GERMANY

Splicing genes, splitting society:
Perpetuating a conflict through the regulation designed to resolve it

November 1995

Bernhard Gill

IIWW
Universityof Erlangen
Bismarkstrasse 12
D-91054 Erlangen
Germany

'GMO Releases: Managing Uncertainty about Biosafety'

A study of the implementation of EC Directive 90/220

Main contractor: The Open University, contract no. BIO2-CT93-0609, 1994-95

This report forms part of the overall final report for the DGXII/E-1 horizontal programme Assessment of the Ethical and Socio-economic Effects and
Technological Risks from Biotechnology

Contents

OVERVIEW

Like many other industrialized countries, Germany had non-mandatory safety guidelines for biotechnology in the 1980s. But Germany also enacted a new law on genetic engineering before the EC directives. The German legislation results from an endogenous, domestic political process; it would have come regardless of EC directives. Since the 1990 Genetic Engineering Act (GEA), all work with GMOs requires an administrative notification or consent which imposes various safety measures, according to the present 'state of the art in science and technology', in order to prevent any harm to laboratory workers, the public and the environment.

Since the mid-1980s, genetic engineering has come under attack from the Green Party, environmental pressure groups and local campaigns. In the German debate, many critics drew links to reproductive technologies, so a broad coalition emerged. This included parts of the labour unions, and the Catholic and Protestant churches. Thus the opposition disrupted and split even the large political parties, the Christian and Social Democrats (Gottweis 1995, Gill 1991).

On both sides, coalitions forged cognitive frameworks which are not easy to overcome. The proponents claim genetic engineering as a 'key technology', while the opponents draw parallels to nuclear energy, which already polarised German society. The opposed sides in Germany are fighting to win — not to compromise. As in many environmental conflicts, the opponents are not integrated into the political system, despite their influence in the media and the local public; no institutions of bargaining and mediation are established.[1]

Germany's GEA, and its implementation, is neither a capitulation nor a compromise. Rather, its institutions reproduce the split of society. This feature can be seen in the GEA's first paragraph, stating the aims: the protection of human health and the environment, as well as the promotion of genetic engineering. The different administrative units which are responsible for the legal enforcement can be seen partly as bastions of the proponents. The chairman of the advisory committee, for example, declares in public that this body works as a counterweight to public suspicion within the regulatory system; he blames the media and hence the administration for 'irrational over-regulation' (Hobom 1994).

The participation provided by the law serves neither to influence the decision-making process in a transparent way, nor to make decisions more acceptable. The narrow procedure excludes all the broader political and

---

[1] O'Riordan & Wynne (1987) characterize Germany's regulation as a corporatist approach. This may be true if an environmental issue is framed as an issue of workers' safety and processed through the established channels to mediate labour conflicts.

ethical issues which lie at the centre of the public controversy. Hence the regulatory procedure is unable to democratise and shape the technological development according to the aims expressed by a wider public.

The 'state of the art in science and technology', a central criterion in the consent procedure, both allows and restricts opportunities for demanding 'evidence of safety'. Its meaning depends upon whether the emphasis is put on past experience, e.g. that 'nothing has happened', or upon the present 'lack of understanding' of how GMOs interact with the environment. Although biosafety research presumably could clarify doubts and change the present 'state of the art', it is directed mainly by the Ministry of Research and Development (BMFT), a strongly engaged promoter of biotechnology. According to the BMFT_s interpretation, the results show that genetic engineering *per se* does not pose a specific risk. Therefore future biosafety research should be done in a 'product-oriented way'.

Because of the strong opposition to genetic engineering, the focus of German debate somewhat lags behind the sequence of particular issues in other countries. The debate now focuses upon small-scale field tests, though there are still conflicts over contained use. The next step, the marketing of GMOs, has not yet drawn much public attention. The German law provides less participation and objection rights in the procedure for market approval than for small-scale field tests, yet this disparity has drawn little comment.

When the GEA was amended in 1993, it relaxed the approval and control procedures for small-scale laboratories, and abolished the oral hearing within the participation procedure for field test consents. Also some minor inconsistencies with the EC law had to be corrected. The 1993 amendment followed a broad campaign in which the supposed 'over-regulation' of GMOs was linked to the prominent debate about industrial investment and employment in Germany. With the recession after German reunification and worldwide economic restructuring, the public mood became generally less responsive to environmental issues.

But the labelling of GMO-derived food is still a strong issue in Germany. After much discussion, the German Health Ministry has changed its position in the EU council of ministers and now supports extensive labelling. Meanwhile German representatives have been lobbying in Brussels to amend EC Directives 90/219 and 90/220[2]; yet Germany itself has not adopted the streamlining already permitted by Directive 90/220. It seems easier to scapegoat 'Brussels' than to overcome Germany's domestic troubles.

---

2 Letter to DGXI from G Schubert , Health Ministry, 5 May 1994.

Actors and institutions

The intensity of the German conflict can be explained by the attitude of the various actors and the institutional framework set by the law.

The opposition

There are various conceptual roots which may explain the strong German opposition. Biotechnology is criticized in terms of 'manipulating life', thus linking its various applications as well as its future possibilities. The issue becomes linked to Nazi racism and eugenics, to the conservative plea for protecting the traditional family and agricultural community values, and to environmentalism, which is particularly strong in Germany. Biotechnology also arouses feminist fears of new patriarchal controls over human reproduction. Many people are concerned about the potential for social discrimination via genetic diagnostics.

On the organisational level, the more traditional figureheads and associations are loosely coupled to the more radical environmental groups. The fundamentalism of the latter is reinforced by the German political system, which gives many opportunities for expressive, antagonistic forms of protest but not for instrumental, policy-oriented environmental lobbying.

The opposition also benefits from the fact that Germany is tightly populated. Rural areas are often within the reach of large towns. They have a culturally heterogeneous population, some of them living there for motives of 'green romance'. Thus the mobilisation against field tests can be surprisingly large in some areas of Germany.

The proponents

Industry is mainly represented by the three large chemical companies (Hoechst, Bayer and BASF), which dominate the respective industrial associations. They maintain a 'command-and-control' management style and often promote their interests by direct political interventions. Typical of their 'dialogue' with the public was a series of large newspaper advertisements advocating amendment of the 1990 GEA in 1992-93.

Industry persuaded the decision-making elites, but not the public. The law was amended, yet public acceptance of biotechnology was further declining, as reflected in the Eurobarometer surveys (Inra Europe 1991, 1993). The above-mentioned companies took a different approach to public relations than did Novo Nordisk, Unilever, and other biotechnology companies in Germany; for example, Boehringer Mannheim has had few problems with the public (Gassen et al. 1992).

Many scientists who engage in the debate, as well as their associations, tend to be even less sensitive to public concerns. The enforcement of the genetic engineering law was perceived in academia as a 'cultural shock' — unlike in industry, which is used to coping with safety regulation (Vitzthum 1993). This reaction may be explained by Germany's prestigious academic tradition, which grants much autonomy to high-level scientists.

The administration

In Germany there are two modes of portraying the state administration as neutral. One is to invite and to mediate between advice from plural interest-groups. The other is to portray the administration as merely executing the political will of a legitimised legislator. Administrations which have much influence and discretionary powers prefer the second pattern because it perpetuates their autonomy.

Within the Prussian-German tradition, the administration portrays itself as governed formerly by Royal law and now by a democratic legislator. In the tradition of the German *Rechtsstaat,* the substantive rights of the citizens are often subordinated to enforcement of political programmes set by a central authority. Discretionary powers are hidden behind formal regulations and supposedly 'objective' scientific expertise.

