.

Biopolitics will remain on the agenda of the EU: The debate on the regulation for traceability and labelling of GM food and feed has only started and there is also growing need for a harmonised policy in some areas of biomedicine, which is not restricted to the contested area of embryo research. In many EU member states, biopolitics has become a field for political experiments with alternative ways to create legitimacy which require deliberation between experts, citizens and policy-makers in order to solve the dilemma of science v. society. It could also serve as an experimental field at the supranational level. Therefore, the significance of the new food safety regime goes way beyond sectoral innovations in institutional design and legitimacy-building, but it could be a test case for the opportunities of participatory European governance and in this way may teach us some lessons for the broader issue of EU legitimacy.

References

Abels, G., 2000, Strategische Forschung in den Biowissenschaften. Der Politikprozeß zum europäischen Humangenomprogramm. Berlin.

Baron, W.M., 1995, Technifolgenabschätzung. Ansätze zur Institutionalisierung und Chancen der Partizipation. Opladen.

Bauer, M.W. and G. Gaskell, 2002, Biotechnology: The Making of a Global Controversy. Cambridge.

Blank, R.H. and S.M. Hines, 2001, Biology and Political Science. London and New York.

Bora, A., 2002, Ökologie der Kontrolle. Technikregulierung und der Bedingung von Nicht-Wissen. In Engel, C., J. Halfmann and M. Schulte (eds.), 2002, Wissen – Nichtwissen – Unsicheres Wissen. Baden-Baden, pp.253-275.

Bradley, K. St. Clair, 1998, Alien Corn, or the Transgenic Procedural Maze. In van Schendelen, M.P.C.M. (ed.), EU Committees as Influential Policymakers. Aldershot, pp. 207-222.

Braun, K., 2000, Menschenwürde und Biomedizin. Zum philosophischen Diskurs der Bioethik. Frankfurt/Main and New York.

Cantley, M.F., 1995, The Regulation of Modern Biotechnology, A Historical and European Perspective. In Rehm, H.-J. and G. Reed (eds.), 1995: Biotechnology, vol. 12, 2nd ed.. Weinheim, pp. 505-681.

Christiansen, T., E. Kirchner (eds.), 2000, Committee Governance in the European Union. Manchester and New York.

Commission of the European Communities, 1991, Promoting the Competitive Environment for the Industrial Activities Based on Biotechnology within the Community. In European Industrial Policy for the 1990s. Bulletin of the European Communities. Supplement 3/91. Luxembourg, pp. 41-54.

European Commission, 2000a, Communication on the Precautionary Principle. COM (2000) 1. Brussels.

European Commission, 2000b, Towards a European Research Area, COM (2000) 6. Brussels.

European Commission, 2000c, Making a Reality of The European Research Area: Guidelines for EU

Research Acitivities (2002-2006), COM (2000) 612. Brussels.

European Commission, 2000d, Proposal for a Regulation of the European Parliament and the Council Laying down the General Principles and Requirements of Food Law, Establishing the European Food Authority, and Laying down Procedures in Matters of Food. COM (2000) 716 final. Brussels.

European Commission, 2000e, White Paper on Food Safety. COM (1999) 719 final. Brussels.

European Commission, 2000f, Science, Society and the Citizen in Europe. Working Document, SEC (2000) 1973. Brussels.

European Commission, 2001a, European Governance. A White Paper, COM (2001) 428 final, 25 July 2001. Brussels.

European Commission, 2001b, Democratising Expertise and Establishing Scientific Reference Systems. Report of the Working Group. White Paper on Governance. Work Area 1: Broadening and Enriching the Public Debate on European Matters, May 2001, Brussels.

European Commission, 2001c, Towards a Strategic Vision of Life Sciences and Biotechnology: Consultation Document, COM (2001) 454 final. Brussels.

European Commission, 2001d, Science and Society. Action Plan, COM (2001) 714 final. Brussels.

European Commission, 2001e, Transgenic Plants: Breaking the deadlock. Brussels. Internet: http://europa.eu.int./comm/research/news-centre/en/agr/01-09-agr01d.html

European Commission, 2001f, Proposal for a Regulation of the European Parliament and of the Council concerning Traceability and Labelling of Genetically Modified Organisms and Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC; COM (2001)182 final, Brussels.

European Commission, 2001g, Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed, COM (2001) 425 final, Brussels.

