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# Mediating Public Concern in Biotechnology

*A map of sites, actors and issues in Denmark, Finland, Norway and  
Sweden*



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## Preface

This publication is the first report from the Nordic research project *Changing Contexts for Mediating Public Concern in the Assessment of Technoscience. Public Responses to Genetic Technologies in the Nordic Countries* (COMPASS). The project is headed by Margareta Bertilsson, Copenhagen University, Department of Sociology, Denmark. The other partners are: Andrew Jamison, Aalborg University, Institute for Social Development and Planning, Denmark; Jesper Lassen, The Royal Veterinary and Agricultural University, Centre for Bioethics and Risk Assessment, Denmark; Marja Häyrynen-Alestalo and Karoliina Snell, Helsinki University, Department of Sociology, Finland; Egil Kallerud and Vera Schwach, Norwegian Institute for Studies in Research and Higher Education, Norway; Thomas Achen, Linköping University, Department of Environmental Science, Sweden; and Mark Elam, Gothenburg University, Department of Sociology, Sweden. The project is funded for a three year period (2002–2004) by the Joint Committee for Nordic Research Councils for the Humanities and the Social Sciences (NOS-HS).

This report documents the first exploratory steps towards an articulated comparative account of approaches and experiences in the Nordic countries concerning the political, economic, social and cultural responses to global, European and Nordic efforts in the appropriation and mediation of modern biotechnology. The national narratives included in this report will subsequently be supplemented with specific case studies on nationally important biotechnology issues, in order to provide windows with higher resolution on the project's key research questions. This will in all provide material for a final effort of synthesis, through which a framework will be sought for the comparative characterisation of social processes of appropriation of genetic technologies in these Nordic countries.

Oslo, March 2004

Petter Aasen  
Director



## Innhold

<b>Introduction: Towards a Biotech Society – Nordic Perspectives .....</b>	<b>7</b>
<i>Marja Häyrynen-Alestalo and Egil Kallerud</i>	
<b>Assessing Genetic Technologies in Denmark .....</b>	<b>23</b>
<i>Andrew Jamison and Jesper Lassen</i>	
<b>Market Orientations and Mediation of Public Opinions in Finnish Biotechnology .....</b>	<b>49</b>
<i>Marja Häyrynen-Alestalo and Karoliina Snell</i>	
<b>The Ambiguity of Progress – Biotechnology in Norway .....</b>	<b>83</b>
<i>Egil Kallerud</i>	
<b>Actors, Issues and Tendencies in Swedish Biotechnology .....</b>	<b>113</b>
<i>Thomas Achen</i>	



# Introduction: Towards a Biotech Society – Nordic Perspectives

Marja Häyriinen-Alestalo & Egil Kallerud

## Modern biotechnology as a source of societal destabilisation

Biotechnology exhibits a generic and hybrid mode of knowledge production through which scientific advancements have opened applications in fields ranging from pharmaceuticals, medical diagnostics and therapy to agriculture, food production, aquaculture, forestry and environmental protection. Modern biotechnology is based on the methods to introduce, delete or exchange particular traits in an organism either by inserting genes from another organism or by otherwise altering its structure. The rapidly advancing knowledge base with links to living organisms and ecosystems has produced new scientific disciplines such as genomics and bioinformatics and novel applications such as gene testing and regeneration of human organs and tissues (Inter-departmental Group on Modern Biotechnology 2000). The methodological development has dramatically expanded the technical-manipulative capabilities of bioscience, raising questions of the emergence of new asymmetries between nature and culture/society. Therefore, aside from the hybrid knowledge base of these sciences there are hybrid realms that challenge the division of nature and society on which the theories of modernisation have been based (Bertilsson 2003).

According to Lau, the new generic technologies may have destabilising effects on the social and legal order (Bertilsson 2000: 9). During the last twenty years the main focus has been on information and communication technologies and on theories that explain the development of the new socio-economic order as an outcome of a knowledge-based, networked economy (e.g. Castells 1996; European Commission 2003). The networks are in turn seen to be functional when the formal national actors, such as the state, industries and the science system, work for common purposes. Even though there are claims that the new social order will also encompass the emergence of a networked democracy and growing citizen participation (Castells 2001), destabilisation primarily stands

for increasing turbulence between the frames of national policy and the needs of global markets (Häyriinen-Alestalo 1999).

Today new forms of governance and citizenship have been called for to diminish uneven developments between economic, social and cultural structures of society. To be responsive to these demands, the networked economy should broaden its view of public participation. The social and cultural dimensions are also weak and limited in many ways. In the current political debate the discourse of openness, transparency, participation and dialogue is pervasive. The strategies for active citizenship have, however, been primarily launched by the European Union and several individual nation-states in order to remobilise public interest in government policy and to rebuild citizen trust in this respect. Therefore there are tensions and ambiguities that fuse with the political ambitions to make biotechnology the «next wave of the knowledge-based economy» (European Commission 2002: 3).

Furthermore, the increasing destabilisation in the case of biotechnology points to a tension between the welfare promises of the biotech society and the uncertainties, risks and responsibilities that challenge the legitimacy of bioscience and its uses. Similar uncertainties and risks have become evident already in environmental issues (Jamison 2001). Both fields contain both the promise of positive potentials and the possibilities of unpredictable and negative consequences. Sand (2002) has pointed to the need of regulation and control mechanisms that may make the justification process more future-oriented. As a rule, the control mechanisms have been used by the super- and nation-states together with international commercial and professional organisations to support market regulation and free competition, to harmonize the respective laws, to reduce risk, as well as to protect free individual choice, distributive justice and human health (CIOMS 2002; European Group on Ethics in Science and Technologies 2000).

Despite the growth of specialised scientific knowledge available for use in risk evaluation, the knowledge base of bioscience has a high degree of complexity. On the other hand there can be only degrees or different forms of risk, and the zero risk and full safety are not possible (Byrne 2002). Being also sensitive to commercial and public concern specialised bioscience knowledge is continuously changing and therefore non-stabilised. Non-stabilisation in turn indicates that the government organisations tend to act strategically and with precaution rather than legalistically and according to specific rules.

Moreover, the expanding manipulative capabilities of biotechnology lay bare tensions and contradictions between the norms of objectivity and truth-value of

science, its ethical standards and the moral conceptions of right and wrong (Häyrynen-Alestalo 2003). In fact, the growing public concern and distrust in the achievements of biotechnology demonstrates processes that are characteristic of disorganised knowledge (Bertilsson 2002). Disorganised knowledge is an outcome of a decentralisation process during which the pressure to open the scientific and political systems to public engagement becomes visible and competing forms of understanding call for a new dialogue between scientists and the wider public.

In many respects, the problems of disorganised knowledge have already been identified in the case of green knowledge, where the diversification of the knowledge making processes and the need for participatory forms of action in dealing with environmental issues is much in evidence (Jamison 2001). Both disorganised and green knowledge question the pragmatic and deterministic ideas of market regulation and the old models of governance. Especially in relation to new genetic technologies a shift «from government to governance», responding to the demand for horizontal modes of communication and structures of power and for new forums of public consultation and response mediation, is clearly called for. Public consultation does not, however, necessarily provide means for solving ethical problems. Bertilsson (2003) points out, in reference to Rose, how modified nature enables further interventions into individual bodily dispositions. Therefore the division of responsibilities moves closer to the ethics and morality of individual choice, and the relationship between individual and collective decisions becomes complicated and difficult to govern.

Due to the risks of the consequences of biotechnological applications and to the difficulty of making the right moral choices, the consultations with the public can no longer be considered as belonging to the category of rational action in the frame of the deficit model (Levidow & Marris 2001). Modern citizen activism or scientific citizenship often takes place in forms that cannot easily be contained within established procedures and forums of public consultation. Thus the definition and management of the new public spaces are difficult. The case of green knowledge provides ample empirical evidence that it is in fact possible to institutionalise politically mobilising activities as a part of formal political process, at the risk, however, that the oppositional and visionary elements of public concern will be lost (Jamison 2001; 2003). Even though new hybrid identities in the form of networkers, translators, facilitators and brokers can be identified in the case of sustainable development, the full extent of representations, competences and expertise that will emerge in the case of biotechnology is as yet unclear.

## The knowledge-based economy as a Nordic effort

The project «Changing Contexts for Mediating Public Concern in the Assessment of Technoscience» (COMPASS) is the undertaking by a group of researchers from four Nordic countries – Denmark, Finland, Norway and Sweden. The project aims at studying modifications and destabilisations in the social and political structures in these countries, in response to the new forms of public awareness and mediation of interests that have emerged through the multifarious processes of socio-political appropriation of modern biotechnology. In the following country reports, some key characteristics are described, concerning the specific forms of participation and agency that have emerged within the specific social, economic, political and cultural contexts of the individual countries. For each country, narratives of national profiles are provided in an attempt to draw out some key links between institutional structures, political cultures, development of industry, key sites of action and forms of actor representations. While all four countries may be seen to adhere to the so-called Nordic model of democracy and of the welfare state, the narratives provided here are as much about very different, even highly divergent, trajectories of development and strategic political choices. In fact, they reflect differences in socio-economic structures, national systems of innovation and in priority setting in science and technology policy.

Today the framing of these policies is in the respective countries influenced by the grand narrative of the knowledge-based economy that pervades policy discourse on the role of science and technology in the new global economic order. This narrative has been articulated and strongly promoted by such cross-national players as the OECD and the European Union (OECD 2001; 2002; European Commission 1998; 2003). The idea of the knowledge-based economy has also been taken up by most of the member countries. In the view of the EU, «the transition towards a knowledge-based economy involves a fundamental structural change ... all the challenges facing Europe need to be reconsidered in the light of this new paradigm» (European Commission 2003). It is characteristic of this kind of argumentation that the new technologies are in the core of modern knowledge production and application.

The knowledge-based economy has provided a framework for new rankings between the «leading» and «lagging» nations and regions. The rankings indicate that the Nordic countries in general, and Finland and Sweden in particular, have become forerunners that are «on the right track» based on key indicators

of investments in the national knowledge-based economies (European Commission 2003: 23ff). As such, the Nordic countries lend support to the articulation and promotion of these narratives. In the case of biotechnology Denmark, Sweden and Finland have been found to be the leading EU performers, Sweden having a leading position in biotechnology publications, the number of dedicated biotechnology firms and the public knowledge about biotechnology. Denmark in turn is the top performing country in terms of USPTO patents and drug approvals (European Trend Chart on Innovation 2002: 4). On the other hand, a study of the actual national enactment or implementation in the Nordic countries provides an entry for a critical assessment and possible deconstruction of the idea of the knowledge-based economy.

Even though all Nordic countries have managed to maintain the core structure of the welfare state (Benner 2003), the experience of Finland demonstrates a more rapid growth of neo-liberal policy and more extensive cuttings of the welfare services than in the other Nordic countries. The increasing unbalance between the investments to the knowledge-based economy and to the public services indicates a need to discuss and re-evaluate the effects of one-dimensional strategies. A new cross-national movement is paying attention to a more multi-dimensional and complex framework than before. Among others the EU has not only picked up this discourse as the framework for its policy to develop Europe into «the most competitive region of the world by 2010». It has also extended and reframed its argumentation to strengthen the knowledge-based society (European Commission 2003: 3).

The recovery of the knowledge-based society not only entails that broad concerns, such as health, social cohesion and sustainable development (ibid: 9–10; 15–17), should be integrated in political orientation. Also public legitimacy and support for science and the new tech-based policies are seen to a high degree to be dependent on the government sensitivity to public concern, the elements of which are accountability, transparency and democratic representation. As the cases of genetically modified food and mad cow disease indicate, public support can no longer be taken for granted. By rejecting GM food, European citizens are also able to affect potential markets. In this respect the four Nordic countries have adopted both similar and dissimilar strategies.

In all of these countries sustainable development has become a crosscutting policy goal having also stabilised the role of public participation in environmental issues. At the same time many institutional structures have been established due to global demands and agreements. In Denmark several storylines of public concern in environmental issues can be identified that are also useful in analys-

ing the participatory forms of representation in biotechnology issues. In fact, the Danish model serves as an example of lay technology assessment to develop participatory science and technology policies. The governments in Finland and Sweden have in turn tended to trust on political consensus and on the formal representative forms of democracy. In Sweden the definitions of the knowledge-based economy are, however, closer to the knowledge-based society than in Finland. Thus the main discourses of concern with genetic technologies (Lassen & Jamison 2003) are reflected in and amplified by the main policy framework within which policies for the promotion and regulation of biotechnology are articulated and implemented.

The Nordic efforts to introduce multidimensional framings may add to the centrality of the Nordic experiences. Biotechnology as the second key component of the knowledge-based economy points also to many destabilising and controversial issues to which the respective countries may be seen as forerunners, as sites of experimentation and innovation, both in the terms of competitiveness through investment in knowledge and in those of governance, cohesion and ethics.

## Biotechnology restructuring Nordic industries

In the visions of the knowledge-based economy several pressures have been set for the transformations in the national industrial structures. In the first place, there is the demand for the promotion of the new tech-intensive sectors. The policy makers have started to speak of specific ICT and biotechnology clusters whose impacts on economic growth are supposed to be the most optimal. From the viewpoint of the new tech-oriented cluster policy, large differences in the industrial structures of the four Nordic countries imply that the commercial and industrial opportunities opened up by modern biotechnology are related to different industrial clusters.

Due to the strong pharmaceutical, electronic and transport (aviation) industries, Sweden has ranked high on the modernisation scale for a long time. The well-established position of the pharmaceutical industry and medical R&D in Sweden provide also a strong basis for exploiting the industrial opportunities of biotechnology. As a result of systematic and generous public investments in ICT, biotechnology and materials technology, Finland has made an exceptionally rapid entrance into the global markets in the 1990s. The Finnish success story may, however, also be seen to reflect the fragility of both the ICT and biotech clusters. The former has had difficulties to keep its competitive status in the

global markets during the last three years. The latter indicates the weak points in the theory of the knowledge-based economy. Even the rapidly growing public and private investments in biotechnology research have not guaranteed economic breakthroughs to Finnish biotechnology products in the global markets (Helsingin Sanomat 2003). In this case also the issues of non-marketable and ethically suspicious products have become visible, though public discussion of these issues cannot be noted.

The introduction of biotechnology as an integral element of the knowledge-based economy tends to simplify many elements of modern disorganisation. As the primary goal is in the new tech-driven economic growth, structural changes are also needed in the science system. Both in Finland and Sweden biotechnological research has integrated universities into bio-centres. The concept of the innovation system that is more widely used in Finland than in Sweden has also tended to rebuild the role of the state as a mediator of socio-economic interests. In Denmark the formal political system has been more sensitive to various forms of disorganisation.

While Finland and Sweden are held forth as the pioneers of the knowledge-based economy, Denmark and Norway present different patterns, partly due to the dominant position in their economies of primary and raw materials-based industries, in particular agriculture for Denmark and petroleum and fisheries/aquaculture for Norway. Being far less R&D intensive industries than the ICT, pharmaceutical and (air) transport industries, the overall knowledge intensity of the Danish and Norwegian economy is far lower than that of Finland and Sweden. While biotechnology presents promising opportunities for some of the industries, it also represents uncertainties and dangers for them. Accordingly, the Danish agro-food industry is both an important export industry and capable for motivating public discussion of modern genetic manipulations, such as with genetically modified food. Therefore the Danish mechanisms of government control are also more responsive to public concern than elsewhere in Scandinavia.

The key Danish agricultural and pharmaceutical companies exhibit innovative approaches in terms of taking public concern into account in their R&D and marketing strategies. In terms of the indicators of investment in the knowledge-based economy, Norway exhibits the distinctive profile of the «lagging» and hesitant latecomer. Pressures from industrial and R&D interests to imitate the Finnish model and to promote more liberal investments in biotechnology are mounting with some apparent successes. Still they are kept in check by well-established, restrictive regulatory policies.

## The social contract on biotechnology in the Nordic countries

The picture drawn by the knowledge-based economy changes, however, when the economic growth-driven representations are replaced by richer accounts, in particular when the dynamics and developments within the political, social and cultural spheres are added. Already some technology barometers tend to indicate a higher position for Denmark when the indicators relevant for the so-called knowledge-value society are taken into account (Naumanen 2003). The results of the European Trend Chart on Innovation (2002: 4–5) show that on the basis of the composite Best Performance Index of biotechnology innovation Denmark scores 60, Sweden 57, Finland 42 and Norway 29.

The new models of governance tend to extend interventionist tendencies to citizens and to emphasise shared responsibilities of a more individualistic style. In the case of new technologies they point to deliberation and dialogue to reconstruct public acceptance and trust of science-driven innovations. At the same time, in terms of political ideology there have been rising neo-liberal ideas of the sovereignty of the markets, making the problem of shared responsibilities complicated (Häyrynen-Alestalo 2001; Hagendijk & Kallerud 2002). Market democracy tends to diminish the political and social value of the state. In a market driven society public welfare services have also increasingly been regarded as dysfunctional. The tension between the welfare state and the neo-liberal ideology is visible especially in Finland that has won many international competitions on the basis of selected competitiveness factors of the economy. In spite of this success, the public mistrust has been increasingly focussed on the national government that has radically cut expenses from welfare services and has also been incapable of solving the serious problem of unemployment. These kinds of political turbulences have also become evident in Sweden and Denmark, but in a minor scale and much later than in Finland.

The ongoing processes may be seen to imply an undermining of the traditional Nordic welfare state model and a change in the ideals of equal opportunities, in so far as earlier principles of equalisation of the opportunity comprised ideas of government intervention, participation through representation and shared responsibilities. Both in Norway and Finland, equalisation of the opportunity has also had a strong regional dimension, which is presently under pressure in particular in Finland due to a rapid concentration of knowledge-based ICT and biotechnology centres and highly qualified labour force into a few growth pole areas. The new government being a coalition of the Centre and So-

cial Democratic parties has, however, adopted a defensive approach by launching a programme for the creation of new competence centres all over the country.

In Sweden and Finland the welfare state was primarily a Social Democratic project with a political consensus of a strong interventionist state. The political system has followed a corporatist strategy that has been mostly exclusive concentrating power to experts, bureaucrats and politicians. Therefore only a limited space has been provided to spontaneous citizen activity. The political system in turn in Denmark has been influenced by a mixture of several new social movements comprising communes in Christiania, academic Marxism, leftist parties and active feminist and environmental movements. They have given more space for public representation and emphasised wider citizen participation. In Denmark public debates about science and technology started to develop already in the 1970s. In the long run the forms of participatory democracy have not, however, managed to strengthen their true mediating function. Even though both risk and ethical discourse of the effects of biotechnology began in Denmark earlier than in the three other countries, the respective activities have not been radical and it is difficult to find direct impacts of these activities on biotechnology policy.

In Norway, the initial, but fairly weak attempts to launch a targeted investment in biotechnology R&D, were soon pushed back as strong concerns with ethical implications of the medical uses of biotechnology set the dominant agenda of biotechnology policy debate in the Parliament and in party politics. Institutional innovations within a political culture exhibiting characteristics of inclusive corporatism have provided a framework for a somewhat late but vivid debate on biotechnology issues, predominantly in terms of ethical, rather than risk, concerns. This debate has also provided a basis for one of the most restrictive policies for regulating biotechnology in Europe. In the context of strong, petroleum-based economy, the biotechnology debate takes place in Norway under conditions of less economic pressure and urgency than in other Nordic countries. While this provides cause for concern in terms of stalled movement towards the knowledge-based economy it may also, due to the uneven developments of R&D, as well as political and cultural aspects of biotechnology, provide more favourable conditions for applying the more cautious approaches. They are dictated by policies that emphasise both risk and ethical concerns.

In all Nordic countries, environmental issues have triggered political and citizen activism, and there are expectations that biotechnology will make the processes of environmental protection and sustainable development more efficient.

There is also some kind of consensus about the issues of health, and the hopes for cheaper, safer and more ethical production of new drugs and medical services are notable. The conceptions of the biomedical treatments differ, however, across the countries.

In Finland collective solidarity is still focussed on the issues of equal opportunities. Even though there is a growing conflict with market governance, citizens tend to have a positive view of the beneficial achievements of all new technologies. For example the majority of pregnant women accept the idea of having access to genetic screening (Jallinoja 2002). In Sweden, and in many respects also in Finland, two overlapping tendencies have had an impact on the weak inclusion of active citizenship. First, modern social progress has been considered as identical to the growth of technological innovations. Second, in spite of the already high level of education, people have been considered as needing specific education and information of new technology-based activities. Therefore also the discussion of shared responsibilities in biotechnology has been weak in both countries.

## Regulation and types of interest mediation

The generic character of biotechnological applications refers to global level developments and social realities. According to Martinelli (2003) there are global flows that direct attention to new forms of normative order and consensus, international public space and transnational civil society. Therefore, the national governments are increasingly inserted into an interconnected social order where collective policy problems of economic, ecological and social security are discussed and agreements of multilateral treaties for the common regulation are made. The rapidly advancing applications of biotechnology have strengthened discussion of the global means of regulatory mechanisms and of the need to institutionalise global, regional and multilateral systems of governance.

Martinelli believes that supranational bodies can contribute to global democratic governance by creating mechanisms of collaboration in policy arenas, by introducing new instruments of human rights enforcements and by pooling resources for achieving common goals. Global governance requires, however, some preliminary definition of democracy in the situation where the growth of injustice is one of the key critical arguments against globalisation. Moreover, examples such as mad cow disease point to new processes of globalisation that are no longer hindered by time and distance and are risks to national security.

It is characteristic of this kind of «bioinvasion» that the lines between animal and human risks become blurred (Business Week 2000).

Due to the risks and ethical problems of the applications of biotechnology, international organizations, such as the Council of Europe, UNESCO, WHO, ILO and the European Union have estimated potential risks and prepared legal processes for their minimisation. During this process technology assessment has moved toward risk assessment and the aims of control and protection have become increasingly visible. The formal international authorities have also started to speak of a precautionary principle and to point to cases where scientific evidence is insufficient, inconclusive or uncertain and where the possible risks to health or the environment are unacceptable (Byrne 2000). Moreover, biotechnology has had an impact on the renovation of the standards of medical applications emphasising respect for all human beings, the protection of health, privacy and rights, the ethical obligation to maximise benefits and to minimise harms and the importance of ethical review committees (CIOMS 1982/1993/2002). All these legal processes and risk assessments are global by their implementation and are therefore also valid for the Nordic countries. Such concerns relate mostly to professional ethical standards, and the mediation of information occurs through the professional channels. The problem is that there is a decline in public confidence in regulatory bodies and scientific expertise also in the Nordic countries, even though it is more evident in Denmark than in Finland, Norway and Sweden.

Aside from other supranational authorities, the EU has made an effort to strengthen its «global» functions by speaking of the common objectives as well as of effective coordination and control in the case of genetic modifications. The control measures have been more restrictive in Europe than in the US. Though the primary aim is for both sides to guarantee the competitiveness of the biotechnology sector, the EU has been more responsive to public concern of food safety and to citizen capacities as consumers. Due to its restrictive regulation, the EU has served as a mediator of control mechanisms that take their credibility of scientific assessment. These mechanisms are supposed to be independent and transparent (Byrne 2000). The goal of mediation has been, however, mostly educational and deliberate: to provide information for the consumers to make an informed choice. Respective legislation serves also as a means to neutralise destabilisation due to emotions and «insufficient reason». In a way the formal regulatory actions have responded to critical discourse and an attempt has been made to maintain control over wider antagonist discourses.

Even though Norway is not a EU member state like Denmark, Finland and Sweden, all four Nordic countries have accepted the view that the EU directives are applicable and binding to them. There are, however, national variations in the timing and scope of regulatory actions. The Norwegian Parliament adopted in the 1990s the most restrictive controlling regime to biotechnology and has used the formal political system of democratic representation as a source of critical mediation. This regime reflects ethical and moral values where everyone is valued with a high respect for human dignity, human rights and personal integrity. The respective laws also make references to risks, social utility and sustainability.

In Denmark several story-lines of the assessment of genetic technology can be identified ending in the late 1990s at an ethical or cultural story-line that comprised the first law on genetic technology and the environment in the world and attempts to promote consensual approaches to public concern and assessment. The mediation of interests has been implemented somewhere in between the formal regulatory actions and informal and discursive, first critical and later on more consensual, forums. Finland has been a latecomer in biotechnology regulatory action, where the respective laws have been passed and the regulatory frameworks institutionalised only after joining the EU in the middle of the 1990s. In Finland the goal to be the top knowledge-based economy on the basis of the ICT and biotechnology clusters have simplified government and public conceptions of the dimensions of regulatory framework. Moreover, the general trust in the good intentions of technology have minimised the need for an antagonist discourse. The mediation of interests increasingly reflects ethical concerns; however, moral values are limited and suppressed by national values of economic effectiveness.

Finally, Sweden seems to be a combination of government-sponsored activism and corporate-sponsored resistance. There is a consensus that ethics is needed in the legal regulation of biotechnology. It has been, however, unclear what status ethical norms should enjoy and from what sources they should be derived. At the same time there exist conflicting political interpretations of how comprehensive and all encompassing the legal regulation should be. As in Finland, the Swedish biotechnology regulation tends to emphasise the innovation system as a virtue in its own right and to see market mechanism as morally neutral. In Sweden there have been, however, stronger strivings to improve the accountability of biotechnology through the improvement of the public understanding of science and technology than in Finland. In both countries also the

institutions in the regulation of biotechnology have had difficulties in interpreting the concept of the public and civil society.

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# Assessing Genetic Technologies in Denmark

Andrew Jamison and Jesper Lassen

## Historical background

The assessment of genetic technology in Denmark can be seen to have gone through three main phases since the 1970s, roughly corresponding to the different stages of technological development<sup>1</sup>. In each phase, there have been somewhat different issues and actors involved, and there have been some rather significant changes in what might be called the story-lines of assessment (see figure one).

Genetic technology was first taken up as a topic for debate in Denmark primarily by critical scientists and science students. It was particularly the group around the journal, *Naturkampen* (Nature Struggle) that first brought genetic engineering to public attention. As elsewhere, the technology was discussed in this first phase in terms of the underlying «theoretical» implications, both in relation to biology, as well as in relation to political and economic theory. As in other countries, issues of scientific responsibility and laboratory safety were also taken up as a kind of «import» item from the United States.

Genetic technology became more controversial in the period of development, primarily in relation to eventual environmental consequences of field trials. Public debate was stimulated by plans of the *De Danske Sukkerfabrikker* (the Danish sugar company, later *Danisco*) to develop and carry out field trials with GM sugar beets. The influence of a strong environmental presence in the Parliament (the so-called green majority) also meant that the early development efforts were subjected to a range of «technology assessment» activities. Members of the environmental organization, NOAH, were particularly active in public education and political lobbying for stricter forms of legal regulation. The

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<sup>1</sup> A more detailed discussion of the historical background is given in Erling Jelsøe, et al, «Denmark» in John Durant et al, eds, *Biotechnology in the Public Sphere*, Science Museum (London), 1998; The changing modes of assessment are discussed in Jesper Lassen, "Changing modes of biotechnology assessment in Denmark," in Miettinen (ed.): *Biotechnology and public understanding of science*, Publications of the Academy of Finland 3/1999, Edita, Helsinki, 1999.

### **Figure 1. The Storylines of Assessment**

ca 1975 – 1984: *scientific story-line* (research phase)

Discussions focused around the theoretical implications of genetic engineering, and were mostly carried out among scientists. In Denmark, a wing of the «radical science movement» was a key actor in this early phase.

ca 1985 – 1996: *environmental, or impact, story-line* (development phase)

Main issues were the control and regulation of field experiments and product development; main actors were environmental organizations and technology assessors (both in academia, civil society, and government). In Denmark genetic technology was discussed widely in the media and technology assessment was institutionalized.

ca 1996 – : *ethical, or cultural story-line* (diffusion and marketing phase)

New discussions focus on ethical aspects, and issues of political accountability. New actors include consumer organizations, philosophers, agriculture and industrial officials, as well as political parties and organizations.

Danish parliament passed a law on genetic technology and the environment in 1986 – the first such law in the world – which included a ban on deliberate releases, although the government could make exceptions in special cases.

There was a rather widespread public debate about GMOs in the 1980s, as part of an institutionalisation of technology assessment, at both the universities (particularly the technological universities, where units for technology assessment were established in both Aalborg and Copenhagen) as well as at the state level (where, among other things, the Danish Board of Technology was created). There were special funds allocated within the Biotechnological Research Programme, which was initiated in 1987, for information activities about the new genetic technologies, and there were many meetings, publications, as well as larger research projects (such as Pegasus at the Danish Technological University, which was a broad assessment of the economic, social and environmental consequences of biotechnology)<sup>2</sup>.

These activities were largely organized according to what might be termed a consensual approach to public assessment. The general idea was to see to it that as many different interests and interest groups as possible were represented in

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<sup>2</sup> See Andrew Jamison and Erik Baark, «Modes of Biotechnology Assessment in the USA, Japan and Denmark,» in *Technology Analysis and Strategic Management*, 1990, nr 2

the discussions, in order to give legitimacy for both the regulatory and support policies of the different ministries (environment, research and industry).

Perhaps the most innovative Danish initiative from this period, and still one of the main activities of the Board of Technology was, characteristically enough, the arranging of so-called Consensus Conferences<sup>3</sup>. Consensus conferences are a staged assessment activity, by which a group of lay people are given the opportunity to question selected experts and prepare a «citizen assessment» document. As such consensus conferences can be seen as one among different deliberative instruments to allow the «public» to take part in technological decision-making.

The first consensus conference was carried out in 1987, and addressed genetic technology in industry and agriculture. Despite a great deal of international attention given to this and subsequent consensus conferences, their direct impact on policy-making in Denmark, as in other countries, has been limited. Their main contribution is probably in terms of the media attention they receive and thus a certain influence over the discourses, or story-lines of public debate.

After the broad discussions of the 1980s, genetic technology became something of a «non-issue» in the first half of the 1990s. NOAH grew less active, as the institutionalized technology assessors – at the universities and ministries – more or less took over the role that NOAH had played in terms of educating, or informing the public. In the food sector, Danisco continued their development of GM sugar beets and the seed company Trifolium was working on GM fodder turnips. Industries like Chr. Hansen and Novo Nordisk also continued their development of enzymes, both for use in the food industry, as well as in relation to medical applications of genetic technology. In 1996, a new phase ensued with the coming of GM products from abroad to the Danish marketplace, and new actors emerged, such as *Greenpeace* and *Forbrugerrådet* (The Consumers Association) which began to discuss genetic technology in terms of ethical and political responsibility.

As the controversy was reopened in 1996, it became clear that the kinds of assessment that had been developed in the past – public participation in the form of e.g. consensus conferences, information campaigns and academic technology assessment – were no longer sufficient in addressing the concerns of at least some important segments of the public. In the most recent phase, there has been a growing complexity of the public attitudes to genetic technology, and the

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3 Consensus conferences have since become an interesting case of «technology transfer» in relation to public accountability and participation. Danish-style conferences have been held in a number of different countries, particularly over the past five years.

emergence of what we have elsewhere termed a «cultural story-line»<sup>4</sup>. There has, at the same time, been increased public funding of bio-ethical research as well as an incipient understanding by many important actors – in business, government and the universities – of the need for ethical and moral assessments of new GM products. One result of this new understanding has been the establishment of the governmental BioTIK committee, as well as the Center for Bioethics and Risk Assessment at the Danish Agricultural University.

Although ethic concerns in this way have come to be taken into account, and new kinds of assessment have been established, the practical implications of these developments remain to be seen. Neither Danish law nor EU regulations take account of anything other than environmental and health risks.

## Research and Development

Throughout the 1980s and into the 1990s a number of national research programmes have supported biotechnological research. At first these programmes were minor investments in a potential technology, but by the mid 1980s, as the technologies were able to demonstrate economic and technical potential in e.g. the production of enzymes and other proteins, the state support became substantial. The parliamentary adaptation of the first major biotechnological research and development programme in 1986 marks the first turning point in public support of biotechnological research. From 1987 and onwards the public funding increases in size and follow a set strategy. For an overview see figure 2.

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4 Jesper Lassen and Andrew Jamison, "Genetic Technologies Meet the Public: The Discourses of Concern," submitted to Science, Technology and Human Values, 2003.