The *Rechtsstaat* prevails in German environmental conflicts. Environmental pressure groups which have a less formalised organisation than trade unions, for example, have not gained institutional access.[3] Administrative decisions are officially justified as juridical acts, not as political ones. Thus the participation procedure for field test consents has a narrow focus. In the marketing approval procedure, the administration is even reluctant to give information access prior to the final decision, as required by Directive 90/220. Administrators expect their decisions to be accepted as expressing the higher legitimacy of the law, supported by objective scientific expertise — not as a contingent outcome of political bargaining. This may be an adequate procedure in some areas, e.g. the criminal law; for precautionary risk assessment however, the administration is unable to mediate the social conflicts (Gill 1995).

German legal tradition

The form of the GEA arose partly from the German legal tradition. Some peculiarities of the GEA, distinguishing Germany from other EU countries, can be explained only in this context. For example, the strict liability was not subject to wider political discussion but was formulated according to the general environmental law. Also the law emphasized the production or test

---

[3] The same is true for the legislation and implementation of the Toxic Substances Act , according to the careful analyses of Schneider (1988). As foreign observers, Brickman et al. (1989) drew a slightly different interpretation. NGOs have generally restricted opportunities in the German policy networks at Federal level (Hey & Brendle 1994).

site more than product marketing (Hohmeyer et al. 1993). In general German environmental policy is dominated by an administrative approach, whereby detailed safety measures are imposed by the authorities. More civil instruments — e.g. political participation, extended citizens' rights to take legal action against pollution, strict liability — are only reluctantly introduced by the legislator (Weidner 1995).

The legal terms used in the GEA are of significance, e.g. *Gefahr*, meaning danger, hazard. Traditionally the law differentiates between two forms of prevention: *Gefahrenabwehr,* meaning that the state representatives have a broad authority (even duty) to avert an immediate hazard, and *Gefahrenvorsorge*, meaning that they have the authority to impose safety measures to prevent future harm. Internationally, environmental policy may distinguish between 'prevention' and 'precaution' (Tait & Levidow 1992), i.e. between risk areas where much experience exists and risk areas where one can rely only on hypotheses (Gill 1995); however, this distinction does not exist in the German language, as both are translated as *Vorsorge*.[4] The term *Risiko* (risk) was only recently introduced into German law, in the context of the atomic energy law and the genetic engineering law; it could mean more hypothetical harm than *Gefahr*.

However, most jurists see no consistent pattern in the statutory use of such terms (Drescher 1994, p.294). One may interpret these semantic differences as expressing an inability to cope with uncertainty, ambiguity and ambivalence. For the German administration, and the general debate, something has to be either safe or not.

Influences on field tests: 'over-regulation'?

Three of the largest chemical companies of the chemical industry (Hoechst, Bayer and BASF) have their headquarters in Germany, yet this country lags behind other industrialised countries in biotechnology innovation. This lag can be seen in the industrial production of chemicals and pharmaceuticals with the use of GMOs, and especially in the field tests with GMOs (Table 1). In comparison, genetic engineering as a basic research method is spreading throughout the scientific disciplines, though there have been many complaints from the scientific community about 'over-regulation'.

Initially, field tests with GMOs were only proposed by non-commercial scientific institutes. With the entry of AgrEvo, an amalgam of Hoechst and Schering, field tests have gained momentum since 1994. Only two field test applications have come from a large plant breeding company — Planta/KWS in 1992. No small company has yet been involved in field tests.

---

[4] Some misunderstandings of the German environmental policy seems to result from this translation problem (e.g. O'Riordan & Cameron 1994).

Table 1: Biotechnology in Germany

Number of approved applications for field trials with GMOs[5] (under 90/220/EEC), number of commercial laboratories, and number of scientific laboratories[6] (under 90/219/EEC)	F	Laboratories	
		(> 10 litre)	(small-scale)
1986	0		
1987	(1)	60	704
1988	0		
1989	1		
1990	1	53	1254
1991	0		
1992	3		
1993	1	58	1929
1994	6		
1995	>20		

The precise sequence of the field tests can be understood as resulting from the bad public image of GMO releases and of some large chemical companies in Germany. It seems not coincidental that the first application came from the Max Planck Institute in Cologne, as a basic research organisation; the next from the Kleinwanzlebener Saatzucht (Planta), a company with a good public image (or no image at all); the last from Hoechst (now AgrEvo), a multinational company that often attracts negative environmental headlines and one of the three post-war offspring of I.G. Farben, known for its notorious role in the Nazi regime. In fact, according to several independent sources, Hoechst had asked several reputable members of the research community to initiate field trials in Germany, in order to prepare the way for

---

5 European Commission, DG XI/A-2: list of SNIFs circulated under Article 9 of Directive 90/220/EEC from 21 October 1991 to 1 July 1994. One application listed for 1992 was withdrawn before the final approval (see Section 4.4). The 1995 figure is an estimate.

6 BGA Jahresbericht 1987, BGA 1990 unpublished, BGA 1993 unpublished. The 1993 figures are calculated by adding the 1990 figures and the new applications between 1990 - 93. The terms 'commercial purpose' and 'large scale' have had various meanings among the *Länder* since 1990: this may explain the apparently small increase in type B laboratories.

chemical companies. This feature of the step-by-step approach may be seen as an attempt to test social reactions — and perhaps to tire them.

In the national and international arenas, Germany's slow commercial development of biotechnology is seen as resulting from 'over-regulation'. This image is used by German proponents of biotechnology to promote amendment of domestic regulations as well as EC directives. They suggest that GMO regulation is provoking rather than calming 'exaggerated fears'. However, this is a superficial perspective, conflating regulation and control.

Strict enforcement

On the one hand, field tests and laboratories are strictly controlled by the *Länder* administrations to avert protest against formal or substantive violation of the law. This is because biotechnology research is so closely scrutinized by the public. For example, scientists at one field test were reported to the authorities because they had begun sowing seeds without announcing it three days in advance; because of weather problems, they told me, they announced the release only one day in advance. In other German environmental areas which also have tight regulations — but where public scrutiny is lacking — the control is far less strict. In German biotechnology regulation, strict enforcement can result from tight, detailed rules in combination with close public scrutiny.

On the other hand, the *Länder* authorities are blamed by scientists and industry for arbitrarily imposing safety measures solely in order to obstruct biotechnology R&D; this is especially the case in Hessen, with its long-standing conflict between Hoechst and the Red-Green government. Consequently, some proponents of biotechnology development demanded even more tight, detailed rules which would restrict the discretionary powers of the authorities. However, because this change could have the effect mentioned above, many German representatives prefer simply to abandon the precautionary intent of the regulation, so that neither the public nor the *Länder* authorities would have any legal instruments to restrict work with GMOs. Such a radical change would be possible only by amending or abolishing the EC Directives.

Fundamental obstacles

However, there are also more fundamental obstacles to commercial R&D with GMOs in Germany. First, there is little impetus to use genetic engineering on a commercial scale. This problem was reported for the initial steps in modern biotechnology in the early 1970s (Buchholz 1979). Even now, German industry, especially plant breeders, are not all convinced that innovation by genetic engineering is necessary. Traditional professional attitudes of chemists and plant breeders may account for this reluctance (Hasse et al. 1994, Dolata 1994).

Second, public suspicion is greater in Germany than in other European countries, though this is only slightly indicated by opinion polls (Inra Europe, 1991, 1993). Qualitative features seem to be more relevant. The opposition is well organised, while 'promoter acceptance' of genetic engineering is lacking; politicians and industry leaders are reluctant to fund its development (Hasse & Gill 1994). Manufacturers, especially food producers, fear product or brand-name boycotts (Heins 1992).

At first sight, then, the 'over-regulation' complaint seems to have some basis. Through a deeper analysis and comparison with other European countries, however, one can see that the apparent 'over-regulation' arises from Germany's mode of handling the conflict; strict enforcement results from practical dilemmas inherent in the national political context. Hence, as foreign observers rightly conclude, Germany's present lobbying efforts in Brussels conveniently blame the EU for the failure of German leaders to promote technological innovation and to overcome their traditional attitudes towards the public.

