Governing GMOs in the EU: A Deviant Case of Environmental Policy-making?

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The central question addressed in this study is how one of the world's strongest and fastest growing sectors—the biotech industry—has seemingly been without influence in the EU's efforts to regulate genetically modified organisms (GMOs), despite the mainstream view of environmental policies that "if an agreement cannot be crafted that gains the consent of the major affected industries, there will likely be no agreement at all."[1] A related, general view claims that EU environmental regulations hardly affect the behavior of the industrial actors.[2] The European biotechnology sector is engaged in heavy competition with its American counterpart, making the industry's ineffectiveness in influencing the EU's GMO policy even more puzzling.

Along with several other OECD countries, the EU aspires to maintain a leading role in the development of new biotechnologies.[3] The policies regulating this sector, most particularly in the area of agri-biotechnology, vary significantly from country to country. The USA has an open market to most agri-biotech products and processes.[4] About 75 percent of soybeans and a third of the corn grown in the USA come from genetically modified (GM) seeds. In contrast, the EU has allowed the release of only a handful of GM plants and has had a de-facto moratorium in place on commercial releases of new GMOs since 1998.[5] The 2001 Directive on Deliberate Release of GMOs was a more stringent version of an earlier Directive on Deliberate Release from 1990.[6] All along, the European biotechnology industry has argued that deregulation of the GMO

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1. Levy 1997, 56.
2. Jordan 1998.
3. The technologies involved are commonly termed "new biotechnology" or genetic engineering, which involves, for example, tissue culture and recombinant DNA techniques.
4. Bernauer 2003.
5. A genetically modified organism is one in which the hereditary material of the living cells of the organism is altered directly through human intervention in a way that does not occur naturally.
6. Bernauer 2003, 81.

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policy would improve the competitiveness of European biotechnology vis-à-vis their counterparts in the USA.

This study looks into various explanations of the apparent lack of influence that the biotech industry has had over EU policy outputs in this particular environmental field. The main analytical framework is drawn from analyses of the formation and effectiveness of environmental policy in the face of influential corporate interests.[7] It builds on the perception that scholars studying environmental politics need to focus more systematically on the role of target groups, in particular powerful industry groups; industry influence on environmental policies is expected to be affected primarily by the degree of unity and coherent strategies, access to decision-making, and the strength of counterbalancing forces. First, industry's limited influence may be explained by a lack of internal unity. This may be in the sense that they are all opposed but unable to join forces through a coherent strategy, or in the sense that the sector is divided with some industry actors actually in favor of the evolving GMO regulations. For example, it is argued that the multinational corporations that dominate the biotechnology sector were comfortable with the development of stricter regulations because they covertly assumed that this would help weed out the competition from smaller companies.[8]

A second explanation, building on König, ascribes the European biotechnology industry's lack of influence to limited access to decision-making.[9] This view is countered by other studies, which conclude that EU environmental policy-making may be just as readily accessible to business as it is in the USA.[10]

Third, a number of scholars have pointed to the strength of counterbalancing forces as the principal reason that the EU was able to enact a strict GMO policy.[11] In a broad approach that examines the changing decision-making framework of the EU, Homeyer[12] and Patterson[13] show how alliances between environmental proponents and EU institutions have paved the way for strict regulations.[14] In other words, the explanation is not sought in the absolute influence of the biotech industry, but the influence of the biotech industry relative to the influence of other groups, such as environmental proponents. As most analyses picture the environmental movement to be increasingly on the losing end in these tugs-of-war—does this imply that the GMO issue constitutes a deviant case of environmental policy-making?

Prior to taking up that discussion, we must look into an alternative, fourth thesis that strict GMO regulations reflect a demand from industry interests for

7. Skjærseth and Skodvin 2003.
8. Miller 1999.
9. König 2002.
10. Grant, Matthews, and Newell 2001; and Levy and Newell 2000. Coen (1999) discusses the prominent role of business in Europe and contrasts it with US lobbying.
11. See, for instance, Bernauer 2003.
12. Homeyer 2002.
13. Patterson 2000.
14. Patterson 2000; and Homeyer 2002. Others have focused on how GMO policies have influenced the discourses and strategies of industry. See Levidow et al. 2002.

protectionist reasons. This view is behind the US move to file a complaint about EU's GMO policy with the World Trade Organization (WTO).[15]

The case study then proceeds by addressing more specific questions drawn from these four theses relating to environmental policy formation within the EU. The study is largely limited to companies and corporations involved in agriculture on the supply side, which involves R&D relating to GM-plants. Following a brief outline of the issue area and the main legislative outputs, the biotech industry's positions are compared to the policy outputs. This is followed by a discussion about precaution and protectionism; concluding that there has indeed been a limited degree of industry influence. The paper goes on to analyze the role of industry in light of the three hypothesized explanations. It concludes that the counterbalancing forces of certain member states and ENGOs, particularly in combination with developments in the EU decision-making procedures, provide the greatest explanatory power. Moreover, the strength of the counterbalancing forces in this particular environmental issue area is boosted by the links between health and environment concerns.

1. GMO Policy Formation and Industry Positions

There is scientific uncertainty about the effects of GMOs with regard to both the environment and human health. The uncertainties regarding environmental effects pertain to the risk of GMOs as exotic species affecting or displacing native species and to the risk of "genetic contamination" in the event of cross-breeding between GMOs and related, native species.[16] The uncertainty about the potential effects of GM food products on human health includes the threat of creating increased resistance to antibiotics and potentially allergenic effects.[17] On the other side, advocates of GM technology argue that GM plants can benefit the environment by, for example, reducing the need for pesticides while at the same time increasing agricultural yield. Other benefits include the great potential for developing healthier food as well as new medicines and vaccines.[18] Against this backdrop, a number of international and regional regulations to safeguard the use of GMOs have been developed. Among the OECD countries, the EU has enacted some of the most restrictive regulations in this field.[19]

The development of the EU's GMO policy can be traced back to the early phases of modern biotechnology in 1975, when industry argued for a self-imposed moratorium on GMO release and the need for regulation.[20] The first