European Commission, 2001h, Questions and Answers on the European Food Safety Authority, Memo/01/248 revised, 18 December 2001, Brussels.

European Commission, 2002a, Life Sciences and Biotechnology – A Strategy for Europe, COM (2002) 17 final. Brussels.

European Commission, 2002b, Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning Novel Foods and Novel Food Ingredients. Discussion paper prepared by Directorate General Health and Consumer Protection. July 2002. Brussels.

European Commission, 2002c, Commission Proposals for a Trustworthy and Environmentally Safe Approach to GMOs and GM food and feed backed by European Parliament. IP/02/992, 3 July 2002, Brussels.

Durant, J., M.W. Bauer and G. Gaskell (eds.), 1998, Biotechnology in the Public Sphere. A European Sourcebook. London.

Eurobarometer, 2000, Eurobarometer 52.1: The Europeans and Biotechnology, Report by INRA

(Europea) – ECOSA on behalf of Directorate-General for Research, Directorate B – Quality of Life and Management of Living Resources Programme, 15 March 2000. Brussels.

European Group on Ethics in Science and New Technologies (EGE), 2000, Citizens Rights and New Technologies: A European Challenge. Brussels. URL: http://europa.eu.int/comm/secretariat_general/sgc/ethics/en/index.htm

European Group on Ethics in Science and New Technologies (EGE), 2001, General Report on the Activities of the European Group on Ethics in Science and New Technologies to the European Commission 1998-2000. Brussels. URL: http://europa.eu.int/comm/european_group_ethics/docs/rap_en.pdf

Feick, J., 2002, Regulatory Europeanization, National Autonomy and Regulatory Effectiveness: Marketing Authorisation for Pharmaceuticals. Max-Plank-Institut für Gesellschaftsforschung. MPIfG Discussion Paper, February 02/6. Cologne.

Gaskell, G. and M.W. Bauer (eds.), 2001, Biotechnology 1996-2000: The Years of Controversy. London.

Gaskell, G., P. Thompson and N. Allum, 2002, Worlds apart? Public Opinion in Europe and the USA. In: Bauer, M.W. and G. Gaskell, Biotechnology: The Making of a Global Controversy. Cambridge, pp.351-375.

Gill, B. and M. Dreyer, 2001, Internationaler Überblick zu Verfahren der Entscheidungsfindung bei ethischem Dissens, Report for the Enquete-Commission “Law and Ethics of Modern Medicine” of the German Bundestag. Berlin.

Gottweis, H., 1998, Regulating Genetic Engineering in the European Union: A Post-Structuralist Perspective. In Kohler-Koch, B. and R. Eising (eds.), 1998: The Transformation of Governance in the European Union. London, pp. 98-141.

Grote, J.R. and B. Gbikpi (eds.), 2002, Participatory Governance. Political and Societal Implications. Opladen.

Haas, P.M., 1992, Introduction: Epistemic Communities and International Policy Coordination. International Organization 46 (1), pp. 1-35.

Héritier, A., 2001, The White Paper on Governance: A Response to Shifting Weights in Interinstitutional Decision-making. In Joerges, C., Y. Mény, and J.H.H. Weiler (eds.), Mountain or Molehill? A Critical Appraisal of the European Commission White Paper on Governance. European University Institute, Jean Monnet Working Paper No. 6/01. Florence, pp. 73-77.

Höreth, M., 1999, No Way Out for the Beast? The Unsolved Legitimacy Problem of European Governance. Journal of European Public Policy 6 (2), 249-268.

Hofmann, H.C. H., A.E. Töller, 1998, Zur Reform der Komitologie: Regeln und Grundsätze für die Verwaltungskooperation im Ausschußsystem der Europäischen Gemeinschaften. Staatswissenschaften und Staatspraxis 9 (2), pp. 209-239.

Holdsworth, D., 2000, Parliamentary TA by STOA at the European Parliament. In Vig, N.J., H. Paschen (eds.), 2000, Parliaments and Technology: The Development of TA in Europe. Albany, pp. 199-228.

Irwin, A., 2001, Constructing the Scientific Citizen: Science and Democracy in the Biosciences.

Public Understanding of Science 10 (1), pp. 1-18.

James, P., F. Kemper, and G. Pascal, 1999, A European Food and Public Health Authority: The Future of Scientific Advice in the EU. A report commissioned by the Director General of DG XXIV. December 1999. Brussels.