Perpetuating the conflict

In summary, Germany's conflict over biotechnology is perpetuated by self-reinforcing traps. Civil servants and scientists tend to follow a traditional approach, claiming that their actions are based only on the law and putatively objective knowledge. They presume that there is only one correct interpretation of the law and one 'rational' solution. Hence they can respond to objections only by blaming the objectors for 'irrationality'; otherwise they would have to acknowledge that their expert knowledge is deficient or that they are biased.

When the objectors are labelled as irrational, they react angrily. As a normal counter-reaction, administrative and industry experts make their safety claims even more precise and restrict the public discussion to technical issues. The more precise the claims, however, the more easily they can be rejected by counter-expertise or even contradicted by factual events, e.g. Chernobyl. The more the objectors are blamed for irrationality, the more awkward it would be for administrators to concede a point, or at least to acknowledge that the conflicting analyses are both value-laden. Meanwhile other objectors are cognitively excluded and emotionally frustrated by the narrowing battle over expertise: they seek other means of opposition, e.g. by destroying field tests.

Thus the dominant legitimation style in Germany perpetuates the original conflict, as the GMO issue illustrates. Germany is the European country where the GMO debate has been the most contentious, though this is not the most prominent of Germany's domestic conflicts over technological development. In the conflict over nuclear energy, even *Länder* administrations often opposed the technology in the mass media and

brought legal actions against it. By contrast, the GMO issue is relatively esoteric and calm. The problem is not that there is a conflict but that there are no compromises, nor even meaningful dialogues; vast energy is expended in endless repetitive debates, rather than in developing a more effective overall policy.

1 LEGAL FRAMEWORK

1.1 Origins of the legislation

The first regulation of rDNA research in Germany was formulated in accordance with the National Institutes of Health's guidelines of 1976, largely without legal force; it was issued by the Ministry of Research and Technology.[7] At the same time, the Ministry planned to make the guidelines legally binding but this plan was criticised as bureaucratic. The most reputable science organisations lobbied against the bill, which was finally dropped in 1981 (Deutsch 1982). At this time the genetic engineering issue received little public attention. The attention came with the first test-tube babies in Germany, after 1982, and intensified through the late 1980s.

According to the Ministry guidelines, deliberate releases had to be approved by the Federal Health Authority, the *Bundesgesundheitsamt* (BGA). In 1987 a German academic scientist, Walter Klingmüller from Bayreuth, tried to get approval for the release of genetically modified *Rhizobium*. The BGA denied its authority, by arguing that the bacteria was modified by *in vivo* conjugation, not by *in vitro* recombination, and therefore would not fall within the guidelines. When Klingmüller released his bacteria without approval, this was seen as akin to an illegal act by the German public. In 1988 the Max Planck Institute in Cologne applied to release genetically modified petunia, and gained BGA approval in spring 1989, but did not conduct the field trial until 1990.

Since 1990 both the deliberate release and contained use of GMOs have been regulated by the Genetic Engineering Act (GEA),[8] with its very detailed ordinances. The GEA was enacted in May 1990, before the EC Directives 90/219 and 90/220 required national implementation. Although the German legislative procedure coincided with the formulation of the EC Directives, it was driven by national conflicts over modern biotechnology (Gill 1991). When in 1989 the Kassel court decided that the insulin plant of Hoechst could not be approved without a special legal base for genetic engineering, the federal government formulated the legislative proposal for the GEA. The early, fast enforcement of the German law led to some inconsistencies both internally, and with the EC directives.

---

[7] Only laboratories which were funded by the research ministry had to follow the guidlines, this was similarl to the situation in the USA, where only grant-aided institutes were directly obliged to follow guidelines. Other research funds, scientific associations and the association of the chemical industry declared that they would enforce the voluntary guidelines within their organisations.

[8] The German 'Law to Regulate Genetic Engineering' (BGBl. 1993 I, Nr. 67, 21.12.1993).

Whereas genetic engineering was formerly under the self-regulation of the scientists, the GEA placed it under the control of the judicial profession and hence the entire framework of German procedural, administrative and environmental law. The GEA goes further in some respects than the EC directive, e.g. on the liability issue, for consistency with the German environmental law — not for policy reasons specific to biotechnology. In 1992 industry and science organisations started a large campaign claiming that Germany's economic problems resulted from restrictions on genetic engineering. Consequently the GEA was amended, i.e. streamlined and somewhat clarified, in 1993.

Also in 1992, the European Commission had criticized the GEA for not complying with the EC Directives on several points.[9] The German government replied that most of the criticized points had no compliance deficits by its own interpretation, and announced amendments to the other points, which were included in the 1993 amendment.[10] In fact, with its reply, the German government clarified the complex interaction of the GEA with the more general regulations in the environmental, administrative and procedural law.[11]

In the other direction, in 1992 the German government — together with the German chemical industry - began to lobby in Brussels to streamline Directives 90/219 and 90/220, particularly to abolish or relax the S1-level for contained use in 90/219. In the Parliamentary debate on the 1993 amendment of the GEA, similar arguments were heard: because the use of genetic engineering is hampered by public aversion in Germany, the GEA should compensate for this handicap and so restore equal competition between Germany and the other European countries.[12] Another argument used was that process-based legislation stigmatizes genetic engineering as dangerous, so its amendment must improve public acceptance: that is, legislative relaxation would demonstrate symbolic support for genetic engineering (Vitzthum 1993).

The relation between Germany and the EU operates at two levels. At the formal level, DG XI may try to enforce compliance, while Bonn tries to change the directives to make them comply with the GEA on the one hand and to streamline them on the other.[13] At a more symbolic level 'Brussels', i.e. the genetic engineering directives, has now acquired the previous

---

9 Letter from the European Commission to the German Federal Government, 06.07.92.

10 'Stellungnahme' (reply) of the German Federal Government to the European Commission, 7.10.92

11 As far as I know, the conflict has come to an end (Vitzthum 1993). In 1995 the legal unit within DG XI which initiated the procedure was abolished by the departing commissioner.

12 Dt. Bundestag, 12. Wahlperiode, Ausschuß für Gesundheit, Unkorrigiertes Wortprotokoll der 65. Sitzung am 30.6.1993, S.114

13 Bundesratsdrucksache 357/93, p.54/55 and Bundesratsdrucksache 357/1/93, p.2/3 .

domestic role of the GEA — as a scapegoat for all the troubles imagined by German biotechnological science and industry.[14]

1.2 Main regulations

The GEA's juridical structure, especially the existence of a law only for genetic engineering, indicates that GMOs are perceived by the legislator as a novel problem. For the health and environmental hazards resulting from a deliberate release or market approval of a GMO, all issues fall within the GEA — and only within the GEA. Medium-based environmental laws, for protecting water, air and natural fauna and flora, cannot be used to prevent the unwanted consequences of GMO releases. Product-based laws should ensure quality, efficacy and safety — e.g. of seeds, pesticides and food, but such laws concern only known hazards of the product — not hazards which may result from the genetic engineering process. Therefore a product containing GMOs has to pass through the market approval, procedures of the GEA as well as those of the corresponding product law. Approval within the GEA can be omitted only if the product law provides for risk-assessment requirements equivalent to the GEA; this seems to be the case only for pesticides, according to one legal opinion (Ott 1992). Even if there may be some conflict between the product approval by the GEA and by product laws, Germany's GMO regulation is process-based. There is also much discussion about whether to require labelling of food which contains GMOs, and perhaps substances derived from GMOs, but nothing is yet settled because the Novel Food Regulation is still pending at EU level.