Figure 2: Major biotechnological research programs in Denmark

Period	Ministry	Focus	Budget-mill DKK
1981–5	Industry	To promote gene technology in the interests of Danish business and society <i>Assessment:</i> Support of technology assessment	10
1984–88	Education	To strengthen basic research at universities within bio-molecular techniques and to improve the training of researchers. <i>Assessment:</i> To build up public expertise in assessments of safety issues related to applications of biotechnology by private enterprises	33
1986–87	Industry	To support research institutions and private enterprises in promising activities within micro-organisms, enzyme and protein technology. <i>Assessment:</i> To support research into safety aspects of contained use of gene technology.	5
1985–89	Agriculture	To establish biotechnological expertise at specific public research institutions and universities. This includes development and use of specific genetic techniques in relation to husbandry, plant breeding, food production and new uses of bio-mass. <i>Assessment:</i> None	27
1987–90	Education	To increase the production of biotechnological PhD candidates. <i>Assessment:</i> None	70
1987–90	Education	To support basic and applied research into biotechnology in the areas of biotechnological methods, fermentation technology, plants, animals, aquatic organisms, food production environment and the prevention and control of diseases. Furthermore a main target was to stimulate research in the private sector. <i>Assessment:</i> To increase knowledge about benefits and risks by supporting technology assessment activities. To inform the public about benefits and drawbacks of different applications of biotechnology.	500
1991–93	Research	To continue the technical research from the first programme and improve the industrial utilisation of the results. To establish biotechnological research centres on plants, the human genome, protein engineering, medicals, farm animals/fish, processes, peptides and ecology. <i>Assessment:</i> To support research assessing impacts of biotechnology on society, technological development, nature and the individual. To support the dissemination of research results to the general public.	456
1994–97	Research	Follow-up on the biotechnological research programmes; continued support of the established centres. <i>Assessment:</i> None	50–70 per annum

Figure 2: Major biotechnological research programs in Denmark

Period	Ministry	Focus	Budget- mill DKK
1998–03	Food, Agriculture and Fisheries	To strengthen the use of molecular and cell biological methods in food research, and to develop and implement the second-generation molecular biology in public and educational institutions. <i>Assessment:</i> « <i>To elucidate people's attitudes and ethical questions regarding the development and use of biotechnology in the food area</i> ». To establish a dialogue the natural scientific research projects and the results of the results from the research into attitudes and ethical problems.	63
1999–01	Research	To establish centres structured around expensive research instruments for shared use. <i>Assessment:</i> None	150
1999–02	Research	To support younger post doc researches within the biotechnological area. <i>Assessment:</i> To support the establishment of interdisciplinary research within centres addressing ethical and legal aspects of biotechnology.	55

It is not surprising that the main interest and focus of public funding in the years after 1987 was to advance the natural scientific knowledge, just as it was in the preceding programmes. As an illustrative example the first research programme<sup>5</sup> allocated approximately 480 mill. DKK over four years expecting a similar private funding of the research activities. Recognising that Denmark is too small a country to cover all aspects of biotechnology, the idea was to build capacities in areas where Danish industry already had a strong basis. The areas identified by the parliament included agriculture, food production and contained uses – clearly referring to the economically significant agri-food, pharmaceutical and enzyme sectors. The focus of the programme was partly on the production of PhDs and graduate students and partly on the establishment of a research infrastructure concentrating efforts in fewer research centres addressing issues like methods and processes, farm animal production, food production, food production and the prevention of diseases.

This line was continued in the second research programme<sup>6</sup>, building, as it was said, «*on the best of the activities initiated under the former programme*» and (again) emphasizing the importance of the private sector, when specifying the important role of businesses in organising and participating in the utilization of

5 Undervisningsministeren, "Forslag til folketingsbeslutning om iværksættelsen af et bioteknologisk forsknings- og udviklingsprogram", Beslutningsforslag nr. B44. 13. November 1986.

6 Forskningsrådenes udvalg vdr. bioteknologi, "Det nye program for bioteknologisk forskning og udvikling", 1990. And: Forskningsrådene, "Det bioteknologiske forsknings- og udviklingsprogram 1991-1995", 1992.

the results. As the table shows, the consecutive programmes on biotechnology has ensured annual public support of 50 – 150 mill. DKK for basic research, education and (industrial) application ever since the first programme.

This focus of the research must be seen in the context of Denmark, lacking rich natural resources apart from the agricultural land (and some North sea fossil fuels), increasingly dependent on a production of products and services with a high content of scientific knowledge. Hence the importance for the Danish government to facilitate a research keeping abreast of the international technological development. Consequently the so-called new biotechnologies were visualised as (necessary) means to maintain a modern industrial production, as it is stated by the minister for the environment in a parliamentary enquiry on biotechnology in general in 1986: «Denmark has excellent possibilities for a position among the leading nations in the world [when it comes to utilizing biotechnology], to create a competitive production, to enter new markets and to earn much needed foreign exchange and good jobs. We can of course not reject this possibility»<sup>7</sup>. Supporting biotechnological research has a natural role in these framings of the issue, almost making it a precondition for maintenance of the welfare state. Such arguments draw heavily in the construction of biotechnology as an economic necessity and consequently almost taking their economic accountability for granted: they are indisputable sources of wealth and therefore economically accountable.

The pure technical and natural scientific research was, however, not the only aspect of biotechnology that was supported in the period until 1996. As described previously, the critical debate grew alongside the increasing research and industrial. Reflecting this criticism, some of the research programmes included aspects of technology assessment, safety research and information/ dialogue. At several occasions the public concern is directly referred to as a reason for including this perspective in the research programmes – like in description of the second major programme, where it is said:

*«Considering the anxiety entertained by the population concerning if the limits to what is seen as desirable research are transgressed, it is important to be open about research and inform about its methods and results. Furthermore continuous assessment of methods and results is important (...) including broader technology assessments clarifying the impacts of the research results on other aspects of the social life, including the economy. Furthermore*

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7 Christian Christensen in: "Forespørgselsdebat nr. F18, 4. February 1986"

*the assessment must include ethical aspects of the research, seen from the point of view of the individual, the nature and the environment in general.»<sup>8</sup>*

The first major contribution to such technology assessment activities were allocated in the first programme, but not with the tacit consent of the conservative led minority government. During the Parliamentary debates on the proposition, the red-green majority forced the government to allocate 20 mill. DKK to information and technology assessment. Compared to funds for the natural scientific research the amount for assessment and information here, like in other programmes, was small, but they did secured the continuation of assessment activities like those initiated by the Technology Council under the Ministry for Industry in 1982, when they supported the Pegasus project carried out at the Technical University. The establishment of the Parliamentary Board of Technology in 1986 (once again against the will of the government), and the Social Scientific Research Council's (SSF) technology-society initiative, increased the focus on technology assessment – including assessment of biotechnology. All in all the 1980s was characterised by the development of technology assessment as a method and the accomplishment of a number of technology assessment activities dealing with of different aspects of biotechnology.

With the new phase of public debate after 1996, the new problems have also been reflected in the public funding of biotechnological research. This was e.g. stressed in the National Strategy for Biotechnological Research from 1998, where it was stated that: *«The development of biotechnology must take place in a way that reassures the public. This requires that ethical and legal aspects are systematically assessed and reviewed through independent research in close dialogue with the biotechnological researchers and relating to the actual research»<sup>9</sup>* Despite these intentions, the national strategy did not point to how this closer link between assessment and biotechnological research should be put into praxis. Some suggestions were, however present in some of the research programmes in the period after 1996.

First of all the programmes took up the heavy focus on basic and applied research but they also suggested new organisations of the assessment activities. Within the programme National Staking on Biotechnology running from 1999 until 2002, priority was given to *«...interdisciplinary research, as far as possible based on collaboration with biotechnological research groups. The main aim of the*

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8 Udvalget Vedrørende Bioteknologi, "Det bioteknologiske forsknings- og udviklingsprogram 1991-1995", Forskningsrådene, 1992

9 Forskningsministeriet, "National delstrategi for bioteknologisk forskning", Forskningsministeriet, 1998.

activities is to produce knowledge and results that are to the benefit of public authorities and business activities within the biotechnological area.»<sup>10</sup> Similar lines were laid out in the call from the Ministry for Food, Agriculture and Fisheries for application in the programme «Biotechnology in Food Research». Here it was stressed that the part of the programme supporting research into the attitudes and assumptions of consumers, should establish a dialogue to the biotechnological research projects supported under the programme<sup>11</sup>.

Partly based on the funds from these latter programmes, a research Centre for Biotechnology and Risk Assessment (CeBRA) was established. CeBRA was launched in 2000 to perform research into two biotechnological areas: genetically modified crops and genetically modified research animals<sup>12</sup>. For the first time research into biotechnology as well as public perceptions and ethics taking place at seven major Danish research institutions were joined in the same research centre. Apart from issuing a newsletter («gene-ethics in praxis») and arranging joint workshops for the involved projects, it is required that a third of the scientific articles from each project are result of interdisciplinary research. The will to go beyond the biotechnological research was further demonstrated as the institutions behind the centre after the end of the ministry funds decided to support the centre for another five years.

The relation between the biological scientists and the public constitutes a serious problem for this and other activities to move the biotechnological research in a more accountable direction. Recent research has thus demonstrated that there is a significant scepticism towards the biotechnological scientific community. In a survey in 1996, 71 % of the asked Danes tended to agree in the following statement: «irrespective of the regulation, biotechnologists will do whatever they like»<sup>13</sup>. A reasonable hypothesis is that this extremely low level of accountability partly can be explained by the unwillingness to let social science or humanities seriously influence the biotechnological research agenda.

## The biotech business

Among the first industrial movers on the biotechnology arena in the early 1980s were the companies Novo and Nordisk Gentofte. Novo as well as Nordisk Gen-

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10 Forskningsstyrelsen, "Støtte til bioteknologisk forskning", 1998

11 Ministry of Food, Agriculture and Fisheries programme, «Biotechnology in Food Research. Invitation of project applications», 1997.

12 See: <http://www.bioethics.kvl.dk/eindex.htm>

13 John Durant et al. (eds), "Biotechnology in the public sphere, Science Museum, 1998. p.261.

tofte had production of human insulin and other pharmaceuticals, and Novo, by far the larger of the two, had in addition industrial enzymes for the food sector and for the washing powder industry as important areas of business. In 1984 Novo and Nordisk Gentofte almost simultaneously announced plans to develop and apply genetically modified organisms in the production of insulin respectively human growth hormone. It is characteristic of this early phase of development of gene technology in Denmark, that both companies surrounded their concrete plans with a high level of secrecy. At that time, there was no compulsory registration of research or other uses of gene technology in Denmark. Instead companies or researchers could, if they wished to, report their use of genetic manipulation to «Registreringsudvalget», where the reports were kept secret to the public.<sup>14</sup> This strategy of relative secrecy of the companies must be seen in the light of the common understanding that gene technology in itself is not different from other technologies, hence regulation should address the products, not the way they are produced<sup>15</sup>. Consequently there is also no need to go public with plans to apply gene technology and stimulate a debate – the secrecy may on the other hand also reflect a (at that time common) perception that avoiding public debate is a useful strategy to ensure a peaceful business environment. The events surrounding Monsanto's introduction of soya to the European market in 1996 proved this latter strategy wrong.

The sudden announcement of concrete plans of application of genetechonology in pharmaceutical production took most parties by surprise, probably because the relative secrecy had left members of the public as well as NGOs and other actors on the political arena parties unaware of the advanced stage gene technology. One outcome was that the announcements became triggers for the first era of public debate of gene technology in Denmark. Another was that the productions plans themselves became subject to intense public attention, forcing both companies to engage in a public dialogue at some level. One expression of this (new) engagement with the public was pamphlets explaining the essentials of gene technology and presenting the companies interests. Other expressions were the organising or participation in public meetings where Novo and/ or Nordisk Gentofte we confronted with opposing actors like NGOs or neighbours.<sup>16</sup>

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14 For a detailed account of the controversy over these first productions, see: Jesper Toft, "Kampen om gene", NOAHs Forlag, 1985.

15 See Pauli Kiel et al, "Interviews med eksperter og repræsentanter for interessegrupper indenfor bioteknologiområdet.", 2. del, Projekt Pegasus Rapport nr. 5, Danmarks Tekniske Højskole, 1984. pp.78-83.

16 See Ole Terney, "Debatten om gensplejsning", Bio-Nyt Forlag, 1986; Jesper Toft op cit.

It seems fair to say that from the starting point the dominant business strategy, as expressed by Novo and Nordisk Gentofte, was that since gene technology should be treated like any other technology, it needed not to be accounted for in any particular way. Just as the view was that no particular public accountability was needed industries involved in gene technology, these industries supported the view that a specific regulation was not needed. In the years following the introduction of the Act on gene technology and environment in 1986, the Association for Biotechnological Industries in Denmark («Foreningen af Bioteknologiske Industrier i Danmark») counting companies like Novo, Nordisk Gentofte, the breweries and sugar industry among its members, accordingly fought the – to their opinion – strict Danish regulations. One example being a comparative analysis of the level of regulation of biotechnology in different countries, published in the hope of influencing the parliament<sup>17</sup>. The set off from this analysis was the notion that biotechnological business in Denmark was impeded by the strict regulation, placing Danish industries in poorer position compared to their foreign competitors.

Around the late 1980s and the beginning of the 1990s things changed. Novo and Nordisk Gentofte merged into Novo Nordisk and went public with the view that regulation is not necessarily in contradiction to business interests. As such Novo Nordisk goes against not only many of their Danish brothers in arms, but also the continued trend in the European biotech industry arguing that regulation is not in the interest of biotechnological industries. Defending this view, representatives of Novo Nordisk argued that there is no documentation for alleged reduced competitiveness resulting from regulation. Instead the argument was that on the one hand regulations provides a known and secure environment for production and on the other hand that regulation is seen as a means to ensure public acceptance of biotechnology.<sup>18</sup> The shift indicates that to proactive industries, like Novo Nordisk, the public is not only perceived of in terms of consumers to be dealt with on the market, but also as citizens who have a say, eventually influencing the political processes and thereby the frames for doing business. Hence public accountability becomes important to businesses like Novo Nordisk, who in the following years develops a charter and a strategy for their relations to the public and other stakeholders. The remainder of the section shall exemplify this trend where business attempts to handle ‘the problem of

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17 See eg. Kirsten Fink & Ole Terney, "Sådan reguleres genteknologi. Praksis og erfaringer", Foreningen af Bioteknologiske Industrier i Danmark, 1988. p.5.

18 See eg. Morten Kvistgaard, «Impact of regulation on the development of biotechnology», Environmental Project No. 322, Ministry of Environment and Energy, 1996. p.10-11.

the public' in a proactive way outside the market by presenting elements of Novo Nordisk's merger between economic accountability to the shareholders and this new broader understanding of accountability.

Novo Nordisk is today partly divided into a number of industries, all now members of different sections of the Novo Group which has an annual net turnover of approx. 26 mill DKK (~3.5 mill Euro). The pharmaceutical activities are gathered in Novo Nordisk A/S whereas the enzyme business are placed in Novozymes A/S. Gene technology is the important basis for many of the activities in the Novo Group, but for our purpose Novozymes is the most interesting, since they cover the use of gene technological methods in the production of enzymes and other ingredients for food and feed production, besides their important production of technical enzymes for the wash powder industries.<sup>19</sup> As it will appear, Novozymes is, however, not totally independent since important frames for production concerning e.g. values and strategies are decided in the Novo Group. This framework includes three important elements of particular importance for the accountability strategies of the Novo Group: the Charter, the triple bottom line accountant system and the stakeholder dialogue.

Statements about common values and commitments are expressed in the Charter, which constitutes the basic criteria or framework for all companies in the Novo Group and their employees. The question of accountability is specifically addressed in one of the values in the Charter, where it says: *«Each of us shall be accountable – to the company, ourselves and society – for the quality of our efforts, for contributing to our goals and for developing our culture and shared values»*.<sup>20</sup> Such value commitments expand the understanding of what the employees and the company need to account for, far beyond the traditional economic obligations. While many companies would probably approve of similar principles, and do their best to ensure that their sales are not affected by criticized (that is unaccountable) actions, fewer explicitly work with values as The Novo Group attempt to do.

The idea that accountability also stretches beyond what is of importance for market performance and production costs, can be illustrated by three commitments included in the Charter, stressing commitment to be financial as well as social and environmental responsible. Essential parts of these commitments include maintenance of openness about products and processes (to the extent openness does not harm competition), and engagement in dialogue with stakeholders and the ambition to live up to the International Chamber of Commer-

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19 The following is partly based on an interview with Kirsten Stær, Novozymes, February 7, 2003.

20 The Novo Group, "Charter for companies in the Novo Group"

ce's Business Charter for Sustainable Development as well as the UN declarations on Human Rights and Biological Diversity.

The maintenance of social and environmental responsibility is important in the construction of the public image of Novozymes. One important tool to ensure this is the so-called triple bottom line accounting system. This system has over the last years been developed by the companies in the Novo Group as a tool to measure and control the performance – and indeed report – not only economic aspects, but also environment, bioethical and social consequences of their business. The ideas of accounting for environmental performance and identify future environmental aims is by no means unique to Novo, but has over the past decade been institutionalised in the public regulation, e.g. requiring certain industries to make annual green accounts<sup>21</sup>. By expanding this required task to also include social issues, the companies in the Novo Group joins, however, a smaller group of more innovative companies.

The basic idea in Novozymes' environmental account is to describe environmental status based on a number of indicators like consumption of resources, release of wastewater solid waste, the accidental release of GMOs, number of animals used for testing and the total contribution to environmental problems like the depletion of the ozone layer, acidification and the global warming.

The social account is made up in a similar way, identifying a number of indicators for social performance. These social indicators are all related to Novo as a workplace and include e.g. the distribution between the two sexes in different positions, average age of employees as well as the health and safety of employees.<sup>22</sup>

The reporting of social and environmental performance are both followed by identification of long term and/or short term aims for the indicators, making these accounts steering instruments in much the same way traditional accounts are used to make budgets and set goals for economic performance. To validate the quality of the selection of indicators and the calculation of the indicator values, Novozymes has in its most recent report included audition of also environmental and social accounts by the same auditors who audited the economic accounts.

The third important tool for Novozymes in their efforts for accountability is the dialogue with the surrounding society. Contrary to most other businesses,

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21 Miljøministeriet, "Bekendtgørelse om visse listevirksomheders pligt til at udarbejde grønt regnskab" BEK nr 594 af 05/07/2002, Copenhagen, 2002.

22 Novozymes, "The Novozyme report (Account and data)" <http://www.novozymes.com/cgi-bin/bvis-api.dll/ar2002/download.jsp>

relations are not reduced to costumers and contractors in the production chain, instead all actors who might have an interest are acknowledged as relevant stakeholders. Of particular interest in this context are the roundtable discussions with NGOs. Within these discussions NGOs are invited to participate in a dialogues about the activities of Novozymes – the idea being that NGO can be a source of inspiration for strategic decisions in the future.

The importance of accountability for gene technological firms was demonstrated by the introduction of the first GM food products to the Danish market by Monsanto in 1996. Although the actual presence of GM soya in the shipments was marginal (2 %), the handling of the situation by Monsanto reinforced the public understanding of an multinational business attempting to force GM soya upon reluctant Danes and other Europeans against their will. By rejecting segregation and only too late being willing to engage in a dialogue with the critics and concerned, Monsanto helped pave the way for the second era of controversy over GM foods.<sup>23</sup> There is little doubt that the continuous effort to ensure and maintain public accountability by Novo Nordisk in the 1990s and the members of the Novo Group in the last years also can be interpreted as a strategy to avoid the involvement in future controversies of similar kind. That this strategy seems to work is indicated by the results of a survey carried out by the Union of Engineers in Denmark in 2000, where ethical and moral performance of 4 major gene technological companies was addressed. In this survey Novo Nordisk came in second, only exceeded by Carlsberg, a well-known contributor of major funding of science and culture for centuries<sup>24</sup>. It is, however, still unsure to what extent the strategy will preserve Novozymes and other companies in the Novo Group as targets of future biotech controversies. This will on the one hand depend on their ability to maintain the stakeholder dialogue at a level, where critical stakeholders feel that their participation in the dialogue makes a difference – if not they may feel tempted to remove the critique and debate from the relatively closed environment of the stakeholder dialogue and open a more public arena for debate and criticism of gene technological activities. On the other hand it will also depend on the ability of companies in the Novo Group to develop methods to expand the social and ethical indicators in the triple bottom line accounting system so that they in the future more specifically up take up

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23 See Jesper Lassen et al, "Testing times – the reception of Roundup Ready soya in Europe", in Martin Bauer & George Gaskell (eds), *Biotechnology. The Making of a Global Controversy*, Cambridge University Press, Cambridge. Pp.279-312.

24 Institut for Konjunkturanalyse, "Danskernes syn på bioteknologi. En analyse af det holdningsmæssige landskab over for bioteknologi", *Nyhedsmagasinet Ingeniøren*, 2000. p.101.

some of the unquantifiable, particularly moral, concerns about gene technology shared by large parts of the public.

## The civic arena: non-governmental organizations

As in most other industrialized countries significant segments of the Danish public, in the course of the 1960s and 1970s, expressed concern over the dominant forms of technological development and their environmental «side effects». In the 1970s, this was primarily related to the development of nuclear technology and the pollution and waste problems associated with industrial production and agriculture<sup>25</sup>. As a result, a number of new environmental organizations came to be established in Denmark, and by the 1980s, some of them started to interest themselves in genetic technology. As mentioned earlier, it was critical scientists who first drew attention to the potential risks and benefits of biotechnology. An actual debate did not develop until 1984, when Novo and Nordisk Gentofte announced plans to develop gene technology in pharmaceutical production. Together with the ongoing preparation of the regulation of gene technology, this opened the way for the development of organised critique in the NGOs.

In the following years NOAH became the most important environmental organization attempting to represent the concerns of the public. NOAH played throughout the 1980s a role as public watchdog, critically partaking in the policy processes in relation to both the development of a national legislative structure, the EU regulation and the first applications for industrial production and deliberate release. With its decentralized structure and focus on «counter-expertise» NOAH can be described as a mild form of participatory protest organisation<sup>26</sup>. Although many proponents of gene technology were critical of NOAH in these years, the form of action was by no means radical in the sense that they broke, or violated any laws. NOAH saw it as its most important task to inform the public about these new technologies – and indeed did so by arranging and

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25 For an overview see: Andrew Jamison et al, *The Making of the New Environmental Consciousness. A comparative study of the environmental movements in Sweden, Denmark and the Netherland*, Edinburgh University Press, Edinburgh, 1990. pp. 66-120

26 For the distinction between public interest lobby, participatory protest organisation, professional protest organisations and participatory pressure groups see: Mario Diani & Paolo Donati, *Organisational Change in Western European environmental groups: A framework for analysis*", *Environmental Politics* vol.8(1), 1999, pp13-34.

participating in many public meetings and continuous publication of books and articles.

During the 1980s NOAH enjoyed a virtual monopoly, when it comes to an organised critique of biotechnology. None of the other «new social movement» organizations dealing with consumer, environmental, third world or other issues where the question of gene technology was potentially important, were particularly active – and most (if not all) had no policy about gene technology policy at all. In terms of assessment, NOAH played thus an important role in these first years of the controversy.

From the start NOAH, first of all having an identity as an environmental – and to some extent a consumer – movement organization, was most active and visible in relation to risk related concerns. They did, however, also raise concerns outside risks to environment and health and translated e.g. a book dealing with genetic technology in a third world perspective, and co-organised a conference on gene technology and intellectual property. Although NOAH in this way also voiced the economic critique and some of its aspects of power, justice and exploitation they never had the success to move the core of the public debate in the media and political processes away from the heavy focus on risks clearly dominating the 1980s.

As the EU regulation is set up in 1990–91 and implemented in the Danish regulation NOAHs disappeared slowly from the public arena, coinciding with a general decline in level of controversy over gene technology in the first half of the 1990s. This left open a space for other NGOs, first of all *Greenpeace* (established in Denmark in 1982) and to some extent *Forbrugerrådet* (The Consumers Association, FR) and *Naturfredningsforeningen* (the Society for the Conservation of Nature, DN). After the reopening of the controversy, a number of organisations joined Greenpeace, FR and DN in taking over after NOAH who now slowly also was building up again. Most of these new organisations were small single-issue organisations devoting their energy combating gene technology. They included e.g. *Oplysning om Genteknologi* (Information about Gene technology, OOG) and *Organisationen mod gensplejsede fødevarer* (the Organisation Against GM foods, OGF). Typically disappearing after a short period of activity, or to the extent they existed over longer timer, virtually without any impact on debate or politics. Among the new organisations was however one, *Danmarks Aktive Forbrugere* (Active Consumers in Denmark, DAF) which proved to be viable and has together with Greenpeace been among the most influential and visible NGOs in the area in the years since 1996.

It is however interesting to note that almost all NGOs have maintained the risk focus of the 1980s. DAF as well as Greenpeace have identities as environmental NGOs and as such they both placed their central focus on the environmental risks. As a leading member of DAF, Jeppe Juul, puts it, «*We are not the Ethical Council, the National Church, nor the Jewish Community.*»<sup>27</sup>. As such, cultural or ethical issues are not taken up by NGOs<sup>28</sup>. Economic concerns dealing with issues of profitability and production, power and responsibility are covered by a number of organisations. Exploitation of poorer developing countries is e.g. an issue taken up by the development organisation *Mellempfolkeligt Samvirke* (MS). Wider consumer issues like concerns about consumers' right to choose on a free market or impacts on food prices that are typically issues dealt with by the traditional consumers' organisations.

What might be termed the discourse of cultural concern, that covers religious and moral aspects raising concerns over e.g. ethics or rights, is poorly covered by NGOs. In a round of interviews with some of the most visible NGO, none of these took up the issues of naturalness of GM plants or animals. Similarly the dominant animal welfare NGO, *Foreningen til Dyrenes Beskyttelse* (the Society for the Protection of Animals, DB) has been strikingly silent in relation to GM foods Annette Weber from DB elaborates this: «*Dyrenes Beskyttelse has so far not a set policy in relation to GM animals. But the issue has to be dealt with under the action plans of other areas (...) and as a result gene technology will be assessed weighing benefits against harm to the animals*»<sup>29</sup>

As a result of this utilitarian approach where usefulness is measured against suffering, animal integrity of trespassing limits to nature seemingly does not play any particular role.

## The policy process: developing an ethical discourse

From the very start for the Danish debate, biotechnology was discussed as an issue raising safety as well as wider social and ethical questions. The concerns were raised to the extent that Minister of the Interior in 1983 decided to set up two committees to make accounts of the need for regulation of safety issues on the one side and ethical issues on the other.

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27 Jeppe Juul, Danmarks Aktive Forbrugere, Personal Interview

28 Lassen and Jamison, op cit.

29 Annette Weber, Foreningen til Dyrenes Beskyttelse, Personal interview 12. December 2000.

*Gensplejningsudvalget* (The Committee for Genetechnology) was set up to suggest the organisation of public administration of the use of the new biotechnological processes with a specific focus on the risks to environment and humans. The mandate for the committee pointed out that ethical questions were not to be an aspect of the account, but would be «taken up in a broader context». <sup>30</sup> Interpreting this mandate, the committee dedicated their overall focus in the produced account to risks related to research and production using genetechnology. In the account «Genteknologi og sikkerhed» (Gene Technology and Safety) the committee concluded that three separate acts were needed to regulate the risks of genetechnology: an act addressing research, an act addressing uses in agricultural production and an act regulating the use of genetechnology in products and production in general.

Parallel to the work in *Gensplejningsudvalget*, the *Udvalg om Ethiske Problemer ved Ægtransplantation, Kunstig Befrugtning og Foster Diagnostik* (The Committee on Ethical Problems Regarding Transplantation, Artificial Insemination and Diagnostics) was set up. Apart from investigating ethical problems of the technologies mentioned in the title of the committee, the mandate also specifically instructed the committee to look into genetechnology («genesplicing»). <sup>31</sup> Although the mandate did not specifically ask the committee to limit its assessment of genetechnology to the area of human uses of genetechnology, genetechnology was presented within a human/medical frame, leading the committee to interpret their mandate as limited to social and ethical aspects of genetechnology and the mentioned new diagnostic methods to the extent they are used or may be used on humans. Safety issues were accordingly not dealt with, but explicitly seen as belonging under the *Gensplejningsudvalget*. Likewise ethical questions related to animals and plants were although these concerns were seen as ethically relevant, seen as falling outside the mandate for the committee. In the report «Fremskridtets Pris» (The Price of Progress) the committee concluded that there was no need for a specific ethical regulation, but recommended instead the establishment of an advisory ethical committee within the human area.

As described here, the first initiatives from Danish authorities led not only to a separation of applications but also a separation of which concerns should be addressed in which contexts. In this way the different mandates and their inter-

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30 Indenrigsministeriets Gensplejningsudvalg, "Genteknologi & sikkerhed" Betænkning nr.1043, Indenrigsministeriet, 1995.

31 Indenrigsministeriets Udvalg om Ethiske Problemer ved Ægtransplantation, Kunstig Befrugtning og Fosterdiagnostik, "Fremskridtets pris", Indenrigsministeriet, 1984.

pretation by the two committees can be seen as both an illustration of the two dominant framings of the gene technological issue until the mid 1990s, but also as an important structuring force behind the development of different framings.<sup>32</sup> In the following years, a tendency to a split of the discussions, and indeed the regulation, can be observed allowing for the development of two separate discourses: *On the one hand* a human-ethical discourse where the focus was on the ethical, and to some extent social questions pertaining to applications directly related to human uses. *On the other hand* a production-risk discourse, where the focus was on the risks to environment and human health. Although ethical questions regarding the use of animals and plants were recognised by both committees, such questions were excluded from the accounts and thus also largely from the following formal policy process and regulation. In addition questions of microorganisms and ethics was not even raised by the two committees.

Hence public authorities and government sought to ensure the accountability of genetchnology in two different ways depending on the area of application. The political and regulatory structures constructed in the following years took up this split accountability: In relation to human applications, accountability of genetchnology was to be ensured by a combination of the *Det Ethiske Råd* (The Ethical Committee) set up in 1987 to advise public authorities<sup>33</sup>, and a number of laws and other regulatory initiatives. For GM foods and other uses of genetchnology in production, accountability was largely reduced to the question of avoiding risks – the means first of all being the laws on gene technology and environment and working environment<sup>34</sup>. Hence the accountability of GM foods was – in the political processes at parliament – mainly seen in the context of risks, whereas ethical and social issues were never seriously addressed. An exception from this picture was the *Det Genteknologiske Råd* (The Genetechnological Council) established in 1987, having a mandate that included risk as well as ethical issues. Ethical aspects became, however, never a key priority of the council, probably due to the dominance of biotechnologists: six representatives from biotechnology and industry were appointed and only one from humanities (a pastor). By example the council did not take up ethical question in its

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32 Similar splits of the debate was observed in: Svend Andersen et al., "Bioteknologi og etik i den offentlige debat - i USA, Tyskland og England", Teknologinævnets Rapporter 1992/2, Teknologinævnet, 1992.

33 Indenrigsministeriet, "Lov om oprettelse af et etisk råd og regulering af visse biomedicinske forsøg", Lov nr. 353 af 3. juni 1987.

34 Miljøministeriet, "Lov om miljø og genteknologi", Lov nr. 288, 1986; and Arbejdsministeriet, "Bekendtgørelse om genteknologi og arbejdsmiljø". 1st September 1987.

first judgement of the Danish situation in 1988, but only addressed limitation to the research and industrial application<sup>35</sup>.

The somewhat ambivalent attitude towards GM foods (and other non-human applications of genetechonology) expressed in the writings from the two committees was repeated in the parliamentary debates over genetechonology. A telling example was an inquiry in 1986 to the Minister for the Environment, raised by *Socialistisk Folkeparti* (Socialists Peoples Party, SF) concerning measures taken to secure humans and environment<sup>36</sup>. Although the enquiry specifically addressed risk issues, the opposition as well as the Minister stressed that there were wider ethical concerns that needed to be addressed, as the Ministry put it:

*«Finally it is my view that there is a need to consider also ethical aspects. The Minister for the Interior has recently submitted a Bill banning certain experiments using genetic manipulation on humans. Similar problems are raised in relation to animals and plants. To me there is a major difference between what science is capable of doing, and what we, keeping our basic philosophy of life in mind, will accept»<sup>37</sup>*

Just as it was the case in the accounts, ethical questions were put aside. The Minister promised to make the issues subject to public debate and consider how ethical questions outside the human area could be addressed in coming acts. Whereas the public debate was stimulated in the following years, ethical questions were never taken up in the regulation set up in 1986, or in the subsequent revisions in 1989 and 1991.

During the 1990s ethical questions beyond the human area began to appear in the wider political processes of genetechonology. The Ethical Council on Animal Ethics (Dyreetisk Råd), was e.g. established in 1991, given the task to oversee ethical questions in relation to animals – although the focus was on animal protection in a traditional sense, the council was also given the task to follow the gene technological development<sup>38</sup>.

The core of the parliamentary inquiry in 1994 was however on technicalities of labelling, legal issues and risks – there was still no developed ethical discussion of GM food matters. Following the re-opening of the controversy in 1996 this picture did however change dramatically. A first sign of this was a debate in

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35 Det Genteknologiske Råd, "Årsberetning 1987", Forskningsdirektoratet, 1988. p.5-8.

36 Forespørgsel nr. F18: Forespørgsel til miljøministeren. 4. February 1986.

37 Ibid.

38 Justitsministeriet, "Dyreværnslov", Lov nr. 386 af 6. juni 1991.

Parliament coinciding with the unloading of the first GM soya in Denmark. Here several speakers took up ethical questions as well specific questions in relation to the consumers' freedom of choice, the power of multinationals, the third world and what benefits are considered legitimate. The most striking example was a statement from the spokeswoman from *Kristeligt Folkeparti* (The Christian Democrats), who elaborated on elements of an ethical assessment – this speech, however, did not evoke any particular resonance among the other parties. Although ethical questions were taken up focus remained on risks, technicalities of regulation and the usefulness of GM foods<sup>39</sup>.