Jasanoff, S., 1990, The Fifth Branch: Science Advisers as Policy Makers. Cambridge.

Jasanoff, S., 2000, Science and Governance: the US Experience. IPTS Report, no. 45, pp. 20-23.

Joerges, C., 2001, Law, Science and the Management of Risks to Health at the National, European and International Level – Stories on Baby Dummies, Mad Cows and Hormones in Beef, Columbia Journal of International Law 7 (1), 1-19.

Joerges, C., K.-H. Ladeur and E. Vos (eds.), 1997, Integrating Scientific Expertise into Regulatory Decision-Making: National Traditions and European Innovations. Baden-Baden.

Joerges, C. and J. Neyer, 1997, Transforming Strategic Interaction into Deliberative Problem-solving: European Comitology in the Foodstuffs Sector, Journal of European Public Policy 4 (4), 609-625.

Joerges, C., Y. Mény, and J.H.H. Weiler (eds.), 2001, Mountain or Molehill? A Critical Appraisal of the European Commission White Paper on Governance. European University Institute, Jean Monnet Working Paper No. 6/01. Florence.

Joly, P.B. and G. Assouline, 2001, Assessing Public Debate and Participation in TA in Europe (ADAPTA). Final Report. Grenoble and Theys.

Joss, S., 1998, Danish Consensus Conferences as a Model of Participatory TA: An Impact Study of Consensus Conferences on Danish Parliament and Danish Public Debate. Science and Public Policy 25 (1), pp. 2-22.

Joss, S., 2002: Towards the Public Sphere – Reflections on the Development of Participatory TA. Bulletin of Science, Technology & Society 22 (3), 220-231.

Joss, S., H. Torgersen, 2000, Implementing Participatory TA – from Omport to National Innovation. In Klüver et al., 2000: European Participatory TA – Participatory Methods in TA and Technology Decision Making (EUROPTA). Report. Copenhagen, pp. 66-86.

Kassim, H., 1994, Policy Networks and European Policy Making: a Sceptical View. West European Politics 17 (4), pp. 15-27.

Klüver, L., M. Nentwich, W. Peissel, H. Torgersen, F. Gloede, L. Hennen, J. van Eijndhoven, R. van Est, S. Joss, S. Bellucci and D. Bütschi, 2000, European Participatory TA – Participatory Methods in TA and Technology Decision Making (EUROPTA). Report. Copenhagen. URL: http://www.tekno.dk/europta

Laffan, B., 2002, The European Commission: Promoting EU Governance. In Grote and Gbikpi, 2002, pp. 121-139.

Landfried, C., 1997, Beyond Technocratic Governance: The Case of Biotechnology. European Law Journal 3 (3), pp. 255-272.

Levidow, L. and C. Marris, 2001, Science and Governance in Europe: Lessons from the Case of

Agricultural Biotechnology. Science and Public Policy 28 (5), pp. 345-360.

Lindsey, N., M. Wambui Kamaraa, E. Jelsøe and A. Thing Mortensen, 2001, Changing Frames: the Emergence of Ethics in European Policy on Biotechnolgy. notizie di POLITEIA 63, pp. 80-93.

Magnette, P., 2001, European Governance and Civic Participation: Can the European Union be Politicised? In Joerges, C., Y. Mény, and J.H.H. Weiler (eds.), Mountain or Molehill? A Critical Appraisal of the European Commission White Paper on Governance. European University Institute, Jean Monnet Working Paper No. 6/01. Florence, pp. 23-32.

Majone, G., 1996, Regulating Europe. London.

Majone, G., 2002, What Price Safety? The Precautionary Principle and its Policy Implications. Journal of Common Market Studies 40 (1), pp. 89-109.

Mazey, S. and J. Richardson, 2001, Interest groups and EU Policy-making: Organisational Logic and Venue Shopping. In Richardson, J. (ed.), European Union: Power and Policy-making, 2nd ed.. London and New York, pp. 217-237.

Neyer, J., 2000: The Regulation of Risks and the Power of the People: Lessons from the BSE Crisis. European Integration online Papers (EIoP) 4 (6). Internet: http://eiop.or.at/eiop/texte/2000-006a.htm.

Patterson, L.A., 2000, Biotechnology. In Wallace, Helen and William Wallace (eds.), 2000, Policy-Making in the European Union. 4th ed.. Oxford, pp. 317-343.

Pedler, R.H. and G.F. Schaefer (eds.), 1996, Shaping European Law and Policy. The Role of Committees and Comitology in the Political Process. Maastricht.