The GEA prohibits deliberate release — as well as all work with GMOs[15] — unless the responsible organisation (*Betreiber*) obtains approval from the competent authority. A GMO is defined as 'an organism with genetic material changed in a way which could not occur under natural conditions — breeding and natural recombination' (§3). 'Organism' is defined as 'a biological entity capable of reproducing itself or transfering genetic material'. The GEA provides a short list of sample methods which would classify the modified organism as a GMO, as well as a longer list of advanced biological methods which would not classify the modified organism as a GMO. The 1993 amendment clarified that no human aspects of gene therapy fall within

---

[14] German protagonists have worked themselves up into such a fury that now they imagine non-existent restrictions. According to a scientist who conducted a gene-therapy trial for the first time in Germany (R. Mertelsmann), his colleagues had advised him that such an experiment would face many administrative obstacles in Germany. When he formally put forward his proposal, however, the only examination he had to face was a review by the ethics advisory board of the university (Friedrich-Ebert-Stiftung: Expertengespräch Gentechnik - Perspektiven der somatischen Gentherapie, 22.3.1993, Bonn, p.45/46).

[15] For S1-work one has only the obligation to inform the authorities and to keep records of the experiments.

the GEA[16]. The GEA differentiates between *Freisetzung*, i.e. field trials, and *Inverkehrbringen*, i.e. commercialisation or other widespread distribution[17]; each has a different procedure (see Appendix III).

In both cases the applicant must provide the literature and his or her own data on the safety of the GMO, and must describe measures to monitor and control the deliberate release — even for market approval. Unlike the atomic energy law, the GEA does not grant regulators broad discretionary power to deny approval (*Versagensermessen*). The competent authority must decide within three months and must approve the application, if the follow criteria are satisfied:

if the applicant is 'reliable', i.e., the organisation or the involved persons have not committed offences against relevant regulations in the past;

if the supervisor and the safety officer can formally demonstrate their competence and — as a result of working hours, geographical proximity to the test site and the hierarchical independence of the safety officer — are able to supervise the release;

if all safety measures are taken according to the present state of the art in science and technology (*Stand der Wissenschaft und Technik*);

if, according to the state of the art in science, there is no expected harm — to people, animals and plants, and the wider environment as a functional system (*Wirkungsgefüge*), including economically important resources — 'which could not be justified in relation to the purpose of the release' (§16).

For market approval, only this last condition must be fulfilled.

The requested information about the GMO, the test site and safety measures are specified in the Genetic Engineering Procedures Ordinance (GenTVfV) which transposes the Appendices of Directive 90/220. What those criteria mean for the burden of proof depends on interpretation, through the bargaining between Competent Authority and the applicant or the law court. The German law distinguishes between 'state of the art in technology' and 'state of the art in science and technology'. The former means that the best available technique must be used to prevent (hypothetical) risks.[18] The latter means that the application can be approved only if no scientific evidence of a risk exists or if the risk can be prevented by an available technique. As far as I know, no applicant has sued against a decision of the Competent Authority in this respect.

---

16 For *in vitro* steps of the process, the contained use regulations apply. As soon as the prepared cells (or vectors, etc.) are applied to human beings *in vivo,* the jurisdiction of the GEA ceases.

17 Distribution to other laboratories and the transport between different sites of a company is not regarded as *Inverkehrbringen*.

18 BATNEEC does not exist in German law but the *Vorsorge*-principle means that the preventive measures imposed by the administration should not be over-reactive in relation to the relevant risks (*Verhältnismäßigkeitsprinzip*).

In 1992 the European Commission criticized the GEA for not regulating information exchange between the German authorities and the Commission. According to §14(5), market approval by other EU countries is also recognized in Germany. In its reply, the German government announced its rule for informing other Competent Authorities about the German approval procedure; this procedure already existed and was followed in practice[19] but was still not formally enacted (by November 1995).

Legal liability for harm from GMO releases is somewhat extended by the GEA. Normally a person must pay for damage only if he/she is judged to be guilty of having caused it by personally attributable negligence or intention. According to the GEA, the responsible person or organisation is liable for all damage caused by the GMO, even _

if the GMO was approved by the authorities, or

if the responsible persons have followed all measures which were known to be necessary, or

if the possibility of damage was not known until the accident occurred (*Haftung für Entwicklungsrisiken*).

Moreover, not only the producer but even the user may be liable in some cases. The European Commission criticized this aspect for extending liability beyond the EC product liability _ Directive 85/374.

The applicant must demonstrate in advance that he or she has insurance or can otherwise pay compensation for any damage. The maximum liability is set at 160 million DM (approximately 90 million ECU). Liability covers only damage to people and property; it excludes damage to the wider environment.

The GEA provides a reduced burden of proof (*Beweiserleichterung*) on the damaged party to some extent. If damage is caused by a GMO, it is initially presumed that the damage is caused by the genetic modification; hence the responsible organisation or person must demonstrate the contrary. But the damaged party must show that the damage is caused by a specific GMO and that this GMO was released by a specific (and hence responsible) organisation or person. To this end, there are some complex information rights for the harmed person. German jurists recognize and sometimes warn that this form of liability may go beyond the regulations in other EU countries and could disadvantage German producers.[20]

For the question of whether or not the government can be taken to court, see Section 6 on public access.

---

19 For example, the German CA circulated SNIFs for all German notifications.

20 P. Lange in Eberbach, Lange & Ronellenfitsch: Gentechnikrecht (Kommentar), Vorwort zur EC Freisetzungsrechtlinie, Rdnr. 85

2 COMPETENT AUTHORITY AND ADVISORY COMMITTEE

2.1 Competent Authority

The competent authority for the approval of GMO releases is the *Zulassungsstelle für biologische Sicherheit*[21] of the Robert Koch-Institute (RKI), a research unit within the Health Department and part of the former *Bundesgesundheitsamt* (BGA)[22]. The *Zulassungsstelle*, which now has about 65 employees, evolved from the much smaller administration unit of about five employees, formerly responsible for the procedures of the safety guidelines. The *Zulassungsstelle* is the main authority for the approval procedure[23] but must involve other administrative units as well. Before a field trial can be approved, the Competent Authority must obtain consent (*Einvernehmen*) from the following authorities:[24]

the *Biologische Bundesanstalt*, a research unit of the Ministry of Agriculture, Food and Forestry;

the *Umweltbundesamt*, a scientific unit of the Ministry of the Environment;

the *Bundesforschungsanstalt für Viruskrankheiten der Tiere*, another research unit within the Agriculture Department, if the trial involves genetically modified vertebrates or genetically modified micro-organisms which are applied to vertebrates.

Also the competent authority of the federal state (*Land*) where the test site would take place must be consulted, though they need not consent.

Before a GMO-containing product may be granted market approval, the following authorities must be consulted, though they need not consent:[25] the *Biologische Bundesanstalt*;[26] the *Umweltbundesamt*; the *Bundesforschungsanstalt für Viruskrankheiten der Tiere* and the Paul Ehrlich Institut, another research unit of the Health Department mostly concerned with vaccination remedies (though only in cases as listed above).

---

21 biological safety approval office

22 The BGA was a larger health research organisations with other six institutes like the Robert Koch-Institut.

23 The *Zulassungsstelle* also has the task to work out standard protocols for contained use and to advise the *Länder* administrations which are responsible for approving and monitoring the contained use applications.

24 The different procedures are summarized in Appendix A.

25 The procedure is summarized in Appendix A.

26 Before the amendment of the GEA, the BBA had to give consent. According to a BBA official, the intention of this change was to streamline the distribution approval procedure.

Until 1990 the former small administrative unit within the Health Department was financed and guided by the Ministry of Research and Technology, which also formulated the guidelines. In the legislative procedure, however, the responsibility for implementing the GEA shifted to the Health Department, apparently for two reasons. First, the Ministry of Research and Technology traditionally has no authority and thus no experience of formulating and implementing laws (Hohn & Schimanck 1990). Second, the Research Department has the task of promoting technology. With the GEA, the government wanted to demonstrate its concern for the health and the environment; this is the first aim in §1 of the GEA, while technology promotion is the second.

