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## 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This remained the general regulatory model also after the NAVF committee was superseded in 1981 by the permanent Committee for the Control of Recombinant DNA Research under the Ministry of Health and Social Affairs.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>1</sup>, all of which were involved in basic and (to a lesser extent) applied

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<sup>1</sup> 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).

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 new biotechnology. All projects related to the injection of growth hormones in salmon 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 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>2</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

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<sup>2</sup> § 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. ']

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 Ministry 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 legitimacy. 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 have 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>3</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 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>4</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>5</sup>, and to form alliances between private and public venture capital for investing in the new, knowledge-intensive industries.<sup>6</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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<sup>3</sup> See, for example, ‘PhotoCure – et lysende norsk eksempel til etterfølgelse’ [‘PhotoCure – a shining Norwegian example for others to follow’], *Genfalt*, 2/2001, pp 11-13. In 2003 Photocure was awarded the ‘innovation prize’ of the Confederation of Norwegian Business and Industry (NHO)

<sup>4</sup> This means that the Norwegian share of applications for biotechnology patents is far below the Norwegian share of patent applications in all technologies.

<sup>5</sup> 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.

<sup>6</sup> 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.

### *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.

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*, Norway's largest newspaper.

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>7</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

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<sup>7</sup> I.e., R&D expenditure as percentage of total national Gross Domestic Product

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 a means to develop this traditionally strong Norwegian sector into a knowledge-intensive industry.

The Research Council has consolidated its role as the embodiment and portrayer 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 narrative within which the Research Council should define its operational role<sup>8</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

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<sup>8</sup> '[...] 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 'endgame', but one which will take a very long time to reach' (Arnold et al., 2001).

the political process of passing the bio-/gene technology acts was 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 patents 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 forward 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, rejecting 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 biodiversity 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 establishing 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 comparatively 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 the 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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