Peterson, J., 1995a, EU Research Policy: The Politics of Expertise. In Rhodes, C. and S. Mazey (eds.), 1995, The State of the European Union, vol. 3. Harlow, pp. 391-412.

Peterson, J., 1995b, Policy Networks and European Union Policy Making: A Reply to Kassim. West European Politics 18 (2), pp. 389-407.

Peterson, J. and M. Sharp 1998, Technology Policy in the European Union. Houndsmills and London.

Pollack, M.A., 1997, Representing Diffuse Interests in EC Policy-making. Journal of European Public Policy 4 (4), pp. 572-590.

Radaelli, C., 1999, Technocracy in the European Union. London and New York.

Randall, E., 2001, The Plan for a European Food Authority and the Politics of Risk in the Union. Internet: http://www.policylibrary.com/Essays/RandallEFARisk/EFArisk2.htm.

Rückert, A., 2000, Die Entstehung der Novel-Food-Verordnung der EU. Berlin and New York.

Salter, B. and M. Jones, 2002, Human Genetic Technologies, European Governance and the Politics of Bioethics. Nature Review Genetics 3, 808-814.

Scharpf, F.W., 1999, Governing in Europe: Effective and Democratic? Oxford.

Scharpf, F.W., 2001, European Govenance: Common Concerns vs. The Challenge of Diversity. In

Joerges, C., Y. Mény, and J.H.H. Weiler (eds.), Mountain or Molehill? A Critical Appraisal of the European Commission White Paper on Governance. European University Institute, Jean Monnet Working Paper No. 6/01. Florence, pp. 1-11. URL: http://www.jeanmonnetprogram.org/papers/01/010601.html

Schendelen, M.P.C.M. van (ed.), 1998, EU Committees as Influential Policymakers. Aldershot.

Shackleton, M., 1998, The European Parliament's New Committees of Inquiry: Tiger or paper Tiger? Journal of Common Market Studies 36 (1), pp. 115-129.

Skogstad, G., 2001, The WTO and Food Safety Regulatory Policy Innovation in the European Union. Journal of Common Market Studies 39 (3), pp. 485-505.

STOA (Scientific and Technological Options Assessment), 1998, Sequencing the Human Genome. Scientific Progress, Economic, Ethical and Social Aspects. Final Study. PE 167.197/Fin.St. July 1998. Luxembourg.

Swedish Presidency, 2001, Conclusions from Umeå: The Ethical Debate must be Strengthened. Press release 12.6.2001. Internet: http://www.eu2001.se/eu2001/news.

Toeller, A.E., H.C.H. Hofmann, 2000, Democracy and the Reform of Comitology. In Andenas, M. and A. Türk (eds.), Delegated Legislation and the Role of Committees in the EC. The Hague, London, and Boston, pp. 25-50.

Vig, N.J., H.Paschen (eds.), 2000, Parliaments and Technology: The Development of TA in Europe. Albany.

Vogel, D., 2001, The New Politics of Risk Regulation in Europe. CARR Discussion Paper. Centre for Analysis of Risk and Regulation, London School of Economics. Internet: http://www.lse.ac.uk/Dept/carr/Publications_folder_web_files/Disspaper3.pdf

Vos, E., 1999, EU Committees: The Evolution of Unforeseen Institutional Actors in European Product Regulation. In Joerges, C. and E. Vos (eds.), EU Committees: Social Regulation, Law and Politics. Oxford and Portland, pp. 19-47.

Vos, E., 2000, European Administrative Reform and Agencies, EUI Working Papers, RSC No. 2000/51. Florence.

Weale, A., 2001, Science Advice, Democratic Responsiveness and Public Policy. Science and Public Policy 28 (6), pp. 413-421.

Weiler, T., 1995, Das Europäische Parlament und die Forschungs- und Technologiepolitik der EU. Baden-Baden.

Weingart, P., 1999, Scientific Expertise and Political Accountability: Paradoxes of Science in Politics. Science and Public Policy 26 (3), pp. 151-161.

Wennrich, C., 1999a, STOA – Die TA-Einrichtung des Europäischen Parlaments. In Handbuch Technikfolgenabschätzung, vol. 2. Berlin, pp. 529-533.

Wincott, D., 2001, The Commission and the Reform of Governance in the EU. Journal of Common Market Studies 39 (5), pp. 897-911.