The Health Department had the expertise and authority for regulating traditional human and domestic animal health hazards from microorganisms, but did not have experience with the wider agricultural and environmental aspects. The *Umweltbundesamt*, and to a lesser extent the *Biologische Bundesanstalt*, sought a stronger position within the consent procedure but failed because the government suspected that they might implement the procedure too stringently, by comparison with the *Bundesgesundheitsamt*. The *Umweltbundesamt* was founded in the 1980s, while the BGA was founded in the nineteenth century. This means there is a difference not only in administrative style but also in the duration (and direction) of capture by societal interests. The *Bundesgesundheitsamt* is well known for its well-established contacts with mainstream science and industry. Indeed, the consequent scandals finally led the government to abolish the BGA, while preserving its smaller units.[27]

[27] The BGA was dissolved by the Minister of Health in 1993 as a consequence of the AIDS scandal; the BGA was regarded as responsible for virus-contaminated blood preparations.

One of these traditionally existing smaller units is the Robert Koch-Institut,.[28] which became the Competent Authority in 1993.

The Health Department was given the main responsibility for additional reasons: the strong preoccupation with contained use and the administrative experience, which also provided a better preparation within the legislative procedure, when several ministries sought to extend their authority. Moreover, the GEA is constructed around the procedural role of the advisory committee Zentrale Kommission für Biologische Sicherheit (ZKBS), which traditionally belongs to the Health Department and which is seen by biotechnologists as representing their interests. This reason became particularly clear when the chairman of the advisory committee (ZKBS) himself declared in public that this body works as a counterbalance within the regulation system; he blamed the media and the administration for irrational over-regulation (Hobom 1994). Thus the choice of the Robert Koch-Institut as the Competent Authority was not a compromise but rather a gain for the proponents of biotechnology, although this was balanced by other measures which provided a partial victory for the critics.

2.2 Advisory committee

The advisory committee, the *Zentrale Kommission für Biologische Sicherheit* (ZKBS), existed prior to the GEA; it was founded with the formulation of the first biosafety guidelines in 1978. Traditionally the ZKBS was - and still is - in charge of classifying GMOs in contained use for various risk and containment levels. Deliberate release is seen as an additional task, which is only now becoming more relevant.

Until 1990 the ZKBS functioned as a self-regulation body of science and industry. It had 12 members: four scientists with expertise in genetic engineering; four other scientists (one microbiologist, one cell biologist, one with an expertise in hygiene, and one ecologist); and four nominated experts (one recommended by the industry associations, one by the unions, one by workplace safety organisations,[29] and one by the research funding organisations).[30]

---

[28] In one case the RKI strongly opposed a distribution approval (rabies vaccine) with the arguments normally used by critics of GMO releases: that the interaction among virus particles cannot be foreseen. Even among the German authorities, it was suspected, that the opposition was motivated by the intention to protect German vaccine production from foreign competition (interview 15).

[29] The German *Berufsgenossenschaften* are corporatist bodies run by industry and union representatives.

[30] E.g. the *Deutsche Forschungsgemeinschaft* as a self-regulation body of the research system.

With the 1990 GEA the composition changed somewhat and the consultation procedure became more transparent. By 1995 the ZKBS had 15 members and 15 substitutes. The membership is confirmed by the Minister of Health and agreed by the Minister of Research, the Minister of Agriculture, the Minister of the Environment and the Minister of Economy and in consultation with the federal state (*Länder*) governments. The membership comprises:

ten scientists: at least two must have expertise in ecology; at least one must have expertise in microbiology, cell biology, virology, genetics, hygiene and safety technology; six must work with genetic engineering methods; and

five nominated experts: one nominated by the industry associations, one by the unions, one by workplace safety organisations, one by the research funding organisations, and one by environmental associations.

Within the three administrative units involved in addition to the ZKBS (RKI, BBA and UBA), there is much expertise in various scientific disciplines. Thus external and more specialised scientists are consulted only when special or sharply disputed questions are at stake. The public legitimation of scientific expertise is portrayed as deriving from the ZKBS, even if its composition is one-third 'political'. And the ZKBS can have substantial influence over the most relevant classificatory decisions within the regulation system. Many details are handled by the full-time employees of the administration because the ZKBS meets only once a month.

From the outside, little conflict is apparent among the bureaucratic, scientific and political forces of the regulatory system, as regards deliberate release — in contrast to contained use, where the Länder as actors provide more conflict and transparency. Even though the ZKBS has a somewhat pluralistic composition, it seems to have no major conflicts. The procedural rules of the ZKBS are designed to favour a dominant chairperson and majority rule, which because of its composition is guaranteed to come from mainstream science.

Moreover, the ZKBS maintains secrecy. Just once a year a thin report is published, which contains only the most relevant decisions. Thus nothing very certain can be said about the discussions within the committee.

There is a formal right to record a 'substantiated' minority vote, which was used by the member and the substitute from the environmental associations to oppose the first approvals for field trials.[31] They both resigned in 1993 because they felt that they had no influence in this body. They reported that

[31] The records are not public, so minority votes are not known and cannot be communicated by the dissenting ZKBS members because they are not allowed to make public any content of the consultation.

it is very difficult to formulate a minority vote, because the majority usually denies the 'substantiation'; hence their objections were not put on record.[32]

Value judgements are formally provided by the GEA, whose §16 instructs that the safety concerns should be assessed 'in relation to the purpose of the release'. There is much debate about this phrase in the juridical community (e.g. Wahl & Melchinger 1994, Drescher 1994). There is no consensus about how to interpret this phrase, which has no precedence in a legislative text and was also criticized in the letter of the European Commission. One could see this sentence as legitimation for hazardous field trials, in the sense that the ends would justify the means, though one could just as well use it as legitimation for the 'fourth hurdle'. Some even claim that the phrase is inconsistent with the German constitution.

In the official argument (*amtl. Begründung*), this statutory clause is justified as necessary. Without §16, it argues, GMO-containing pesticides could not be developed, because the very aim of pesticides is to damage some parts of the wider environment (see above, Section 1). The authorities interpret the clause to mean that first they assess whether a release poses a risk. Only if a risk exists would the phrase be relevant. No such notification has yet been received, according to all the regulators whom I have interviewed.

In the German administrative culture, regulators attempt to assess notifications 'scientifically' as bearing 'no risk', rather than openly acknowledging the value judgements implied by the above phrase of the GEA. Indeed, two of the regulators I have interviewed at BBA and UBA conceded that even the normal risk-assessment process is full of implicit value judgements. One regulator justified such value judgements by arguing that an internal plurality within the administration mirrors public opinion. Nevertheless, officials do not publicly acknowledge that a concrete decision was guided by judgements which went beyond objective knowledge. Illustrating the usual claim for objectivity, the Competent Authority pretends that all decisions, e.g. in relation to the step-by-step procedure, are programmed by Directive 90/220 and the GEA (RKI letter, 7 June 95).

This political game has a paradox: The more discretionary power is given, the more it must be rationalized by the claim for objective knowledge. Otherwise the administration would be acknowledging that it is taking political decisions.

Another point of ethical and juridical uncertainty comes from the GEA (§1): the procedure must prevent damage not only to people, economically useful organisms and things, but also to the wider environment. Because there exists no well established concept for the dynamic conservation of nature, no

---

[32] Contribution at an internal meeting of environmental groups on the issue of whether and how to participate in advisory bodies in Frankfurt/Main, (autumn 1993.

one can be certain how to assess ecological shifts resulting from deliberate release as juridically relevant 'damage'.