15. Bernauer 2003, 83.
16. A central—and politically controversial—example is found in Mexico, where genes from transgenic maize were found to have wandered into native populations. Quist and Chapela 2001.
17. ICSU 2003. See also www.freenetpages.co.uk/hp/a.pusztai/.
18. See for instance, http://www.agbioworld.org/newsletter_wm/index.php?caseid=archive.
19. The term "regulations" is used here in the general sense to mean part of a regulatory framework, not in the sense of EU *Regulations,* which are directly legally binding for member states.
20. The historical background presented here builds partly on Patterson 2000 and it is greatly indebted to Homeyer 2002.

move towards regulating biotechnology in the EU was developed by the Commission by Directorate-General (DG) XII (Science, Research, and Development) in 1978. It proposed a directive that would require notification and authorization by national authorities prior to all research and work involving recombinant DNA (rDNA). This was replaced in 1980 by a new proposed directive, which required only notification of rDNA work. The result ended up as a recommendation only, which was agreed to by the largest European scientific organizations.[21] The world's leading country in rDNA research—the UK—strongly resisted and vetoed the proposal for a directive.[22] At this point, the EEC decision-making process was still characterized by unanimity in the Council and by the European Parliament merely presenting its opinion.

By the mid 1980s, new proposals were made for a directive on the deliberate release of GMOs into the environment. The ensuing debates focused on three main areas of contention:

- vertical (modifying existing sector regulations) or horizontal (establishing new cross-cutting regulations for all fields using biotechnology, such as pharmaceuticals, veterinary medicines, chemical substances, food additives and feedstuffs) legislation
- regulating the process (genetic engineering in general) or product (any novel traits displayed in an organism)
- science-based regulations or based on the precautionary principle.

The Commission proposal started out with an emphasis on vertical legislation, thus pacifying DG-Industry and DG-Research. DG-Environment was given the leading role (*chef de file*) based on their experience in regulating dangerous substances and hazardous industrial activities.[23] In this role as *chef de file*, DG-Environment could draft the Directive on Deliberate Release of GMOs, thus setting the terms of the debate as well as presenting it to its "own choice" of Council of Ministers—the Council of Environmental Ministers. Directive 90/220, with the support of the European Parliament ended up with a horizontal, process-based and precautionary approach.[24] At this point in time, the decision-making process for Deliberate Release followed Article 100A (now Article 95) of the newly adopted Single European Act (SEA). The SEA signifies qualified majority voting in Council for Internal Market legislation and strengthens the participatory role of the European Parliament.

The Maastricht Treaty came into force in 1993 and further increased the influence of the European Parliament by providing it with potential veto right through co-decision. The formal process of replacing Directive 90/220 started in 1996 with proposals for deregulation, on the one side, and for more stringent

21. These included the European Science Foundation (ESF), the European Molecular Biology Organization (EMBO), and the European Federation of Biotechnology (EFB). Patterson 2000.
22. Homeyer 2002.
23. Homeyer 2002, 115.
24. Patterson 2000.

regulations, on the other. The proposals for deregulation included differentiated risk categories and more streamlined product approval. The proposal for new requirements included monitoring and a more limited authorization period. After four years of negotiations, the new Directive 2001/18/EC on the Deliberate Release of GMOs replaced the former 90/220. It sharpens the regulations by introducing more stringent assessment procedures, introducing amendments on labeling, and by saying that authorization of products is valid for a fixed time period only. Meanwhile, in 1998, an unofficial moratorium on the commercial release of GMOs was forced through by the "hard-core" group: Denmark, France, Greece, Austria, Italy, and Luxembourg, later joined by Belgium and Germany.[25] The moratorium has blocked EU imports of a range of genetically-modified goods and the US corn industry complains that it is losing at least $300 million a year in sales to the EU.[26]

In the aftermath of Directive 2001/18, EU Environmental Ministers have agreed on two *Regulations*, one on mandatory labeling and traceability (EC) 1830/2003 and one on GM food and feed (EC) 1829/2003. These give a tolerance threshold of 0.5% for accidental presence of GMOs and a minimum threshold of 0.9%, below which there is exemption from labeling. Foodstuffs and feed produced using GMOs are required to be traceable throughout the product chain. Remaining contested issues include how to deal with the "co-existence" of GM plants and conventional farming, and traceability and labeling as conditions for putting an end to the moratorium on marketing approvals of GMOs. In addition, there has been much controversy related to the demand for including GMOs in EU environmental liability rules. The moratorium came to a partial end in May 2004 through the approved import of Syngenta's Bt-11, for sale as tinned sweetcorn and co-existence has been left to the national level. The remainder of this study focuses on the four outputs highlighted in bold characters in Table 1.

1.1 Industry Positions Compared to Policy Output

At the EU level, the largest biotechnology coalition is the European Association for Bioindustries (*EuropaBio*), which represents 40 international corporations and 17 national biotechnology coalitions (about 1200 companies). Another large grouping is *BelgoBiotech*, which organizes a great number of small Belgian biotechnology companies as well as multinational corporations, such as Bayer Cropscience, Monsanto, Pioneer Hi-Bred and Syngenta.

At the outset of developing the new biotechnologies, there was an outspoken interest in regulation also among scientists. At the Asilomar Conference in 1975, a number of scientists involved in biotechnological innovation asked for

25. The moratorium came as a response to the Commission's approval of imported genetically modified soy and corn in 1996 and 1997. Bernauer 2003.
26. 'US keeps hinting at WTO complaint vs EU biotech', *Planet Ark*, 17 January, 2003, as at: http://www.planetark.org/dailynewsstory.cfm/newsid/19451/story.htm.

Table 1
Summary of Main Policy Outputs

1975. The Asilomar Conference: General agreement on need for regulations of GMOs.

1978–80: Proposed Directive on *notification* and *authorization* of experimental releases and placing on the marked of GMOs. Turned down by industry and the UK (unanimity in Council). Ends up as a recommendation for *notification* only.

1987: The Single European Act provides the European Parliament with increased power by opening for qualified majority voting in Council.

1990: Directive on Deliberate Release of GMOs 90/220 (and Directive on Contained Use of GMMs 90/219). Dir. 90/220 reintroduces *authorization.* Since then, 18 such authorizations have been granted.