Whereas the soya controversy primarily served as an eye-opener for the inability of the existing regulatory structures to cope with the concerns of the public, the announcement of the cloned sheep Dolly a few months later, added major elements of ethics to the parliamentary debate. Now a central focus of the debate of GM foods was the ethical questions, leading to the following parliamentary decision:

*«Considering that:*

- the biotechnological development raises ethical and environmental questions concerning humans, animals and plants and that*
- human cloning is forbidden in Denmark in research as well applied on humans*

*The Parliament urge the Government to:*

- Ensure that animal cloning is limited to research*
- Ensure experiments on full grown cloning is limited to the extent that no fully developed /subjects are produced.*
- Ensure that cloning of domestic animals is not taking place*

*(...)*

*Before end of 1997 (...) work to find a method ensuring that intervention against developments offending the ethical norms of society can take place in due time; and that a foundation for a renewed debate in the general public as well as in Parliament of the ethical limitation to research, is created.»*<sup>40</sup>

Neither Dolly nor the GM soya was surprises in a scientific sense: GM food just like the cloning techniques, been subject to intense research and development

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39 Forespørgsel nr. F25, 12. December 1996.

40 Forespørgsel nr. F64, 22-23. May 1997.

activities in many countries for more than a decade. Regardless of this, they took the public by surprise and hence also the Parliament and public authorities, who had been working hard in the 1980s to construct frames ensuring the accountability of GM foods. In a way the events after 1996 clearly demonstrated the goal of publicly accountable GM foods had not been reached, and it is in this light the urge to create the basic framework of an ethical debate about limits to research must be seen. In the area of GM foods, ethics thus diverged from risks in the sense that risks at the national level had been subject to continuous assessments, several accounts and parliamentary enquiries and scientific reports; and internationally risk assessment was accepted as a scientific discipline. Unlike this the ethics of GM foods had never had national attention nor developed into an acknowledged scientific discipline noticed by the political processes. Many had, as demonstrated above, stressed the importance ethical questions in relation to GM foods, but so far the issue had been allocated to public debates and meetings – it was never taken seriously and made subject to e.g. research activities, parliamentary enquiries or accounts. The period following the reopening of the controversy in 1996, can largely be understood as period, where the frameworks of a GM food-ethical discourse is under construction in the sense that a vocabulary and taxonomy of ethical concerns related to GM foods is created by public authorities and in Parliament.

In the past, ethical societal aspects of genetechonology had primarily been taken up by *Teknologirådet* (The Danish Board of Technology), but this changed after 1996, as the issues were taken up in other contexts also. Among the most important new domain of debate and discursive construction was *Erhvervsministeriet* (The Ministry of Trade and Industry), who had previously only related to the gene technologies from a strictly business oriented point of view. Among the initiatives set up by the Minister was the so-called BioTIK group, a working group with 11 members counting philosophers, biologists, theologians, medical doctors and other academics who had been working in and around biotechnology. The task of the working group was to produce a discussion paper that could serve as the basis of a balanced debate and increase the understanding of the public concern. By the end of 1997 the working group produced the report *De genteknologiske valg* (The Genetechnological Choices)<sup>41</sup>; a report, discussing issues (visions as well as problems) identified to be central for the decision making about gene technology. One outcome of the report was a suggestion of ethical criteria for development and application of genetechonology, for the first

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41 BioTIK-gruppen, "De genteknologiske valg", Erhvervsministeriet, 1997.

time seriously integrating the different human and non-human applications and including ethical, risks as well societal concerns.

In March 2000, the Minister presented a statement on ethics and gene technology to the parliament<sup>42</sup>. This statement, receiving general support among the political parties, repeated the conclusions of the report from the working group, and stated the policy the government wanted to pursue. This included among other things 1) To work for an international convention on the inclusion of ethical considerations in the regulation of biotechnology in plants and food. 2) To work for the inclusion of ethics in the in the regulation of gene technology, in particular ensure the inclusion of ethics in the revision of the EU-directive on deliberate releases. 3) To develop guidelines for ethical assessment of new biotechnological methods. 4) To support debate and information.

One outcome of the statement was the establishment of the so-called BioTIK secretariat under the Ministry for Trade and Industry in 2001. The secretariat joined nine ministries working for realising the ambitions of the statement, that is on the one hand the incorporation of ethical principles in the regulation of and decision-making about biotechnology, and on the other hand the establishment of a basis for public consultation and information. These attempts to twist the policy process in a more ethical direction, have, however, not yet led to any significant regulatory changes. The 2002 revision of the central law in regulation GM foods, The Act on Genetechnology and Environment, does include provisions for ethical considerations, but, following the line of the revised EU directive for deliberate release, these are not mandatory.

In summary Danish assessment of genetic technology is still characterised by a strong utilitarian, cost-benefit orientation, focusing on risks to health and environment versus economic benefits. Cultural and ethical stories have certainly begun to be told, and even officially sponsored, but their influence on policy-making and broader political and economic discussions remain marginal at best.

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42 The Danish Ministry of Trade and Industry, "The Danish government statement on ethics and genetic engineering", The Danish Ministry of Trade and Industry, 2000.

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# Market Orientations and Mediation of Public Opinions in Finnish Biotechnology

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## Biotechnology as a national competitiveness factor

Since the late 1980s Finland has followed the strategy of the OECD by paying more attention to «new promising technologies» (OECD 1988; Science and Technology Policy Council 1987). A corporatist decision has been made concerning the responsibility of the state to finance specific high-tech fields, such as information and material technologies, and biotechnology. The increasing interest of the government in new technologies has been related to the rise of market-orientation and commercial ethos and to a change in the political ideology from the welfare state to the neo-liberal state (Alestalo 1997). The membership of the European Union in 1995 has made the neo-liberal preferences even stronger. Due to a new corporatist agreement the transformation from the politics of equal opportunities and community ethos to market competition, market governance and market democracy has been rapid (Häyrinen-Alestalo 2001; 2002). As market orientation has been seen as a collective aspiration of all policies to foster the international competitiveness of the economy, technology policy has become highly selective with the primary focus on information and telecommunication technologies (ICT). The rise of Nokia as a world market leader in mobile phones has strengthened this orientation.

The chosen strategy has been a mixture of the ideas of the knowledge-based society, new growth theory and the new economy (Stehr 1994; Grossman & Helpman 1991; Castells 2001; European Commission 1998; OECD 2001; Tekes 2001; Science and Technology Policy Council 2003). In the strategy human capital and competencies are significant determinants of economic growth. There is also a tendency to see new-tech products as having wide potential markets and the most effective cost/benefit ratio.

In the current Finnish political vocabulary the national innovation system stands for economic expansion, collective representation and information mediation (Science and Technology Policy Council 2003; Miettinen 2002). This system is composed of networks between various producers of knowledge and the criteria of their performance are similar for all of them. The criteria are derived from the international markets and emphasise competition and effectiveness (Allardt 1998; Häyrinen-Alestalo 1999). The citizens are invisible actors in the national innovation system. They are mostly consumers and customers who have local importance in front of the pressure for globalisation (Cabinet programme 1995; Ministry of Finance 1996; Sitra 1998; Snell 2002).

Due to the success story of the Finnish ICT sector biotechnology has been for a long time «an area of high potential benefit» (OECD 2001; OECD 2002; European Commission 2001). The ICT-driven international competitiveness has also strengthened the tendency to see the generic importance of biotechnology through the lenses of ICT and to regard the issues of social, ethical and moral responsibilities as only secondary.

In the following we outline and analyse the changing context of Finnish biotechnology and the main issues and actors present in the field. We use here for the most part the term biotechnology, even though the term covers a large range of scientific fields, industrial sectors and applications. This choice has been made because in much of the basic material used in this report no differentiation is made between gene technology and biotechnology. Aside from the documents and results of earlier research we also draw on personal interviews among science and technology policy makers and biotechnology experts that we have made in 2000–2003.

### The new hope of technology policy

In 2000 the global economic environment became turbulent due to ICT-driven economic uncertainty. Although Finnish policy makers have been unanimous in their predictions of the short length of the economic instability, they have had to revise the estimations of economic growth several times. Today they agree that the ICT sector has not fulfilled all political promises.

With the falling validity of the new economy thesis, more and more weight has been given to the market expectations of biotechnology. These hopes follow the prospects of the European Commission (2002: 3) seeing «life sciences and biotechnology to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies». Our interviews indicate, however, that in the view of the Finnish tech-

nology policy makers, biotechnology has been called a promising field for too long. They have started to ask what is the new new-tech after ICT and biotechnology. Still there is a strong trust on the commercial potential of biotechnology. *The National Technology Agency (Tekes)* mentions the field as one of the key technologies (Tekes 2001). There are also hopes that a new biotech Nokia can be established. Still the idea of the generic nature of biotechnology is unclear.

The Biotechnology 2000 Working Group (2000) and the Evaluation Panel of Biotechnology in Finland (Academy of Finland 2002) that were set up by the Ministry of Education to consider the promotion of academic biotechnology research and industrial applications have paid attention to the science-based peculiarity of biotechnology and to the need to be patient when waiting for scientific and commercial breakthroughs. In fact, in the shadow of ICT, biotechnology has received political understanding of its long-term application process. When the new economy thesis has shown its fragility, the questions of the economic value of this field have become louder. Strong market orientation has prevented, however, the discussion of the rights and responsibilities of the state, industry and academic researchers. Today the European Commission (2002: 4) speaks at the same time of the need «to examine measures required to utilise the full potential of biotechnology and to strengthen the European biotechnology sector's competitiveness in order to match leading competitors» and of the need «to ensure that those developments occur in a manner which is healthy and safe for consumers and the environment, and consistent with common fundamental values and ethical principles». Even though the Finnish policy makers are aware of the latter demands, they are primarily keen to know how national competitiveness can be maintained by investing in biotechnology production.

The hardening attitude was also visible in the speech of the former Prime Minister Lipponen at the opening of Helsinki Biocentre 3 (Lipponen 2002). Aside from pointing to the complex characteristics of biotechnology and to the need to have an open discussion of these complexities and ethical problems, he presented normative expectations of the future commercial success. In his view the state has supported research and technology programmes of biosciences and biotechnology for over 20 years and it has the right to expect real evidence of the effects of this funding. It is now time for this research to show its capability to compete for new markets, knowledge-based innovations and for highly competent labour force. Our interviews indicate that this view is shared among many technology policy makers.

By following the OECD strategy, the Finnish policy makers have identified growth clusters for the development of the national economy. According to Te-

kes, the strong clusters are ICT, forestry and metal industries, the rising key clusters being bio-industry and knowledge-intensive services (Tekes 2002b: 2). As a response to the growing demands for globalisation, the national focus is also on the most «change-activating technologies». Aside from ICT and material technology biotechnology is mentioned as being capable of responding to this challenge. The identification of the key clusters is one way of searching for a more stable economic environment and of pursuing a selective policy. According to Tekes (2002a: 11) a cluster is composed of highly competent producers, customers and competitors. An effective, specialised and competitive cluster tends also to develop into a centre of competence. The value of the centre of competence can in turn be estimated on the basis of its international market share and of the growth of productivity, surplus value, and employment.

By regarding biotechnology as a «change-activating new-tech» Tekes has made references to its rapidly expanding applications but has also started to pay attention to the ethical issues. Accordingly, an increasing understanding of the living organisms has created new conditions for the development of new medicines, diagnostic methods, vaccines, chemistry, forestry and foodstuffs. The generic characteristics of biotechnology have improved the quality and effectiveness of various materials and production processes in respect to sustainable development. Due to high potential expansion of biotechnology and difficult issues of ethics and values, wider applications should be based on jointly made agreements of the future uses (Tekes 2002a: 6). Tekes provides, however, no plan of the ways the common choices will be made and no proposal of the type of actors who are going to take part in this process. When asked about the possible forums where the discussion of the effects of new technologies can take place, the technology policy makers mostly refer to the formal groups of representation even though they scrutinise the closed circles and normative structures of decision-making. They also wonder who has the responsibility to make the political choices and who could be the responsible partners.

In recent years biotechnology has been integrated as a sub-theme into several technology programmes of Tekes, such as Innovation in Foods, Diagnostics programmes, Drug programmes, Polymers for the Future and the Finnish Forest Cluster Research Programme. The New Biotechnology Programme was initiated in 2002. Even though Tekes has good experiences of the programme-based activities, their overestimated surplus value and diffuse policy relevance has been criticised (Tuomaala 2001). The Evaluation Panel of Biotechnology in Finland has also been troubled of the limited in-house expertise of Tekes in making the grant decisions (Academy of Finland 2002: 55). Moreover, our notions

indicate that the issues of responsibility are mostly left open or they refer to the intellectual property rights or to the right to publish the results freely. Among the evaluation criteria of performance there are questions about the actual or expected economic impact of the results or products. Due to the complexity of the surplus value and market governance in biotechnology, it is often impossible to identify real or latent markets. The sensitivity to moral and ethical issues makes the customer choices also labile. Sometimes the products cannot provide clear benefits for the producers or customers (Häyrinen-Alestalo 2001; 2002; also Academy of Finland 2002).

The technology programmes of Tekes are based on the efforts to establish networks to form centres of competence, a model taken from the EU. In the case of biotechnology, academic producers of knowledge have been integrated into the system by establishing biocentres. These centres are a combination of the centres of excellence strategy of the Ministry of Education and the Academy of Finland as well as of the centres of competence strategy of the Ministry of Trade and Industry, Tekes and the relevant cities and industries. In comparison to the centres of competence in ICT, the biocentres are more science-oriented. Therefore it has been difficult to judge their commercial value and to link high-level science to top rated market value (Pelkonen 2001; Häyrinen-Alestalo & Peltola 2003).

Recently Finnish technology policy makers have redefined the welfare cluster and have started to discuss the conditions of its development. In the Tekes terminology the development of welfare and the growth of the markets are based on the choices of the citizens, on the changes in the living style and structure of population, and on the social development of society (Tekes 2002a: 10). The revised view of welfare services is dependent both on market functioning and on customers' choices, where the chemical and biotech cluster provide new possibilities for the life-science industry. These industries are expected to serve both the goals of welfare and the demands for globalisation and sustainable development (Tekes 2002a: 21). In this way the collective and individual responsibilities move towards market orientation and private competitive action.

### Biotechnology in the scientific excellence policy

Due to the strong commercial ethos Finnish technology policy has become a super-policy with impacts on the goals of science, university and education policies (Häyrinen-Alestalo 1999). Still there have been a few attempts to integrate the activities between various policies, although there have been discussions of the need to have horizontal means for information and interest mediation. In-

flexible forms of communication have also prevented the development of horizontal structures to include public concern and participation. Accordingly, *the Ministry of Education* draws the guidelines for science, university and education policy and *the Academy of Finland* is responsible for the financing of academic research and doctoral education. The *Ministry of Trade and Industry* is the primary technology policy maker and Tekes takes the responsibility for allocating public funding to technology development programmes and industrial research.

Due to a rapid concentration of public expenditure to Tekes there has been tensions between the science and technology systems, the representatives of the former having accused the government of a systematic favouring of technology projects and industries (Allardt 1987). The government's additional funding program for 1997–1999 also raised criticism from the side of the Academy and the universities accusing the goals as aimed «at making the national R&D system to work more effectively for the national economy, business, industry and employment» (Academy of Finland 2000), i.e. for the knowledge-based economy. Today the technology policy makers tend to speak of a harmonised innovation system indicating a balanced funding for science and technology.

Even though the Academy of Finland has spoken of «scientific research and universities in the national innovation system» (Academy of Finland 2000: 12–14), its view of the knowledge-based society has been more science-driven than that of Tekes. Mostly the Academy has stressed the long-term effects of scientific activities on societal development and the need of «making the importance of basic research known in the entire society and among policy makers in particular» (Academy of Finland 1993: 6).

During the last ten years, the promotion of biotechnology has been linked to the general strategy of the Academy of Finland in five integrated actions:

*First*, the Academy has made an effort to strengthen the scientific quality of Finnish academic research and its international recognition and visibility. In this respect new international partnerships and agreements have been made. In biotechnology, important agreements were made in the late 1980s with the European Science Foundation, the European Molecular Biology Laboratory and the European Molecular Biology Conferences. The membership in the EU in 1995 provided Finnish researchers with the possibility to apply for funding from the EU's framework programmes. There have been 446 Finnish participants and 106 coordinators in the EU biotechnology projects between 1996–2001 (Academy of Finland 2002).

*Second*, to guarantee the high quality of the Academy funded research the Academy has identified and funded centres of excellence. The first ten centres of excellence in research were selected in 1994 and three big biotech units, i.e. Biocentrum Helsinki, Biocenter Oulu and Biocity Turku, belonged to this group. According to the National Strategy for the Centres of Excellence (1997: 22–27) the aim is to identify the highest national top having the capacity to reach the highest international top. The centres of excellence are expected to attract other top quality groups and networks as well as to do research in nationally important research fields and to be capable of estimating future socio-economic needs.

*Third*, the Academy of Finland has financed large research programmes that are supposed to be capable of solving new socio-political problems. A growing number of these programmes are joint projects with Tekes. One of the first big research programmes of the Academy was the Development Programme for Biotechnology and Molecular Biology in 1988–1992. One of the latest joint programmes of the Academy and Tekes is related to the intellectual property rights in new-tech research applications. This issue has been considered to need special attention due to the growing market expectations of biotechnology industries. It is characteristic of the Academy of Finland that it has been interested in the issues of the intellectual property rights and ethics as a general problem of the science system. In its reports no specific attention is paid to the risks and uncertainties that are related to biotechnology or to public concern in this respect. So the Academy has seen citizen participation and public concern as needing no extra efforts.

*Fourth*, in order to promote the state and quality of Finnish science, the Ministry of Education and the Academy of Finland have requested peer reviews of specific scientific fields. In this respect the European Molecular Biology Organisation (EMBO) Review Group made evaluation of Molecular Biology and Biotechnology Research in Finland in 1996. The main purpose of the judgement was to identify the successful and emerging research teams on the basis of past performance and to present future plans in order to recognise future needs and risks. The issues of commercial and industrial involvement were also mentioned (EMBO 1996). The Evaluation Panel of Biotechnology in Finland (2002) has also paid attention to the Academy's activities in the promotion of biotechnology research.

Both review groups have referred to the rapid advancements of academic biotechnology research in Finland. They have also found more success in the respective industry than is being recognised. In the view of the groups the biotech

centres in the key universities are of top international quality, even though the evaluators have also noticed some weak groups in a couple of more peripheral universities. In the view of the EMBO Group there are two contrasting trends in the organisation of molecular biology and biotechnology in Finland: one is to build up expertise in peripheral universities and the other is to develop centres of excellence in some of the larger universities (EMBO 1996: 21). Between the two evaluations a concentration process has been going in Finland the Helsinki region predominating now both in ICT and biotechnology research.

*Fifth*, the Academy of Finland has on the initiative of the Ministry of Education set up Graduate Schools aiming at improving the quality of postgraduate training. From the very beginning these schools have been integrated to the centres of excellence. According to the chosen strategy, top quality research groups are innovative and good educators by the definition. A notable part of the government additional funding has been allocated to this purpose. The aim has been to dedicate new places to fields that are important to the development of technology, the natural sciences and knowledge-intensive business (Academy of Finland 2000). Even though ICT and biotechnology have been favoured already in the first selections of the doctoral schools, a kind of balance was earlier maintained between these fields and other disciplines. The decisions from 2001 and 2002 indicate, however, a notable concentration in biotechnology. When the humanities and social sciences have lost their share of the total school places, biotechnology has been the winner in this respect.

The recent strategic approach of the Academy of Finland has been a mixture of a growing but still relatively weak commercial ethos and a strong concentration programme of the scientific excellence. This approach has also concentrated the issues of new responsibilities and risks of biotechnology into the hands of the scientific elite. A search for new rankings of competence tends, however, also to favour individual choices and to weaken a collective scrutiny of the rights and responsibilities. This makes the elite vulnerable to growing public concern.

### **From a concentrated effort to dispersed research and biobusiness**

New biotechnology is a diffuse field and its roots in Finland can be traced to various sources and industrial sectors. The Finnish biochemistry research and industry got started in the 1920s. The development of biochemistry is much credited to A. I. Virtanen, the only Finnish scientist to receive the Nobel price (Alestalo 1979). Another important branch of industry that has long traditions in Finland and has ties to biotechnology is industrial enzyme productions. The-

re are also strong links to the medical sector and pharmaceuticals as well as dormant connections the former number one industry of Finland, the forest industry.

When trying to define some kind of starting point for Finnish *gene technology research* the year 1980 would be a good candidate. That year a group for DNA-combination technology was established in Finland. The initiator and one of the major financiers for the group was *Sitra*, the Finnish National Fund for Research and Development, which is a public foundation that functions under the Parliament. The aim was to introduce the new technology to Finland and create a knowledge base for the research. It was a state lead effort that was hoped to be of utility to many fields. The research group had members from universities, VTT (Technical Research Centre of Finland) and the National Public Health Institute (Kuusi 1991, 22). The research that centred on the bacteria *bacillus* resulted also in the establishment of the first Finnish biotechnology company, *Genesit*. Seven large Finnish state corporations, representing a wide range of fields (forest industry, pharmaceuticals, chemical industry, food industry) held shares in the company, but it did not succeed. The closedown of the company in 1991 has been put down to number of factors: the bacteria's disappointing performance to produce enzymes, rapidly ageing work processes, over-emphasis on applicable results instead of basic research and emerged contradictions between commercial and scientific interests (Kettunen 2002, 22; Kuusi 1991, 22–23).

Even though developing biotechnology R&D is still in many ways a state-lead project, the private sector is increasing its share as a financier and as a researcher. The public sector used € 24 million for biotechnology research in 2000. This was 4,8 % of the total research and development financing directed to the public sector. The universities spent € 91 million on biotechnology research which was 11,5 % of the total research expenditure. Industry's investments in biotechnology research in 2000 were estimated to be € 223 million. Altogether € 338 million was spent on biotechnology research in 2000 (Source: Statistics Finland 2001). Half of the resources for the research and development of biotechnology come from the state funding.

### Universities and research institutes in the innovation framework

As biotechnology is a research intensive branch of technology, universities play an important role in the research and development of the field. In the field of gene technology the importance of universities as research institutions can be

seen for example in the notifications made to the Board for Gene Technology. Between 1995 – March 2002, the Board approved 204 different notifications concerning the use and release of genetically modified organisms. University units have made over half of these notifications.<sup>43</sup>

Biotechnology research is concentrated in five university cities: Helsinki, Turku, Oulu, Kuopio and Tampere. The state has invested heavily to develop biotechnology centres especially through the scientific excellence policy in these five regions and the universities have been making the most of the biotechnology boom. This is apparent in the utilisation of funding as well as in the strategies of the universities and as a result several new institutes and research and education programmes in biotechnology have been created. Biotechnology, along with ICT, is seen as a means for the universities to introduce market orientation into their activities (University of Helsinki 2003). Many different mediating organisations have been established to aid the commercialisation process but the universities are struggling with this new market-oriented role (Pelkonen 2001).

The *University of Helsinki* has two biocentres with different profiles. *Helsinki Science Park* hosts departments from three faculties and the separate Institute of Biotechnology. In addition a new Faculty of Biosciences will be created in the area in the beginning of 2004. The motivation for this is stated to be the growing importance of biosciences and preparation for the potential growth of the field. Although creating a specific faculty for biosciences is seen as a tool for promoting the field, its effects on interdisciplinary research and education and thus creating possible new technologies and applications has been criticised. The other concentration, *Biomedicum Helsinki* is the centre for biomedical research and teaching and is also a host to the *Finnish Genome Center*. The *National Public Health Institute* is also a partner in Biomedicum. The National Public Health Institute in itself has a number of projects in gene and biotechnology dealing for example with multifactoral nationally common diseases and vaccinations. *The Helsinki University of Technology* has also laboratories dealing with biotechnology. These laboratories work in co-operation with closely located *VTT* (Technical Research Centre of Finland) that has a large biotechnology research unit.

Even though large part of the biotechnology research is concentrated in the capital area, the «bio boom» started in Turku. *BioCity Turku* was the first biocentre to be established in Finland. It is a joint organisation of *the University of*

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43 Every institution, research group or company that uses gene technology has to file an application with the Board of Gene Technology which then processes these notifications. The figures here are calculated from data received from the Board of Gene Technology.

*Turku* and the *Åbo Akademi University*, with the *Turku University Hospital* and *National Public Health Institute* also taking part (See Kivinen & Varelius 2003). *The University of Kuopio* has profiled itself in animal biotechnology, neuroscience and health related biotechnology. Biotechnology research is concentrated in A.I. Virtanen Institute. It is located in the *Kuopio Science Park*. Research and education in biotechnology is also done at the *University of Tampere*. Fields of specialisation in Tampere include medical biotechnology and health informatics. *The Medipolis Science Park* was founded in Oulu alongside its successful ITC science park. It hosts the *Biocenter* where biotechnology research is concentrated. Biotechnology is one of the three fields of emphasis in the university. The areas of expertise in the *Biocenter* include collagen research and developmental biology.

The innovation storyline is repeated at universities also through the creation of biotechnology business programmes. The *University of Oulu* together with its biocentre, the city of Oulu, Tekes, European Science Foundation and other partners has also created a *BioBusiness Programme*, which is marketed as a research-based new business development programme. The aim is to «develop the business know-how of scientists and other key specialists and train them to work successfully in a business environment» (*BioBusiness Oulu* 2002). The *Helsinki School of Economics* joined the game by launching a *Biotechnology Management Program* in 2002. The programme can be taken as an individual module or it can be chosen as part of the university's *International MBA degree*. It is mainly targeted at people working in biotechnology with core courses in venture capital in biotechnology, high-technology marketing and IPR management.

Lately, the universities have started to pay more attention to ethical and societal issues related to biotechnology and research in general. Ethics and social responsibility appear more often in the latest strategies. One notable reason for this is the so-called *third mission* of universities that will be set in the new university law. In addition to research and education the universities are supposed to fulfil their societal function. In many cases this is interpreted as closer connections with industry and more efficient utilisation of research results. However, ethical and social issues are also incorporated in the *third mission*. Education of the general public and active communication are emphasised, but there are no references to bottom up communication – hearing the public in the issues of science.

## Old industry and new business

Most of the biotechnology companies have their origins in university research projects and half of them are located at biocentres or science parks (Hermans & Luukkonen 2002). Depending on the source and definition, there are 90–120 companies in Finland that deal with biotechnology. *Finnish Bioindustries* – the industrial association of biotechnology industry – has in its registers about one hundred companies. The association was formed in 1997 by the initiative of large already well-established companies who work in many fields, biotechnology being only one of them. Small companies and university research units also played a part, however, in the discussions concerning the role and formation of the association. According to the association, out of the 90 companies in 2001 40 % are micro companies (under ten employees); 32 % are small enterprises (10–50 employees); and middle sized (51–250) and large companies (over 250) have a 14 % share (Source: Finnish Bioindustries). As these figures show, the biotechnology sector is still so small that it has no capacity to contribute to the much talked about change of industrial structure.

The most common field of biotechnology among the companies belonging to the association is diagnostics (one fourth of the companies), followed by services (just under one fourth) and pharmaceuticals (one sixth). However, the pharmaceutical companies are in general older and much bigger both in terms of annual turnover and in number of personnel. The older companies operate in many fields and only parts of their functions are related to biotechnology. In the interviews with various experts, the fields mentioned above and industrial enzyme production were seen to be the core competencies of Finnish biotechnology. Biomaterials and biotechnology related to the environment were regarded to be the rising fields in Finland. Most of the Tekes funding is however directed to R&D in the fields of medicine and health. One reason is that there are hardly any applications for funding R&D in the agricultural sector as industry sees it as too risky. In general customer demand and concerns are taken seriously and they direct the operations of companies. On the other hand the industry would like to have state support in the sector for the «transition period», meaning the opposition of GMO-foods. There is a strong belief that this kind of an attitude is just a passing phenomenon.

Another potential field of application of biotechnology is the forest industry. New enzyme biotechnology is relatively common in the forest industry compared to other countries. The application of biotechnology in forestry, however, is still very limited (Laestadius 2000). From the three important Finnish paper and pulp producers Stora-Enso has announced that it refrains from commercial

use of genetic engineering. However, it takes part in basic research in the field. M-Real has stated that it is not using GMOs or transgenic technologies in its products and is not doing research in the field. This is not because of lack of interest, but because of the customers' demand (Gädda 2002). In the statement of UPM-Kymmene on the use of genetically modified organisms it is written that «UPM-Kymmene will not use genetically modified wood raw material in its products until the safety of both the production and use of such material has been established by the authorities» (UPM-Kymmene 2000). The forest industry is however encouraging universities to do research on gene technology, but without getting their own hands dirty. The industry is pushing the responsibility for developing this new technology to research institutes and universities. While the industry seems to be responding to customer demands and concerns the research side is not expected to do so.

In addition to purely market-driven customer orientation, many large and international Finnish companies are following the global trend and developing strategies of corporate social responsibility and ethical guidelines. For example *Teollisuus ja työnantajat* (2002), the association of industry and employers, has published guidelines for corporate societal responsibility that are said to include tools for «self-evaluation and development of activities». The three pillars of societal responsibility are the economy, the environment and humans. The human side – social responsibility – consists of four major elements: the well being of personnel; product safety and consumer protection; good methods of action and co-operation in the network of enterprises; relationships with surrounding communities and supporting activities of public utility.

The Finnish Bioindustries has developed ethical guidelines that all the member companies and organisations have to agree to follow. The guidelines emphasise open discussion, improving the quality of life, human dignity and biological diversity. Providing information and participating in public discussion are listed as objectives but there are no references to developing bottom-up communication. Usually only big international companies have developed strategies of social or corporate responsibility and ethical guidelines. The small companies are new and still in the process of trying to find suitable markets and have not made similar attempts. Whether these strategies are only rhetorical or have some consequences for the working patterns of the companies and their surrounding environment remains to be seen.

From the small, new «pure» biotech companies only two have gone public and are listed at the Helsinki Exchanges (HEX). These companies have been regarded as prime examples of success in Finnish biotechnology. *BioTie Therapies*

(listed at HEX on 29.6.2000) is one of the first biotech companies in Finland, situated in Turku's BioCity. It focuses on cell receptor research and its products targeted to specific areas of inflammation, thrombosis and cancer. BioTie underwent a merger in 2002 with *Contral Pharma*, another pharmaceutical company and *Carbion Oy*. Contral Pharma specialised in research and developing treatment for alcoholism and dependency problems, and its competence areas stretch beyond biotechnology. BioTie Therapies has been in the headlines also because of a patent dispute it had and won against *Orion*, a large Finnish pharmaceutical company. The CEO of BioTie believes that the year 2004 will produce a zero-result, meaning that it would be the first year without loss. This demonstrates the difficulties that small companies have in finding market segments to function in.

The operating area of *Biohit* (listed at HEX on 18.6.1999) is diagnostics. Biohit develops, manufactures and markets liquid handling products and accessories as well as diagnostic test systems for use in research, health care and industrial laboratories. Biohit has mainly international markets. In 2001, 96 % of the annual turnover came from abroad. Like BioTie, Biohit's finances are still on the negative side. Another so called success story is *Bionx Implants*, a company that produces surgical implants. It got started from the work of two Finnish researchers. Today the manufacturing plant is still in Tampere, Finland, but the company headquarters are in the USA and it has been listed on the Nasdaq. All of the people interviewed emphasised the fact that there is no use in forming a biotechnology company for only Finnish markets. Finland is too small and companies have to think global in order to succeed.

The founding of new companies and their strategic development is aided by number of public and private financial sources. An important venture capital investor in biotechnology is Sitra. In 2001, biotechnology was the fifth most funded field by Sitra (9,9 million €) (Sitra 2002). In the private sector there are some venture capital firms that have profited in new technologies. For example *BioFund* (founded in 1997) is wholly dedicated to financing biotechnology and life sciences. It has an investment portfolio of € 185 million from which half has been directed to Finnish companies. BioFund's primary investors are domestic insurance companies, pension funds and foundations. Risk financing has been one of the problems identified in the commercialisation of biotechnology research. But it is said that recently the situation has improved.

While ethical and social issues are being incorporated in the strategies of large companies as a result of customer orientation and internationalisation, small companies face ethical issues in these processes of funding. Both public and pri-

vate financiers go through strict evaluation of applications and they state that all ethically dubious projects and companies will be automatically dismissed. The evaluation processes are done by the experts in the field which means that social implications and ethics of research and development are assessed by «enlightened experts» without the help of for example bioethical experts or lay opinions.

## Regulatory and strategic measures for biotechnology

Regulation and control of biotechnology is attributed to a large number of different organs mainly functioning under various ministries and even though the Parliament is the main legislative authority the politics of biotechnology are played to a great degree inside the ministries and their boards and committees. The Parliament has had to deal with the introduction of new laws concerning gene technology, and along with expert opinions heard, various reports to aid the decision-making have been commissioned and produced. These also include aspects of public concern and opinions (for example Salo *et al.* 1998). Issues in gene technology have been dealt in various standing committees and in open discussion in the Parliament. However, there has been a political consensus about the importance of investing in biotechnology, and gene technology has not become a sensitive or controversial political issue. Only some members of the Green party have been active in promoting discussion about the risks and benefits of gene technology.

### Regulation and legislation mediated from the EU

Finnish biotechnology regulation is very EU-dependent and the EU is the origin of most activities in regulation. All major laws and regulating boards are the result of EU directives. The most important law concerning biotechnology in Finland is the Law on Gene Technology (377/95) which is based on the first two directives (90/219 and 90/220) about gene technology. The law is applied in use, production and sales of genetically modified organisms. Issues concerning human genetics are embedded in laws that concern medicine in more general. One of the most recent laws dealing with medical biotechnology is the law concerning the usage of human and animal tissues (101/2001). Another important law related to biotechnology is the Act on Medical Research (488/1999) and the respective statute (986/1999). When becoming a member of the EU in 1995 Finland had to incorporate these directives into its own legislation and this resulted in the new law. In the beginning of 1995, Finland was the only EU country to-

gether with Greece that had not legislation about gene technology (von Troil 1995: 44).