Zito, A.R., 2001, Epistemic Communities, European Union Governance and the Public Voice.

Science and Public Policy 28 (6), pp. 465-476.

Endnotes

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(1) The term “biopolitics” is not used in the Foucaultian sense, but in analogy to the political science terms of politics, policy and polity as suggested by Robert Blank and Samuel Hines (2001, 6ff.; 99ff.). In this sense, biopolitics, for example, refers to the political processes and conflicts related to the political management of biotechnology.

(2) In 2002, there was intense debate among the EU institutions about the question, if this kind of research should be funded with EU money. The compromise finally achieved states that no such research shall be funded until the end of 2003. Until that time, the Council shall decide on bioethical guidelines.

(3) Tension and competition between the executive and the legislative branch have been a central motive for the founding parliamentary TA institutions in general.

(4) STOA is important for the co-ordination of parliamentary TA institutions in Europe via the European Parliamentary TA Network (EPTA) founded in 1990 and financed by STOA.

(5) The Biomed I programme (1990-1994) earmarked 4.67 Mio. ECU for ELSA studies. ELSA became a horizontal activity in the fourth framework programme (1994-1998), i.e. it was extended to all research in the life sciences. Subsequently, ELSA studies were also conducted under the BIOTECH and the FAIR (Fisheries and Agriculture Research) programme, and an ELSA concertation group was set up. The fifth framework programme introduced bioethical guidelines. Projects funded with EU money have to follow the Helsinki Declaration on medical research involving human subjects (1964), the UN “Universal Declaration on the Human Genome and Human Rights” (1998), and the Council of Europe “Convention on Human Rights and Biomedicine” (1997). Even if the EU as such could not ratify the Bioethics Convention, it nevertheless adopted it as a major ethical framework for its funding policy. For international bioethical regimes cf. Braun 2000.

(6) EGE’s main tasks are: “To help break down barriers between disciplines in fields which require a multi-disciplinary approach, not only scientific and legal, but also philosophical, sociological and economic; to provide European decision-makers (i.e. also the Parliament and the Council; G.A.) with clear and up-to-date basic information, enabling them to be properly informed in carrying out their duties; and to promote dialogue that stimulates mutual tolerance so that all viewpoints can be expressed before the Community authorities decide on appropriate regulations.” (EGE, 2001)

(7) Article 3 of the Charter states that eugenic practices, the use of the human body (or parts of it) for profit-making and reproductive cloning are prohibited. In addition, some EU member states and institutions want to make this ban on reproductive cloning global. In 2001, France and Germany proposed a UN convention against such cloning. The European Commission and the European Parliament have suggested to the other member states to support the Franco-German proposal in the UN.

(8) The European Parliament and Council Directive 98/44/EC on the protection of biotechnological inventions (patenting directive) is, of course, a most important regulation for research and product

development in both areas. Its history has been very controversial, above all, due to normative judgements on the patentability of human genes and parts of the human body. Since this directive is of no direct relevance for my hypothesis, I will not attend to it any further in this paper.

(9) For a detailed discussion of this case and its effects cf. Toeller/Hofmann, 2000; Hofmann/Töller, 1998; Bradley, 1998.

(10) The ban on market authorisation has also influenced the applications for the approval of field experiments, the second aspect regulated in Directive 90/220/EEC respectively 2001/18/EC. The number of approvals decreased enormously in all member states since 1999.

(11) Further safeguards concern risk assessment, monitoring and traceability of GMOs, time limited authorisation, and a ban of markers for antibiotic resistance from 2005 onwards.

(12) The crisis revealed the Commission's selective use of scientific expertise, its mismanagement, its strong focus on the market (instead of consumer protection), and implementation deficiencies; it led to growing distrust of the public towards regulators in the members states as well as on the supranational level (cf. Joerges, 2001, 6ff.; Neyer 2000; Vogel 2001, 12ff.). Furthermore, it gave the European Parliament a first opportunity to exercise new powers via establishing an inquiry committee (Shackleton, 1998).

(13) The conflict focuses, amongst other things, on a threshold for labelling. In its position adopted on July 2, 2002, Parliament opts for a lowered maximum threshold for labelling (0.5% instead of 1%). With regard to the issue of participation, the new proposal for GM food and feed suggests a more inclusive consultation process by making the application for market release and the risk assessment available to the public for comment (cf. Commission, 2002b, 22; Commission, 2002c).