1993: Maastricht Treaty provides the European Parliament with added influence through co-decision.

1997: Regulation (EC) 258/97 on Novel Foods and Novel Food Ingredients sets out rules for *authorization and labeling* of food products containing GMOs.

1998: De-facto moratorium on commercial release of GMOs established by France, Denmark, Greece, Italy, Austria, Luxembourg and (later) Germany and Belgium.

2001: Directive 2001/18 on Deliberate Release of GMOs. Puts in place a *step-by-step approval* process, with a *time limit* on authorization, before release into environment or placed on market.

2003: Regulation on labeling and traceability (EC) 1830/2003 and Regulation on GM food and feed (EC) 1829/2003.

2004: GMOs included in liability directive.

Directive 2001/18 on deliberate release has still not been transposed into national law in most member states. Regulations, in contrast, take immediate effect as soon as they are formally approved.

regulations and proposed a self-imposed moratorium on their own activities until such a framework was in place.[27] Since then, the sector rapidly grew more confident in their technological results and more concerned with competitiveness. The European biotechnology sector cites concern for employment and competitiveness when arguing for a less restrictive regulatory framework in line with their American counterparts. Moreover, a major strategy of the European biotech industry has been to turn the biotechnology discussion away from environmental and health risks and to focus instead on ethical issues.[28] This allows

27. The Asilomar Conference in 1975 (California) formed the start of guidelines and regulation of modem biotechnology. Bennett et al. 1986, 103; in Homeyer 2002.
28. Hansen 2001.

for a focus on the potential benefits of genetic engineering, such as food security issues and the development of new medications.

This position has been stable and can be seen in industry's responses to the Commission's current biotechnology strategy. According to the General Secretary of EuropaBio, the EU Commission's document *Life Sciences and Biotechnology—a Strategy for Europe, January 2002* is "particularly welcome at a time when Europe's fledgling biotech industries are struggling to keep pace with their international rivals. We have more companies than the US but we generate fewer products."[29] Here, EuropaBio is fully supported by the Union of Industrial and Employers' Confederation of Europe (UNICE), which stresses the importance of "removing obstacles to biotechnological entrepreneurship," "clear criteria for risk management," and "rapid decisions."[30] The same standpoint is also made by the European subsidiaries of US-based companies.[31] In his analysis of European GMO regulations, Bernauer also concludes that European biotech firms have persistently lobbied for laxer approval and labeling regulations.[32]

With the very first proposal for a Directive on Deliberate Release of GMOs in 1980 it seemed that the biotech industry was able to successfully exercise influence over the policy process. Since then, however, EU regulations have become increasingly strict in spite of opposition from industry. The industry groups were not able to stop DG-Environment from formulating horizontal, process-based regulations in the Directive on Deliberate Release 90/202. The 1998 unofficial moratorium on GMOs and the revised Directive on Deliberate Release (2001/18/EC) represent further tightening of the EU regulatory framework for GMOs. The biotechnology sector did influence the Commission in its review of Directive 90/220 on Deliberate Release in 1996 in the sense that a revision of the Directive was called for, partly in terms of deregulation. However, the review also called for new requirements, and this is what came through in Directive 2001/18. During the course of these policy developments, industry has opposed horizontal legislation, time-limits on authorization, labeling, liability, and later restrictions on co-existence, and has then had to contend with them one after the other.[33] The EU has left it to member states to devise rules on the co-existence of GM and non-GM crops, but the issue is hardly resolved. Industry also became greatly troubled by the European Parliament veto of the Directive on Patents in Biotechnology in 1996.[34] The controversial Patent Directive spent ten years in the pipeline (1988 to 1998) and was regarded as very important for enhancing competitiveness in biotechnology. Hence, its establishment may be seen as a victory for industry, carrying some consolation in the

29. EuropaBio, "A new beginning for biotech in Europe?" Press release, 23 January 2002. Available at http://www.europabio.org/articles/article_114_EN.pdf.
30. UNICE. ref: PW/DI/2211/biotech/general, 22 November 2001, www.unice.org.
31. Coen 1999.
32. Bernauer 2003, 83.
33. Patterson 2000. Further substantiated by interview with EuropaBio, 2 June 2003.
34. Patent Directive on Biotechnology, 98/44/CE OJL 213 of 30 July1998.

face of the stringent Directive on Deliberate Release of GMOs. The long fought-for Patent Directive nevertheless provides a more cumbersome patent process in the EU compared to that in the US, allowing for more exceptions and for farmers' rights to save seeds for own production.[35] Industry has succeeded in avoiding strong language on liability, but in most important aspects, the regulatory framework fulfils the demands by the environmental groups.[36] Does this imply that the GMO issue is a deviant case of environmental policy-making?

1.2 Precaution or Protectionism?

An alternative interpretation can be found in the WTO case, which has been filed against the EU GMO policy on the grounds of protectionism. On that basis, it could be argued that the strict regulations are motivated by protectionism rather than precaution—as the USA based critics are sometimes wont to do.[37] The claim that environmental concerns act as a decoy for protectionism is well known from other issue areas. When cases of conflicting principles between trade and environment first began to appear before the GATT—such as the 1991 tuna dispute between the USA and Mexico over the right to use market restrictions to protect dolphins—the trade regime's challenge of the environmental policy of the US came unexpectedly to the member countries.[38] Obviously, protectionism and precaution may go hand in hand, but a strong presence of the former would leave our case a less deviant one in terms of environmental policy-making. So, how does the evidence stand?