The preparation of the law on gene technology, however, did not start from scratch when the membership to EU was confirmed. Finnish researchers and authorities started to discuss regulation of gene technology much earlier. Already in 1979 the Ministry of Social Affairs and Health established an expert group to discuss DNA technology and prepare statements about it. The ministry got the idea for this from researchers in the field. So, before the mid 1990s, controlling and regulating gene technology was not yet institutionalised. Instead it functioned on more or less volunteer basis inside the professions who were using the technology. The established expert group was transformed into the more permanent and institutionalised Advisory Committee on Biotechnology in 1991. It aided the preparation of the law on gene technology that had started in 1989.

The process of introducing new regulations and legislation has not changed much from this. Most of the new additions and needs for renewal emanate from the EU. Researchers and other experts are however very aware of the developments in their field and are involved in many international committees and boards, but the final push for implementing changes comes from the EU and other international organisations not from national activities.

Researchers and decision-makers interviewed recognised that Finland by itself is a small player and does not really have any possibilities of changing the direction of development in biotechnology. However, they still had somewhat nationalistic views about technology and its control. National authorities and researchers are regarded to be trustworthy and competent while the same cannot be said about all the other countries. Biotechnology is seen as a national project (see Väliverronen 2002) that «we» have to participate in, and we are good at it despite the field being mostly controlled by international legislation and market forces. Transnational frameworks and national factors are constantly and simultaneously being introduced as competing and supplementing sides in biotechnology.

A common view among state officials and members of different boards is that legislation of gene technology and biotechnology has gone almost too far. The laws include flaws that are seen to hinder research and development and they are regarded to impose unnecessary changes on activities that have been regulated successfully previously by for example the medical community.

*«This has been in my opinion a little contradictory. In for example the European Union it has been very clear that the Commission has, when drawing up these directives, aimed at diminishing regulation. Because today we know better than twenty years ago what the consequences can be. The end result, it is different. The regulation has, in spite of this, increased because the people have been worried about the fact that one can do so many things, and what are all of their consequences» (Member of the Advisory Committee on Biotechnology).*

Also the process of regulation in Finland and Europe is seen among the informants to be complicated and bureaucratic. On the other hand clearer rules of conduct are being asked for especially from the side of university researchers aiming at commercialising their research and from the side of the private sector. There is uncertainty about the limits and possibilities of the existing regulatory framework.

### State regulation and official bodies

Biotechnology belongs as a field under the control of number of ministries. The general division of labour and responsibilities in the issues of biotechnology between different ministries is as follows: *The Ministry of Social Affairs and Health* directs and controls generally, and especially in health issues, the compliment with law on genetics. *The Ministry of Environment* controls and advises in legislation concerning the environmental effects of genetically modified organisms. When it comes to bringing new products to the market, *the Ministry of Trade and Industry* and *the Ministry of Agriculture and Forestry* are in charge of the issues. This structure of control has resulted in a set of dispersed strategies and visions. Since the beginning of 2002 the ministries have been working together to construct a common ground in biotechnology issues and to enhance co-operation between different bodies. Currently however, there is no common biotechnology policy in Finland that would overlap the division of labour between the different ministries and this co-operation of the ministries is not aiming at creating one. The goal of the co-operation group is to share information between the ministries and ensuring that statements (for example to EU) are congruent.

Instead of one policy, there are a number of different strategies and memos from the various ministries and their working groups that deal with specific aspects of the technology. However, only the Ministry of Agriculture and Forestry has been actively developing a coherent strategy for gene and biotechnology for

the whole ministry (Ministry of Agriculture and Forestry 2003). As a pilot project, a strategy was first developed just for the department of agriculture (Ministry of Agriculture and Forestry 2000). The strategy development also included separate reports on ethics, legislation, research, environmental effects and economic effects on the food chain. The ethics report (Launis 2000) was made by a philosopher from the University of Turku. He is also member of the Board for Gene Technology and the Advisory Committee on Biotechnology, and seems to have the role of an official bioethical expert in Finland.

In addition to the ministries, two specific bodies have been set up that are dedicated to gene and biotechnology: *the Board for Gene Technology* and *the Advisory Committee on Biotechnology*. The establishment and institutionalisation of both of these is largely the result of EU legislation and the Law on Gene Technology. The Board for Gene Technology functions under the Ministry of Social Affairs and Health and its responsibilities include processing applications and notifications of the use of genetic technologies; giving rules of procedure in complying laws on genetics and making decisions for specific cases. It is the highest national authority in gene technology. The Board was founded to fulfil the controlling functions defined in the Law on Gene Technology in 1995. Its members are representatives of four ministries named above. In addition ethical expertise is required to be represented on the Board. The reputation of the Board has suffered, because it was accused of not working openly enough. This issue got as far as to the Finnish Supreme Court and the Board has had to open its files to the public. This case shows that although number of new boards have been established to work along with already existing ones, it cannot be said that they would have created new and more open forms of functioning or mediating public opinions. Characteristic for the Finnish model of governance is to incorporate new questions and their problem solving inside the existing system (see Bergman 1998).

The biggest effort to incorporate public views into decision-making has been made by the Advisory Committee on Biotechnology. The Committee became statutory through the introduction of the Statute on Gene Technology (821/1995). Its mission is to promote co-operation between officials, researchers and others working in the field, to follow discussion on biotechnology and to develop education and distribution of information in biotechnology. The Advisory Committee publishes also an informative journal called «*Geenitekniikka tänään*» (Gene technology today). Members of the Committee are composed of state officials, as well as representatives of the academia and industry. There are also representatives from the consumer organisation and environment and ani-

mal rights organisations. Because of the relatively broad bases of representation and the goals of the Advisory Committee, it functions as a mediating organisation more clearly than any other board or organ devoted to biotechnology. Other organisations do not include lay members.

The Advisory Committee on Biotechnology concentrates on gene technology that is not directly related to human health. Ethical issues concerning human genetics and health care are the responsibility of *the National Advisory Board on Health Care and Ethics (ETENE)*. It deals with ethical issues related to health care and the status and rights of patients. It can also take initiatives and make advisory opinions and recommendations on ethical health care issues and foster discussion on them. ETENE has a *Sub-Committee on Medical Research Ethics (TUKIJA)*. Research ethics are more generally discussed also in *the National Advisory Board on Research Ethics*. Established in 1991, the council is nominated by the Ministry of Education. The task of the council is to promote discussion and inform the public about research ethics. It also prepares statements about research ethics in general and can comment on actual cases. In 2002 the advisory board published its guidelines for good scientific practice (National Advisory Board on Research Ethics 2002). The board is very active in raising discussions about research ethics inside the academia and decision-makers, but the discussions do not necessarily reach the public.

Working under the Ministry of Environment, the *Finnish Environment Institute* is one of the five expert authorities defined to have a special function in the Law on gene technology. The task of the Institute is to evaluate the environmental risks of GMOs. *The National Food Agency* processes applications for novel foods and controls, together with the communal authorities, the marketing of food products. *The Board for Novel Foods*, was established (as a result of the directive on novel foods in 1997) to evaluate the safety of proposed novel foods, including products made with the help of gene technology. There are also other institutions that have activities in relation to biotechnology for example the *National Agency for Medicines* and *the National Veterinary and Food Research Institute*.

## NGOs and public participation

When the policies, strategies and memos of Finnish officials concerning biotechnology's different aspects are compared to those of the European Union a strong difference in how the publics are being framed is detectable. In the documents of the European Union there is a great emphasis on citizen participation

while Finnish documents contain a more passive idea of citizens. Instead of being active and participating citizens, they are perceived more as a population-like object of action, that can be studied and controlled, or as human beings that are worthy as such and thus need to be cherished and respected (Snell 2002). The lack of the citizen aspect in the biotechnology documents has to be put however in a wider context. There has been active discussion about civil society and citizen participation in Finland in more general environmental issues. Indeed, there are many NGOs and citizens movements, but they seem to be targeted towards other areas like environmental protection and animal rights. Biotechnology has not become a big issue among the public.

There have been some attempts both from the side of NGOs and the state to create forums for discussion about gene technology. However the meetings and hearings arranged have been sporadic events with little results. Public attitudes are therefore more often mediated to the decision-makers through surveys and consultations of NGOs. Citizen and consumer barometers are used in constructing a public opinion that is then used as bases for policies (Rask 2002).

Another shift that is detectable is the trend to replace citizens by consumers. Actually, consumers are given more active roles than citizens, even though they have clear limits for their action. Consumers make decisions concerning only themselves by buying or choosing not to consume and act in the market, not in the society. From their choices, the industry and decision-makers can make their conclusions. Public concern is therefore mediated through markets and consuming habits instead of public forums of discussion (Snell 2002).

Another reason for lack of open resistance towards gene technology can be explained by the positive attitude of Finns when it comes to technological development. According to various surveys science and technology are highly valued among the public (Tiedebarometri 2001, Eurobarometer 1997, 2000). Public attitudes towards science and technology are in general more positive in Finland than in many other European countries (Miettinen & Väliaverronen 1999, Salo *et al.* 1998). This can be seen in the results of surveys that have been conducted about public attitudes and knowledge about biotechnology in the countries of the European Union. In the first Eurobarometer survey on biotechnology (Eurobarometer 1997) Finnish citizens were the most optimistic about biotechnology.

Even in Finland, however, concern about research and the applications of biotechnology are growing. The follow-up survey showed that the Finns were no longer the most optimistic, but still were the ones who believed the most, that biotechnology's applications are not risky (Eurobarometer 2000, 31). When as-

ked, who do people trust in the issues of biotechnology the most common answer in Europe were consumer organisations. Finns on the other hand trusted most the medical profession. Also universities were trusted and they received much higher scores from Finns than from the average European (Ibid. 76–77). Thus scientists and experts were regarded to be trustworthy. Finns see that Finnish science and scientists are reliable, because science is not commercialised. Commercialisation is regarded to be a problem that is occurring elsewhere in the world (Snell & Laurén 2002). Another important aspect to note is that even though Finns are generally optimistic about genetic technologies it does not mean that they are not critical (Jallinoja & Aro 2000). Options are pondered, but the conclusions reached are often positive towards new technology and products.

### The NGOs representing the public

The NGO sector in Finland has long been very active for example in the issues of environmental protection (Järviöski 1991). Genetic technologies, however, have not caused wide activism. There is currently only one NGO that is dedicated solely to resisting gene technology. The association is called *Kansalaisten bioturvahdistys* (Citizens Biosafety Association). An examination of the main environmental and consumer associations in Finland in spring 2002 revealed that *Kansalaisten bioturvahdistys* actually is the only NGO that has ongoing activity around genetic technologies. Other NGOs have had campaigns dealing with gene technology previously but do not have permanent information mediation or campaigns about it. In 2000 there was a joint campaign involving a number of associations dealing with GMO foods, which included actions in supermarkets, handing leaflets etc. This was not a national effort, however, but part of an international action campaign. Patient organisations have also been rather silent in public discussion about genetics.

According to all of the experts interviewed public discussion about genetics and biotechnology is generally weak. It was also thought that the discussion from the citizen side is mainly conducted by *Kansalaisten bioturvahdistys*, which is often regarded to be more of a nuisance than a constructive party of discussion. *Kansalaisten bioturvahdistys* is a small group whose two leading figures write actively to Finland's leading newspaper *Helsingin Sanomat's* opinion pages. The statements of the group are strongly negative towards genetic manipulation, including food products, plant manipulation and vaccinations. This gives the public discussion a narrow and one-sided label and the experts

feel that public discussion does not bring any constructive points of view to their own knowledge.

Despite lacking an active and public role, the NGOs play an important role as the mediators of public opinion in the issues of biotechnology. A small number of NGOs are involved in the Advisory Committee on Biotechnology. The Advisory Committee has currently 30 members (15 members and their deputy members). From these 30 two are from *Suomen Luonnonsuojeluliitto ry.* (The Finnish Association for Nature Conservation), one from *Animalia ry.* (Federation for the protection of animals), one from *Juliana von Wendtin säätiö* (a foundation promoting scientific progress without animal testing), and two from *Suomen Kuluttajaliitto ry.* (Finnish Consumer Association). Even though this kind of NGO involvement as representatives of the public in advisory organs is not new, it is taken perhaps more seriously than before. The chairman of the Advisory Committee on Biotechnology stated that these groups have been very active and constructive parties in discussions. These NGOs work in a corporatist manner that is a well-established working model in Finnish governance. *Kansalaisten bioturvayhdistys* on the other hand is an antagonistic movement that is grouped together with «fox girls», activists who released animals from fox farms in the late 1990s.

When the law on genetics was revised in 2000, one new addition to the law was a passage concerning the hearing of the public (36a §). It is stated, that if the Board of Gene Technology sees it appropriate, in certain cases, the Board can make a decision to hear the opinions of some groups or the public. This passage concerned the usage of GMOs in closed spaces. There is no mention about taking public opinion into consideration in any other form in the law. This passage is very descriptive of the Finnish situation despite the fact there have been a couple of attempts to start «public discussion». One of the most notable efforts was the seminar on genetic technologies in the beginning of 2002 hosted by the Ministry of Health and Social Affairs. The seminar was not regarded as a success, because of relatively weak participation. It is questionable, however, to judge people for a lack of interest because the seminar was arranged by invitation only.

Another public hearing was organised by *Kansalaisten bioturvayhdistys* in 2001. The impetus for the event was the case of «Transgenic cattle in Lapinlahti» (more of this case later). The representatives of company Pharming and the researchers from the University of Kuopio, who were the major players in the transgenic cattle -project, were invited, but they boycotted the event. The hea-

ring received also rather negative publicity as Helsingin Sanomat (14.1.2001) wrote about «an atmosphere of brain washing» in the discussion.

The law on genetics is currently undergoing yet another revision. The directive (2001/18) that has caused the revision emphasises public hearing in the decision-making. When asked about the influence of current trend in EU to involve citizens more in the decision-making and evaluation process, and whether this will bring changes to Finnish procedures, a Member of the Board of Gene Technology answered:

*«Well, it [citizen participation] is clearly emphasised more in these new directives, so in some way it has to be followed through. Yes, it has to be increased for sure, but in what form? These public hearings, if there is no public it will not succeed very far. But maybe it will increase a little now. We have to act on it as far as it will be in the law.».*

How statutory public hearings would take place was still unsure during the interview. As organised public events were seen unsuccessful, the chairman of Advisory Committee on Biotechnology felt that consulting NGOs might be the only possible way to proceed. Seeing the NGOs as representatives of the public is regarded not only to be an easy and economic means but it is also seen to offer more structured opinions and views than consulting citizens some other way. Other viable alternatives have not been presented. Whether the NGOs represent the people accurately, however, is often questioned.

Researchers and biotechnology authorities systematically say that public discussion is needed. Many are, however, sceptical about the willingness of people to participate in discussion and the «blame» is put on citizens. There seem to be some expectations of a bottom-up model emerging in public discussion about biotechnology. Top-down models like consultation and surveys still prevail in practise. The biotechnology experts also think that discussion is not always worthy as such, if there are no proper reasons for the discussion. Discussions have also a bad reputation among some of the interviewed. Participating in a discussion or being an active promoter of discussion is thus not tempting. This means that it is not necessarily the lay people but the experts who are not interested in changing opinions.

Even though the engagement-side is relatively weak, there have been numerous occasions and forums for informing the public about biotechnology and its research. The Academy of Finland hosted a series of events in 1999 where biotechnology research was presented to the public. The Days of Science

gather people biannually to public presentations about developments in science. In 2003 the area of emphasis was biotechnology. Also *Studia generalia* lecture series have been arranged dealing with biotechnology at the University of Helsinki. The latest platform for informing the public was launched in September 2002. The site [www.bioteknologia.info](http://www.bioteknologia.info) has been established as part of the NeoBio research programme funded by Tekes. Originally, there was supposed to be notable resources also for ethical, legal and social research in the programme, but that diminished to financing a consulting company to do a survey concerning information needs of the public. On the basis of that work the internet site was constructed. Though very little can be said about the success and impact of the site, it is clear that Tekes has taken the more progressive steps in informing the public compared to the Academy of Finland.

## The media and issues of discussion

Helsingin Sanomat is the biggest daily newspaper in Finland. The opinion pages of Helsingin Sanomat are widely read and are a kind of a national institution. Many nationally and locally (the capital area) important discussions are started in these opinion pages. The topics and viewpoints of the writings vary, as does their capacity to create a discussion. The most active discussions have been about GMO-products and their safety, but there have been also discussions about GMOs and developing countries, human cloning and stem cell research. A concerned member of a NGO or a researcher in the field often starts the discussions.

Helsingin Sanomat has also weekly environment and science pages. New developments in gene technology and possible controversies are covered in these pages. Bigger articles are written by science journalists but most little news articles are quotations from science journals or from other international sources. News about gene technology are also now and then published in the international news and economic pages. International issues like GMOs and the developing countries also penetrate the discussions of national branches of international NGOs. In the media these issues are labelled «external», and not really affecting Finland. For example the claims that human embryos have been successfully cloned and are waiting to be born were widely published. Many of the news articles or stories in television include the line «This can not happen in Finland because...». Even though these issues can create discussion in a national level, they are mostly treated as news from the outside world. New findings by Finnish scientists are also reported (Laurén 1998). These findings have

also the status of news. They differ from the international news in the sense that findings of Finnish scientists are reported in a very nationalistic tone. One could conclude from the news articles that in Finland, researchers are doing good work and are in the international front-line. The foreign scientists on the other hand do questionable research and together with the politicians from their countries let bad things happen.

A research about the news on human genetics on the pages of Helsingin Sanomat between 1994–1997 shows that the articles have mostly covered findings of new links between genes and diseases or other scientific discoveries. The articles were mostly neutral or positively oriented towards gene technology (Laurén 1998). During the last few years the more critical articles have gained ground, but in general Helsingin Sanomat is still neutral or optimistic (Väliveronen 2002). Along with a positive tendency towards technology, Helsingin Sanomat reflects the attitudes of the Finns in the respect that the sources used in the articles were mostly researchers and experts from universities or representatives of the medical profession (Laurén 1998). In the economy section and other financial newspapers, attention has been directed to the new and promising biotechnology companies and the stories follow the innovation storyline and lately also ruptures in it.

Television coverage of biotechnology on the national TV-channels happens mostly through the news and through science programmes. The national channel YLE1 broadcasts a science programme every week and there have been several episodes focusing on gene and biotechnology. The material is usually internationally produced. YLE hosted also an evening of interactive discussion about gene technology in 1998 where the audience could send e-mails and SMS to experts in the studio. The two commercial channels MTV3 and Nelonen have a more scandal-seeking approach to biotechnology. Especially Nelonen has aired documents that deal with gene technology and the possible future horror scenarios. These programmes are, however, made without exception abroad. The science magazines *Tiede* and *Tieteen kuvalehti* have covered gene and biotechnology extensively. But like TV programmes much of the material is written by international journalists and edited by international publication houses.

### Controversial issues

A variety of issues have been covered in different forms of public discussion and the media. Here are listed some of the most visible national controversies of the last few years. These are controversial issues in the sense that they have received a great deal of attention in various forms of media and the coverage has had im-

plications on the underlying issues or the issues in themselves have caused changes in practises.

1. *Conflict of interest.* A conflict of interest was reported and discussed in the case of one the members of the Board for Gene Technology (Tuula Pehu). Her validity to work as an unbiased state official was challenged because of her being involved in a patent application for a virus resistant potato together with her sister (Eija Pehu). As a result Tuula Pehu resigned from the Board. The case was covered regularly for example in Helsingin Sanomat. This case demonstrates the two interrelated aspects that are important to both the Finnish public, as well as to the experts: trust and financial profit. As described, experts and the public generally trust the researchers as well as regulatory and controlling authorities. The trust is, however, weakened in the eyes of the public if search for financial profit becomes integrated in the issue. The decision-makers and policies on the other hand emphasise the role of biotechnology in creating profit and ensuring national competitiveness, which is seen to create dilemmas for both public and private organisations.
2. *Openness of the Board of Gene Technology.* Representative of the Green Party and MEP, Heidi Hautala asked for information from the Board of Gene Technology in 1997 about a GMO-product, but was refused any information. She took the issue to Supreme Administrative Court where she accused the Board of violating the openness principle of public institutions. The court ruled the case in her favour. Since then the documents and applications to the Board have been made more easily available to the public, but the reputation of the Board has suffered. This was not, however, a case of creating new more open ways of functioning, but ensuring that the Board follows already established practices. There are still opposing views about what information should be made available to the public. There are fears that providing too much information can be a hindrance to companies and their business operations, as well as a security risk for experimental crops.
3. *Misuses of research funding and unethical research conduct* in medicine and biotechnology. There have been two very thoroughly followed cases of misconduct in research. Even though they are not directly linked to gene technology, these cases are relevant, because very often when biotechnology research and its financing is discussed the potential for misuse and misconduct is brought up. These suspicions are presented largely because of the two cases. This also prompted the development of ethical rules for

research (National Advisory Board on Research Ethics 2002). One of the cases was the embezzlement of research funds by a professor of neurology, Paavo Riekkinen, from the University of Kuopio. After using grants from medical companies and other research funds to his and his family's personal expenses, Riekkinen received a two-year sentence. Also his son, a neurology researcher himself, was accused of embezzling funds. The other case concerns the financial, ethical and professional misconduct by a Parkinson's disease researcher, professor Urpo Rinne at the University of Turku. The investigations about Rinne not informing his patients enough and even neglecting their care are still going on.

4. *Transgenic cattle in Lapinlahti*. Dutch company Pharming started to produce hLF (human Lactoferrin) with transgenic cattle in a farm in Lapinlahti, in eastern Finland. The project started with about 50 cows, but there were plans to increase the number as high as 2000. The hLF-high milk produced was used only for testing purposes for the company's laboratories. Two potential applications of the milk were researched. The first application planned was a medicine used to help blood clotting in operations. The other target was to create a novel food preparation for people with diseases such as cancer and AIDS. The transgenic cattle project received much attention in the media and also activated public discussion. The hearing arranged by the NGO, Kansalaisten bioturvayhdistys, was held around this issue. In 2001, the Dutch mother company Pharming filed for legal moratorium and the Finnish part of Pharming filed for bankruptcy. The cows were slaughtered except for a few that were left for laboratory purposes. The ending of the hLF-production in Lapinlahti was due to the financial problems of the Dutch company.
5. *Transgenic «golden calf» Huomen*. The case above is closely connected to this fifth one, the case of one transgenic cow called Huomen («Morrow»). Huomen was born in 1993 at a research farm of the University of Kuopio. It was the first transgenic calf in the world. It had a human gene that produced erythropoietin (EPO), a hormone that increases growth of red blood cells. The birth of Huomen got Pharming interested in Finnish research and enabled the project in Lapinlahti. The life of Huomen did not go as planned. The goal was that Huomen would produce 60–80 kg of EPO in her milk. The annual demand of EPO for medical purposes globally was estimated however to be only 20 kg. During the 1990s the demand of EPO grew, but this was because it was used among athletes as a performance enhancer. This created an ethical dilemma. Huomen was slaughtered in 2001 because

it was overweight and had joint disease and the EPO-cow project ended (see Väliverronen 2002).

In addition to the concerns about searching for financial profit at the cost of public good present in the cases, the last three issues deal also with animal rights and ethical aspects. The issues presented here have been brought to public discussion and kept there by relatively few actors. The association Kansalaisten bioturvayhdistys was involved in the both cases of transgenic cattle and some members of the green party have been actively promoting discussion about genetic manipulation and the openness of decision making. The National Advisory Board on Research Ethics has been an active and critical voice in the cases of research misconduct and prompted by situations like in the conflict of interest case it has also published a memo concerning the relationship between researchers and the private sector and problems arising from it (National Advisory Board on Research Ethics 2001).

## Conclusions

In Finland the growth of biotechnology research and development has been rapid during the last decade. There have also been growing politico-economic expectations of the capability of the biotechnology cluster to transform the structure of the industry. The advancements in biotechnology are related to a variety of major changes reflecting a radical change in the political ideology from the welfare state to the neo-liberal state. New international market openings for new technologies, emphasis on commercial ethos instead of community ethos, as well as a general trust of the Finns on the benefits of new technologies all have contributed to the issue. It is characteristic of the country that the political system has been able to agree both on the welfare state programme and thereafter on the goals of the neo-liberal state. Lately, however, citizens have been demonstrating against the competitive model.

Even though the legitimate basis of ICT has been shaken in the beginning of the new millennium, the political pressure on new technologies has not lessened in Finland. On the contrary expectations of biotechnology to be the next global market winner after ICT are high. Concomitantly a multilevel programme aiming at securing the development of biotechnology has been accomplished by the government. The measures comprise a generous public funding to biotechnology research, attempts to change the infrastructure of university research by establishing biocentres and other centres of competence, an integration of doc-

toral schools to centres of excellence in research, financing of research and technology programmes between universities and industries as well as subsidies to biotech industry. Aside from the attempts to promote biotechnology for its own sake all these efforts indicate a tendency to strengthen market orientation in the biotechnology sector. Still there are more evidences of the high quality of Finnish biotechnology research than of the high market competitiveness of its industrial applications.

As in the other European countries there is an increasing international/EU pressure to control the development of biotechnology in Finland. All necessary laws have been passed by the Parliament and new official bodies have been established to fulfil the controlling and regulating functions. The interest representation is, however, traditional. The respective ministries function in a discretionary way having only few efforts to develop more horizontal ways of action and information change. Therefore attempts to develop a coherent biotechnology policy have been rare. Sector-based responsibilities make it also difficult to solve the growing tension between the common and private good.

Traditional forms of action also predominate in regarding the public concern and action. The government has launched the national innovation system as a modern model of societal cooperation and responsibility. The primary goal in this frame is to advance the coherence between the activities of universities and industries. The citizens are invisible actors in the national innovation system. When they come to the scene, they are customers who are needed to stabilise the markets, and through their choices to make estimations of the appeal of the products. It seems that here are the roots for new citizen mistrust. A strongly market oriented political system has not managed to advance the components of the common good.

As regards public concern, there is a national peculiarity to see a difference between international and national ways of scientific action. The citizens and the academic researchers in the biosciences tend to have a strong trust on the neutrality and purity of Finnish science. Ethical and moral problems come from abroad. At the same time both the decision-makers and the public are increasingly concerned of ethical issues and of the role and responsibilities of various actors in solving these issues. Still they are not sure how ethical and moral problems can be solved. They wonder what kinds of forums should be favoured to promote the discussion of shared responsibilities and who are the relevant partners. The Finnish system for tackling emerging problems and risks is still very expert-led. As the authorities are trusted to do a good job, it seems to many that it is not necessary to construct new forms of action because the old system still

functions well. Therefore the pressures from the EU to integrate the public into the decision-making system pose difficulties. These kinds of uncertainties also become visible in the role of the media in biotechnology issues. Even though there are attempts to mediate neutral information, the publicity is mostly on ethically or morally suspect issues and the attempts by the public to influence biotechnology issues are downplayed.

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# The Ambiguity of Progress – Biotechnology in Norway

Egil Kallerud

## Prehistory

There was little public awareness and no controversy concerning biotechnology in Norway during the 1970s. The risk issues that were intensely debated in the US and most European countries following the Berg letter and the Asilomar Conference did not become an issue of public controversy in Norway (Høviskeland, 1995) in contrast to Sweden, for example (Olofsson, 2002). At this time there were few research projects within the field in Norway, and the minimal policy debate concerning these issues was largely delimited to one of the five research councils at the time, the Norwegian Research Council for Science and the Humanities (NAVF), which was largely concerned with university research. The debate, took place mainly in response to initiatives of the European Science Foundation. NAVF put into place a minimal regulatory framework, establishing a temporary DNA committee in 1976 which was to follow the international debate about the issue, and consider the future extent of Norwegian research in the field. The mandate of the committee was later extended by the government to include an assessment of the need for regulation and control of research. As such, a regulatory model based on self-control by the research community was established. In 1979, Norway was held up in international debate as a model country in its success in evading the establishment of separate laws for the regulation of DNA research, and keeping control within the research community itself (Høviskeland, 1995: 162).

This remained the general regulatory model also after the NAVF committee was superseded in 1981 by the permanent Committee for the Control of Recombinant DNA Research under the Ministry of Health and Social Affairs. This committee remained in office for two three-year periods. The option to establish a separate legal and regulatory framework for the field was at this time firmly – and successfully – rejected on the grounds that a strict control could easily be enforced through these minimal measures, given the small scale and the low

level of relevant activity in the Norwegian research community. A hiatus of two years followed the demise of the committee in 1987 before a new control committee was established in 1989. By then, however, biotechnology had become an important issue in the *Storting*, the Norwegian Parliament, initiating the process that was eventually to lead to the adoption of two separate acts on gene technology (1993) and medical applications of biotechnology (1994). Unlike the case of its predecessor, members of the new control committee of 1989 were not purely professional, partly reflecting the shift of focus of the biotechnology policy agenda from contained to deliberate release of genetically modified organisms (GMOs). The control committee of 1989 was abolished in 1991 when the Norwegian Biotechnology Advisory Board (*Bioteknologinemnda*) was founded.

The absence of a general public debate and political awareness about the new biotechnology explains why this became one of five 'main target areas' in the 1985 White Paper on research policy with little or no attention paid to any other aspect than the immense economic and research potential of the new technology. That biotechnology became a main research policy priority area was the result of initiative and lobbying by the research community through four of the five research councils<sup>44</sup>, all of which were involved in basic and (to a lesser extent) applied microbiological research. This was a researcher-led initiative, since little or no industrial activity existed that could be mobilized for its support. The priority area was organized as a joint effort of the four research councils, largely through the coordination and re-labelling of existing activities and budget items within the research councils. Later, key persons behind the initiative complained about the lukewarm financial support by government of this area in particular (Hatling, 1992).

The public scepticism towards biotechnology, which had been latent hitherto, surfaced when a break-through in a research project on salmon breeding was announced at a press conference in May 1985 (Hunsager et al, 1988: 91–93). Here, the news was released that an experiment to integrate the growth hormone from 'a mammal' into the genome of the salmon had been successfully performed, speeding up the growth of salmon. Despite the researchers' reluctance to answer a direct question by a journalist present at the conference, it emerged that the 'mammal' hormone in question was actually human. The news triggered and cemented Frankenstein connotations in the public's perception of the

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44 In addition to NAVF, the research councils involved in the biotechnology priority were the councils for industrial research (NTNF), agricultural research (NLVF) and fisheries research (NFFR). In 1993 these councils were, together with the fifth council for applied social research (NORAS) merged into one single research council, the Research Council of Norway (Norges forskningsråd).

new biotechnology. All projects related to the injection of growth hormones in salmos were terminated a few years later. It is still strongly emphasized, particularly by the salmon aquaculture industry, that the genetic modification of salmon itself is a non-issue in Norwegian policy for salmon aquaculture. This event signalled the emergence of the highly sceptical Norwegian public opinion on the new biotechnology. It was ultimately to lead to the establishment of a regulatory policy for biotechnology in the early 1990s that was distinctively restrictive by international standards.

## Government, parliament, political parties

The Norwegian politics of biotechnology have been strongly influenced by the political situation in the *Storting* since the mid-1980s. Biotechnology emerged then as a salient issue in Norwegian politics at this time, as a consequence of the strong links that were then forged between biotechnology and the issues of abortion and 'selection society'. These links were initially established within a debate in the *Storting* on *in vitro* fertilization (IVF) which led to the passing of a separate Act of Artificial Procreation in 1986.

A pattern of party political alliances that still pervades Norwegian politics on biotechnology crystallized within this debate. On one side is the Christian Democrat party (*Kristelig Folkeparti*) for which abortion and controversial aspects of IVF and artificial procreation are key issues for asserting a political profile as strongly concerned with ethical issues in general, and abortion/eugenics in particular. In its political manifestos, references to biotechnology are invariably on the problematic aspects, raising issues of eugenics and the dystopia of a future selection society. At the other end of the political spectrum is the Labour Party (*Arbeiderpartiet*), whose overriding interest is that the industrial potential of biotechnology should be exploited. In biotechnology policy issues the Christian Democrats are often supported by the other two centre parties – the Centre Party (*Senterpartiet*), with its anti-EU, even anti-capitalistic stance, and the small Liberal Party (*Venstre*) – to form the core of a 'technology-sceptical' political alliance. The Socialist Left Party (*Sosialistisk Venstreparti*) is an additional and increasingly influential partner in this 'sceptics' faction.

The position of the Conservative Party (*Høyre*) is more ambiguous, uneasily combining and balancing its concern with industrial potential with a commitment to Christian values. Its alignment with the Labour party on the first concern is, however, often troubled by the emphasis by the Labour party on state initiative and pro-active leadership. The Conservatives prefer to emphasize the

role of private industry at the cost of state initiative and active governmental agencies. Despite its name, the Progress Party (*Fremskrittspartiet*) is a right-wing populist party whose position in biotechnology issues is more ambiguous and unpredictable, although frequently supporting the pro-technology policies of the Labour and Conservative parties. Its nationalist inclinations have provided a political basis for establishing unexpected alliances with the Labour Party in certain science and technology policy issues concerning state support to private industrial R&D.