3 SCIENTIFIC PERCEPTIONS OF RISK

The debate on deliberate release can be understood as an epistemological issue, i.e. as a controversy between various subdisciplines of biology, especially molecular biology and ecology (von Schomberg 1993). This may be true for the USA, but academic ecology is not so prominent in the German political debate. More notable are alternative science organisations, in particular the Öko-Institute. These were founded during the struggle against atomic energy to provide critical expertise; they must finance themselves on a day-to-day basis by politically motivated contributions[33].

In the USA, politically relevant debates between scientists are fought out in public, including in scientific journals such as *Science* (Jasanoff 1986). In Germany, elite scientists tend to restrict their debates within exclusive circles and behind closed doors; they exclude or marginalize any persons who publish dissenting views. As a consequence, academic science organisations seem hardly receptive to environmental criticism, while the alternative science organisations are more independent from the academic consensus and tend to be more politicised. The cognitive basis of their criticism is formed by the results of biosafety research all over the world.

3.1 Polarized stances

Apart from a few individuals, academic ecologists play little mediating role in Germany, as compared to the USA (Tiedje et al. 1989). This difference may have two reasons: firstly, the German conflict was politicised from the start; established ecologists, who in USA engaged themselves later on in the debate, feared being identified with radical ('emotional', 'irrational') criticism. Secondly, there are no funds which would promote interdisciplinary research in this field. Traditionally biology in Germany is subdivided into 'two cultures'; one has a reductionist, technologically-orientated approach, while the other has a more holistic, observationally-orientated approach (cf. Harwood 1989).

These 'two cultures' also have different risk perceptions: the former believe in prediction and calculation, without which they could not produce technological artefacts; they believe in knowledge and certainty. The latter, confronted with given phenomena, see their models often failing to explain

---

33 Contributions from citizens and consultants (*Gutachteraufträge*) from political organisations.

natural complexity; they take uncertainty and ignorance into account. Those polarized cultures result in antagonistic risk perceptions, though more diverse positions exist in Germany.[34]

Position 1: There exists no risk from genetic engineering as such. There is a need to prevent only the natural risk, which may come from the pathogenicity or other unwanted effects of the host organism, the vector and the transferred genes. The risk of the GMO can be predicted from its elements.

Position 2: Genetic engineering may be risky as such. By transferring a gene, not only the gene-coded effect is to be seen but also possible changes on various levels (cf. Bonß et.al. 1992). In particular:

i) As it is not clear where the new gene is integrated in the genome, the adjacent genes of the integrating locus may change its effects and/or change the regulation of the genome.

ii) New and unforeseen biochemical pathways may arise downstream from the transferred gene.

iii) New and unforeseen interactions between the GMO and its environment may arise.

Hence the risk of a GMO cannot be predicted alone from its elements. This position is named by its protagonists the 'synergistic approach' - in contrast to position 1, which they call the 'additive approach'. The simplest political consequence from position 2 is to oppose genetic engineering as such. A more modest approach is to plead for more scrutinity in precautionary measures, e.g. a stricter step-by-step procedure with more tests in the greenhouse or in a microcosm before a field trial is started.

The GEA's wording is something like a compromise between the two positions in that it states that the risk level for laboratories is provisional, and that the resulting GMO should be assessed. However, neither from (the inconsistencies in) the law, nor in practice, is it clear how to handle these uncertainties. There is no consensus, neither among the sciences or among the regulators, about what approach to the risk assessment should be used. Critiques, such as those from the Öko-Institut, maintain that the 'additive approach' is used in practice.

In practice, however, there exists at least a symbolic compromise between the two positions. There are preventive measures for laboratory risk-level 1, defined as 'no risk'; and there is monitoring of test sites, even if no risk can be shown during the approval procedure. Such efforts are made, even if the

---

[34] The following discussion is documented in Gloede et al. 1993, pp.15-60.

risk-assessment procedure is inconsistent and perhaps inadequate to reduce the remaining uncertainties.

In this debate, advocates of position 1 meanwhile have conceded that such unpredictable effects exist, but that they are rare and also occur in natural recombination or in other natural events, e.g. transposon effects. Hence the risk from genetic engineering is not higher than, and not unlike, the natural or traditional biological risks. So any unforeseen damage is rare, acceptable in its effects, and can be minimized by traditional preventive measures.

3.2 Herbicide-resistant crops: technology assessment procedure

Deliberate release has remained controversial, especially with the aim of developing herbicide-resistant crops, despite safety regulations. During 1991-1994 the *Wissenschaftszentrum Berlin* organized a technology-assessment procedure on the impacts of transgenic herbicide-resistant crop plants. Present were representatives from industry, various disciplines (molecular biology, plant breeding, agricultural engineering, ecology), administration and NGOs. Under the circumstances of the ongoing procedure, all initial stances (of NGOs, of industry) were examined for their logical consistency. The NGOs left the procedure during the closure meeting, thus demonstrating their dissent (Gill 1993). From the conclusions of the organizers, one can discern a convergence on ecological risk issues (Daele et.al. 1994/4, pp.121-144), as follows:

As regards the 'non indigenous (exotic) species model', the debate concluded that experience with the introduction of non-indigenous plants may be appropriate to predict the overall statistically aggregated risk, but that the prognosis on a particular genetic modified crop plant should start from the phenotypic properties of the non-transgenic host plant (ibid., p.133). Non-indigenous plants may have the advantage that no competitors exist, but the disadvantage that they are not adapted to the indigenous environment. Therefore no *a priori* difference in risk can deduced from this category. Even indigenous plants, e.g. rape, can be risky (ibid., p.134). Even more problems have to be taken into account when genetically modifying less domesticated, long-living plants, e.g. trees (ibid., p.123).

The transgenic property, e.g. virus resistance more than herbicide resistance, may propagate the spread of the manipulated plant in various environments. But the same is true if the property is developed by traditional plant breeding. Unintended increases in biological fitness and ecological adaptability in various environments are not anticipated systematically by the traditional approval procedure (i.e. DUS tests) for food plant varieties. There was consensus that not only the overall extinction of species should be prevented but also the loss of biodiversity in distinct ecosystems.

There was disagreement about whether particular risks are introduced by the novel method of genetic engineering as such. NGOs' representatives maintained this claim, while the dominant participants rejected it as 'speculative', i.e. beyond the boundary of acceptable 'good reasoning'. NGO members then tried to turn around the burden of proof — i.e. that it should be demonstrated that there is no particular risk due to the genetic modification process. But this demand was rejected as impossible. A mainstream molecular biologist argued that the probability for horizontal gene transfer from the herbicide-resistant crop to microorganisms in the rhizosphere may be increased by the use of transgenic sequences derived from bacteria; the participants acknowledged that this could be seen as a particular 'quality' of the genetic modification technique which is used. Most could not see this as a particular risk, but even some non-NGO participants conceded that it would be a sign of 'good technological practice' to minimize the unintended effects, e.g. by trying to use only plant-specific rDNA sequences (Daele et al. 1994/3, p.90).

The majority maintained that the existing case-by-case and step-by-step approach is justified. It should be complemented by a monitoring regime for the period after the market approval (Daele et al. 1994/4, p.143). If the assessment procedure proves valid for the discovery of ecological risks from transgenic plants, then it should be for the approval of conventional plants (ibid., p.143).

Despite this extensive assessment procedure, the debate mainly revolved around the NGOs' claim about rDNA-specific risks and damage to non-agricultural environments. By default, that focus marginalized the more pragmatic and internationally more relevant issue of whether herbicide-resistant crops would change the patterns of herbicide use and crop rotation. That issue was being raised by some European NGOs (and even Competent Authorities) against the PGS marketing application, but the technology assessment workshops treated such effects only as economic damage.