The arguments in favor are easily marshaled, given that European agri-biotech does seem to be lagging behind their North American counterparts. There was a significant drop in market capitalization of Europe's biotech companies in 2001.[39] The setback in European biotechnology leads us to the question of how their counterparts in the US have fared. In their yearly assessment of the biotechnology sector, Ernst and Young sum up the relative size and funding situation of EU biotechnology companies compared to their US counterparts: "The US-European difference has arisen due in part to a dramatic disparity in the level of investment in the two industries."[40] A 2002 report by DG-Enterprise maintains that "Europe in fact lags significantly behind the US in all facets of the commercial development of biotechnology."[41] The report stresses stronger scientific and industrial base, better communication between academia and industry, and stronger Intellectual Property Rights (IPR) regime in the USA as important explanatory factors for the US leadership, in addition to the differences

35. Bernauer 2003, 200.
36. See Memorandum, "Progress Report on GMOs," 30 January 2003, European Environmental Bureau.
37. Bernauer 2003, 83.
38. See Chaytor and Cameron 2000.
39. See Ernst and Young 2002.
40. Ernst and Young 2001, 9.
41. European Commission 2002, v.

in public opinion and regulatory framework. However, the report also stresses the lack of standardized survey procedures, which makes it difficult to compare competitiveness in biotechnology.[42]

Another trend that points in the protectionist direction is found in the slowdown of R&D. The EU has seen significant delays to new GM varieties and applications. Small and medium-sized enterprises (SMEs) have stopped participating in innovative plant biotechnology research, and large biotech companies have relocated research, field trials, and commercialization of new GMOs outside the EU. In the words of European Research Commissioner Philippe Busquin, "A recent Commission survey of private biotech companies and public research institutes reveals that 39% of the respondents have cancelled research projects on GMOs over the last four years. In the private sector alone, 61% of respondents have cancelled research projects in this field."[43] The Commission has published further evidence of this collapse, reporting relocation of research and commercialization outside the EU and withdrawal of small biotech firms from plant biotechnology research.[44] In Belgium, the biotech industry proclaimed a self-imposed moratorium on all new field trials on the grounds of confusion in rules and hostility against the biotechnology sector.[45] A similarly careful attitude can be found in BASF, stressing that "We see transgenics as the future. All we are saying now is our current products are non-GM."[46] In 2004, Syngenta followed Monsanto, DuPont, and Bayer Cropscience in closing down its biotech crop research operations in Britain and moved to the United States. In stark contrast, interest in GM technology continues to grow outside Europe, with many new applications being researched and followed up in field trials.[47]

The problem with all this "evidence" is that it can as easily be used to demonstrate the opposite. European biotech industry has been hard hit by the strict regulations, which have led to a decline in investments and in effect innovation. This interpretation is supported and extended by that of Bernauer,[48] who rejects the notion that strict regulations reflect protectionist demands from European biotech industry: they are no less victims of the regulations than their foreign competitors and they have been constantly lobbying for deregulation of labeling and approval systems. In assessing the costs and benefits for industry of the regulations, we must remember that competitiveness involves both a scientific component and a market aspect. The biotech industry may lose out in terms of innovation and development of new GM products but still win the race for accessing the European market. In the long term, the success of this strategy is

42. European Commission 2002, 3.
43. *Environment Daily,* 17 March 2003, 1406.
44. http://www.environmentdaily.com/articles/index.cfm?action=article&ref=14062.
45. Press release, Brussels 19 December 2002, available online at: http://www.belgobiotech.be/code/page.cfm?id_page=91&Type=BB-press.
46. Bruce Cranfill, the products marketing manager, BASF. Reuters News Service, Planet Arc, 22 February 2002. http://www.environmentdaily.com/articles/index.cfm?action=article&ref=14062.
47. Gaskell et al. 2003.
48. Bernauer 2003, 81–84.

greatly dependent on which way public opinion turns. The short term verdict supports the claim of limited industry impact on policy-making.

The following sections look at each of the hypotheses described earlier, and assess the degree to which they can account for the biotech industry's limited influence of EU policy in the regulation of GMOs.

2. Changes in Unity and Coherence

Given the policy outputs discussed above, the influence of the biotech industry seems to have diminished over time. If lack of unity were a source of explanation for this development, then we would expect that the internal unity of the biotech industry has become weaker over time. The empirical material suggests, however, that developments have been the other way around. Most important in this respect is the establishment of EuropaBio in 1997, which strengthened the internal unity within the European biotechnology sector. EuropaBio is the result of a merger between multinational corporations[49] and small, national-based companies[50]. However, in the initial phases, the industry groups were indeed late in entering the legislation stage in a coordinated manner. This again is explained by a number of factors, most importantly related to differences in national culture, technological sectors, and size.

National differences in the approach to biotechnology policy constitute a first cause of the initial disunity within the sector. While there is now a trend towards larger and fewer corporations, the traditional diversity among many smaller firms highlighted national differences. The ranking among firms across Europe depends heavily on the criteria used. In terms of numbers of companies, Germany and the UK, then France, Switzerland and Sweden are at the forefront.[51] Consumer perceptions also vary among member states, with Austria, Greece, Belgium and France becoming increasingly negative to agri-biotech while the Netherlands, Spain, Portugal and Finland hold more positive views.[52] The countries that argue against the moratorium and in favor of deregulation are primarily found among the biotechnology leaders.[53] However, the hard-core group behind the moratorium consists of both leaders (France, Denmark, Germany, and Belgium) and laggards (Austria, Greece) in the biotechnology race. Until the mid 1980s, European biotechnology was marked by national rivalry and a lack of organized commercial interests involved in EU decision-making:[54] While Denmark and Germany initially passed very restrictive regulations, France and the UK employed a system of monitored self-regulation.[55]

49. The Senior Advisory Group Biotechnology (SAGB), formed in 1989.
50. The European Secretariat of National Biotechnology Associations (ESNBA).
51. European Commission 2002, vi.
52. Bernauer 2003, 107.
53. European Commission 2003.
54. Homeyer 2002, 105.
55. On the early Danish regulations, see Hansen 2001.