The salience of ethics in Norwegian science and technology policy in general, and biotechnology policy in particular, may partly be seen as a consequence of the political influence of the sceptical faction, and in particular by the key political role of the Christian Democrats. For a period of three decades nearly all Norwegian governments have been minority governments, and during the 1990s in particular it has become increasingly difficult for them to establish a stable parliamentary basis. A recurrent feature of this situation has been that most minority governments have come to depend on the support, participation or leadership of the Christian Democrats in order to survive. Thus, through shifting configurations of party alliances, this party has been able to ensure that its core issues remain at the centre of the political agenda.

The highly contentious issue of Norway's relationship to the EU is generally a core part of most biotechnology issues, through the many EU regulations which Norway has to adopt under the Economic Area Agreement (EEA). This agreement between the EU and EFTA countries which came into effect in 1994 forms the mainstay of Norway's relationship to the EU after full Norwegian membership was rejected in the referendum of that year. The Centre and Left Socialist parties strongly oppose Norwegian membership in the EU, while the Conservative and Labour parties are generally in favour (although some internal opposition does exist within the Labour Party). The Christian Democrats have been opposed to Norwegian EU membership and, similarly to the Liberal party, and strongly supported the EEA agreement as a viable alternative in the longer term to full membership, ensuring – allegedly – both access to vital markets and retaining more national independence than the full membership option.

The outcome of a number of issues affecting biotechnology policy has thus depended on which (minority) government has been in power at the time of any resolution. This applies, for example, to the establishment and reorganisation of the Technology Board (*Teknologirådet*), issues concerning organizational structure and nomination of members to the Biotechnology Advisory Board, and the

controversy over the implementation in national law of the EU directive on biotechnology patents.

## Legal and regulatory framework

Two separate Acts – one essentially concerned with environmental aspects of gene technology (The Gene Technology Act, passed in 1994), the other with medical applications of Biotechnology (the Biotechnology Act, passed in 1993) – form the main pillars of the regulatory framework for biotechnology in Norway. As indicated above, the minimal regulatory framework in operation throughout the 1980s was largely based upon internal control by the research community itself. Neither risk nor R&D issues triggered a more extensive public debate or more extensive political awareness of potentially adverse aspects and effects of the new technology. It was in the Parliamentary debate on biotechnology and IVF, rather than a response to more general public concern and debate, that biotechnology became an important parliamentary and party political issue towards the end of the decade. Media coverage and public debate was scant at this time, and did not increase until the time when the two acts in question were coming up for final consent by the *Storting* (Høviskeland, 1995).

The new possibilities that had been created for medical-genetic services within this context, prenatal diagnostics in particular, provided the background for a request by the *Storting* that the Labour Government present a report to the *Storting* on the state and challenges of modern biotechnological research (Høviskeland, 1995: 115–118). As an extension of the IVF issue, the Government should ‘present a White Paper on the ethical guidelines for research and development in biotechnology and gene technology’ (Innst. O. nr. 60: 1986–87). Thus, ‘ethics and morality became code and arena for the debate on IVF and medical uses of biotechnology’ (Hviid-Nielsen, 2000: 269). The early and strong focus in Norwegian debate on ethical aspects of biotechnology, rather than on risk and R&D, reflects, then, the fact that a broader public debate originated in the process of the IVF Act, where issues of prenatal diagnostics, eugenics and abortion predominated.

Two commissions were appointed by the Government to prepare the political process for establishing a general regulatory framework for biotechnology. The first, ‘the Biotechnology Commission’, was established in June 1987, primarily to address ‘environmental and health issues’, while ‘the Ethics Commission’, appointed in 1988, would address medical applications and human aspects of biotechnology. This bifurcation of the process was later built into the

regulatory framework in the passing of two separate acts, the Gene Technology Act of April 1993 regulating health, safety and environmental aspects of biotechnology, and the Biotechnology Act of June 1994 which addressed human/medical applications. Ethical issues were salient in the debate that led to both acts and a set of principles is stated for each. The Gene Technology Act stipulates that the approval of manufacture and commercialization of GMOs must be contingent on their social utility and ethical acceptability; they must meet the requirement of sustainability, and be without detrimental health and environmental effects. The Biotechnology Act stipulates that the application of biotechnology in medicine must be in the interests of human beings in a society where everyone is valued, in accordance with the principles of respect for human dignity, human rights and personal integrity, and without genetic discrimination. The Norwegian laws are considered to be highly restrictive, for example through their provisions that applications must meet **with** the requirements of not only of the avoidance of risk, but also of social utility and sustainability.<sup>45</sup> While the precautionary principle is not explicitly part of the act, it is used in its application due to its centrality in the preparatory documents to the act (Bioteknologinemnda, 1999).

### The Norwegian Biotechnology Advisory Board

A key institution in the Norwegian government structure for biotechnology is the Norwegian Biotechnology Advisory Board. This board was established in 1991 as part of the regulatory structure of genetic technology following a proposition by four members of the Christian Democrat Party to the *Storting* in June 1989. One of these later became the Prime Minister in two minority governments, including the present government. The existence and general functions of the Board were subsequently formalized in both acts passed in 1993 and 1994 (in § 26 and § 8–4, respectively).

The Board extends and supports the normal regulatory functions of the two ministries that are formally responsible within government for managing the two acts, i.e. the Ministry of Environment (Gene Technology Act) and the Mi-

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45 § 10 of the Gene Technology Act states that approval of deliberate release of GMOs is contingent on social utility and sustainable development:

'Utsetting av genmodifiserte organismer kan bare godkjennes når det ikke foreligger fare for miljø- og helsemessige skadevirkninger. Ved avgjørelsen skal det dessuten legges vesentlig vekt på om utsettingen har samfunnsmessig nytteverdi og er egnet til å fremme en bærekraftig utvikling.' ['The release of GMOs may be approved only when no danger of health or environmental damage exists. In deciding, considerable importance should be attached to whether the release is socially useful and contributes to sustainable development.']

nistry of Health (the Biotechnology Act), which determine applications for the approval of GM projects involving deliberate release of GMOs and commercialization of GM products. The Board provides advice to the two ministries both on issues of general policy and on individual projects. The unique, hybrid nature of the Board as regulatory body lies in its role as a formally independent collegial body, operating at arm's length from government and the two ministries it serves. In addition, a key component of its mission is to 'promote informed public debate', and in this connection has produced a large number of reports addressed to the general public and to schools. It has organized numerous public conferences on most topical issues in biotechnology, and it has supported and co-organized all three lay conferences on gene technology issues in Norway (two on GM food, and one on stem cell research) – in partnership with the research ethics committees and the Norwegian Board of Technology.

The Biotechnology Advisory Board is basically a regulatory, and hence an expert body. Included among its current 24 members are 16 nominated on the basis of their technical expertise on aspects and fields of research and application of biotechnology. These also include experts associated with NGOs as well as experts on ethical, legal and social aspects, including 'critical' social scientists. The remaining eight are nominated as representatives of organized stakeholder groups, such as the Research Council of Norway (RCN), the fish farming industry, farmers' organizations, the national employers' organization, the largest employees' organization, as well as environmental NGOs (*Naturvernforbundet*, member of Friends of the Earth), the Norwegian Association of the Disabled (*Norges Handicapforbund*) and the Norwegian Consumer Council (*Forbrukerrådet*). Thus, in a unique way the Board combines both educational (informing the public) and deliberative (stimulus to public debate) functions with expert (regulatory) and corporatist functions. It is explicitly stipulated in the paragraphs of both the acts which define the status and functions of Board, that its records and decisions shall be public, even when discussing single applications for approval of GM projects/products (with a few exemption clauses). Its negotiations and statements are regularly covered in the media and extensively quoted in political documents and debate. It recognizes and emphasizes the controversial and value-laden character of the issues with which it deals, and does not attempt to reach consensus at all costs. The message is thereby given that such issues as it handles cannot be decided by science and expertise alone, but encompass a range of values and viewpoints that need to be given a voice in the debate. Voting takes place regularly, frequently with a majority decision. The Board is perceived as a successful institution in terms of political impact and le-

gitimacy. To some extent it may thus be seen as the institutionalised arena for an on-going quasi-public debate (by proxy) on biotechnology issues, ensuring that major concerns are taken into account and most voices will be heard, as new contentious issues and developments have to be addressed by political and regulatory authorities.

In this capacity, the independent status of the Board is seen as essential. But this status is somewhat ambiguous as indicated by several formal links to and dependence on Government (appointment of members, request for advice, civil servants as members/observers). The independence of the Board has been an object of contention and adjustment throughout its history. For example, this issue was addressed in an evaluation in 1998 in which proposals were put forward to enhance the (perceived) independence of the Board (Statskonsult, 1998). The outcome of that process was that those members representing ministries were deprived of their right to vote while retaining a role as observers with a right to attend meetings and take part in discussions. The independence of the Board also became an issue in 2000 and 2001 following a proposal by the Labour Government that as part of a more general reorganization of all agencies and institutions linked to the Health Ministry the Board should be made an integral part of the new organization. This was strongly opposed by the Board itself. The proposal was repealed, and its independent status outside the normal chain of command re-confirmed after a new Centre-Right Government took over after the general election in autumn 2001. There is, however, mounting concern that the independence of the Board is becoming increasingly compromised and jeopardized by what is seen as unabashedly political appointments of members of the Board by the Labour Government in 2000 as well as by the centre-right government in 2002 (Sirnes, 2002). During the short period when the Labour government was in office following the resignation of the Centre Government in April 2000, it appointed a majority of predominantly 'pro-technology' members and a former Labour minister of health as chair; while the incoming Centre-Right government appointed 'sceptics' to all the three positions which were vacant in 2002.

## Biotechnology as R&D priority

### Biotechnological industry

An evaluation of biological research in Norway from 1999 was highly critical of the volume and quality of biological research, biotechnology included. While

the quality of a number of basic research groups at universities was acknowledged, the report was critical of applied activities (Norges forskningsråd, 2000b). Commercial biotechnology in Norway is scant, in stark contrast to its neighbouring Scandinavian countries. This is reflected in a survey and analysis of Norwegian biotechnology by Cap Gemini Ernst & Young in 2000 (Norges forskningsråd, 2000a). By applying the standard criteria used in the annual reports by Ernst & Young on European Life Sciences, the report identified 31 biotechnological companies. Half of these had just one employee, 6 had more than 10 employees, and just one had more than 100 employees (Dynal ASA, the biotechnological activities of which has later been established as a much smaller, separate company, Dynal Biotech). In the marine sector, however, many companies mainly working with more traditional biotechnological and biochemical technologies, are increasingly taking up genetic technologies. Although the criteria applied may be fuzzy, the overall picture of commercial Norwegian biotechnology is the same as that given in a special issue of *Nature Jobs* on Norwegian biotechnology in 2002. Of the 15 companies highlighted by *Nature Jobs*, 12 are on the Cap Gemini list, and 35 companies which develop biotechnological products are reported as being included among those members of the newly established Forum for Biotechnology within the national employers' organization. Some of the characteristics of the Norwegian biotech industry are its strong focus on diagnostic medical products, and on marine applications. Compared to the other Scandinavian countries, there are few pharmaceutical companies in Norway, and only a fraction of these are engaged in the development of new pharmaceuticals. The lack of venture capital and of large, industrial locomotives is often noted as a key characteristic of Norwegian biotechnological sector and a serious barrier to the development of a successful strategy for the nascent Norwegian biotechnology industry.

While Norway is ranked on the European average on aggregate indicators of innovation in biotechnology, its single major relative strength is on the indicator 'Dedicated Biotechnological Firms' (DBFs), that is, firms that are often founded on results from university research (European Commission, 2003: 19). PhotoCure is one such company that is often held up as model on how to exploit industrial opportunities in biotechnology research.<sup>46</sup> It is among the larger Norwegian modern biotechnology companies, although with no more than 35 employees (2002). Many of these were recruited when a large part of the R&D

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46 See, for example, 'PhotoCure – et lysende norsk eksempel til etterfølgelse' ['PhotoCure – a shining Norwegian example for others to follow'], *GenIalt*, 2/2001, pp 11-13. In 2003 Photocure was awarded the 'innovation prize' of the Confederation of Norwegian Business and Industry (NHO)

activities of Nycomed, the former Norwegian pharmaceutical company, was transferred abroad after its merger with Amersham Ltd. After a successful emission in 2000, PhotoCure had a capital base of 300 million Nkr in 2001. In 2002 its equity capital was 185 mill Nkr, sales revenues were 29 mill Nkr, and an operating loss of 128 mill Nkr. It is a spin-off of research at the Norwegian Radium Hospital (*Radiumhospitalet*), and manufactures cancer-related therapeutic and diagnostic products based on its proprietary photodynamic therapy technologies.

The low level of Norwegian commercial activity in biotechnology is indicated by the low proportion of biotechnology patent applications by Norwegian firms to the Norwegian Patent Office (*Patentstyret*). From 1993 to 2000, 72 of a total of 992 patent applications in biotechnology were made by Norwegian individuals or companies. While Norwegian patent applications account for 21 percent in all branches, it is only 7 percent in biotechnology. The marginal role of biotechnology in Norwegian patenting is seen by the 'specialization index' for biotechnology patents of 0.4 (Research Council of Norway, 2003).<sup>47</sup> In only three industrial branches is the specialization index for patents of Norway as low as this, among them polymer chemistry and pharmaceuticals.

In April 2001, a 'Forum for Biotechnology' was established under the aegis of the NHO, as an organization for promoting the interests of the developing Norwegian biotechnology industry. A Bio-marine Forum was also established early in 2002 on the initiative of Investorforum, a group counting among its members the largest Norwegian venture capitalists. During the last few years Investorforum has established itself as a powerful lobby for industrial and venture capital interests. It proved its political influence by succeeding in securing political support for an earlier 'new economy' initiative to convert the site of the former Oslo Fornebu Airport into a world-class ICT-cluster. Their strategy is to encourage the Norwegian state to undertake an active role as venture capitalist based on the large Norwegian Petroleum Fund (*Oljefondet*)<sup>48</sup>, and to form alliances between private and public venture capital for investing in the new, knowledge-intensive industries.<sup>49</sup> Having now turned to the emerging Norwegian biotechnology industry, in particular within the strong marine sector in Norway, this group adds political momentum to the efforts to coordinate R&D and industrial interests within the biotechnology domain.

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47 This means that the Norwegian share of applications for biotechnology patents is far below the Norwegian share of patent applications in all technologies.

48 The Norwegian Government Petroleum Fund was established in 1990 with income from the net cash flow from petroleum activities plus the return on the Fund's assets. Expenditures from the Funds are mainly transfers to the Fiscal budget to finance the non-oil budget deficits.

## Biotechnology research

As indicated earlier, biotechnology was established as a main science policy priority area in 1985, based on coordinated initiatives by researchers and with little industrial backing or results. The science policy strategy of channelling research funds through a number of main target areas was effectively dismantled at the beginning of the 1990s. By then the number of areas had increased from the initial 6 to 9, disillusionment with the effectiveness of the target area organization had become general, and the growth of public research appropriations first levelled off and then decreased. This particularly affected that part of public research funds which was channelled through the research council organization. Along with the other main target areas biotechnology ceased to be a priority area on the political agenda. In the White Paper from 1993, the target area priorities idea was replaced with other, more general priorities. Biotechnology had no salient place in any of these new priorities. The remnants of the earlier priority areas receded in importance as they became redefined as no more than parts of the general programme portfolio of the Research Council. At the time, the new Research Council of Norway was experiencing decreasing funds and a serious managerial crisis following its reorganization, leading to a paralysis that took several years to overcome.

In November 1994, the Ministry of Trade and Industry asked the Research Council to undertake an analysis on the state and potential of Norwegian biotechnology. This resulted in an action plan published in 1996 (Norges forskningsråd 1996). Based upon this, the Research Council adopted an action plan for biotechnology, '*Strategi for bioteknologi*' (Norges forskningsråd, 1997). In June 1998, the Ministry of Trade and Industry published a 'National strategy for commercial (*næringsrettet*) biotechnology' developed by an interdepartmental working group (with members from the ministries of Fisheries, Research, Environment, Health, and Agriculture as well from the Ministry of Trade and Industry), and based upon the fore-mentioned documents. Throughout the 1990s the Research Council funded several research programmes for biotechnology. The Research Council estimate that its current appropriations for biotechnology amount to about 250 million Nkr (2002), that is 7 percent of its total budget.

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49 Its ICT Fornebu proposal created an interesting political alliance when it gained support of the Labour Party and the populist right-wing Progressive Party: But there was also strong opposition among other political parties and the IT research community. Nevertheless, the proposal met with (partial) success as IT activities have been established at Fornebu following a protracted and tumultuous process in Parliament, although at a lower level of support and activity than envisaged. The 'vision' was later to become a casualty of the dispute between the state and the local authorities on the development of the site, and the burst of the ICT financial bubble in 2001.

Despite this, biotechnology did not re-emerge among the main priority areas of Norwegian research policy as given in the last White Paper on research from 1999. Genetic technology was counted among the fields to be supported under medical/health research, one of the designated thematic priorities – the other three being ICT, marine research and energy/environment-related research. While the Research Council had now overcome its managerial crisis and had exerted considerable influence on the White Paper, it did not propose that biotechnology should be a priority of its own. The Council had, however, been instrumental in establishing both marine, including aquaculture, research and medical/health research as priority areas of high relevance to biotechnology.

By 2002 biotechnology had achieved a status similar to that of the main priority areas when the government allocated 100 million Nkr to functional genomics research. This was the successful result of an unusually consensual and broad initiative taken in 2000 by the national biology community – comprising all universities, a number of public research institutes and some regional colleges, and strongly supported by key players such as industry and the Biotechnology Advisory Board. This initiative took its inspiration from the Swedish genomics priority, and capitalized on the announcement in June 2000 that the human genome had been sequenced and the limitless opportunities that its availability was seen to create for functional genomics and proteomics research. The national plan for a new FUGE (*Funksjonell GEnomforskning*) programme was developed as a joint effort by all major research institutions, and coordinated by the Research Council. The plan proposed an annual appropriation of 300 million Nkr in new resources. Despite its unusual scale within a Norwegian research policy context, it was seen as realistic due to the establishment in 1998 of a new source of research funds from the proceeds of the Government Petroleum Fund. The emergence of biotechnology as a political priority was seen as compatible with, and as an extension of, existing science policy priorities by the fact that the main priority areas within FUGE are basic biotechnology research and applied research in medical and marine fields. Although FUGE was ‘only’ allocated 100 mill Nkr in 2002, it was a major political success. It was not only one of the largest Norwegian research programme ever but had also been established within less than one year after originally proposed.

The FUGE initiative triggered several other initiatives. A conference on ‘The Biotechnology Society’ was held on 6 June 2001, where the Prime Minister was a keynote speaker. His speech was published that same day as a feature article in *Aftenposten*, one of Norway’s largest newspapers.

The FUGE programme, and the biotechnology priority of which it forms the nucleus, may then be seen as marking a watershed for Norwegian biotechnological R&D. Biotechnology regained the political prominence it lost with the disbanding of the main target research areas in the early 90s. FUGE represents a major injection of new funds for genetic research, and provided a basis and a framework for the coordination and consolidation of key research, industrial and financial interests for promoting the new technology and its commercial opportunities. However, as in the 1980s, the events of the last couple of years echo key characteristics of earlier biotechnology policy. There is still a dependence on initiatives from the research community rather than industry, indicating the low level of commercial activity in Norwegian biotechnology. Hence support and initiative from public, governmental players such as the Research Council remain as crucial as was the case in the 1980s.

### ELSA research

As a formal requirement of the Government, research on ethical, legal and social aspects (ELSA) of biotechnology became an integral part of the FUGE programme which commenced in 2002. ELSA research had been emphasized in the 1998 governmental action plan on biotechnology, and a separate 'Biotechnology, ethics and society'-programme was already under way in 2001 as part of the biotechnology programme of the Council. As a consequence of the FUGE appropriation in 2002 and its ELSA requirement, this programme was postponed to allow for the two programmes/sources of funds for ELSA research to be coordinated.

### GM salmon

Genetic modification of salmon still remains a sensitive issue in Norwegian debate concerning the role of biotechnology in R&D and industry. It is established Norwegian policy that Norwegian aquaculture will not take up genetic modification of salmon as such, a basic realisation of the aquaculture industry being that consumers do not want GM salmon. This policy is partly a result of the events in the mid-1980s, referred to earlier, when the news about the experiments with injecting the gene for the human growth hormone into the genome of the salmon triggered a public uproar. However, concerns have been raised that less cautious players in countries such as Canada, Chile and Cuba may be overtaking what is seen as the competitive advantage of Norwegian salmon aquaculture, being less hesitant to experiment with genetic modification of the salmon genome. In the event that consumer attitudes may change in the future, a

market for commercial GM salmon could arise for which the Norwegian salmon aquaculture industry will be unprepared. As the Norwegian salmon production based on more traditional breeding techniques will emerge as less cost-effective than GM salmon, one of the most important Norwegian export industries may become jeopardized. Although the policy that GM salmon will not be developed by Norway is not directly challenged, there are concerns that a restrictive policy even in research may make Norway unprepared for the possible, even probable, consumer acceptance of GM salmon in the future. In addition, there are many uses of genome research and GM techniques in aquaculture for optimizing traditional breeding techniques, and for producing fodder and medicines. Other than the genetic modification of the fish itself these options provide the justification and basis for a major research project funded by the Research Council to the tune of 45 million Nkr for mapping the genome of the salmon. The project thus performs a careful balancing act, expressly respecting, but implicitly challenging established restrictive policy. On the one hand it denies that modification of the commercial product is an option – ‘at the present moment’, while at the same time a preparedness is being built up for the possible scenario that GM salmon may be accepted by consumers in the not too distant future.

### The Research Council of Norway

While the Research Council of Norway cannot lay claim to all credit for biotechnology having re-emerged as a high-level science policy priority, it played an essential role as coordinator of initiatives and provider of a policy frame that has been successful in mobilizing political support. The single research council that emerged in 1993 from the merger of the five earlier councils is more than a research council as conventionally defined. Its role in market-near, commercial R&D activities is considerable.

The 1993 White Paper on research policy indicated a fundamental re-assessment of prevailing science policy approaches, advocating a shift towards innovation policy in line with conceptions that were being developed at that time within the OECD (Miettinen, 2002). Coinciding with the research council re-organization, these shifts in policy could be seen as spelling out a template for the Research Council to assume a vanguard role in developing and promoting the new policy framework. However, the first years of the Council as a united organization were troubled: strong conflicts arose on issues of internal governance, and budgets declined considerably during the first few years of its existence as a unified organization.

Following a change of leadership in 1995, the mission of the Council as carrier and promoter of the new innovation policy crystallized towards the end of the decade. By way of a successful political resuscitation of the classical 'GERD indicator' of R&D policy,<sup>50</sup> the Council helped to establish increased funding of R&D as the overarching goal of R&D policy, emphasizing Norway's position as a laggard in the developing 'knowledge economy'. Within a five-year period the gap between Norway and the OECD average in terms of the GDP indicator was to be closed, – an extremely ambitious goal given the low average R&D intensity of the strongly resource-based Norwegian economy (petroleum, fish). The framework envisages a transition towards the knowledge-based economy to replace the still prosperous, but waning, 'oil economy'. The Research Council has been instrumental in establishing 'the knowledge economy' (OECD, 1995) as a framework for Norwegian science and technology policy. Here, biotechnology is framed as the new technology – after ICT – that will bring another wave of radical technological innovation, and help us take a new leap towards the knowledge-based economy. Initially, biotechnology played a somewhat subdued role in these initiatives by the Council, but particularly through the FUGE programme it regained its prominence as a science policy priority area in its own right. Following repeated failures, efforts to become a vanguard ICT country have become increasingly half-hearted, the centrality of biotechnology has increased, in particular as a consequence of the Council's successful initiative to establish marine R&D and industry as a main priority, and its promotion of biotechnology as means to develop this traditionally strong Norwegian sector into a knowledge-intensive industry.

The Research Council has consolidated its role as the embodiment and por-trayer of the visions and strategies of the emergent knowledge-based economy. It has done so by eliciting a self-representation of Norwegian science, and science policy, as highly stagnant and laggard. Representations of the much stronger performance of its Nordic neighbouring countries play a prominent role in the articulation of these self-depreciatory discourses. These have been reflected, amplified and cemented in the context of an evaluation in 2001 of the single, powerful Research Council of Norway by an international panel of renowned experts. Here, the key ingredients of the framework of the 'new economy' (including the GERD indicator, the R&D intensity of industry, the role of large companies, the standard setting significance of Finland and Sweden, the resource-based Norwegian industrial structure) was articulated into a coherent policy

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50 I.e., R&D expenditure as percentage of total national Gross Domestic Product

narrative within which the Research Council should define its operational role<sup>51</sup>. Thus, momentum was added to the frames, analyses and proposals that had already been initiated and promoted by the Council itself for some years.

In recent years, however, the Council has been the victim of reductions in government funding for industrial research, particularly since the advent of the centre-right Government in October 2001. The Council was re-organized in 2003, after which its role as main, formal agency for providing science and technology policy advice to Government will be discontinued. Its promotion of an active industrial role for the state in industrial policy and for targeted funding of key technologies/applications does not sit comfortably with the present government, dominated by the Conservatives, who prefer more indirect and general policy measures in industry and in R&D policy.

## Public opinion and civic society

From Eurobarometer surveys on public perception of biotechnology, Norway has consistently emerged as a country in which expectations of biotechnology are among the lowest in Europe. In 1999, for example, 32 percent of the respondents were 'optimists' (i.e., supporting the claim that: 'Biotechnology will improve our way of life'), compared to the EU average of 41 percent. Further, 37 percent were pessimists, far higher than the EU average of 23 percent. The 'negative majority' (5 percent) in Norway of pessimists over optimists (omitting the 'undecided'- and 'do not know'-responses) may be compared to the 1 percent majority of pessimists in Denmark, and the majority of 11 percent of optimists in Finland, for example (Hviid Nielsen et al., 2001: 246). The strongly sceptical profile of Norwegian attitudes to biotechnology that has emerged from these recent surveys, coincides with results from surveys undertaken in the early 1990s when the political process of passing the bio-/gene technology acts was

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51 '[...] Norwegian GERD/GDP has stagnated since the mid-1980s, while that of the other major Nordic countries has continued to rise, leaving the Norwegian economy as the least research-intensive by the mid-1990s. The most striking feature [...] is perhaps the way Finnish expenditure began to pull away from the Norwegian at the end of the 1980s, pulling further ahead through the economic crisis [caused by the collapse of the Soviet Union]. ..... Based on the other [Nordic] countries' experience and national development needs, the required trajectory for Norway could involve tracing out a Nordic development path in R&D expenditures [...] The first stage is to raise large companies' investments in R&D towards the Danish level. Given the Norwegian industrial structure, this will mean increasing the R&D intensity of existing large companies but also building new ones. As industry becomes more research-intensive, it makes sense to expand R&D expenditure in the higher education sector, as has been done in Finland, to a level above the EU and OECD averages. We might think of the Swedish R&D investment as an 'end-game', but one which will take a very long time to reach' (Arnold et al., 2001).

under way. These results have been interpreted as evidence of a strong match between public opinion and the restrictive policy that has been adopted in Norway. At the same time Norway has consistently scored above the European average on knowledge. Thus, the Norwegian public perception of biotechnology has been held forth as a case that belies the 'deficit model' assumption that ignorance is the main predictor of scepticism.

As indicated above, ethical issues, and in particular those related to IVF, prenatal diagnostics and selective abortion, play a prominent role in Norwegian biotechnology politics, indicating a central role for church organizations and individuals associated with religious movements. The controversial issues related to the reproductive technologies that brought genetic technology onto the agenda of the *Storting* in 1985–86 had primarily been debated between theologians and medical researchers during the early 1980s (Brekke, 1995). Hence, theologians are active in public debate on biotechnology and many are members of relevant committees such as the research ethics committees of medicine and science, and the Biotechnology Advisory Board. Key members of relevant committees may be selected for their combination of expert qualifications and religious leanings. This applies, for example, to one former chairman of the Biotechnology Advisory Board, re-nominated as expert representative of the Board in 2000, and to the first chair of the Norwegian Board of Technology, who is both a nuclear physicist and an active member of a lay religious movement.

We have already seen that The Biotechnology Advisory Board comprises representatives from the Norwegian Consumer Council, the Norwegian Association of the Disabled, and Friends of the Earth. Environmental NGOs have been intermittently engaged in biotechnology issues, mostly GM food and patent issues. An important role has been played by ForUM (*Forum for utvikling og miljø* – Forum for Development and Environment), an umbrella organization for about 60 different NGOs ranging from all major environmental organizations such as Friends of the Earth and anti-war and nuclear organizations, to Attac, and aid, religious, and animals' rights organizations. ForUM was established in 1992 as a continuation of the organization established in 1987 as a framework for collaboration between the Government (Ministry of Environment and Ministry of Foreign Affairs, including Foreign Aid) and environmental NGOs, in large part for preparing Norwegian participation in the 1992 Rio Conference. ForUM is funded by the Ministry of Environment and the Ministry of Foreign Affairs. At one time ForUM had a working group on biotechnology patents (now disbanded). Its statement during the public hearing on the first Bondevik government's proposal to veto the adoption of the EU directive on biotech pa-

tents in Norwegian law was a major reference for several organizations, expressing their general support to the statement by ForUM.

### The Norwegian Board of Technology

A 'Danish model' Norwegian Board of Technology was established in 1998 at the initiative of the *Storting*. The issue came up during a parliamentary debate in 1996 on the government's IT policy which was seen by many members of the committee to be overly concerned only with industrial opportunities and progress at the expense of social and ethical aspects of IT. While the proposal met with general support in the *Storting*, a convoluted birth history of the new institution ensued, initially due to a controversy over the institutional location of the Board. Should the Board be an institution directly linked to the *Storting*, which would amount to a structural innovation – and anomaly – in the political organization of Norway. Or was it to be an 'independent' governmental institution on a par with several other governmental institutions performing their activities at arm's length from government? A conflict emerged as the Labour Government sought to apply a generalized concept of technology assessment that would be less committed to the Danish model and thus open for a solution under the aegis of the Research Council of Norway. But a majority in the *Storting* specifically emphasized aspects of lay participation and enhancing public debate they saw as inherent in the 'Danish model'. The controversy was temporarily settled when the Centre Government took over in 1997 and a 'Danish type' agency was established in 1998 as an independent institution under the Ministry of Church, Education and Research. However, as a consequence of an internal discussion in the incoming Labour Government (2000–2001) about the governmental organization of R&D policy and budgets, ministerial responsibility for preparing the decision to establish the Board was transferred from the Ministry of Research to the Ministry of Trade and Industry. The latter announced its intention to change the mandate, composition and geographical location of the Board so that it would be redefined as a 'forward looking' and technology-support agency rather than the stronghold for technology scepticism as the Minister of Trade and Industry regarded it. The ensuing conflict in which the Board protested against what it saw as a 'change of mission' was not settled until a new change of government took place late in 2001. A White Paper by the new centre-right Government in March 2002 supported the Board, in particular in its opposition to the proposal to relocate the institution from Oslo to the Technical University of Trondheim. But the changes introduced by Labour Government to the Board's mandate (with an emphasis on opportunities and a for-

ward looking approach, epitomized in a new role for the Board in 'foresight'), and the composition (more technologists) remained. These were now seen by the Board as compatible with its basic mission, as restated in the 2002 White Paper.

While the initial impetus for the establishment of the Board was a parliamentary debate on IT policy, it established itself as an institutional stronghold for lay or civic participation in Norwegian technology policy, despite the difficulties caused by the controversies of 1997 and 2000. This was mainly achieved through two lay technology conferences it co-organized together with the Biotechnology Advisory Board on gene technology. These were the 2000 follow-up conference on GM food, and the 2001 conference on stem cell research. Its subsequent efforts to establish itself as a voice to be reckoned with in other technological domains (ICT, energy) seem to have met with less success, as have efforts to establish regular links to the *Storting*. Thus, the long-term viability of the Board does not yet seem to be ascertained.

## Selected issues

All established issues in international debate about biotechnology are also present in Norwegian debate, and phrased in much the same terms. However, the revisions and modifications that take place regularly do not seem to depart substantially from the overall restrictive policy, the broad outline of which was put in place more than a decade ago.

A process of review and revision of the Biotechnology Act is presently in its final stages following a two-stage evaluation of the law by the Biotechnology Advisory Board in 1998 and 2000. Although the law will be amended, following the resolution in the *Storting* in 2003, no major changes in general policy can be said to have taken place. There is a disagreement between the parties, reflecting the general configuration of parties' positions on biotechnology issues as well as between members of the Biotechnology Advisory Board on research on fertilized human ovula and on therapeutic cloning. The lay technology conference on stem cell research in November 2001 supported research on fertilized eggs left over from IV fertilization, but not therapeutic cloning. There have been split votes on both of these issues within the Biotechnology Advisory Board on several occasions. The prohibition of both research on fertilized eggs and therapeutic cloning is upheld in the new act. As a consequence of its opposition to stem cell research on fertilized eggs, the Government has increased funding for adult stem cell research in its budget.