3.3 Shift in risk debate

In the German debate one can now observe a shift which may have happened earlier in other countries. Initially, safety arguments were based on the claim that the rDNA would be biologically contained within the host organism. When biosafety research showed that the spread of transgenes is not contained within biological barriers, the regulatory response was not tighter restriction but rather the 'so what?' question. If there are 'no barriers' in nature, then this is interpreted by protagonists as evidence of safety — i.e., as more proof that genetic engineering is a 'natural' method, and that evolution already must have created all harmful recombinations.

As one critic from the Öko-Institut ironically commented: 'Demonstrated risks are natural risks are no risks' (Tappeser 1994, p.1). The critics argue that nature must have some barriers - without which the evolutionary mechanism of isolation would not exist — and that such barriers may be violated by genetic engineering. For example the inactivation of transgenes, often observed by plant biologists (Finnegan & McElroy 1994), is interpreted as a process which could be such a barrier.

Hence critics insist that genetic engineering as a method is special. They emphasize models other than the dominant molecular biology dogma, and suggest that these may prove more adequate to explain complex natural phenomena (e.g. Goodwin et al. 1993). This perspective claims no clear cut, close analogy to harmful events or experimentally testable risk hypotheses. Testable risk hypotheses, they argue, are already considered by industry for economic reasons. These critics see their role more as indicating the ignorance which lies beyond such tests.

In general, a paradigm shift in the risk debate has followed the steps from confined field tests to market approval; this shift is also promoted by the growing commercial interests. An early issue was whether the GMO or the novel genes may spread itself biologically; now there is the question of whether the GMO can cause harm. With market approval, dissemination is intended and not very controllable, for social and now better demonstrated biological reasons.

One regulator, a microbiologist, acknowledges that the arguments for the shift from the first to second releasing step — from confined trials to market approval — are not very consistent. He also acknowledges that the 'so what?' question about harm should have been asked from the beginning. He personally states that the decision on harm is also a question of value judgement and that this should be made more explicit. The discussion about what constitutes less or more severe 'environmental harm', and about the un/predictibality of long-term ecological effects, has just begun.

The shift in the risk debate has not been reflected in the regulatory risk concepts until now because the concepts remain implicit. Attempts to formalize the risk-assessment procedure, as started by the British and Dutch Competent Authrorities, seem to have little resonance in Germany. A notable exception is the UBA (Umweltbundesamt 1995), which tries to accommodate the British concepts to the provisions of the GEA.

Nevertheless it is worth noting the differences in the self-evaluation of the regulatory system by the various authorities. The UBA representative states that only the most severe immediate damage of clear-cut risk scenarios can be prevented, e.g. the spread of an organism with the strong ability to degrade lignin, thus destroying forests and humus. By contrast the RKI claims, 'All aspects relevant for safety are reviewed and assessed according to the criteria given by the genetic engineering law. Therefore no damage —

as defined by genetic engineering law - occured and is to be expected.' (RKI, letter to author, 7 June 1995, p.1)

4 STEP-BY-STEP PROCEDURE

4.1 PGS application

As regards the PGS application for herbicide-tolerant oilseed rape, the RKI seemed to support the approval.[35] However, it has given no public comment, on grounds that the final decision is still pending (letter of 7 June 1995) — even though the CAs completed their voting procedure in February 1995. The RKI tries to prevent a public debate in which it might come under fire for its EU-level consent. The political tactic becomes clear when one remembers that the RKI was not at all silent when opposing market approval for the recombinant rabies vaccine; its vocal opposition contrasts with its present request that administrative deliberations should generally take place behind closed doors.

Meanwhile the UBA is fighting against the approval — not only in the administrative realm, but also in the political realm, and to some extent in the public arena. The UBA emphasizes the potential changes in herbicide use and agricultural practice which cannot be regulated under the German pesticide law.

Clearly the decision on the PGS application serves as a precedent for future products from other companies. Nevertheless, no public argument links the PGS application with the development of similiar phosphinothricin (Basta)-resistant plants by the German-based AgrEvo.

4.2 Meanings of the step-by-step procedure

The first problem with the step-by-step procedure is that it is not fully implemented in the genetic engineering law — for which the European Commission criticized the German government. The government claimed that the EC Directive 90/220 does not make the step-by-step procedure mandatory for the national authorities.[36] Nevertheless Germany's three relevant authorities do try to implement the step-by-step approach. The GEA has three somewhat contradictory points which allow or restrict the approach:

---

[35] 'Streit um Gentechnik-Raps' in der Süddeutschen Zeitung v. 9.2.1995, p.23. Compare also an undated draft of a press release, probably from RKI, which makes a half-apology for accepting the approval in Brussels and feebly attempts to accommodate the position of the UBA.

[36] See the reply of the German government to the European Commission from 7.10.1992. A German jurist states, regarding the EC Directive, 'The resolution of the juridical assessment problem is still pending, if the existence of a field test approval is a mandatory prerequisite to submit a marketing application' (Simon 1994, p.360).

The aim to prevent risk, in §1 of the GEA, allows scope for this approach.

The fact that there exist no discretionary powers — for the authorities to deny an approval for other than perceived risks according to the current state of the art in science — restricts the possibility of this approach.

The requirement that safety concerns should be assessed 'in relation to the purpose of the release' (§16 of the GEA, see above) is seen by one regulator as also restricting any step-by-step approach.

In practice German regulators seem to have little difficulty in enforcing information requirements and confinement conditions, because the applicant cannot really oppose official decisions, in the current adverse public climate (see Section 6). A 'step' is hence defined by the amount of information the applicant must provide for the next step. The amount needed — its scope, and the plausibility of risk scenarios to be tested — seems to be often contentious among the three authorities; it is finally decided by arguing and bargaining among them. (In all my interviews, I obtained no clear-cut account of what is defined as 'evidence of safety'.[37])

4.3 Relaxing the procedure?

The step-by-step approach means that the assessment procedure may be relaxed step-by-step. The GEA provides the opportunity for such streamlining by the option for two ordinances (see below). So far this option has not been used by the government. Regulators of the UBA and the BBA explain this by citing the relative lack of experience with field tests in Germany.

Even the RKI seems to be reluctant to clarify the step-by-step procedure: 'A general statement is not possible; it depends specifically upon the type of simplified procedure. Possibilities are imaginable for agricultural and horticultural crop plants' (letter from 7 June 1995, p.2).

At the same time, however, the German government was lobbying Brussels for the relaxation of the EC directives. Perhaps political forces regard Brussels as a better arena to promote their relaxation campaign, because in Germany they would face much public opposition. Moreover, the RKI does not want to give up its discretionary powers associated with a less formal step-by-step procedure, regardless of regulators' risk perceptions.

The regulation is often criticised for bureaucratism, though in quite different ways. One regulator thinks that the amount of standard information required for common crop plants should be reduced. Another regulator thinks that the cooperation with the applicant is better in other countries —

---

[37] One may ask if the interview method is at all a useful research tool for this question. A comparison of the files in different countries could be a more insightful approach, though more costly.

e.g. United Kingdom, France and the Netherlands — where the authorities have more possibilities to discuss the application with the applicant and to establish specifically designed monitoring programmes.

4.4 Difficult releases

The question of whether there had been special problems with particular applications, for scientific or political reasons, was not answered by the RKI. The other two authorities claimed that they had no particular problems with individual cases in Germany, except with oilseed rape or sugarbeet to a small extent; as a contrast, one regulator cited the satellite-RNA virus-resistant tomato case in Italy. With one German case, the procedure took a very long time on account of deficiencies in the application from academia; in general industry is better equipped to handle complex organisational problems. In at least one case, an application to release a microorganism was withdrawn, on advice from the RKI.