A second dimension of divergence pertains to the technological sectors, such as the agricultural and pharmaceutical sector. According to EuropaBio, the inability of the biotech industry to speak with one voice stems from natural and inherent differences between the technological sectors involved.[56] This goes some way in explaining why it took industry so long to react to the first Directive on Deliberate Release (90/220). Part of the decision-making process behind the directive included the formation in 1984 of the Biotechnology Steering Committee (BSC) and its Secretariat, the EEC's Concertation Unit for Biotechnology in Europe (CUBE). CUBE, in spite of its coordinating mandate, failed to include large parts of European industry because the established associations of European chemical and pharmaceutical industries were not interested.[57] The pharmaceutical sector is only marginally affected by the Deliberate Release Directive.[58] This is partly because most of their research takes place as Contained Use and partly because Deliberate Release aims at GMOs and does not affect genetically modified micro-organisms (GMMs).[59]

Third, the biotechnology sector is divided in terms of corporate size, ranging from small-scale firms to multinational corporations. The application of biotechnologies may be carried out at different levels of complexity and of investment.[60] One interpretation of the apparent mismatch between stringent policy and biotech interests is based on the perception that the multinational corporations have been less concerned with avoiding strict regulations as this provides them with a competitive edge compared to the small-scale companies.[61] According to this view, the multinational corporations are less affected by stringent rules compared to the small-scale firms. The crux of the GMO-policy dispute concerns the scope of EU biosafety regulations set against EU competitiveness in biotechnology. Competitiveness involves not only innovation, but also market access. In international trade, competitiveness may be enhanced by the ability to flag GM-free produce. The multinationals can afford to wait for future market access, and in the meantime they can channel their scientific capital to their US-based branches. Studies of SMEs in the biotechnology sector bear out the impression that this process is taking place. SMEs have less capacity to manage the uncertainty, and there are few independent agri-biotechnology SMEs, as many have been purchased by multinationals.[62] This notion has also been corroborated in interviews with small and medium sized companies.[63]

56. Interview in EuropaBio, 2 June 2003.
57. Homeyer 2002, 99.
58. Hansen 2001.
59. Personal communication, Professor Julian Kinderlerer, 5 February 2003. Professor Kinderlerer is Assistant Director of the Sheffield Institute of Biotechnological Law and Ethics, University of Sheffield; member of Advisory Committee for Genetic Modification (ACGM) since 1984; member of Advisory Committee for Releases into the Environment (ACRE) until 1999. Substantiated by interviews with NN, Danish pharmaceutical company, 5 February 2003.
60. Sasson 1988, 14.
61. Miller 1999.
62. Grávalos et al. 2002.
63. Personal communication, Rikke Bagger Jørgensen, Risø Research Institute, Denmark, 3 Febru-

The above interpretation is broadly rejected by the association of the biotech industry and by environmental spokespersons, although for different reasons.[64] Environmental nongovernmental organizations (ENGOs) maintain that the small-scale actors would be equally happy to leave GMOs well alone. This argument may partly be put down to wistful thinking, and it is probably most valid for farmers in the agricultural sector who do not stand to benefit greatly one way or the other.[65] EuropaBio argues that indifference is really not a logical strategy for the multinationals, but still agrees that industry is getting to the point where they prefer "some kind of regulation" to the uncertainty of waiting. This argument must be dealt with cautiously for two reasons. First, EuropaBio represents both large and small companies and thus needs to stress internal unity. Second, the applicability of this explanation is likely to be limited to the post-moratorium phase. The moratorium increased the uncertainties regarding the regulatory framework. In their direct dealings with the Commission, multinationals are reported to have gradually become more concerned with reaching agreement on a framework than about the actual content of that framework.[66]

Summing up, the ineffectiveness of European industry in opposing the first Directive on Deliberate Release (1990) can be put down to their internal dissonance. Internal unity has, however, been greatly improved since the mid 1990s. First, EuropaBio was established in 1997, thus strengthening the internal unity across national cultures, sectors, and size within the European biotechnology sector. Second, the common trend seems to be for companies to enter into large coalitions, in addition to the trend for mergers within this sector.[67] In conclusion, the strengthened internal unity means that this factor cannot account for the enduring ineffectiveness represented by the establishment of Directive 2001/18.

3. Changes in Access to Decision-making

The second thesis assumes that the biotech industry's limited influence has been due to its lack of access to decision-making fora. The bulk of the evidence speaks against this explanation, however. Throughout the development of European GMO policy-making, the industrial sector has sought and maintained good working relations with the Commission.[68] First, as a reaction to the devel-

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ary 2003. Substantiated by interviews with NN, Danish pharmaceutical company, 5 February 2003.

64. Interviews, Greenpeace and EuropaBio, Brussels, 2 and 4 June 2003.
65. Bernauer 2003, 84.
66. In a meeting (2000) between eight commissioners and the largest biotechnology players (Monsanto, Syngenta, Nestlé, DuPont and Unilever) industry contended that their main concern was for the policy-makers to reach a decision—any decision—as long as they could have certainty about what they were dealing with. Interview with Professor Julian Kinderlerer, Chair of the meeting, 5 February 2003.
67. See for instance Pistorius and van Wijk 1999.
68. Interview in EuropaBio, 2 June 2003.

opment of the two 1990 directives and the rapid commercial growth in biotechnology, the biotech industry enhanced its efforts to enter the stage. Monsanto, ICI, Ferruzzi, Rhone Poulenc, Sandoz, Unilever, and Hoechst established the Senior Advisory Group Biotechnology (SAGB) in 1989. They persuaded the Commission to establish the Biotechnology Co-ordination Committee (BCC) in 1990 with SAGB as its interlocutor.[69] The Group aimed to prevent trade barriers between USA and Europe, and their main goal was to increase European competitiveness and change the image of biotechnology. This strategy aimed to change the institutional set-up to strengthen the corporate channel to EU decision-making. Second, in response to the Maastricht Treaty, the SAGB changed their strategy and intensified their lobbying of the European Parliament in an effort to match the ENGOs.[70] As Directive 90/220 is based on 100A of the Single European Act, the ENGOs had more influence, on top of more interest in the matter, through the enhanced role of the European Parliament. Third, industry's positions with the Commission were supported by the Bangemann Communication, which emphasized public funding of biotechnology research and harmonization of legal frameworks, including legislation on intellectual property rights.[71] In the end, the Commission did decide to call for revisions of the two Directives, but as we have seen these revisions did not accommodate the wishes of the industry.