The provisional prohibition on xenotransplantation which came into force in 2000 and applicable until 31.12.2002 was extended in May 2002 up to 2005. This followed the more cautious position advocated by the minority faction of a public commission which published a report on the issue in June 2001, and widely supported in the subsequent hearing process.

A new law on biobanks was passed by the *Storting* in October 2002. Yet again, the main players were split on the emphasis on regulation and industrial opportunity. In the proposal submitted by the Government to the *Storting*, support for industrial activity had been excluded as an explicit overall goal of the law, leaving diagnosis, therapy, education and research. While it was acknowledged that the law, as proposed and subsequently passed, will not necessarily hamper industrial interests, the minority in the *Storting*, consisting of the members from the Labour Party and the progressive party, saw the deletion of industrial activity from the overall goals of the regulation as part of a general restrictive bias of the draft law. According to this minority, it exhibits 'a strong regulation – almost an overregulation – of the relationship between biobanks and the individual, while the relationship between biobanks and societal interests [elsewhere explicated as 'societal interests, including industrial activities [(*næringsutvikling*)] is weakly regulated – amounting almost to an under-regulation' (Innst.O. nr 52 (2002–2003)).

Norwegian restrictive policy on issues such as the release of GMOs remains in place. Revisions of EU directives have gradually moved closer to already well-established Norwegian policy. The EU directive 98/81/EF on contained use of GMOs was passed as a routine issue, since the new, more restrictive regulative was seen to approach that of existing Norwegian Law, while – being a minimum directive – still allowing for more strict national regulation. The new regulative 2001/18/EF on the deliberate release of GMO, the implementation of which is still pending, raises more serious concerns. While continuing the trend that EU policy approaches that of Norway by incorporating the precautionary principle, and emphasizing openness and public participation, the new regulative requires total harmonization of policies in EU and EEA countries, and may not allow the application of the additional criteria of social utility, sustainability and ethics in regulatory practice.

## GM food

The restrictive Norwegian regulatory policy concerning the approval of commercial GMOs, is partly based upon the stipulations in the Gene Technology Act that products shall meet with the requirements of social utility, ethics and

sustainability. No GM food products are approved in Norway, and no application is presently pending, all submitted applications having been withdrawn.

The GM food issue was amplified as an issue of public debate through its selection as the topic of the first experiment in 1996 with lay technology assessment conferences on the Danish model. Pre-dating the establishment of the Board of Technology in 1998, it was organized as a joint effort by the three research ethics committees and the Norwegian Biotechnology Advisory Board. The statement by the lay panel fully supported established Norwegian regulatory policy emphasizing the importance and the need to specify social utility and sustainable development as additional criteria for the approval of GM products. A follow-up technology assessment conference on the same issue was held in 2000 with the same panel as in 1996. The organizers of this conference were the Board of Technology and the Biotechnology Advisory Board. One of the issues that was strongly focused was whether Norway should adopt a formal moratorium on the approval of GM products, a position that had recently been supported by a majority of the Central Committee of the Labour Party. The support by the lay panel to the moratorium was a major part of its statement. Another core issue of the conference was GM food safety. A committee appointed by the Ministry of Health had discussed this issue extensively in a recently published report, addressing in particular the applicability of the precautionary principle as defined by EU communication on the principle that had recently been published. The restrictive criteria for applying the principle that the committee advocated, and strongly opposed by one of its members, met with scepticism by the lay panel which also emphasized that assessment of risk must be combined with assessment of utility. The Norwegian stakes of the GM food issue were spelled out by the Minister of Health, namely that the restrictive Norwegian policy must not be perceived as a trade barrier which might result in other countries introducing countermeasures to Norwegian fish exports.

### The EU directive on biotechnological patents

The biotech patent issue, i.e. the adoption in the EEA agreement involving the EU and EFTA countries of EU directive 98/44/EF on 'the legal protection of biotechnological inventions', stands out as the biotechnology issue on which the survival of two minority Governments has been at stake within the last 4 or 5 years. The issue has been a latent, contentious issue since the late 1980s, returning from time to time on the Norwegian political agenda, largely due to its raising fundamental issues about Norway's relationship to the EU. A national consensus on a – predictably – restrictive biotechnological patents policy, rejec-

ting the patenting of plants and animals, had been established in 1989–1990 on the basis of assessments and proposals presented in a separate report from 1989 by the Biotechnology Commission specifically on this issue (NOU 1989). However, under the EEA agreement which came into effect in 1994, the EFTA countries would have to adopt a large number of EU directives. While there is a formal right under the agreement to veto the adoption of directives in national law, the actual use of that right is at the risk of triggering penalizing countermeasures by the EU Commission. The biotechnology patent directive issue soon became a symbol of the consequences of such an agreement in terms of loss of national independence. Here, a policy on what for several political parties is a highly important issue would have to be adopted on formal grounds, although it was expected to go starkly against national, consensual policy. The biotechnology patent directive has eventually become the single issue which most strongly puts to the test the reality of the veto option under the EEA agreement, and hence the EEA agreement as such as a viable alternative to full membership of the EU.

Following the agreement in the EU Parliament and the Council of Ministers in June 1998 on the final text of the directive, the first Bondevik centre Government signalled in 1999 that it would propose that the veto option should (finally) be used in this case, and that the government would resign should the *Storting* reject its proposal to do so. The formal proposal on the issue was not, however, presented to the *Storting* until January 2003. In the meantime, the centre Government had been replaced, first by a Labour Government (March 2000 – October 2001), and a new centre-right Government (October 2001 – currently in office), a minority coalition between the Conservative, the Liberal (*Venstre*) and Christian Democratic parties. The Conservatives are in a dominant position, holding 10 of 19 ministerial positions. These parties strongly disagree both on EU policy in general and on the biotechnology directive issue in particular. In negotiating the platform for collaboration, the coalition parties merely ‘agreed to disagree’ on the issue.

When the new minority Government finalized its proposal to the *Storting* to approve the adoption of the directive in national law, the nine Ministers from Liberal (*Venstre*) and Christian Democratic parties – the Prime Minister included, made it publicly known that they had opposed the proposal, and lost, in the internal vote within the government on the issue. In support of their minority vote the minority faction within the government protocolled, its emphasis on ‘the ethical counterarguments against the extensive access granted by the directive to patent living material, plants and animals, on concerns for biodiver-

sity and for the developing countries and their exploitation of their own genetic resources' (St.prp. 43 (2003–2004): 90). When the issue was put to the vote in the *Storting* in January 2003, the parliamentary members of these two parties voted against the proposition, as did the members of the Centre and Socialist Left parties.

While the *Storting* approved that the directive be adopted in to national patent law, the decision is far more than a simple 'yes' decision. The formal decision to include the directive in the EEA agreement is embedded in an extensive and complex set of modifying and follow-up measures, introduced to ensure a 'restrictive' practice within the discretion allowed by the directive for its implementation in national law. This includes guidelines to ensure a restrictive practice concerning where to draw the line between discovery and invention, to prevent extensively broad patents, and to ensure a strict application of the criterion of inventiveness. A key concern is to ensure that Norway may remain in a position where it can credibly support the interests of developing countries in international negotiations on these issues. It also strongly supports the resolution of November 2002 by the European Parliament, suggesting that the Commission changes the wording of the directive to exclude the patentability of isolated genes and gene sequences of the human body.

## Summary and conclusion

In summary, we can retrace some of the key features that may be seen to define key aspects of the socio-political appropriation in Norway of the new biotechnology.

Comparatively speaking the history of biotechnology in Norway is one structured by paradoxes. It was initially characterised by the hegemony of R&D interests, and the quasi-absence of any form of broader public debate and political awareness of the controversial aspects of biotechnology. The issues raised were dealt with within a minimal regulatory framework, based on self-governance by the research community and as part of R&D policy only. Until the latter part of the 1980s, risk and ethics issues attracted little general political attention. Biotechnology emerged at that time as a R&D policy priority without debate on any aspects other than its research and commercial opportunities, and with relatively little political attention or support outside the research policy community. When biotechnology became a public issue, it was through the parliamentary process rather than through general public concern and debate, as the potentially controversial uses of biotechnology were drawn into parliamentary debates

on abortion and IVF issues in the mid-1980s. Issues of ethics rather than risk became the initial predominant frame for phrasing the political stakes of the new biotechnology. Risk and IPR issues became grafted onto this process as the international agenda, in the EU in particular, for the creation of a regulatory framework for gene technology had to be taken up in the national political process.

However, the incident in 1985 and the public outcry over the news of the growth hormone-enhanced salmon indicated a strong, latent public scepticism towards the new genetic techniques. Henceforth, the rejection by consumers of GM salmon in particular, a key Norwegian export industry, and GM food in general, became a dogma of Norwegian policy for aquaculture/food production, confirmed by subsequent periodic surveys of public opinion on the issue.

Several characteristics of 'Norwegian style' mediation of all the different, and conflictual, concerns and expectations aroused by modern biotechnology may be related to the conditions defined by the structure and present performance of the Norwegian economy. These mediation processes may thus be seen to take place under conditions of comparatively lower economic stakes and weaker R&D and commercial pressure than in most other countries. The prosperous Norwegian economy based upon abundant income from oil and gas production takes the edge off the sense of economic urgency of seeking competitive advantage in the core areas of the 'new economy'. At the same time, given the general industrial structure of Norwegian economy, the voice of the industrial interests is relatively weak. In Nordic terms, the private biotechnology sector in Norway is very small, essentially due to the absence of research-intensive pharmaceutical industry in Norway.

This relative weakness of R&D interests became evident as the virtually all-dominant R&D frames in discourse on biotechnology of the first half of the 1980s were politically overshadowed and marginalised with increasing concerns in the political process in the late 1980s in Parliament, first with ethical, and later with environmental issues. This led to the establishment and institutionalization of a highly restrictive regulatory policy for biotechnology during the first half of the 1990s. Here, ethics played a central role in framing the acts. Criteria of human rights, social utility and sustainability were more or less explicitly written into the act, and also as part of the criteria for case-by-case approval of biotechnological research projects, services and products.

Party politics and the political process in the the *Storting* have played a strong role in making biotechnology issues politically salient due to party configurations in which the Christian Democrat party is in a key strategic role for estab-

lishing viable government coalitions. The strong emphasis of this party on ethics in general, and on abortion, IVF, eugenics and other ethics issues pertaining to biotechnology in particular, has been instrumental in raising the general political stakes of biotechnology issues. The complex and unpredictable political conditions, characterised by minority governments and unstable party political alliances that have prevailed in Norwegian politics throughout the whole period during which biotechnology politics have become a central policy domain, may thus be seen to have pervasively impregnated Norwegian politics of biotechnology.

A strengthening of R&D interests in biotechnology took place in the latter part of the 1990s, following the consolidation of the Research Council of Norway as an increasingly influential voice for the promotion of innovation policy and knowledge-intensive economy, and the emergence of coordinated industrial efforts to promote biotechnology (Biomarine Forum, Forum for Biotechnology). These and other R&D interests capitalized on the opportunity presented by the announcement of the mapping of the human genome, and succeeded in securing – in Norwegian terms – a huge government appropriation for a new genomics research programme. The FUGE programme was the result of a successful exploitation of the publicity attracted by the announcement in 2001 of the mapping of the human genome, having crystallized an alliance between the RCN and research institutions as well as industry and investor interests.

The conjunction of marine research and biotechnology since 2000 as *de facto* priorities of R&D policy, and the definition of aquaculture as a future key industry for Norway, has made the issue of how to deal with gene technology in salmon aquaculture a major policy issue. It has been a virtually uncontested dogma of Norwegian policy within this domain that the public does not want GM salmon, the genetic modification of the salmon itself has in official terms been a non-issue. This position has become challenged by policies for GM research phrased in terms of developing other uses of GMOs in aquaculture, but also of competence building for modifying the genome of the salmon itself, in case consumers may eventually change their opposition to GM food, and for seeking patents on genes of the salmon bred in Norwegian aquaculture.

The RCN emerged in the late 1990s as an increasingly coherent and influential policy voice for R&D, and hence as a key site for promoting R&D and industrial interests in biotechnology. Its political impact seems, however, to have decreased in recent years, as indicated by reductions in government funding for industrial research, particularly since the advent of the centre-right Government in October 2001, and a major re-organizing of the Council in 2003, after

which its role as main, formal agency for providing science and technology policy advice to Government will be discontinued.

Beside these R&D policy institutions and processes is another institutional cluster, mainly based in regulatory and/or advisory functions. It comprises the research ethics committees, the Technology Board and above all, when talking about biotechnology, The Norwegian Biotechnology Advisory Board. Except for the recently established Board of Technology, which performs no regulatory tasks, they operate within a regulatory framework which has remained largely stable for more than a decade, both in terms of policy and institutional structure. The Biotechnology Advisory Board plays in particular holds in particular a key position in Norwegian politics of biotechnology. Within the framework of established regulatory policy, it is the major player for producing publicly and politically credible ethics and policy discourses. Its debates, negotiations and votes are extensively covered in the media, and their statements are extensively used in the political process. It has established and retained its unique institutional identity as a hybrid, independent institution, operating at arm's length to any one party in the debate. It is extensively engaged in activities to enhance public understanding and debate about biotechnology. Thus, educational (informing the public) and deliberative (stimulating public debate) functions are grafted onto its regular role as expert, regulatory body. At the same time its corporatist structure ensures that key stakeholders' concerns are taken into account in the policy process. In view of the broad range of stakeholder groups that are represented in the Board, it may be seen to operate on the basis of a kind of 'inclusive corporatism', seen as a distinctive feature of consultative procedures in the Norwegian political culture (Dryzek, 2000). In addition, as the proceedings of the Board are public, it may be seen as an arena for public debate in itself, providing a sufficiently broad framework and credible standards for debating biotechnology issues to secure a key role for its input to public debate and to the political process

Thus, the Board embraces to a considerable extent deliberative and participatory forms of governance, although these are embedded in a corporatist institutional structure, and closely associated with an educational approach to public understanding and debate. These components are sufficiently extensive to leave restricted scope for the Board of Technology, whose main or sole purpose is to facilitate and enhance inputs from broader publics to technology assessment, to assume an active role on its own in biotechnology. After some initial successful projects, some of which were in biotechnology and then in cooperation with the Advisory Board of Technology, the Technology Board remains a compara-

tively marginal player, and its role in the longer term in the structure of technology policy still unsettled.

The three committees for research ethics that were established in 1989 may also be seen as part of this institutional cluster, on the basis of their obligation to stimulate public debate on research ethics issues. The committee for science and technology became very early a strong supporter of new forms of technology assessment, and played a key role in the process that led to the establishment of the Board of Technology.

Contemporary Norwegian biotechnology politics may thus be seen as in a process of (moderate) polarization, taking place within a bifurcated institutional structure of science and technology policy. There is, on the one hand, a well-established regulatory framework, set up to implement and develop an overall restrictive regulatory policy that has remained stable for more than a decade. Within this domain, lay participation, public debate and deliberative practices are integral and increasingly more extensive parts of normal procedure. On the other hand, a process of coordination and consolidation of pro-biotechnology interests has taken place, leading not only to the revitalisation of policies for biotechnology R&D and innovation, but also to new offensives that challenge parts of established regulatory policy.

The political process by which the Board of Technology was established is one indication of the increasingly polarized and bifurcated character of the politics of (bio)technology on the contemporary Norwegian scene. The outcome that was negotiated within a protracted and conflictual process that spanned almost six years, may be seen as a relative 'victory' for the critical voices over the promotional, and thus as another indication of the hegemony of this voice in Norwegian biotechnology, and science and technology, policy.

The recent adoption of the European directive on the protection of biotechnological inventions on the other hand, is a relative 'victory' for promoters of R&D and the 'new economy'. Nevertheless, traces of entrenched restrictive biotechnology policy remain in this decision as well, as the foreseen negative consequences of the adoption of the regulative, as argued by its opponents, were taken into account by incorporating a large number of counteracting and modifying measures into the decision. Thus, government adopts the directive, mainly in terms of complying with the request of national industry for equal competitive terms, while – in apparent contradiction to this – simultaneously taking the arguments of the critics on board by laying down rules for 'the most restrictive practice in Europe' for granting biotechnology patents.

Contrary to appearance, the decision may not only be an effect of stronger influence of R&D interests. Equally as important may be the fact that this issue is firmly embedded in the more general and highly politicized issue of Norway's difficult relationship to the European Union, as mainly defined by the EEA agreement. The patent directive issue became the ultimate test issue, as EU policy here was seen to diverge from Norwegian to such a high degree that a veto would finally be justified. The final positions of the parties reflect primarily their positions in the membership issue, rather than their views on the substantive issues raised by the directive as such. So the decision may as much be seen as a victory of the 'pro-membership' majority in Parliament, and not necessarily as a result of stronger influence from R&D and industrial interests on biotechnology policy.

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# Actors, Issues and Tendencies in Swedish Biotechnology

Thomas Achen

## A short politico-legal history of Swedish gene technology

### Gene technology and environment

As early as 1981, the Swedish Committee on Gene Ethics started its work on biotechnology and humans, and in 1990, the Committee on Gene Technology, Environment and Safety began its work. The final legal acts resulting from these committees were promulgated in 1992 and 1994, respectively.

In 1992, the Committee on Gene Technology, Environment and Safety (Genteknikberedningen) published a report entitled 'Gene Technology – a Challenge' (Genteknik – en utmaning). The committee was commissioned to focus, first of all, on the level and quality of knowledge in Swedish society regarding assessment of ecological risks related to gene technology. Second, the committee should assess the ethical principles required to create normative regulation of gene technology in relation to the environment. Third, the committee should consider the structure and organization of the control system required for authorization of various uses of, for instance, GMO in field trials. The committee should also address questions of intellectual property rights. The scope of this report does not allow discussion of the latter issue.

Characteristic of this particular committee is that its focus was on the *problem of knowledge* in relation to gene technology. The report dealt with questions such as: what do we know and what should we know more about? These questions, in turn, were linked to the *principles* one should apply in assessing extant and future knowledge in this field. This strong emphasis on knowledge renders this committee report unique in a Nordic context, above all because ethical concerns are perceived as *epistemological problems*. Thus, the Swedish committee on gene technology and the environment has framed the analysis of genetic technologies differently than have similar committees in Norway and Denmark.

Another significant feature of the report should be mentioned. The committee argued that risk assessments regarding GMO are always influenced by various normative references. The committee stressed that it constitutes a major democratic problem if such sets of norms are not made explicit. In other words, the report wants citizens to know about the *interests* at stake. It is unusual in a Nordic context to encounter a piece of law-drafting that explicitly emphasizes the relation between power and knowledge as regards risk assessment of new gene technologies.

However, even Denmark and Norway consider it pertinent to address the collection, systematization, and application of new knowledge concerning the consequences of introducing, for instance, GMO in different eco-systems. What is unique to the Swedish context, however, is that the relation between the *generation* of knowledge and the fundamental *state of uncertainty* as well as the *normative framing* of scientific knowledge is presupposed to be a necessary point of departure for future legal work.

On March 24 1994, the Swedish government presented a bill on gene technology and environment to the parliament<sup>52</sup>. The government emphasized the importance of biotechnology with respect to the general development of the Swedish economy. Furthermore, the government stressed the need for advanced knowledge on gene technology as a basis for qualitative assessment of the environmental and ethical problems associated with such technology. It is striking that the government explicitly contradicted the committee's suggestion that various aspects of gene technology application should be included in extant legislation, for instance, within the fields of forestry and agriculture. However, the government argued that because the committee on environmental protection was simultaneously drafting new environmental legislation (i.e., miljöbalken), based on the principle that environmental issues should *not* be included in extant legislation, it would be more consistent to employ the same principles also with respect to genetic technologies. Hence the government ignored the counsel of the biotechnology committee on this important point. The legislation on genetic technology was eventually included in the new environmental protection act (miljöbalken). It should be noted that the government was in agreement with the committee on the notion that a new gene technology advisory board should be founded.

By the end of May 1994, the bill was handed over to the Parliamentary Committee on Agriculture (jordbruksutskottet). No major changes were undertaken

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52 Riksdagens snabbprotokoll 1993/94:116 Torsdagen den 2 juni 1994, p.4 column 1.

and the agriculture committee generally approved of the government's tightening of the legislation (i.e., relative to suggestions from the preparatory committee). Finally, on June 2, 1994, the bill was debated in and subsequently approved by the parliament<sup>53</sup>. Many of the discussants criticized the fact that the government had chosen to 'design' the bill as a frame-law. The risk of incoherent legal interpretations and the right of the government and the authorities to issue regulations based on a general authorization as stipulated in the bill were criticized. The government at that time was a Conservative – Moderate Party and Centre Party– coalition government, and the Social Democratic Party was particularly critical of the bill. This criticism was tied to the fact that it was a Social Democratic government that, in 1990, appointed the committee on gene technology, environment and safety. Later this change of government proved to be an obstacle even to the new environmental legislation (miljöbalken), which the Environmental Protection Committee (miljöskyddskommittén) was drafting at that time<sup>54</sup>.

In order to provide a more comprehensive understanding of the political and legislative history of Swedish biotechnology, I shall address the legislative work on gene technology applied to humans.

### Gene technology and genetic integrity

Within the past 20 years, Sweden has produced a number of experts' and government reports dealing with the use of biotechnology in medicine. The Gene Ethics Committee produced its first report entitled 'Genetic Integrity' in 1984. A year later, the Committee on Insemination published a report entitled 'Children through artificial procreation'. And in 1989, the final report on the unborn child entitled 'The Pregnant Women and the Foetus – Two Individuals' was published. Until October 25, 1990, when the government proposed a bill on the use of gene technology on humans, the 1984 report provided the normative guidelines for biotechnology and pregnancy<sup>55</sup>. As regards the political and legislative history of Swedish biotechnology, the 1984 report is significant because it shaped Swedish politics and legal regulation within the entire field of biotechnology in medicine. Therefore, let me address more explicitly this report and the process of legislation it led to.

The Swedish government decided to appoint the gene ethics committee at its meeting on February 19, 1981. The instructions to the committee stipulated that

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53 The first draft was published in SOU 1993:27.

54 Regeringens proposition 1990/91:52 Om användning av genteknik på människan m.m.

55 SOU 1984:88 Appendix 1 p.226.

the committee's work should be complete by the end of 1982. However, the instructions regarding the committee's mission were so comprehensive that the time limit proved to be unrealistic. The committee was supposed to examine the ethical, humanitarian, and social issues related to the implementation and use of genetic technology in medicine. It was required that the committee's investigations should result in a proposal for new legislation on genetic technology and medicine<sup>56</sup>. Yet another reason for the delay was related to the fact that the committee initiated an evaluation of not only Hybrid-DNA techniques (genetic engineering would be the term used today), but also of diagnostic techniques.

The normative point of departure for the gene ethics committee was derived from a number of documents such as the UN declaration on human rights, the Helsinki declaration, statements made by the Vatican and the world council of churches, UNESCO, as well as documents on ethical issues from various countries. The committee concluded that there was a profound consensus in all the examined declarations and documents concerning what it means to be human and, thus, what the concepts of human dignity and integrity entail. However, the gene ethics committee argued that concrete norm formation is not solely a question of assessing and considering facts. Norm formation, the committee argued, is constituted by *normative concepts* such as 'freedom' and 'justice', which must be evaluated in the context of norms inherent in local worldviews, ideologies, and experiences<sup>57</sup>.

The committee eventually formulated 11 ethical norms, which, they argued, should serve as the normative framework for future regulation of genetic technology in medicine. The committee developed this argument further by stating that it *might* even be necessary to include a paragraph in the constitution regarding protection of the human genome<sup>58</sup>. In the context of policy- and law-making in the field of genetic technology in the Nordic countries, this is the only example of a constitutional proposal concerning protection of the human genome<sup>59</sup>. However, the gene-ethics committee eventually concluded that ethical norms should not form part of the actual legislation in terms of positive law. The main reason for the exclusion of ethical norms from the law as such was

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56 Op.cit. Achen 1997 p.213.

57 Ibid. p.218. Op.cit. SOU 1984:88 p.193. The term constitution means 'The instrument of government' (regeringsformen).

58 There is, however, a source of inspiration in the corresponding French legislation. See Peter Kemp, Mette Lebech and Jacob Rendtorff (1997): Den bioetiske vending. Spektrum, p.136-155.

59 These bills where: 'Lag om användandet av genetik vid allmänna häloundersökningar', 'lag om forskning på och behandling av befruktade mänskliga ägg' samt lagen om 'förändrat tillsyn med personalen inom sjukvården'.

that *if* ethical norms such as *vulnerability* or *integrity* were introduced into the legislation, those norms would no longer be adjustable. An alternative solution was suggested in which these norms should be included in the *ethical guidelines* already in operation for those persons and organizations involved in medical applications of genetic technologies. It was suggested that the National Board of Health and Welfare (socialstyrelsen) create these guidelines.

In 1990, the Swedish government proposed three bills based on the committee report<sup>60</sup>. The government accepted without hesitation the ethical norms proposed by the committee. However, at the same time the government clearly announced that it wanted some of the guiding norms, suggested by the committee, included in the legislation itself. The National Board of Health and Welfare should be in charge of other normative matters, ensuring that they are incorporated into the board's ethical guidance to hospitals, physicians, and other relevant groups.

With respect to the use of germ-line therapy the government considered such therapy ethically unacceptable. The government was less liberal than the committee, which had actually suggested that germ-line therapy have potential for use in the future<sup>61</sup>. Another area in which the government had a more restrictive attitude than did the gene ethics committee was with respect to research on fertilized human eggs. The committee suggested that limitations in this area should only be expressed by means of the above-mentioned ethical norms and not by positive law. The government, however, wanted restrictions regarding research on fertilized human eggs to be stated in and regulated by positive law. On February 5, 1991, a bill was handed over from the government to the Parliamentary Committee on Social Affairs<sup>62</sup>.

The Parliamentary Committee on Social Affairs had requested, on a number of occasions, comprehensive legislation on genetic technology (including the environment and genetic technology in medicine). The government agreed with the committee as to the need for such comprehensive legislation. However, the government argued that, because technological development in the area of genetics is so rapid, any further delay of legislation in this field would be unacceptable. Hence, despite the fact that most political parties, including the government, would prefer comprehensive legislation, the pressure to produce a regulatory framework forced the government to refrain from a prolonged pro-

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60 The issue at stake is the discussion of therapy that aims at enhancement vis-à-vis therapy intended to cure diseases.

61 Op.cit. Achen 1997 p.222-223.

62 Stefan Rubenson (2000) Miljöbalken – Den nya miljörätten. Nordstedts Juridik. p.17.

cess of law-drafting work. The majority of the parliamentary committee eventually agreed with the government's reasoning regarding the need for a swift legislation process. However, the opposition represented by the Centre Party, the Left Party, and the Christian Democratic Party all expressed firm criticism concerning what they saw as the *compartmentalization* or *disintegration* of genetic legislation.

As mentioned above, a comprehensive legal framework on the environment was promulgated in Sweden in 1998. This new environmental protection act (miljöbalk) is important to address here, as it contains an important chapter on GMO. I shall address this act in the following section by accounting for the political process that led to the completion of this new legal framework.

### The 1999 Environmental Protection Act

In 1993, the Committee on Environmental Protection appointed by the conservative government in 1991 published its report. The main part of this work was a suggestion for comprehensive environmental legislation. Technically speaking, the new legislation suggested by the committee aimed at integrating 15 previously autonomous laws on various aspects of environmental protection<sup>63</sup>. Besides this integration of extant laws, the new environmental law introduced the *precautionary principle* as the guiding norm for all regulation of the environment. Second, the law introduced a number of goals regarding the quality of water, soil, air, and so on.

Based on the committee recommendations, the government proposed a bill on a new environmental protection act to the parliament in 1993. However, the conservative-led coalition government resigned after the general election in 1994, and Sweden again had a Social Democratic government. This was important for the legislative work, as the new government did not approve of the bill presented to the parliament by the former conservative government. Therefore, on November 24, 1994, the new Social Democratic government re-started the process of creating a proposal concerning new and comprehensive legislation on environmental protection<sup>64</sup>. On July 4, 1996, the environmental protection committee presented a report on what was called «strengthened and co-ordinated environmental legislation for sustainable development»<sup>65</sup>. Eventually, on

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63 Dir. 1994:134 Tilläggsdirektiv om nytt förslag till miljöbalk.

64 SOU 1996:103 Miljöbalken – en skärpt och samordnad miljölagstiftning för en hållbar utveckling. Del 1 & 2.

65 SFS 1998:808 Miljöbalken. 13 kap. §§ 1 & 10.

December 4, 1997, the government turned over a bill to the parliament. This bill was accepted by the parliament and came into effect on January 1, 1999.

In the context of the present survey report, Chapters 2 and 13 of the environmental protection act are of special interest.

Chapter 13 is on gene technology, and the paragraphs are more or less directly copied from the 1994 legislation on biotechnology and environment, which I discussed above. One significant feature of the environmental protection act on GMO is that §1 clearly states that ethical considerations should be applied both in the case of confined use of GMO and in the case of deliberate releases of GMO into the environment. This provision is elaborated somewhat in §10, which states that ethical considerations should be applied also when GMO is released onto the market<sup>66</sup>. The provision regarding ethical considerations in the environmental protection act is applied even with respect to obtaining authorization and in relation to the duty of notification whenever someone wishes to release GMO into the environment or introduce GMO products onto the market<sup>67</sup>. The Gene Technology Advisory Board (GTAB) is briefly mentioned in §19. This paragraph defines the right of the government to regulate the mission, organization, and procedures of the GTAB<sup>68</sup>.

Chapter 2 § 2 of the environmental protection act stipulates that anyone intending to undertake any kind of business or activity that affects the environment must obtain the knowledge needed to enable application of relevant precautions for health and the environment<sup>69</sup>. Similarly, § 3 stipulates that the best available technology should always be applied. As regards the field of gene technology, this means that violation of the legal regulation of the use and trade of GMO or an insufficient risk assessment cannot be excused with reference to lack of knowledge.

The importance of obtaining and making use of appropriate knowledge is one of the significant points in the Swedish environmental protection act. This requirement is highly pertinent in relation to Chapter 13 on gene technology. Even the requirements regarding the ethical considerations expressed in Chapter 13 are among the most celebrated characteristics of this new legislation.

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66 Ibid. §12.

67 To a certain degree also Chapter 14 on chemical products and biotechnical organisms regulates the development and application of GMO.

68 Op.cit. SFS 1998:808. Chapter 2 deals with the general precautionary rules.

69 It is interesting to note that the constitutional board (lagrådet) was very doubtful regarding the ethical provisions in the environmental protection act. Prop. 1997/98:45 vol.2, p.480-482. The act is currently being revised. However, there is no indication thus far that these issues have been dealt with. See SOU 2000:116 Uppföljning av miljöbalken - v-ssa lagtekniska frågor and SOU 2002:50 Miljöbalken under utveckling - ett principbetänkande.

However, the implementation and legal status of these provisions are very insecure. I have on several occasions discussed these issues with legal experts at the Court of Appeal for the Environment (miljööverdomstolen) concerning the ways in which they would interpret these ethical provisions. Their answers have thus far been evasive<sup>70</sup>.

### Potentials and Risks in Biotechnology

On October 16, 1997, the Swedish government sanctioned appointment by the minister of education of a committee that should examine the potentials and risks related to biotechnology. The committee was established on February 16, 1998, and called The Biotechnology Committee.

The reason for appointing this committee, I would argue, was that the government had realized the significance of a new mode of knowledge production conceptualized by Gibbons et al. as mode 2, which, as Gibbons et al. argued:

«...calls into question the adequacy of familiar knowledge producing institution»<sup>71</sup>.

According to Gibbons, the production of knowledge in mode 2 occurs when scientific knowledge reaches the phase of *application*. Since the 1970s, the Swedish biotech industry has moved with surprising speed from basic to applied research. This development is well documented, e.g., in the report *The Swedish Biotechnology Innovation System* published by Vinnova in 2001<sup>72</sup>.

This is precisely what the biotechnology committee was aiming at in its report<sup>73</sup>. The report's emphasis on two interrelated major problems in Swedish biotechnology policy, which are usually not highlighted, is most conspicuous:

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70 Michael Gibbons et al. (1994) *The New Production of Knowledge*. Sage Publications, p.2.

71 Vinnova Innovation in Focus VF 2001/02.

72 The instructions to the committee are very comprehensive and complex. See Dir.1997:120.

73 SOU 2000:103 Att spränga gränser – bioteknikens möjligheter oh risker. P.13 & 14. Biopolitics denotes a new area of politics and policymaking with the objective of defining, e.g., the social, legal, cultural, economic, political, institutional and ethical dimensions of the governance of human and non-human genes or products containing modified genes.

1. *The democratic problem*: Citizens have insufficient opportunities to influence the direction of technological development in society. The need for a dialogue among researchers, experts, politicians, and citizens is urgent.
2. *The political problem*: The ways in which Sweden handles biotechnology administratively and in terms of legislation are characterized by fragmentation. Sweden lacks a coherent overall and long-term biopolitics<sup>74</sup>.

These points are interesting, as they clarify a possible change in how science and technology, according to the committee, should be governed in Sweden. This report was the first in the politico-legal history of Swedish biotechnology to announce an urgent need for socio-political change in the governance of biotechnology in Sweden. The changes anticipated in the report could be interpreted as a move towards a new kind of scientific citizenship<sup>75</sup>. Hence, the report may be seen as the first sign of a new emerging governmentality in the field of science and technology in Sweden<sup>76</sup>. It is governmentality concerned with the complex ways in which science, technology, and society intersect.