(14) Many member states are now in "a mood for dialogue", as Alan Irwin (2001) calls it. For example, most member states have earmarked funding for research into ethical issues and (participatory) TA; moreover, they have integrated bioethics into policy-making and policy advice, e.g., by establishing permanent national ethics committees. The relationship between science and democracy in the biosciences has been subject of several government reports in Britain; participatory instruments such as a public consultation and a citizen foresight project have been put to the test. Many member states have acquired experiences with consensus conferences, citizens' juries and other methods of so-called participatory TA, particularly in relation to biomedicine and biotechnology (cf. Klüver et al., 2000; Joly/Assouline, 2001). In Germany, the year 2001 was declared "the year of the life sciences"; exhibitions, series of discussions, and the first German national consensus conference on genetic testing supported by the federal ministry of research BMBF were sold as "science in dialogue". The Netherlands has seen a broad public debate on biotechnology invoked by the parliament. So there have been many activities in the member states promoting a dialogue between experts, citizens and policy-makers.

(15) Some developing countries have recently either banned the import of GM crops in the framework of international food aid or allow it under strict conditions only.

(16) The EU-US Consultative Forum, a body established in the early 1990s to discuss controversial issues over biotechnology, states in its report in 2000: "transparency in decision taking, inclusive and meaningful participation (act) as the foundations of confidence in public institutions" (quoted in Gaskell/Bauer, 2001, 116).

(17) This view is supported by the Council. At the Nice summit in 2000, the heads of government have furthermore decided in their resolution on the precautionary principle that it shall also include greater civic participation to embrace all possible views in risk assessment (Vogel, 2001, 16).

(18) The recognition of the need to integrate stakeholders structure goes back to a report by James et al. (1999) commissioned by the Director General for Consumer Protection (DG XXIV) and eventually found its way into the White Paper on Governance and the EFSA structure. I am grateful for this hint to one of the EioP commentators.

(19) For an extensive critique of the White Paper cf. the contributions in Grote/Gbikpi, 2002; Joerges et al., 2001; also Wincott, 2001.

(20) Due to the strong economic incentive, the EU favours producer interests over other societal interests. At the same time, the institutions and most of all the Commission acknowledge this bias and try to balance opposing interest by promoting the organisation of some so-called 'weak' and 'diffuse' interests, e.g. in the environmental sector (cf. Mazey/Richardson, 2001; Pollack, 1997).

(21) A consensus conference is a form of TA conducted by lay-people. Proponents cherish this method as a form of participatory democracy and as an alternative model for shaping the relationship between citizens and experts. The premise or participatory TA is that “many sciences and technologies have … far-reaching and direct repercussions for individuals and society at large; hence there is a need to bring ethical, environmental and social implications into play. … the evaluation of scientifically and socially complex issues … by exclusive expert bodies has come in for increasing public criticism for disregarding viewpoints and interests other than their own, and lacking public accountability” (Joss, 1998, 2f.). Many EU member states have experience with this instrument; a thematic focus has been on biotechnology and biomedicine. The structure of the political system and the underlying socio-political culture are decisive for the success or failure of the procedure (cf. Klüver et al., 2000). However, consensus conferences at the European level – whether pan-European or simultaneously in all (or some) member states – bring along severe practical difficulties, firstly, of recruiting lay-people for the citizen’s panel, secondly, for deliberations of lay-people given the multiplicity of languages, and, thirdly, for the proper institutional environment on the supranational level.

(22) They point out that, for example, the problem of values in scientific risk assessment is taken up in the paper on democratising expertise. This results in tensions and contradictions between the various Commission documents (Levidow and Marris, 2001, 351f.).

(23) Further examples are the enhanced role of expert committees in the Commission. When the Charter of Fundamental Rights was under debate in 2000, President Prodi asked the European Group on Ethics for a report on how the Charter would affect citizens’ rights in relation to new technologies (EGE, 2000). In addition, a Life Sciences High Level Group was formed in April 2000. Concurrently with the consultation process for a strategy for biotechnology, the Commission organised a first “stakeholder conference”, held in September 2001. One medium enjoying great popularity also in the science/society debate is the Internet. The Commission has established an Internet forum on “Biosociety”, which is meant to serve as a “playground for open and pluralistic debates”. Finally, the Commission itself is funding research on the relationship between citizens and governance particularly with regard to a knowledge-based economy via its framework programmes for RTD.