Since its establishment in 1997, EuropaBio has been active in lobbying the Commission and the European Parliament. The association expresses faith in the ability of the Commission to eventually provide the sector with improved opportunities through innovation policies.[72] In assessing the effect of access, however, we need to look closer at what parts of the decision-making apparatus these lobby groups can reach. The main allies for the biotechnology industry groups within the segmented Commission have been DG-Industry (DG-Enterprise since 2000) and DG-Research. In EU environmental policy-making, DG-Environment has commonly had to fight both DG-Industry and DG-Agriculture, and it is generally judged to be the weaker of these.[73] In the case of GM policy the tables are a bit turned, however, as DG-Agriculture has traditionally been less hostile to DG-Environment in the GMO case.[74] The farmer and consumer groups in Europe concur in their skepticism about GMOs, although this may be changing as agriculture commissioner Franz Fischler has announced a more lenient approach to co-existence between GM plants and traditional agriculture.[75]

69. Homeyer 2002.
70. While most lobby groups in the EU concentrate on the Commission, the biotechnology sector differs in their focus on the European Parliament. Coen 1999.
71. European Commission 1991; and Patterson 2000.
72. Interview in EuropaBio, 2 June 2003.
73. Sbragia 2000.
74. Personal communication, Ingmar von Homeyer; interviews in DG Environment and DG Agriculture, 2003.
75. ENDS Issue 1431, 25 April 2003, reports that Fischler agrees with biotechnology supporters that costs should be shared more evenly: "Coexistence works both ways."

In sum, industry has succeeded not only in enhancing internal unity, it has also succeeded in strengthening access through the corporate channel to EU decision-making. The business community has increased their physical presence in Brussels and in effect enhanced lobbying and institution building. Granted, as a recipient for lobby groups, the EU policy-making system is itself characterized by a diversity of interests with evolving legal powers. This adds uncertainty to its receptivity to lobbying. As indicated by other studies of environmental policy, increased access and participation do not, however, automatically spell increased influence on policy-making.[76] Thus, we need to look at the participatory strength of counterbalancing forces before concluding about the role of access.

4. Evolving Strength of Counterbalancing Forces

European ENGOs have reason to be rather pleased with the output of European GMO policy, which goes quite a long way in matching their positions on the issue.[77] In this section I look further into the influence of these and other environmental proponents in actual policy-making, relative to that of industry. The influence of the biotech industry is partly dependent on its relative strength compared to other, opposing interest groups. This section deals with the roles of the "hard-core" member states and ENGOs. Their roles are seen in light of the evolving decision-making procedures in EU institutions.

4.1 Member States and Public Opinion

The domestic strategies of EU member states have been important throughout the development of community-level GMO policy. By the mid 1980s the transnational organizations of scientists were no longer asking for international harmonization of regulations. The Commission was becoming worried about the EU losing out to USA and Japan in terms of the competitiveness of its biotechnology industry.[78] Moreover, member states had started to enact their own widely diverse biotechnology regulations. This made the Commission worry about the Internal Market and spurred the need for harmonization, resulting in the 1990 Directives.

During the 1990s there was an interesting interaction between EU institutions and the member states. As pointed out by Homeyer,[79] first, DG-Environment allied with recently established national biotechnology authorities, which were eager to strengthen their role by implementing the 1990 Directives. DG-Environment enjoyed support from the European Parliament, the Environment Council, the US Environmental Protection Agency, and even had some support

76. Skjærseth and Skodvin 2003.
77. See, for example, Memorandum, "Progress Report on GMOs," 30 January 2003, European Environmental Bureau. Substantiated in interview with Eric Gall, Greenpeace, 4 June 2003.
78. Russell 1988, 172–173; in Homeyer 2002.
79. Homeyer 2002.

from DG-Agriculture from time to time. Second, the Commission could not risk undermining its own legislation and be seen to be disturbing the harmonization of the Internal Market. Third, at the start of the 1990s, industry was still split between the interests of the multinationals and the small, national-based companies. This allowed the European Secretariat of National Biotechnology Associations (ESNBA) to develop closer ties to DG-Environment at this time than did the group of multinational corporations constituting the Senior Advisory Group Biotechnology (SAGB). The smaller, national associations may have been more receptive to the strong public opinion against GMOs within certain member states.

Through the 1990s, the high level of scientific uncertainty about the effects of GMOs on the natural environment and on human health has been accompanied by a similarly high level of political dispute and public distrust of regulatory authorities in Europe. The EU moratorium on approval of new GM crops emanated from strong pressure by the "hard-core" group of member states. The immediate background for the moratorium was growing European concerns over health and food safety, spurred by the recent traumatic events of mad cow disease (BSE) and scandals involving HIV infected blood.[80] On a more profound level, the European anti-GM mood is based on a general distrust of the trend towards larger multinational corporations and decreased public funding and control of the agricultural sector.[81] Widespread mergers imply that ever fewer and larger multinational corporations are increasingly dominating research, innovation and marketing within the biotech industries, which also combine agri-biotech with pharmaceutical industries.[82]

Finally, the growing unity of the counterbalancing forces seems to have been strengthened by external activities. With regard to the USA complaint to the WTO, EU Trade Commissioner Pascal Lamy maintained that such a move would be counterproductive and that Brussels would "fight" the litigation. EuropaBio made it clear that they do not consider the US move to be at all helpful.[83] This view was substantiated during interviews, both by EuropaBio and by Greenpeace.[84] Both agreed that the US challenge may have been aimed at "divide and rule" but would be more likely to strengthen European opposition to GMOs.[85]

80. Lok and Powell 2000.
81. As pointed out by Dr. Robert L. Thompson, World Bank, at the International Conference on GM Food, 5 February 2003, Oslo. Organized by the Norwegian Biotechnology Advisory Board.
82. See Bernauer 2003, 5–6, 26–7.
83. The EU's biotechnology and crop protection industries fear that the action could further politicize the biotechnology business in Europe or spark a consumer backlash. EuropaBio: "It would have been preferable to solve this issue without WTO action," ENDS Issue 1442, 13 May 2003.
84. Interviews, Greenpeace and EuropaBio, 2 and 4 June 2003.
85. 'US decision seen soon on WTO biotech complaint vs EU'. *Planet Arc*, 31 January 2003 as at: http://www.planetark.org/dailynewsstory.cfm/newsid/19643/story.htm.