The biotechnology committee provided a new framework for the entire field of biotechnology by defining 21 issues that should be integrated into a novel Swedish politics of biotechnology. However, the content of the majority of these 21 issues is not new. They deal with developing countries, the risk of a monopoly situation on the market, the importance of patenting and commercialization of university-based research, and so on. The novelty of these 21 suggestions is related to the overall ambition to *integrate* these issues into a new and comprehensive *biopolitics*. Below, I shall give an account of issues one and two. In addition, I shall conclude this section by briefly discussing the prospects of applying the notion of national 'styles' of governance of biotechnology.

### Issue 1: A New Biotechnology Authority

This issue deals with the organization of the Swedish authorities on gene technology. The committee argued that the present organization of the administrative and institutional framework regarding gene technology is not transparent and that a much higher degree of co-ordination between various issues, authorities, procedures, etc. is necessary. The committee suggested that in order to

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74 Mark Elam and Margareta Bertilsson: Consuming, Engaging and Confronting Science – The Emerging Dimensions of Scientific Citizenship. In Margareta Bertilsson (ed.): *Science Governance: Problems and Prospects*. Sociologisk rapportserie no.6 2002, Köbenhavns Universitet.

75 I use the term governmentality in accordance with the theoretical framework developed in Mitchell Dean (1999): *Governmentality – Power and Rule in Modern Society*. Sage Publications.

76 Op.cit. SOU 2000:103, p.31.

achieve such co-ordination, the GTAB should be transformed into a Gene Technology Inspectorate (genteknikinspektion)<sup>77</sup>. The committee is critical to the fact that the present responsibility for biotechnology is divided between 14 different authorities. The new biotechnology inspectorate, however, should be established on the basis of today's biotechnology advisory board. Hence, the objectives and tasks of the board should be drastically expanded in order to fulfil the need for stronger integration of the governance of gene technology<sup>78</sup>. The committee argues:

*The consequences of the present division of the control of biotechnology applications is that there are inconsistencies in risk assessment and in ethical judgement depending on which authorities are carrying out these assessments<sup>79</sup>.*

According to the committee, this situation makes it difficult for politicians and citizens to gain an overview of the field of biotechnology. The transformation of the GTAB into a biotechnology *inspectorate* should focus, therefore, on new and controversial applications of biotechnology. The old and established applications of gene technology should be left explicitly to authorities in the respective areas, such as agriculture, environment, fishery, and forestry. The committee emphasized that the areas of responsibility of the new biotechnology inspectorate should include:

*Monitoring the application of advanced biotechnology. Consequently the new authority will have the overarching responsibility for, e.g., xeno-transplantations, gene therapy and cloning. Also, the inspectorate should be given responsibility for all issues inherent in Chapter 13 (the regulation of release of GMO into the environment, my italics) of the environmental act (miljöbalken) as well as biotechnological organisms and biological pesticides.../.../...also illegal genetic tests, handling of information obtained from genetic testing, artificial procreation, pre-implantation genetic diagnostics, bio-banks<sup>80</sup>.*

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77 An increase of the budget from under 3 million SEK to 15-20 million SEK. Ibid. p.327.

78 Ibid. p.323-24.

79 Ibid. p.324.

80 Ibid. p.331.

As can be seen from this quotation, the range of tasks assigned to the new biotechnology inspectorate is broad and includes both human and non-human applications of genetic technologies. The all-inclusive tasks of the new gene technology inspectorate are likely to raise concern within the regulatory system regarding the line of demarcation between the new authority and extant authorities charged with various regulatory tasks in the field.

## Issue 2: A new Technology Assessment Board

By addressing the issue of technology assessment, the biotechnology committee explicitly criticized the 'democratic deficit' in the Swedish governance of science and technology. The biotechnology committee argued that:

*The citizens have no opportunity to influence a development that can certainly have consequences for them as individuals as well as for society as a whole; indeed it is a development that is potentially a question of life or death. This is a democratic problem*<sup>81</sup>.

The committee stressed that it is of pivotal importance to remedy the democratic deficit in the governance of science and technology, not only in the field of biotechnology, but also within areas such as traffic, energy, and education. The committee brought to the fore the fact that there is no institution or organization devoted to the assessment of technology in Sweden. Each authority is supposed to monitor and assess technological development in its own area of competence. Consequently, the committee argued in favour of adopting a similar model for technology assessment as that in operation in Denmark and Norway<sup>82</sup>.

The committee seemed to implicitly criticize expert- and authority-based technology assessment, which have been the predominant approaches in Sweden thus far. One example of this is the Technological Foresight processes in the field of biology, in which gene technology plays a crucial part<sup>83</sup>. It is a significant feature of technological foresight that the project group on biology and bio-

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81 Ibid. p.335-336. It is interesting to note that the European technology assessment institutions are co-operating within the European Parliament Technology Assessment in which Sweden does not have representation at present. See Simon Joss and John Durant (eds.) (1995): Public Participation in Science. Science Museum and European Commission Directorate General XLL. P.17-49.

82 The initiative to launch a process of technological foresight came from IVA and NUTEK/VINNOVA in 1997. The process was concluded by the end of the year 2000. See [www.tekniskframsyn.nu](http://www.tekniskframsyn.nu)

83 For a discussion of the significance of civil organizations, e.g. environmental organisations, see Andrew Jamison (2001): The Making of Green Knowledge. Cambridge University Press. Also Andrew Jamison & Brian Wynne: Sustainable Development and the Problem of Public Participation. In Andrew Jamison (ed.) (1998): Technology Policy Meets the Public. Pesto Papers 2. Aalborg University Press. p.7-17.

logical resources consists only of representatives of various biotech companies as well as those of a number of specialized private and university-based research institutions. This may create a particular and restricted science and technology community due to the absence of citizens or civil organizations<sup>84</sup>. The formation of such an expert community contradicts the argument of the biotechnology committee that citizens must be given a decisive role in the governance of science and technology.

These observations suggest an ambiguity in the Swedish case. This ambiguity, I will suggest, is concerned with the *co-existence* of two tendencies regarding the governance of biotechnology in Sweden. One kind of governmentality derives from ideas in which societal progress is considered identical to technological innovation. The rationality inherent in this type of governmentality constitutes *innovation as a virtue in its own right*<sup>85</sup>. The other kind of governmentality is stimulated by a rationality that foregrounds the *importance of Public Understanding of Science and Technology*<sup>86</sup>. The co-existence of these two tendencies, which I shall call governmentalities, constitutes a troublesome ambiguity in the overall Swedish governance of science and technology, which needs to be explored further.

In concluding this section I would like to stress that the report published by The Biotechnology Committee has not yet had any substantial impact on the discussions and priorities in Swedish bio-politics. What we have seen thus far is that a number of politicians have proposed motions in the Standing Parliamentary Committee on Agriculture and Environment regarding regulation of food and foodstuff. These propositions as well as the rejection of them by the majority have been accomplished with more or less explicit reference to the report from The Biotechnology Committee. How should one account for this situation? It seems plausible that the environment-friendly part of the opposition, e.g. the Centre Party, the Green Party and the Liberal Party, has tried to benefit from the environment-friendly and consumer-oriented approach in the committee report, whereas the Government, on the other hand, has strived to find ways to handle the radical suggestions and analyses concerning Swedish and

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84 Op.cit. Elam & Bertilsson (2002), p.18-22.

85 Ibid. p.28-42. Elam and Bertilsson discuss the deliberative democratic transformation of the public understanding of science into a public engagement with science. See also Alan Irwin (1995) *Citizen Science*. Routledge. p. 26-31.

86 Andrew Jamison: Sweden: The Dilemmas of Polarization. In Andrew Jamison & Per Östby (eds.) (1997): *Public Participation and Sustainable Development – Comparing European Experiences*. Pesto Papers 1. Aalborg Universitetsforlag. p.15-43. And Andrew Jamison (1982): *National Components of Scientific Knowledge – A Contribution to the Social Theory of Science*. Research Policy Institute. University of Lund. p.165-195.

international biopolitics presented in the report. Hence, we are still waiting for a governmental answer to the report – an answer that might bring about an interesting new approach to the overall Swedish governance of biotechnology. Obviously, the controversial suggestions contained in the committee report may also result in *political silence* on the part of the government.

## National style of governance of biotechnology

The co-existence of different governmentalities in Sweden led us to ask whether one could conceptualize this co-existence in terms of a national *style* of governance? In order to answer this question one would need a definition of the notion of ‘national style’. Without pretending to conduct a full-scale analysis, I would like to suggest, at this point, in what way the notion of ‘national style’ could be applied in this case. Andrew Jamison provided a definition that I think could be utilized<sup>87</sup>. According to Jamison, the notion of ‘style’ contains four interrelated levels: 1) metaphysical bias 2) national scientific interest 3) institutional structures and 4) scientific leadership<sup>88</sup>. The first level:

*«...would be a reflection of certain metaphysical streams of thought that are dominant in a particular country»<sup>89</sup>.*

The questions raised at the first level are directed towards the fundamental «figures of thoughts», as Jamison puts it. On the second level the idea is that:

*«...the metaphysical bias encourages certain areas of study rather than others»<sup>90</sup>.*

This in turn leads to an «identification of national scientific interests»<sup>91</sup>. According to Jamison, the third level, focusing on institutional structures, is actually intermediate to ‘metaphysical bias’ and ‘national scientific interests’. This mid-level can be identified when the first and the second level are «...brought toget-

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87 Op.cit. Jamison (1982) p.187ff. Jamison’s model is developed from categories provided by Henry Brookman (1979): *The Making of a Science Policy*. Diss. Amsterdam.

88 Ibid Jamison (1982). p.189-190.

89 Ibid. p.190.

90 Ibid.

91 Ibid. p.191.

her into scientific knowledge»<sup>92</sup>. Finally, Jamison argued that, with regard to scientific leadership on the fourth level, it:

*«...is not so much leadership as relative prominence that will concern us; what becomes interesting is the degree to which Sweden and Denmark, in our case, can be said to be «successful» in the international arena, the degree to which their «national styles» converge (my italics) with an internationally dominant style»<sup>93</sup>.*

What I would call the co-existence of two modes of governance in the field of biotechnology in Sweden does qualify, to a certain extent, as a national style of governance. On the level of *metaphysical bias*, the ambivalence of governance in Swedish biotechnology can be traced back to a tension between ideas of rationalism, technocracy and centralism, on the one hand, and a democratic model based on the ideal of deliberations and citizens' engagement, on the other. Research in Swedish political history of ideas has shown that the rationalistic side of this dualism has long been dominant<sup>94</sup>. Hence, the development of certain areas of research has been shaped in accordance with these «figures of thoughts». Large-scale, technically and scientifically advanced projects have been the predominant model. The tension between this science-based rationalism and the deliberative democratic idea of citizens' engagement has been present in Swedish political life for decades. The initiation of huge scientific and technically advanced projects is seen as a means by which democratic ideals can be realized, thus enabling formation of *the good life*. In Sweden, the term 'the art of social engineering' (social ingenjörskonst) captures this interdependence between political democracy and scientific/technological progress. As argued above, the biotechnology committee has challenged this association of science, technology and politics by arguing that contemporary governance of biotechnology lacks democratic involvement.

In terms of national scientific interest, Sweden has followed a path of developing large-scale research programmes in areas such as nuclear energy, bio-

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92 Ibid. p.193.

93 See e.g. Yvonne Hirdman (1990): Att lägga livet till rätta – studier i svensk folkhemspolitik. Carlssons. Sten O Karlsson (1993): Arbetarfamiljen och det nya hemmet. Symposion Graduale. One of the publications from the Committee on Swedish Democracy (Demokratiutredningen) is of interest here Le-kmannastyre i experternas tid. SOU 1998:102. Demokratiutredningen, skrift nr.6.

94 Within the framework of the Compass Project, I will conduct an in-depth study of the GTAB. This study will include interviews with all members of the board as well as examinations and analysis of documents produced by the GTAB. The objectives of this study were presented to the GTAB at its December meeting 2002 in Stockholm, Sweden.

medicine, nanotechnology, information technology and biotechnology, all of which have been identified as pertinent areas. This rationale has contributed to the establishment of technological innovation as a virtue in its own right, while at the same time evoking a democratic problem concerning the legitimacy of these programmes in terms of public understanding and public involvement in science and technology. When the metaphysical bias and the national scientific interests are brought together into scientific knowledge, certain institutional structures are called for. The process of structural formation should be comprehended in terms of a struggle between the actors who have scientific interests, e.g. scientists, state agencies, politicians, universities, companies and interests organisations. One such actor is the Swedish Gene Technology Advisory Board.

Finally, on the level of scientific leadership, the above-mentioned ambivalence could be taken as an indication that there is some degree of bewilderment as to what 'style' of scientific leadership would be the most appropriate. The problem may be framed as follows. Swedish biotechnology has, through legislation and through the political mandate given to various authorities, devoted itself to striking a balance between two aims: a) Sweden should belong to the group of nations most advanced in terms of science and technology and b) achieving this should ideally involve a radical democratic approach. Now, the policies needed to manoeuvre between these two considerations are notoriously difficult to create. Hence, the categories used by Jamison to bring out the meaning of a 'national style' can help us to pinpoint various epistemological, structural and ideological aspects that contribute to the ambiguity that characterizes the Swedish appropriation of biotechnology.

In order to develop this suggestion further, I will examine this ambiguity from yet another angle by discussing the Swedish Gene Technology Advisory Board. The focus is here on the tasks assigned to GTAB and the way in which GTAB has conceived of these assignments.

## The Swedish Gene Technology Advisory Board<sup>95</sup>

In 1978, the Swedish minister of education appointed a special one-man investigation that should examine «...whether, and to what extent, the present legislation is sufficient to control the research on hybrid-DNA»<sup>96</sup>. The conclusion of

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95 DsU 1978:11 Hybrid-DNA tekniken under kontroll. p.3.

96 Ibid. p.157.

the work of this investigator was twofold. First, it was concluded that new legislation was needed and that it would have to be more rigorously than «...the ordinary control of laboratory techniques»<sup>97</sup>. Second, the investigator stated that in order to carry out this rigorous legislation, there was an urgent need for formation of a new authority, which should be responsible for the overall control in the field of DNA technology<sup>98</sup>. Already in 1980, a committee on hybrid-DNA issues was established. Until 1994, the committee on hybrid-DNA was the central advisory body to the Swedish government; its mission included monitoring technological development and informing the public as well as issuing licenses for DNA-related research and production<sup>99</sup>.

As I mentioned above, a crucial point in the history of Swedish gene technology politics was the establishment of the Committee on Gene Technology, Environment and Safety (genteknikberedningen) in 1990. One of the conclusions published in 1992 by that committee was that a new board on gene technology should replace the former committee on hybrid-DNA. This suggestion eventually led to the inauguration of the GTAB on July 1, 1994.

With respect to the mandate of the new board, it is striking how very broad it was, and that *ethical issues* were pinpointed as its *main objectives*. However, at the same time it was expected that the new board should continue the work of its predecessor, the hybrid-DNA committee. GTAB should consist of 16 members of whom 5 members should be researchers, 5 should represent various authorities, and 5 should be representatives of political parties represented in the parliament. Finally, the committee suggested that the board should also include one expert in the field of ethics. The committee explicitly pointed out that it is *not* necessary to include members of social movements and non-governmental organizations on the board.

Today the GTAB consists of 16 members of which 7 are members of political parties represented in the parliament. Seven members are affiliated with research units. Of the 7 researchers, 2 members work in the social sciences and the humanities. Six members have been appointed by two of the major research councils in Sweden<sup>100</sup>. It is mandatory that the chairman and the vice-chairman

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97 Ibid. p.163. The wording control and DNA technology, etc., was the terminology used in the late 1970s.

98 Op.cit. Achen 1997, p.182.

99 The Swedish Research Council (VR, Vetenskapsrådet) appoints 4 members of which 1 must be an ecologist and the Swedish Research Council for Environment, Agricultural Science and Spatial Planning (FORMAS) appoints 2 members of which one must have experience in animal welfare. One member must be an expert in ethical matters and is appointed by the government. For more details, see the mission of GTAB in SFS 1994:902.

100 Op.cit. Elam and Bertilsson (2002), p.48.

both be lawyers who have practised professionally as judges. Each term lasts for 3 years.

The construction of the public, in terms of 'the citizen', contains «all sections of the national population at large /which should/ be directly represented in deliberations over major technological issues». Mark Elam and Margareta Bertilsson elaborated on this argument by saying that the scientific citizen:

*Participate[s] in the task of deciding what constitutes opportunities and acceptable risks in the carrying out of science-based new combinations. They are members of collectivities that define and delimit themselves more completely by their capacity for producing and disseminating new types of useful knowledge.../...For citizens to identify themselves as 'scientific citizens' they will need to be persuaded to prize new rights and freedoms and to accept new duties and obligations*<sup>101</sup>.

Citizens, according to this account, do not become scientific citizens all by themselves. A strategy, or rather an interaction between the science-producing bodies and the public, is needed. However, the outcome of this interaction is not easy to anticipate, as the rights, freedoms, duties and obligations could all be interpreted in ways contrary to what is desirable to or anticipated by the scientific institutions. Hence, engaging in the creation of the scientific citizen involves a certain risk of displaying the very problem of legitimacy that lies at the heart of the concept of scientific citizenship.

Gustaf Brunius<sup>102</sup> argued that the traditionally optimistic view on science and technology in Sweden entered a new phase after the consultative referendum on nuclear energy in 1980<sup>103</sup>. According to Brunius, the scepticism that increasingly pervaded the Swedish science and technology discourse is detectable in the current scepticism and anxiety regarding gene technology. When asked about the prospects of using consensus conferences in order to remedy this scepticism, Brunius pointed out that consensus conferences are not part of the Swedish tradition, and that there is not much interest in introducing this type

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101 Interview with head of GTAB secretariat Gustaf Brunius, May 30, 2002.

102 For a comprehensive discussion on political history on nuclear energy in Sweden see Jonas Anshelm (2000): *Mellan frälsning och domedag: om kärnkraftens politiska idéhistoria i Sverige 1945-1999*. Symposium. See also Dick Kasperowski and Aant Elzinga: *Public Understanding of Science for Democracy, some notes on the «Swedish Model»*. In Reijo Miettinen (ed.) (1999): *Biotechnology and Public Understanding of Science*. Academy of Finland.

103 The integration is done through Förordning 2002:1086 om utsättning av genetisk modifierade organismer i miljön issued by the ministry of the Environment.

of deliberation into the Swedish governance of science and technology. However, the GTAB actually hosted a consensus conference on October 14–15, 2000 dealing with the issue of genetic testing.

Brunius emphasized that the new EU directive 2001/18/EG on genetically modified organisms (GMO), which came into effect on October 17, 2002 (replacing directive 90/220), *might* change the status of the public, when the directive is integrated in Swedish legislation<sup>104</sup>. The reason for this prediction is that the new directive presupposes that the public should be assigned a more prominent role in the assessment of risks associated with GMO's. Depending on the political interpretation and institutional framing of the new directive, Sweden *might* experience a growing interest in including the voice of the public in discussions of Swedish gene politics.

The notion of the public seems to be somewhat problematic for GTAB, as mentioned above. As Brunius rhetorically asked: what is the public anyway? And how can one distinguish between momentary fluctuations in public sentiments and more politically significant concerns regarding gene technology?<sup>105</sup> Bearing in mind that the 1994 committee argued in favour of *not* including interest groups and lay-people in the GTAB, it is important to note that even Brunius argued in favour of this model of representation.

Brunius standpoint is based on a report submitted to the government in 1999 in which the biotechnology committee examined the tasks and composition of the gene technology advisory board<sup>106</sup>. The biotechnology committee argued, on the one hand, that it is obvious that a number of groups have a special interest in the work of the advisory board. These include, for instance, organizations representing persons suffering from diseases such as haemophilia and cystic fibrosis as well as interest organizations representing farmers, fishermen, the pharmaceutical industry and the food industry. On the other hand:

*Different interests [it could be argued] need not be represented in the executive bodies of different authorities in order to obtain information. Furthermore, it is by no means evident that increased confidence is an end in itself for the public control.../...It can be ascertained that none of the authorities handling gene technology issues has any interest representation in its executive body.../...Neither in the Amsterdam treaty nor in the Århus declaration has the question concerning interest representation in authorities*

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104 Interview with G. Brunius May 30 2002.

105 SOU 1999:70 Gentekniknämnden. p. 5.

106 Ibid. p.51. My translation.

*been addressed. According to this committee, there is no reason to grant any exemptions from these principles by allowing interest representation in the Swedish Gene Technology Advisory Board*<sup>107</sup> (My italics).

The argument put forward at this point is twofold. First, that the production of *public confidence* should *not* be interpreted as an end for the public control carried out regarding gene technology. Second, because the absence of interest representation is *legio*, there are *no particular* reasons to integrate such representation into the gene technology advisory board.

The authorities' efforts to control gene technology are explicitly separated from the production of public confidence. However, the mission of the GTAB clearly states that the GTAB shall «...inform the public about the development within GTAB's field of responsibility so as to maintain the public interest in ethical and safety questions while at the same time stimulating the public debate»<sup>108</sup>. This key objective actually has a status similar to that of the objectives dealing with pure control and monitoring of gene technology. The argument on the part of the biotechnology committee, that public confidence should not be an end for authorities carrying out control, seems to be based on a quite narrow interpretation of the GTAB's mandate.

In strict administrative terms, the GTAB is just another part of the administrative structure in the state apparatus. On the other hand, however, the GTAB has been given a mission, which presupposes that it constitutes a specific link between the state apparatus and the public. However, the biotechnology committee conveyed a narrow interpretation of the role of the GTAB, in the sense that it downplayed the importance of addressing the issue of public involvement in science and technology and the confidence gap between science and the public.

Let me once again return to the arguments made by of the head of the secretariat at GTAB, Gustaf Brunius. Brunius considered that the issue of information to the public is problematic. He argued that information seems only to be necessary or possible in some specific situations, for instance, if there is what he calls a «window» to the public. The crux of the matter, according to Brunius, is whether it is possible to verify and make use of such windows. One problem is that different techniques create different patterns of reactions in the public. For

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107 Op.cit. SFS 1994:902 2§.

108 The notion of reflexivity applied here is inspired by the way in which this concept is elaborated in Ulrich Beck, Anthony Giddens and Scott Lash (1994): *Reflexive Modernization: Politics, Tradition and Aesthetics in the Modern Social Order*. Polity Press.

instance, xenotransplantation, radiation from mobile phones, GMO in foodstuffs, and so on, create non-predictable reactions in the public. Brunius stressed that it is difficult to determine what sub-groups of the public should be taken into account when assessing and providing information on the implications of a new technology.

In the contemporary discussion on public anxiousness and critique regarding GMO, it is often argued that these reactions have a strong resemblance to religiosity. This is an argument with which Brunius agrees. Interpreting public reactions as having a religious character is tantamount to differentiating between a rational and an irrational response to gene technology. This argument conveys the general confusion regarding how authorities such as the GTAB should make sense of the normative grounds upon which organizations and individuals act. Objective information, science-based assessments and expert knowledge are in this respect much easier to interpret in a way that can be related to the functional logic of contemporary gene politics.

However, if the notion of public confidence in gene technology is to be taken into account, one needs to improve the ability of administrative and political bodies in the field of gene technology to handle the complexities and antinomies inherent in various public responses. To increase their ability to handle this complexity, the institutional framework needs to be endowed with a new kind of reflexive capacity<sup>109</sup>. A pertinent component of such a reflexive capacity is the ability to understand the ways in which citizens interpret nature. Empirical studies conducted in Sweden suggest that conceptions of what are legitimate or illegitimate interventions in nature by means of gene technology depend on the various worldviews people hold<sup>110</sup>.

One of the most important resources for monitoring people's opinions and worldviews is the Eurobarometer survey. The Eurobarometer survey was carried out in 1993, 1996, 1999 and most recently in 2002. In the section below, I will present some preliminary analyses from the 2002 survey concerning public opinion on biotechnology carried out by Torben Hviid Nielsen and colleagues at Oslo University.

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109 Susanne Lundin and Malin Ideland (eds.) (1997): *Gene Technology and the Public – An Interdisciplinary Perspective*. Nordic Academic Press. See also Carl Reinhold Bråkenhielm and Katarina Westerland: *Worldviews and Genetics*. In *Ibid.* p.29ff. For an elaboration of the notion of 'thick' moral argument see Michael Walzer (1994): *Thick and Thin – Moral Argument at Home and Abroad*. University of Notre Dame Press.

110 The numbers indicate an opinion-balance and not percentage. See Torben Hviid Nielsen, Örnulf Seip and Trond Haug: *Hva mener og vet nordmenn om bioteknologi? Noen resultater fra Eurobarometer 58.0 (2002)*. Center for Technology, Innovation and Culture, University of Oslo. Arbeidsnotat nr.20 mars 2003. Section IV. The authors point out that the Swedish figures in this case are not entirely reliable.

## Eurobarometer Survey 2002

When asked about their expectations for biotechnology, Swedes have by far the most positive expectations, and these have risen from just above 30 in 1996 to just above 50 in 2002<sup>111</sup>. A relative increase in the level of expectations can be seen in Norway and Denmark, as well as in the EU as a whole. It should be noted that the expectation rate has been rising throughout the period 1996–2002 in Sweden, whereas it has been rising in Norway, Denmark and the EU only from 1999 onwards. What we see in Sweden is, thus, a long period of uninterrupted high expectations concerning the impact and future perspectives of biotechnology.

Eurobarometer 2002 reveals a very striking pattern in the EU as regards the relationship between *expectations* for biotechnology in relation to *knowledge* about biotechnology. The general conclusion to be drawn from the Eurobarometer survey is that there is no straightforward relationship between expectations and knowledge. In France, Holland and Sweden, *expectations* and *knowledge* are above average. However, in Norway, Finland, Denmark and the United Kingdom, *expectations* are *below* average while *knowledge* is *above* the average level in Europe. The tentative conclusion to be drawn from these findings is that the relationship between expectations and knowledge, which has previously been comprehended as linear, has become much more complex and unpredictable<sup>112</sup>.

The way in which people interpret and comprehend biotechnology is heavily influenced by how actors in the field of biotechnology behave. In section one and two I provided a sketch of the politico-legal actors and the political and legal norms they have created. In section three I provided some findings on what Swedes, in comparison with the other Nordic countries and EU, expect from biotechnology and what they know about this technology. The number of actors involved in producing, distributing and implementing knowledge on biotechnology is of course much larger than those dealt with thus far. Hence, the remainder of this paper will concentrate on providing an account of a number of actors dealing with, e.g., the financing and commercialization of biotechnology.

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111 Ibid. section X.

112 Personal communication with project manager Anna Sandström at IVA 31/1 2003.

## Research councils and academies

### Royal Swedish Academy of Engineering Sciences (IVA)

The Royal Swedish Academy of Engineering Sciences was founded in 1917 and is the oldest engineering academy in the world. It consists of 700 members. The members of the academy are professors in various scientific disciplines and technology as well as industrialists. More than 90 % of the funding comes from private donors and from various research-funding bodies such as VINNOVA (see section 3.2). The academy receives only a very limited grant from the state.

As mentioned earlier, IVA has been one of the driving forces behind the Swedish Technological Foresight project. Just before Christmas 2002, the project Technological Foresight II was initiated. The Foresight project is partly financed by VINNOVA<sup>113</sup>.

VINNOVA and IVA are also co-operating on a project on the Swedish biotech industry. In this project, the issue of the ability of Swedish industry to obtain patents in the US is explored and evaluated. The overall objective is to find ways to stimulate Swedish biotech industry on an international market<sup>114</sup>.

From December 2002 to the end of 2004, IVA is conducting a project called Science Generation. The objectives of this project are to identify and map attitudes towards biotechnology. The project will take a closer look at ethical issues related especially to aspects such as GMO and medical applications of gene technology.

IVA can be seen as one of the important proponents of biotechnology, in general, as well as of genetic engineering, in particular. This is not to say that IVA ignores the ethical and ecological impacts of these technologies, but the overall approach is one of technological optimism and a firm belief in the necessity of promoting the establishment of applied research in the field of biotechnology.

One way for IVA to fulfil its mission to promote and develop Swedish engineering and science is by hosting the Internet website [www.genteknik.nu](http://www.genteknik.nu). This website is one result of an earlier IVA project funded by, e.g., The Knut and Alice Wallenberg Foundation. A book was published concurrently with the launching of the website. Both the book and the website are directed towards young people, with the aim of piquing their interest in gene technology.

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113 Ibid.

114 Vinnova, årsredovisning 2001, p.1. These objectives are expressed also in the instructions from the government. See Regleringsbrev för budgetåret 2002 avseende Verket för innovationssystem, m.m. Näringsdepartementet 2001-12-20.

This website was designed to create a sort of interactive encounter with gene technology itself. The design conveys to the user a fascination regarding what the technique can do and the anticipated expansion of the scope of this technology in the future. The information is closely linked to ongoing research concerning cures for various hereditary diseases, stem cell research, cloning, and genetic modification of bacteria, plants and animals. As mentioned, it is very much the technique as such that is in focus on this website, as well as in the above-mentioned technological foresight project. The ethical, social, political, or indeed democratic or philosophical aspects of developing and implementing gene-technology are clearly regarded as secondary compared to promoting a general positive attitude in society towards these technologies. However, as argued above, IVA is not sidestepping these issues, but certainly incorporating them in a specific order of priority.

### Swedish Agency for Innovation Systems (VINNOVA)

Vinnova is a new and potentially powerful actor on the Swedish biotechnology scene. However, the objectives of Vinnova include a great deal more than just biotechnology.

Vinnova came into operation on January 1, 2001. Vinnova is the product of a merger of three R&D institutions: RALF, KFB and NUTEK. The funding that these three institutions had at their disposal has been taken over by Vinnova. Hence, Vinnova has an annual budget of 1 billion SEK<sup>115</sup>. Vinnova is a Swedish authority. Besides financing, monitoring, evaluating and developing Swedish innovation politics, Vinnova has other, more traditional duties usually associated with authorities, such as control and monitoring.

In the annual report from 2001, Vinnova's overall mission was defined as promoting sustainable growth for Swedish industry, society and working life. Development of effective systems of innovation was emphasized as yet another crucial task, as was financing applied research and development. Vinnova's activities should create a «measurable sustainable growth» and contribute to the development of new areas of industrial growth<sup>116</sup>.

In the area of biotechnology, Vinnova distributed a total of 125.8 million SEK in 2001; that is, before Vinnova was established in 2001, 68 million SEK had been linked to projects approved by FAS, KFB and NUTEK, which was transformed to the new Vinnova. These projects all lie within what Vinnova calls the FUD initiative, which is a program for research, development and de-

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115 Vinnova, årsredovisning 2001, p.4.

116 Ibid. p.14, 15 & 16.

monstration (program för forskning, utveckling och demonstration). A number of new programs were initiated during 2001. The figures concerning the program 'biotechnology' are as follows. In 2001, Vinnova received 43 applications focussed on biomedicine, 31 on bioprocesses in industrial productions and 76 on innovative foodstuff. Vinnova approved 4, 9 and 17 applications from these three categories, respectively. A total of 13.9 million SEK was granted<sup>117</sup>.

125.8 million SEK spent on biotechnology is a significant sum of money in Swedish research and development. As Vinnova accelerates its funding activities in the future, without being limited by the obligations it inherited from FAS, KFB and NUTEK, this amount is likely to increase.

In the context of the Compass project, it is interesting to note that Vinnova is not financing only research and development in the area of biotechnology. In order for a project to be of interest to Vinnova, it must have a clear industrial potential. This potential is evaluated in the context of an overall theory about the nature and scope of technological innovation<sup>118</sup>. It is argued that innovations are basically a «transformation of knowledge to new products and services, processes and work procedures.» Innovation systems, it is argued, consist of networks of organizations, people and norms that constitute the necessary framework for creating, distributing and exploring technology and knowledge<sup>119</sup>. Innovation, it is argued, is about reciprocal learning and the integration of a number of different areas of politics. This complexity, Vinnova argues, can be taken into consideration by applying a «system perspective»<sup>120</sup>. In order to bring together the overall theory of innovation and empirical studies, Vinnova has initiated a number of projects dealing with biotechnology and the dynamics of innovation systems<sup>121</sup>. In the annual report for the year 2001, it is argued that the *triple helix* (as part of or as the expression of the system perspective) is now influencing all FUD programs<sup>122</sup>.

All in all it seems reasonable to conclude that Vinnova is potentially a very influential actor on the Swedish biotechnology scene. The strength of Vinnova as a leading actor in the field of biotechnology is emphasized in its ambition to co-operate with other research funding institutions and authorities such as For-

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117 [www.vinnova.se/innovations/bakgrund.htm](http://www.vinnova.se/innovations/bakgrund.htm) 24/5 2002.

118 Ibid. p.1.

119 Ibid.

120 [www.vinnova.se/forskning/innsys/projekt/pågående%20projekt.htm](http://www.vinnova.se/forskning/innsys/projekt/pågående%20projekt.htm) 24/5 2002

121 Vinnova, årsredovisning 2001, p.2. Triple Helix means the integration of research, industry and politics/ authorities.

122 Ibid. p.5.

mas and the Swedish Research Council<sup>123</sup>. I shall discuss these two in the sections below.