4.2 ENGOs and the Link between Environment and Health

A predominant view among scholars of environmental politics is that European-level industry groups have the upper hand in influencing EU environmental policy compared to the ENGOs.[86] In a recent study of the climate change issue, the influence of ENGOs is found to have declined despite increased participation.[87] Since their heyday of the 1980s and early 1990s, environmental issues have dropped on most political agendas. During the 1990s, Germany has decreased its environmental pusher role within the EU, partly as a result of unification and economic recession. Moreover, there is a trend towards health-issues taking the place of environment on political agendas, and this was also apparent in the 2002 UN World Summit on Sustainable Development. In Johannesburg, health and poverty reduction outshone environmental questions compared to the two previous UN environmental summits in Stockholm and Rio.

The early efforts of the ENGOs focused on loss of biodiversity, "patents on life" and the potential negative impacts on small-scale farmers of the South.[88] As GM products were about to enter the European markets in 1996, the European environmental NGOs turned their attention to food safety. Friends of the Earth-Europe, Greenpeace International, and the British Soil Association joined forces and activists started demonstrating against GM food imports and GM test crops, stressing the dangers to human health and the distrust of the public food authorities.[89]

The area of GM policy may represent a deviant environmental case in this respect. There is a strong element of human health issues added to that of environmental problems within this field. The health issue has been fuelled by fatal scandals involving the administration of HIV-contaminated blood and human disease through BSE. Against this backdrop, it can be assumed that when environmental issues are strongly linked to human health, this may leave ENGOs with more leeway in influencing policy-making.[90] The next section will allow a closer look at how this message was carried into the political decision-making processes of the EU.

4.3 EU Institutions and Counterbalancing Forces

The discussion of the influence of counterbalancing forces must also include a discussion of how they are able to access EU policy-making institutions. In the context of the previous hypothesis, the access of the biotech industry to policy-

86. Grant et al. 2001; Levy and Newell 2000; and Sbragia 2000, 304.
87. Skjærseth and Skodvin 2003, 169.
88. Fowler et al. 1988; and Kloppenburg 1988.
89. Shurman 2004.
90. According to Greenpeace, this alliance was not apparent from the start, but increased its strength during the later phases of policy-making. Interview with Eric Gall, Greenpeace, 4 June 2003.

making was significant only in an absolute sense; here it is being considered also in its relative sense. In the later phases of policy development leading up to the revised Directive 2001/18, the counterbalancing forces seem to have increased their access. This has taken place through the revisions in overall decision-making procedures within the EU. It may thus be argued that the industry groups have been increasingly forced to share their access with these counterbalancing forces. This is seen in the application of Article 100A (now Article 95), which enhances the role of the European Parliament. Admittedly, the changing decision-making procedures of the EU may in principle work both ways with a view to environmental interests. Unanimity may lead to the environmentally infamous "law of the least ambitious programme,"[91] or it may direct the process towards increased consensus building. Qualified majority voting associated with the Single European Act (SEA) has the potential to either strengthen or undermine environmental policy, depending on member states' interests and how they play the two-level games in the EU. Let us take a closer look first at European Parliament relations and second at two-level games in the GMO case.

First, responding to the changing policy-making procedures, the industry groups have recently reoriented their lobbying to concentrate much more on the European Parliament. It is, however, recognized that ENGOs have a much longer tradition than industry in working with the Members of Parliament and it is they that have strengthened their voice. Second, with regard to the two-level game, industry and ENGOs alike consider it an added strength of the ENGOs that they are much better positioned by their national offices to work through the member states.[92] In effect, ENGOs have increased their relative degree of access compared to industry through the revisions in overall decision-making procedures within the EU.

This still leaves us with the question of how ENGOs have been able to utilize their participation and access to substantially influence policy-making in this field. Increased access and participation are no guarantees for increased influence on policy-making and industry groups tend to make alliances with more powerful parts of the Commission.[93] According to sources in the environmental NGOs, the main reason for their success in the GMO case rests on their timely argumentation and action. What is more, industry and ENGOs agree that ENGOs are better at dealing with the media and that they have more credibility than industry.[94] The ENGOs did not enter the policy process significantly until 1996/97. At this point the Commission was authorizing the first import approval of GM soybean and later on Bt maize. Greenpeace stopped the first shipment of GM soybean in the port of Antwerp in 1996. Greenpeace and Friends of

91. Underdal 1980.
92. Both of these points were stressed in interviews in EuropaBio, 2 June 2003 and with Lorenzo Consoli, journalist, former policy advisor to Greenpeace, and Eric Gall, Genetic Engineering Policy Advisor, Greenpeace European Unit, 4 June 2003.
93. Skjærseth and Skodvin 2003.
94. Interviews in EuropaBio and Greenpeace European Unit, 2 and 4 June 2003.

the Earth then went on with a campaign in EU supermarkets to avoid GM food.[95] The campaign reportedly had a domino effect—as one company after another decided to go along, many more felt forced to follow suit. In this way, ENGOs were able to utilize the food scare in public opinion.

This section has brought us to the importance of information and knowledge in the biotechnology issue area. The high level of scientific uncertainty provides companies with a wide scope for using their own scientific reports as a basis for argument and action, and they also have a high interest in utilizing this scope. Most studies on GMOs are based on information provided by research laboratories and/or released by industry. They mainly focus on technological developments outside Europe; little research has been done on the situation within Europe.[96] In 1998, Monsanto invested US$ 5 million in an advertising campaign designed to convince the Western European public of the benefits of GM crops.[97] The multinationals within the biotechnology sector have a firm belief that if the public receives enough information about GMOs and biotechnology, it will come around to accepting the technology and its products.[98] On the other hand, that scenario very much depends on the kind of information that people receive and are receptive to. In several studies and opinion polls across Europe, researchers have made the claim that the more knowledge people had about biotechnology, the more they came to distrust it, rather than the other way around.[99] These findings are in themselves controversial, and other researchers point out that the "yes group" has not increased in relative terms—it is simply the "don't know group" that has dwindled.[100] A recent finding indicates that improved knowledge is likely to engender a more positive attitude towards GM technology, but not towards GM food[101]—again stressing the significance of health concerns. The persistent uneasiness about GMOs in Europe is also explained as a result of people putting more trust in information from ENGOs compared to industry as well as regulatory authorities.[102] In any case, knowledge may be a double-edged sword for those who wish to wield it. In summary, a strong and skeptical public opinion has persisted in the EU—combining environmental and human health concerns—and these voices have acquired increased access through the revisions in the decision-making procedures within the EU. This would seem to go a long way in explaining the defeat of major affected industries.