### The Swedish Research Council (VR)

In 2000, the Swedish parliament promulgated a new act on the organization of the Swedish financing system for *basic research*. By January 1, 2001, The Swedish Research Council began its work. The Research Council replaced four previous research councils<sup>124</sup>. The new structure in Sweden resembles the structure for financing basic research that Norway has had for a number of years. The total amount distributed by the research council in 2002 was more than 2 billion SEK; of this amount, 700 million SEK or approx. 35 % was distributed to the natural and technological sciences. Life Science and biotechnology is one among 8 areas in the field of natural and technological sciences. Biotechnology could expect to receive approx. 80–90 million SEK per year.

As mentioned, the research council is entirely devoted to financing basic research. The objectives of the research council are strictly to identify and promote the most outstanding research in Sweden. But the research council is also obliged to identify possible ways to promote and finance cross-disciplinary research.

The research council is potentially a very powerful actor in Swedish biotechnology. It is still too early to say what part that the council will play. Thus far we have seen one example of the discursive power that the council can exercise in the case of the ethical issues related to stem cell research. The council concluded that research on stem cells derived from embryos created for IVF treatment that proved not to be suitable, or for other reasons no longer necessary for the treatment, should be allowed<sup>125</sup>. The council ruled out the possibility of deriving stem cells from embryos created solely for research purposes and from embryos created through therapeutic cloning. The reasons for not allowing the latter as sources for obtaining stem cells are based on legal as well as ethical considerations. It should be mentioned that the research council announced on March 21, 2002 that it intended to grant 75 million SEK to Swedish stem cell research. Fifty million came from the American NGO, The Juvenile Diabetes Research Foundation. Twenty million was contributed by the research council and 5 million by the Swedish Diabetes Research Fund<sup>126</sup>. The action taken by VR when

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123 [www.vr.se](http://www.vr.se) 24/5 2002.

124 [www.vr.se](http://www.vr.se) pressmeddelande 12/4 2001: Klart med etiska regler för svensk stamcells forskning.

125 [www.vr.se](http://www.vr.se) press release 21/3 2002: 75 million SEK for Swedish Stem cell research.

126 These figures are based on my own assessment of figures found on [www.vr.se](http://www.vr.se).

ruling in favour of stem cell research as well as the granting of 20 million SEK to this research is a clear indication of its ambition to promote Swedish biomedicine. It is interesting that in this case VR is both carrying out normative judgements and funding the research in question. The research council distributed a total of 1.7 billion SEK in 2002 to be used during the period 2003–2005. Besides stem cell research, the council financed 28 projects in 2003 within gene technology and biotechnology. The majority (27!) of these projects are in the natural sciences. Approximately 60 million SEK was granted to these projects<sup>127</sup>.

### The Swedish Research Council for Environment, Agricultural Sciences and Spatial Planning (FORMAS)

FORMAS is yet another new research council in Sweden, which has a certain impact on the promotion and funding of biotechnological research and knowledge production in Sweden.

Like VR and VINNOVA, FORMAS began operations on January 1, 2001. FORMAS is formally a part of the ministry of the environment. However, it is regulated by both the ministry of the environment and the ministry of agriculture<sup>128</sup>.

In 2002, FORMAS distributed a total of 254 million SEK for 200 projects for the period 2003–2005<sup>129</sup>. In 2002, only 3 projects in biotechnology received funding amounting to a total of 8.1 million SEK. However, in 2001, the Swedish government decided to contribute 20 million SEK to interdisciplinary research within the framework of FORMAS. FORMAS eventually decided to launch a program on Risk and Risk assessment – The Development of Biological and Agricultural Sciences. Twelve million SEK was distributed within this program and divided among 4 projects. Two of these projects dealt with GM crops, one with genetically modified trees, and the other with using micro-organisms to control pathogen fungus<sup>130</sup>.

In the context of Swedish biotechnology, FORMAS is, and will increasingly be, an important resource for the promotion of interdisciplinary research. Whe-

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127 FORMAS receives two spending authorizations (regleringsbrev). The one from the ministry of agriculture regulates only the use of approx. 5.7 million SEK for purposes directly under the jurisdiction of the ministry of agriculture.

128 [www.formas.nu/presmeddelande/26/11/2002](http://www.formas.nu/presmeddelande/26/11/2002): Formas delar ut 254 miljoner till frontforskning för hållbar utveckling.

129 [www.formas.se/presmeddelande/7/5/2002](http://www.formas.se/presmeddelande/7/5/2002): 12 miljoner till forskning om risker med GM-växter.

130 Regleringsbrev för budgetåret 2002 avseende Forskningsrådet för miljö, areella näringar och samhällsbyggande. 20/12 2001. P.2.

reas VINNOVA is heavily oriented towards applied research and VR focuses entirely on basic research, FORMAS occupies an intermediate position. The research projects funded by FORMAS can be categorized as both applied and basic. In the spending authorization dated 20/12 2001 from the ministry for the environment, it is explicitly stated that FORMAS should promote research that could increase the role of research in Sweden's overall competitiveness. However, at the same time it is stated that the research funded by FORMAS should be an expression of the highest scientific standard. A crucial task for FORMAS in fulfilling these obligations is to assess and prioritize interdisciplinary research and to help construct the necessary intellectual and structural framework for such research<sup>131</sup>.

### The Foundation for Strategic Environmental Research (MISTRA)

Mistra is one of the research foundations created in 1993 when the conservative government led by the Moderate Party in coalition with the Liberal Party redistributed the capital in the wage-earners' investment funds into three new research foundations. SSF, which I will discuss below, was one of the three foundations. Mistra was granted 2.5 billion SEK, which by the year 2000 had grown to 4.8 billion SEK due to developments on the stock market. MISTRA contribute 250 million SEK per year to various research programmes<sup>132</sup>. The research funded by MISTRA comprises large programs that run for 4–5 or more years and include researchers from various disciplines. One crucial objective for MISTRA is to contribute to concrete solutions to environmental problems.

As this report is being written (May 2003), MISTRA is in the process of evaluating a number of new programs dealing with «The New Biology». Some of the programs that will eventually receive funding are likely to focus on various applications of biotechnology including risk and ethical issues.

Mistra can, and will be I believe, a very significant actor in Swedish biotechnology research. The most interesting feature of the MISTRA program, but also one of the most problematic in many ways, is its ambition to create interdisciplinary research groups. This has the potential to generate new and exciting knowledge on, e.g., the discursive translation of scientific findings into a legal and political context. However, MISTRA still has a long way to go before its in-

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131 Mistra Annual Report 2000. P.3.

132 Malin Mobjörk at the department of Water and Environmental Studies, Linköping University is currently writing her Ph.D. thesis on Mistra.

terdisciplinary ambition will result in new ways of conducting research. But the potential is great<sup>133</sup>.

### Swedish Foundation for Strategic Research (SSF)

As mentioned above, SSF was created in the process of transforming wage-earners' investment funds into research funds. SSF was granted 6 billion SEK, or 60 % of the total sum redistributed for research purposes<sup>134</sup>.

Like MISTRA, SSF only funds large research programs, PhD programs or graduate programs. SSF has thus funded, e.g., six research training programs at the universities in Lund, Göteborg, Linköping, Stockholm, Umeå and Uppsala in the field of biomedicine and bioscience. The list of projects and programs funded by SSF in the life sciences is comprehensive, and the amount of money distributed each year is approx. 1 billion SEK. The life sciences account for approx. a third of this. Like MISTRA, SSF is authorized by the government to successively distribute the entire capital in the foundation to research purposes. SSF has estimated that the capital at its disposal will last until at least 2020<sup>135</sup>. A similar estimation has been made for MISTRA.

In the context of the Compass project, it is important to note that SSF has been one of the main funding authorities behind the Swedish ELSA program. ELSA deals with the ethical, legal and social aspects of genome and gene technology research and was formally established in 1999. ELSA has primarily focused on financing doctoral and post-doctoral research as well as seminars and conferences. At least 10 research projects of a duration of 2–3 years each have been funded by ELSA. Despite ELSA's relatively limited financial means, I believe it has been a very significant initiator of research activities as well as a broader public debate on biotechnology in Sweden. Presently (May 2003) it is quite unclear what role and what scope ELSA activities will have in the future.

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133 [www.stratresearch.se/fcreat.htm](http://www.stratresearch.se/fcreat.htm)

134 [www.stratresearch.se/programblad](http://www.stratresearch.se/programblad)

135 These positions can be exemplified through the work of Maarten Hajer (1995): *The politics of Environmental Discourse*. Oxford University Press. And Timothy W. Luke (1997): *Ecocritique – Contesting the Politics of Nature, Economy and Culture*. University of Minnesota Press.

## Environmental organizations: Greenpeace, Swedish Society for Nature Conservation and Friends of the Earth Sweden

Greenpeace (GP), Swedish Society for Nature Conservation (SNF) and Friends of the Earth Sweden (MJV) represent three rather distinct organizational and political cultures. One could argue that SNF is more an expression of ecological modernization, whereas GP and MJV represent a tradition of *radical ecology*<sup>136</sup>.

Greenpeace, for instance, has for a number of years been engaged in a campaign against GMO crops in Sweden. The criticism has been directed mainly towards the risk of GMO contamination of crops and soil. Greenpeace has been especially critical of the fact that no environmental impact analysis (EIA) is required for GMO field trials. The problem, according to Greenpeace, is that these field trials correspond with the definition in the environmental protection act (Miljöbalken kap.6) of activities requiring an EIA before approval. I have no information about whether this critique holds despite the new directive 2001/18/EG.

SNF has run a similar campaign in Sweden for a number of years. SNF has stressed not only the contamination issue, but also the problem of whether, e.g., genetically modified rice is a prudent solution to the lack of sufficient high quality food supplies. SNF has argued that GMO tends to consolidate the conventional and pesticide-dependent agricultural system of production, instead of promoting new and more ecologically sound modes of production. They also point out that most of the GMO crops grown in developing countries are soybeans and maize, which are exported to be used, e.g., as animal feed in Western countries. SNF has been important in voicing the opinion that GMO should not be rejected all together, and that we need more research on contamination risks, better risk assessment instruments as well as development of alternatives to GMO solutions<sup>137</sup>.

On September 29, 1999, Friends of the Earth Sweden launched a campaign demanding a five-year ban on genetically modified organisms and crops<sup>138</sup>. The strategy adopted by MJV has been much more confrontational than that adopted by SNF. The campaign for a five-year ban on GM was explicitly designed to challenge senior politicians and industry at a number of public mee-

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136 [www.snf.mondosearch.com](http://www.snf.mondosearch.com)

137 [www.mjv.se/matt/stopp](http://www.mjv.se/matt/stopp)

138 MJV remissvar på EU kommissionens förslag til ändrat direktiv om genmanipulerade organismer. 28/4 1999. P.4 ([www.mjv.se/jordbruk/gmo.html](http://www.mjv.se/jordbruk/gmo.html))

tings. The campaign attracted some attention in Sweden and contributed to bringing about a public debate on GM crops and food. It is obvious when one reads through the material provided by MJV that their approach to GMO is not only a question of risk and the need for further research. The critique goes beyond this, and argues for a new economic system in which the production of food is determined by a logic that is essentially non-capitalistic. MJV argues that the socio-economic aspects of GM crops and food production must be included in the scientific evaluation of risks – a standpoint that the EU commission could not accept in the preparatory process of the new directive 2002/18/EG on deliberate release of GMO<sup>139</sup>. In a response to SOU 2000: 103, which I have discussed elsewhere in this report, SNF argues that the notion of risk provided in this committee report is too narrow to provide any clarity or guidance<sup>140</sup>. SNF restricts itself to arguing that risk research must be improved both qualitatively and quantitatively before large-scale use of GMO can be accepted.

It is fair to argue that both Greenpeace and MJV, but most of all SNF, have been essential for stimulating a public debate in Sweden on biotechnology, especially in the area of GM food and the use of GMO in agriculture.

In the last section of this paper, I will concentrate on two very important actors in Swedish biotechnology: the pharmaceutical and the plant breeding industries.

## Pharmaceuticals and agrobiotechnology

The biotech industries in Sweden can be categorized as follows: Pharmaceuticals, Agriculture, Food, Chemistry, Environment and Forestry/Pulp & Paper<sup>141</sup>. It is within these sectors than one can expect to find biotechnology activities. Sweden has important biotech activities in all of these sectors. However, the dominant sector in terms of turnover and number of employees is the pharmaceutical sector. Hence, it is natural to concentrate on this sector. However, I shall also comment on the plant-breeding sector (included in the agricultural sector), as the introduction of GMO into agriculture and food production plays a significant role in Sweden. At the same time, it is an application that has been heavily debated, unlike the pharmaceutical applications of biotechnology,

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139 SNF remissvar: Att spränga gränser – Bioteknikens möjligheter och risker. p.2. 25/10 2000.

140 The Swedish Biotechnology Innovation System. VINNOVA innovation in focus VF 2001:2. p.2.

141 The special advertising section amounts to a total of 16 pages. Five pages are devoted to an article dealing with the structure of collaborations in Swedish biotech.

which seem to be imbedded in a widespread consensus on the necessity of that kind of research and development.

### Pharmaceutical Industry

Swedish biotech industry, in general, and the pharmaceutical industries (biotech-pharma), in particular, are very concerned about showing the outside world that Swedish biotech is at the forefront of research. Supported by IVA and VINNOVA (see sections 4.1 & 4.2), the entire Swedish biotech industry produced a special advertising section in the journal *Scientific American* in 2002. Here, as elsewhere, IVA and VINNOVA emphasized that the main reason why Sweden has become a «force in biotech» is «the science of collaboration,» as is stated in the title of the introductory article<sup>142</sup>. Collaboration between academia, industry and authorities in combination with a strong public health sector is repeatedly emphasized as being the main ingredients in the Swedish success story.

One important aspect of the dynamics of the Swedish biotech-pharma sector is the geographical clusters of biotech industry, universities, hospitals and venture capital in the Stockholm/Uppsala region and in the Lund/Malmö/Copenhagen region, the latter named Medicon Valley. The Medicon Valley concept was established in 1993 and based «...on the observation that Öresund was home to 60 % of all Nordic pharma companies, 11 universities and 26 hospitals.../...Now the region is home to about 101 biotech companies, more than 70 pharma companies and 32 venture firms»<sup>143</sup>. There is no doubt that Medicon Valley rests heavily on the assumption of the dynamic effects of collaboration and co-location. It should be mentioned that Medicon Valley is the result of a new kind of entrepreneurial initiative in which industry, universities, hospitals and venture firms are connected in networks emerging around concrete research and development projects. The role of the state is that of an actor among other actors, that is, the state is not the primary force for integration of these diverse actors. Rather, *integration* in this case should be comprehended as the result of complex interactions between numerous independent decision-making centres. The role of the state becomes that of the provider of frameworks and procedures (legal, political etc.), not of terms, contents and outcome

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142 Ludger Wess: Northern Lights. *BioCentury*. The Bernstein Report on Biobusiness. August 5, 2002. p.5.

143 This argument is inspired by Mats Benner's concept of 'post-academic research' politics in Mats Benner (2001): *Kontrovers och konsensus – vetenskap och politik i svensk 1990-tal*. SISTER rapport 1. This argument are based also on the analyses of the altered relationship between state-marked, public-private in Ove K. Pedersen, Niels Å. Andersen, Peter Kjær & John Elberg (1992): *Privat Politik*. Samfundslitteratur.

of collaborations between actors in this field. Naturally, this 'situation' has consequences for the possibility of formulating research and technology politics in the first place. However, within the framework of this report, I cannot elaborate on this argument<sup>144</sup>.

In the Stockholm/Uppsala region, the Karolinska Institute (KI) is the major biotech institution. KI is at the moment the largest biotech research and development facility in Scandinavia. Even in a European comparison, KI is one of the major centres. These clusters are very important, as they support the creation of new forms of collaboration between companies and academia, etc. However, it is evidence that:

*«Geographic co-location does appear to be important for one cohort, namely smaller biotech-pharma firms located in regions of strong medical research»<sup>145</sup>.*

McKelvey et al. argued that biotech-pharma is «exceedingly global in terms of both knowledge and markets for R&D collaboration,» but at the same time dependent on a local structure for knowledge development, that is, to create new ideas «...and to reap the economic rewards through innovations»<sup>146</sup>. Research carried out in Sweden suggests that the agreements between firms involving co-development of technology are «...most likely to be between a Swedish firm and a Swedish university, indicating the probable importance of having a strong national basic scientific community»<sup>147</sup>. The establishment of clusters of biotech-pharma actors has been heavily promoted over the past decades in Sweden. The quoted research suggests, however, that these clusters are of decisive importance for a certain type of company and benefit a certain kind of collaboration. The powerful clusters do not constitute the solution to all problems concerning biotech-pharma, but rather an important solution to a certain set of problems specific to small and medium-sized companies.

The Journal *BioCentury* published in its August 5, 2002 issue an article entitled 'Northern Light'<sup>148</sup>. The overall argument in this article is that the Swedish success story has been brought about not through huge state funding but through «...the initiative of determined science managers in Scandinavia's re-

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144 Maureen McKelvey, Håkan Alm & Massimo Riccaboni: Does Co-location matter for Formal Knowledge Collaboration in Swedish Biotechnology-Pharmaceutical Sector? 2003 Manuscript in press. p.21.

145 Ibid. p.22.

146 Ibid. p.24.

147 Op.cit. *BioCentury*. August 5 2002. p.1.

148 Ibid.

search institutions and the efforts of experienced pharmaceutical industry executives»<sup>149</sup>. Again, it is the collaboration between various actors that is the key to explaining the extraordinary growth in the Scandinavian biotech-pharma industry. The editor Ludger Wess enthusiastically described the Swedish situation, for which «Stockholm-based Karolinska Institutet is the paradigmatic case»<sup>150</sup>. In this case, much of the credit goes to one individual – Hans Wigzell. Wigzell is quoted as saying that because the mission of KI is to improve human health in general it would be «...unethical not to commercialize and apply the basic research performed in the KI labs»<sup>151</sup>. The commercialization that Wigzell mentioned came about in 1995 when the government allowed universities in Sweden to set up commercial enterprises. KI established KI Holding AB in order to start this process. Under this umbrella, two centres were established. One was the technology transfer unit Karolinska Innovations AB (KIAB), and the other the Centre for Medical Innovations (CMI)<sup>152</sup>. Based on the investment of five venture investors, KI created a fund (Karolinska Fund) with a total of \$50 million in capital<sup>153</sup>. Besides allowing the universities to form commercial enterprises, the 1990s also saw another very important development that affected Sweden's ability to boost its biotech-pharma industry, namely the change in rules concerning the pension funds, and the restructuring of the research financing system in Sweden during the period 1994–1998<sup>154</sup>.

In the late 1990s, the rules for pension funds were eased in Sweden. The immediate result was that a tremendous amount of money poured out onto the market in a search for investment opportunities. The reform that started in 1998 and was finalized in 2001 included a «...significant liberalisation of the investment rules for the funds of the National Pension Insurance Fund so that about 70 % of the assets can be invested in equities»<sup>155</sup>. The result of this change was that the amount of money available increased tremendously. At the same time there was a 'biotech hype' in Sweden, which canalized a large amount of the freed capital to the biotech-pharma sector. The political or rather ideological change in the Swedish pension politics has played a decisive role in providing

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149 Ibid.

150 Ibid.

151 Ibid.

152 Ibid.

153 Ibid. p.2. See also Op.Cit. Mats Benner (2001). p.90-166.

154 Op.cit. BioCentury. p.3.

155 Ibid. p.3 The amount of venture capital increased in Sweden from approx. 20 billion SEK in 1990 to approx. 200 billion SEK in 2000, according to Swedish Venture Capital Association.

good financial circumstances for hundreds of new biotech-pharma and other biotech companies in Sweden<sup>156</sup>.

It is safe to argue, however, that the single most important factor in the Swedish biotech-pharma industry boom is the existence of the companies Astra and Pharmacia. Pharmacia merged with Upjohn in 1995 and with Monsanto in 2000 and formed Pharmacia Corporation. Astra in turn started collaboration with the US-based Merck & Co in 1996, and in 1999 Astra merged with British Zeneca to form AstraZeneca<sup>157</sup>. Large portions of new Swedish companies in the biotech-pharma sector can be traced back to these major companies in terms of products, staff and management. One way of measuring the importance of Astra and Pharmacia is to look at the number of papers in biotechnology-related science co-published by Astra and Pharmacia with other Swedish organizations. These figures reveal that there is very close collaboration between Astra, Pharmacia and the public research organizations. During the period 1986 to 1997, Astra published a total of 498 papers with Swedish universities. During the same period, Pharmacia published a total of 580 papers, and they both published 13 papers with other firms, five of which were published as a result of collaboration between Astra and Pharmacia<sup>158</sup>.

The growth of the Swedish biotechnology industry including the biotech-pharma sector has been 400–600 % over the past decades. In 1996, the industry had a turnover of 120 billion SEK and employed 75,000 people worldwide<sup>159</sup>. The growth has continued although, at a slightly slower pace.

In Sweden, 80 % of all biotechnology companies have between 1 and 50 employees. Only 2.1 % or 3 companies have more than 500 employees<sup>160</sup>. The total number of companies in Sweden in 1999 was 144, of which 141 firms were categorized as micro-sized (81), small-sized (58) or medium-sized (2)<sup>161</sup>. Still a very large portion of the growth in turnover derives from the large companies. Vinnova argued in their survey report that despite this fact, it is highly pertinent to look after and support the many smaller companies, due to their potential in terms of product and process innovations.

In many ways, the Swedish biotech-pharma industry is a success story in terms of innovations, investments, increased turnover and the number of employees in this sector. Simultaneously, this development also poses a number of

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156 Op.Cit. Vinnova Innovation in Focus VF 2001:2. p.13-14.

157 Ibid. p.132 Table B8.

158 Ibid. p.27.

159 Ibid. p.24.

160 Ibid. 23-24.

161 Ibid. p.38ff and p.113 Table A1.

challenges for the future. In the Vinnova report quoted above, it is argued that the interfaces between firms and universities are still muddled by bureaucratic procedures and problems of creating linkages between certain industry interests and appropriate academic research. Another critical issue mentioned in the Vinnova report is the question of how to maintain a high educational level in the technical and medical fields.

After this brief exposé of the Swedish biotech-pharma industry, I will provide a short account of the agro-biotech sector in Sweden. This sector amounts to only 8 companies, with a turnover of only 603 million SEK in 1999, which was actually a decrease by 6.4 % since 1997<sup>162</sup>. However, it is still an important industry and has been in Sweden for quite some time. Above all, agrobiotechnology is considered to have a great future potential. One obstacle to the development of this group of firms has been the unclear legal situation in the EU area concerning deliberate release of GMO into the environment. With the new directive 2001/18/EG on deliberate release, this situation could change. However, this remains to be seen.

### Agrobiotechnology

A number of major players in the field of plant breeding are active in Sweden. Just as in biomedicine, the application of gene technology in plant breeding is regarded as an important area of research and development in Sweden. However, whereas the application of gene technology in the development of pharmaceuticals and new diagnostic methods is generally conceived of as positive, the introduction of genetically modified seeds and crops has caused a tremendous critical debate on, e.g., the ecological, economic and social impact of the application of genetic technology. In this regard, Sweden is not different from many other countries. The significance of the situation in Sweden is that Sweden has a comparatively large and advanced industry both in the field of biomedicine and in the field of plant breeding. Hence, the ways in which the conflicts regarding genetic technologies are handled internationally as well as domestically do have an economic impact on Sweden.

The commercial activities concerning research and development of GMO plants and crops in Sweden have been marked by a decrease over the past 3–4 years. According to the Swedish Board of Agriculture (jordbruksverket), in 1998 the total area used for field trials on various genetically modified potatoes was 345.2 hectares. For sugar-beets the total area was 1.3 hectares, and for rape

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162 Jordbruksverket. [www.sjv.se/net/SJV/Startsida/Ämnesområden/24/5/2002](http://www.sjv.se/net/SJV/Startsida/Ämnesområden/24/5/2002).

6.7 hectares. These figures increased during 1999, especially concerning field trails on genetically modified potatoes with enhanced starch production, which increased to a total area of 336.15 hectares. During the years 2000 and 2001, the total area used for field trails diminished. By 2002, the area used for various field trails in Sweden was 4.28 hectares for potatoes, 0.24 hectares for sugar-beets, 8.51 hectares for rape, and 140 square metres for other crops<sup>163</sup>. Field trails with rape have been on a stable, but low, level during the period 1998–2002. These figures indicate a somewhat reluctant attitude on the part of various companies to engage in the development of genetically modified crops. One obvious reason for this is the unclear situation regarding the future of GMO in Europe caused by the de-facto moratorium on the approval of new genetically modified crops and foodstuff in Europe<sup>164</sup>.

The field trails in Sweden have been carried out by the following companies:  
Amylogene (a company owned by Svalöf Weibull and the Swedish producers of starch in southern Sweden)  
Svalöf Weibull, Plant Science Sweden.  
Aventis, Plant Genetic Systems.  
Syngenta, Novartis.

It is a significant feature of the biotech companies that there has been a strong tendency to merge into larger units. One example of this is the company Hilleshög, which carried out field trails on sugar beets and rape from 1989–1997, and which was bought by Novartis in 1998. Syngenta eventually bought Novartis in 2001. In the annual report from Syngenta 2001, it is stated that the company's merger «...is largely complete and the delivery of synergies on track»<sup>165</sup>. Another example is Svalöf Weibull, which has merged with the German company BASF. Until 1998, Svalöf Weibull was owned by a cooperative of Swedish farmers. In 1998, the Canadian market for rape seed, which was crucial to Svalöf Weibull, was drastically diminished by the introduction of GMO rape from competing companies. BASF took over 40 % of Svalöf Weibull and a joint company called Plant Science Sweden was established. A sum of 7 billion SEK will

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163 The moratorium was a consequence of a meeting of the European ministers of the environment in Luxembourg in June 1999 regarding the revision of directive 90/220. Some countries (e.g., France, Greece and Denmark) argued in favour of a moratorium, and six countries argued in favour of an extremely restrictive policy for approval of new GMO products. The consequence was that the de facto stop for approvals of GMO products that had been practised in the EU since 1998 would continue until the new directive (2002/18 which came into effect in October 2002) had passed the commission and the EU parliament. See Nyhetsbrev från LRF om internationella frågor. No.22 2/7 1999. p.1-2.

164 Syngenta Annual Report 2001. p.3.

165 Årsöversikt 2001 Svalöf Weibull p.24-28.

be invested in this company during the period 1998–2008. The goal is clearly to become a major player on the global market for genetically modified seeds<sup>166</sup>.

From 1991 to 2002, a total of 31 field trails concerning potatoes have been carried out in Sweden. The company Amylogene conducted 24 of these. Plant Science Sweden and BASF plant science conducted 5 trails and The Swedish Agricultural University and Lund University one trail each.

A total of 36 field trails have been conducted on rape in the period 1989–2002. Aventis conducted 17 and Svalöf Weibull 12. The Swedish Agricultural University carried out two. Various small companies and actors carried out the rest.

As regard sugar-beets, a total of 17 field trails have been carried out from 1993 to 2002. Syngenta (former Hillesehg/Novartis) carried out all of these 17 trails<sup>167</sup>.

In an interview that I conducted with vice director and chief of the plant breeding section at Svalöf Weibull, Anders Nilsson, in June 2002, he anticipated a renewed growth in the development and introduction of new genetically modified seeds and plants when the European moratorium was lifted. The event that Nilsson was waiting for was the new EU directive on deliberate release of genetically modified organisms 2002/18/EG. The new directive came into effect on October 17, 2002, and the moratorium has actually been lifted as a consequence of this<sup>168</sup>. However, in Sweden, as well as, e.g., in Denmark, the next hurdle to overcome is the conflict between conventional and ecological agriculture concerning the environmental and ecological prospects of using, e.g., genetically modified seeds<sup>169</sup>. The future of genetically modified seeds and plants in Sweden is by no means likely to be free from tensions and frictions between various interest groups.

## Continuity and dependency

As this report meets its deadline, VINNOVA published a new report on Swedish Biotechnology as a follow up to the 2001 study quoted in the previous section<sup>170</sup>. I have not had the opportunity to study this report in detail. However,

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166 Op.cit. [www.sjv.se](http://www.sjv.se) 24/5 2002.

167 The new directive regulates the labelling and tracing issue, which was the primary reason why a number of European countries voluntarily introduced a moratorium in order to ease the harsh critique of the handling of GMO expressed by a large number of consumer and environmental organizations.

168 This conflict was evident in a hearing on genetic technology in food production, conducted by Danish Radio on October 28, 2000 and initiated by a committee on genetic technology and society, of which I was a member, within The Danish Academy of Technology and Science.

169 Anna Sandström & Lennart Norgren: Swedish Biotechnology. VINNOVA Analysis VA 2003:2.

170 Ibid. p.6.

judging from the general conclusions and figures, the picture is similar to that presented in the 2001 report. In this respect continuity seems to be the dominant feature of Swedish biotechnology. However, some changes have occurred.

The total number of biotech companies with less than 500 employees has increased by 35 % between 1997 and 2001 to a total of 183 companies. Likewise, the numbers of employees has increased by 48 % to about 4000 employees. The turnover also increased by more than 30 % between 1997 and 2000, amounting to approx. 4.4 billion SEK in 2000<sup>171</sup>. Now, this seemingly positive tendency is reported by VINNOVA to have a darker backside.

It is concluded that the growth in number of employees and turnover is not financed by profits generated in the companies, but by an infusion of venture capital<sup>172</sup>. In general, the growth of the biotech industry is hampered by the very limited amount of venture capital and seed financing capital. This of course increases the industry's dependency on venture capital firms, seed financing companies and public authorities.

The regional concentration of Swedish biotechnology to Uppsala/Stockholm, Göteborg, Lund/Malmö continued between 1997 and 2000. The collaboration between industry and universities in these cities is increasingly important. Linköping is mentioned as an up-and-coming region for life science with potential for establishing biotech companies.

Finally, the sector agrobiotechnology has shown less impressive growth compared to biotech-pharma companies. However, despite stagnation in the agrobiotech sector, this sector could report net profits each year. In other words, there is no seed capital or venture capital dependency in this sector<sup>173</sup>. The stagnation in agrobiotechnology is due to consumer resistance and therefore a problem of expanding the market for, e.g., GMO crops.

Despite this somewhat disturbing picture of the current situation in Swedish biotech industries, according to VINNOVA, the future perspectives for Swedish biotechnology remain very optimistic.

## Concluding remarks

A struggle with four interrelated sets of problems has marked the politico-legal governance of biotechnology in Sweden:

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171 Ibid. p.75ff.

172 Ibid. p.50-51.

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1. There is a consensus in Sweden that ethics are needed in the legal regulation of biotechnology. On the other hand, however, it has been unclear what status ethical norms should enjoy and from what sources they should be derived.
2. There are conflicting political interpretations of how comprehensive and all-encompassing the legal regulation should be.
3. Recently, the biotechnology committee argued that the political and democratic implications of biotechnology have not been sufficiently analysed and dealt with in Sweden. In order to remedy this, the committee suggested that Sweden should form a new authority responsible for the entire range of biotechnological applications. It was also suggested that Sweden form a new technology assessment body to improve the accountability and appropriation of biotechnology.
4. Swedish governance of biotechnology is characterized by the co-existence of two modes of governmentality: a) one that celebrates innovation as a virtue in its own right, and b) one that strives to improve the accountability of biotechnology by improving the public understanding of science and technology.

There is in Sweden today a huge number of research councils, biotech and venture capital firms, university departments, hospitals and authorities, all of which are involved in developing the innovation capacity and commercialization of biotechnology. Sweden has experienced a tremendous increase in venture capital, new biotech firms and new collaborative networks. Today, Sweden is among the leading nations in the biotech-pharma sector. The expansion can be explained partly by the presence of Astra and Pharmacia, which have served as locomotives for the development of the biotech industry in Sweden. This dependency can be considered an advantage in some respects, but it also contributes a certain vulnerability to the entire biotech system in Sweden. Another explanation for the growth in the Swedish biotech industry is the structural changes in pension funds and wage-earners' investment funds in 1990s. These changes were important prerequisites for the increased availability of investment capital.

It is a characteristic feature of the situation in Sweden that the role of the state throughout this process has been continuously redefined. The landscape of biotechnology governance has changed. On the one hand, the state has lost influence, as the dynamic of the sector is based on networks, projects and negotiations in which the state is only one actor among others. On the other hand, the

new research councils described in section 4, in combination with the fact that university-based research is crucial to the development of the entire sector, leave the state a crucial role in the governance of biotechnology. The governance of Swedish biotechnology is a good example of a broader tendency in Sweden towards a research policy defined by what Benner (2001) called post-academic ideals. These ideals imply that, e.g., commercial, macro-economic, social and political ideals are introduced *on par* with more 'traditional' academic ideals in the governance of biotechnology. The absence of an analysis of what this means for democracy and scientific citizenship is striking in contemporary Sweden.

This ambiguity is probably one of the reasons why the biotechnology committee called for a coherent and comprehensive biotechnology politics.

The role of citizens in the Swedish 'biotech hype' is unclear. The biotechnology committee attempted to bring the question of the citizens onto the political agenda of biotechnology. However, we have not yet seen a political response. Swedish biotechnology therefore remains captured in a field of tension between conflicting modes of appropriations of biotechnology. This 'situation' calls for further research on modes of appropriation through, e.g., detailed case studies.

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