95. Interview with Eric Gall, Greenpeace, 4 June 2003.
96. Gaskell et al 2003. See also Myhr and Traavik 2002.
97. Shurman 2004.
98. Syngenta "expressed disappointment at European reluctance to consume genetically modified produce," Chief Executive Michael Pragnell of Syngenta. Reuters News Service, Planet Arc, 4 March 2002. Available at www.syngenta.com/en/customer/biotech.asp.
99. For a recent comparison between European and US consumers' perceptions, see Gurau and Ranchhod 2003.
100. On the interpretations of findings, see Gaskell et al. 2001; and Hviid Nielsen et al. 2002.
101. Verdurme et al. 2003.
102. Gaskell and Bauer 2001, 52–79.

5. Conclusions and Future Challenges to EU's GMO Policy

This study has looked into how unity, access, counterbalancing forces, and the ulterior motive of protectionism can explain the apparent lack of influence the biotech industry has had in the EU's GMO policy-making process. Revisiting the fourth thesis, protectionism as a driving force for strict regulation has not been demonstrated. When industry complies with the stringent rules this is prompted by the need for internal market access and it hardly contributes to enhancing technological competitiveness. The specific nature of biotechnology should be kept in mind as adaptive innovation is hardly an option: Unlike the situation in ozone and climate issues, the biotech companies hardly face the option of "cleaning up" their old, polluting products through technological innovation. Rather it is the new, innovative products themselves that present both potential environmental solutions and environmental problems.

The main puzzle dealt with in this study is how one of the world's strongest and fastest growing sectors—the biotechnology industry—seemed to exercise so little influence over EU environmental decision-making and come to be faced with such strict regulations. Explanatory factors within the EU broadly account for the situation. First, the biotech sector has traditionally been heterogeneous with great variation in terms of size, national cultural traits, and technological orientation. In effect, there was initially little scope for a unified approach from industry to affect EU's GM-policy. However, that explanation only holds up for the early phases of decision-making, as internal unity was greatly strengthened during the 1990s. Following the moratorium, the multinationals may have been inclined to accept a higher level of regulations rather than live with uncertainty, but their bottom line has been to ask for deregulation. Second, an examination of access to decision-making arenas demonstrated that limited access could hardly account for the limited influence.

This picture was adjusted, however, by the study of "relative" access and the increased scope for ENGO influence through the changes in EU decision-making procedures. The relative strength of the counterbalancing forces seems to have the greatest explanatory power. The biotechnology industry has suffered from low credibility with the public in their efforts to project a positive picture of biotechnology. Carried by a strong public opinion, a coalition of environmental agents succeeded in stemming the demand for deregulation and induced a strengthening of European GMO policy. This finding may seem puzzling in view of the several predictions that environmental proponents are increasingly losing out to business groups in affecting EU policy-making and that agreement on policy will be hard to achieve against the will of major affected industries. The answer, and an important lesson, is that the link between environmental issues and health issues seems to have provided ENGOs with greater influence on GMO policy-making compared to other environmental policy areas.[103]

103. This raises another puzzle. The pharmaceutical industries are only marginally affected by the Deliberate Release Directive (2001/18), which aims at GMOs and does not affect genetically

The health aspects were boosted by the BSE case as well as HIV infected blood, while GMO risks to the natural environment have not materialized and have had less of a mobilizing force. The StarLink episode of 2001 led to a similar public outcry in the US and shows how the public reacted as traces of GM corn—approved for animal feed—was found in human food.[104] StarLink, in contrast to BSE was, however, merely a scandal, not a lethal scandal. This raises the question of how the GM issue will fare once concerns for human health have been pacified through labeling and improved consumer choice.

The dark horse in the future developments of GMO legislation, however, is the effect of *external activities,* such as the WTO challenge and the dispute over food aid to Africa.[105] In the short run, these challenges are likely to unify and strengthen European opposition to GM foods, but the long-term effects may be a weakened opposition outside the current EU Membership. The US move may represent a strong signal to the rest of the world to accept GM plants or face similar trade challenges.[106] There may eventually be sufficient political and ecological effects in European countries outside the EU and world-wide to obstruct the EU's GMO policy. If African and Asian fields follow the GM furrows of North and South America, the EU opposition may become increasingly redundant. An interesting question is thus how global aspects of the GM controversy are setting the pace for what is politically feasible also within the EU.

Finally, a brief comment on the potential effects of the EU enlargement is in order. The EU has pushed for the introduction of strict GMO regulations both for the internal market and through the Cartagena Protocol on Biosafety (adopted 2001). These policies have been met with strong resistance from the largest GM producers. Given the strength of this resistance, both the Cartagena Protocol on Biosafety and EU Directive 2001/18 have gone much further in regulating GMOs than what was predicted as politically feasible at the outset of these processes. Several of the ten new EU member states have also ratified the Biosafety Protocol and most have already voted in line with the "hard core" group.[107] As these countries do not generally have a very large biotechnology sector, the pressure for deregulation could be expected to decrease with enlargement. On the other hand, there may be an increased willingness in these countries to build up a strong biotechnology sector. The new member states are largely dependent on agriculture, politically oriented towards the USA, and in general have a less environmentally "fearsome" public opinion. This raises another interesting question for future research as well as political challenges.

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modified micro-organisms (GMMs). Medicines and vaccines make abundant use of GMMs but this has not prompted a similar reaction among counterbalancing forces.

104. Moreover, Monsanto now faces similar problems in the US with regard to introducing their GM-wheat. Wheat, as opposed to corn and soybean, is used directly as human food—and hence invokes human fears. See Prakash and Kollman 2003.
105. The Bush administration also accused the EU of contributing to famine in Africa through its opposition to GM crops. See e.g. *ENDS Environmental Daily,* Issue 1450, 23 May 2003.
106. As pointed out by Eric Gall, Greenpeace, 4 June 2003.
107. *Environment Daily,* Issue 1689, 17 June 2004.

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