From my study, I would say that petunia has faced the most problems for political reasons — because it was the first case, with most public awareness. As one regulator stated during an interview, the petunia field test was 'irresponsible', for public-relations reasons. That is, the applicant (the Max Planck Institute in Cologne) would have known already that the transgene behaviour was irregular; in their greenhouse experiments, the colour of the blossoms was other than predicted. In the public debate, this result was interpreted as verifying the general unpredictability of the effects of genetic engineering and was thus associated with 'risk' (Lau 1993).

5 RISK ASSESSMENT RESEARCH

In German biotechnology policy, 'risk-assessment research' does not exist as an official term. Rather, such activity is labelled 'biosafety research', in order to obtain the acceptance of the biotechnology community. (For budget figures, this report uses a ratio of 2 DM to 1 ECU.)

5.1 Funding

There is one important research fund, supplied by the Department of Research and Technology (BMFT). This is part of a larger fund for biotech-nology research, amounting to about 140 million ECU annually. During 1988-1993 the Ministry of Research and Technology invested 0.8 billion ECU in biotechnology research and 16.7 million ECU in biosafety research, respectively; thus biosafety research comprises 2% of the budget (Katzek &

Wackernagel 1991, p.56). In addition the Land Bayern provided approximately 1.25 million ECU during 1989-1994.

The content of the biosafety research is diverse. It includes food safety, deliberate release and gene therapy; only a small part is devoted to contained use (BMFT 1988-1994). In 1994 it was announced that the same amount of money should be spent within the next year as in the past for biosafety research, and that it should be focused more upon monitoring field tests (BMFT 1994, 'Vorwort').

It is easy to identify these special funds but more difficult to identify biotechnology research in general, because it spans funds which may be categorized according to other criteria. Also relevant are the general budgets of the various research institutions such as universities, which do not specifically indicate the money for biotechnology research in general, nor for biosafety research. I once estimated the overall funding of biotechnology research in Germany as amounting to 1.5-2 billion ECU in 1990 (Gill 1991, p.94). These funds are more dedicated to basic research than to the development of GMOs for release and marketing.

Germany is among the six most actively involved countries, according to an aggregation of 284 biosafety research projects (Katzek & Wackernagel 1991, p.70; see also Table 2).[38] However, in relation to the strong public concern in Germany, one may wonder why biosafety research is not funded more extensively here. Germany allocates far less funds than Denmark, as a proportion of the Gross National Product.

The Technology Assessment Unit at the German Bundestag proposed that the country overcome its social polarization by intensifying biosafety research (Gloede et.al. 1993), but this initiative was blocked by industry. The initiative, started in 1990 after the decision on the GEA, lost support because the Green Party did not re-enter Parliament after the elections in late 1990. It coincided also with the campaign to connect the biotechnology issue with the 'Industry location in Germany' debate, which resulted in the relaxation of the GEA(see Section 1). Thus until now the initiative found no resonance in the political realm.

Table 2 International comparison of biosafety projects

[38] A new report, commissioned by the UBA and under preparation by the TÜV Hessen, is expected in 1996 and could not taken into account here.

	Number of biosafety projects
Germany	52
Denmark	36
France	15
United Kingdom	79
Netherlands	21
USA	61

5.2 Attitudes to biosafety research

In general one can discern five attitudes to biosafety research in Germany. Such attitudes are paraphrased in quotes below:

i) 'Biosafety research is nonsense, because GMOs are predictable and safe. If we do biosafety research, we admit that there is a hazard, thus stigmatizing work with GMOs.' The *Deutsche Forschungsgemeinschaft*, the most reputable research fund in Germany, reserved special funding for biosafety research in the early 1980s, but no scientist was willing to apply for this money (*Der Spiegel*, 21 November 1983, p.235).

ii) 'Biosafety research must be done to show the public that their concerns are taken seriously and that no hazardous effects will occur. It must be done even if biosafety research may be scientifically boring, because the probability is low that interesting effects can be observed.' This attitude is now prevalent in the scientific community.

iii) 'Biosafety research would be worthwhile if there existed clear-cut risk hypotheses to test. As long as such hypotheses do not exist, one can only monitor the spread of the GMOs.' However, this effort is not worthwhile because it is clear — especially from the microbiologist's viewpoint — that no biological containment exists; therefore, at least for market approval, the only relevant question is whether the GMO is safe in *any* environment.

iv) 'Biosafety research is worthwhile to reduce the remaining uncertainties. Field tests of GMOs should be accompanied by ecological monitoring. Depending upon the results, safety measures should be

relaxed, continued or tightened.' This opinion is held among some regulators and is shared by some, but not all, scientists engaged in biosafety research.

v) 'Biosafety research is nonsense, because the relation between the GMO and its environment is too complex ever to be predictable. The release of GMOs should be forbidden.' This opinion can be found among some critiques of GMO research.

5.3 Relevance to regulatory policy

For Germany's biosafety research, there is no clear link between particular projects and concrete regulatory problems — e.g. in defining steps or relaxing controls. Both applicants and the regulatory authorities cite the international literature to justify their safety claims — though not particularly the German literature.

Opponents and even regulators criticise the focus of existing biosafety research. They argue that a lot of routine R&D is financed in the name of constructing 'safe vectors'. Funding is mainly directed by the BMFT, which has the official role of promoting biotechnology within the political system. The BMFT takes the stance that biosafety research should be necessary for 'scientific' reasons. Here 'science' seems to be represented through molecular biologists as referees and advisors, though the BMFT does not make public who they are. Biosafety research is dominated by molecular biology methods, yet an interdisciplinary approach is needed, according to critics. Regulatory agencies such as the UBA have little means to direct research which could be helpful for their regulatory tasks, or to create a broader and more pluralistic risk-research community.

6 PUBLIC ACCESS

For public access, the German law distinguishes between field trials and market approval of GMOs. For field trials, either a more elaborate or a more simplified participation procedure is applied; for market approval, no participation is provided. The three procedures are summarized in Appendix III.

For field trials, only the more elaborate procedure has been applied so far.

§18 of the GEA provides for public participation in the approval procedure of GMOs which are not exempted by one of two ordinances:

in §14, the option to issue an ordinance to comply with the simplified procedure, as foreseen in the EC Directive 90/220 and issued by the EC Decision 93/584, for GMOs for which enough experience has been gathered.

in §18, the option to issue an ordinance to exempt from public participation the approval of GMOs whose spread in the environment can be contained.

So far, no such ordinance has been issued — even though the EC adopted a provision for simplified procedures in 1994. Therefore the exemptions do not yet exist in practice. The EC decision for the 'simplified procedure' may apply directly without a special translation into German law, but nothing official seems to be settled.

In these cases the simplified participation procedure would apply, as described below (Section 6.2). In all other cases, i.e. up to now, public participation follows the elaborate procedure, as described in the 'genetic engineering hearing ordinance'[39].

6.1 Field trials: elaborate participation procedure

a) When the application is complete, the Competent Authority informs the public in its official register (*Bundesanzeiger*) and in local newspapers, where the application will be displayed.

b) One week after the publication, the application is displayed at the seat of the Competent Authority in Berlin and in the rooms of the local authority for a period of one month. The display may withhold only information which was defined as a 'commercial secret', and the names and personal dates of the responsible persons — but not of the applicant. The 'commercial secret' is restricted by the provisions for minimum information disclosure in §17a of the GEA, which transposes Article 19 of Directive 90/220. The citizen has

---

39 Following §18, paragraphs 2 and 3, of the GEA

the formal right to obtain a copy, but only of a short popularized version of the application.

c) Until two weeks after the end of the display period, objections to the application can be sent to the Competent Authority or the local authority.

d) Until the end of 1993, when the GEA was relaxed, an oral hearing (*Erörterungsveranstaltung*) had to be held, where the objections were discussed. The 1993 amendment abolished this hearing — for reasons mentioned below — though not the public participation as such, as is sometimes claimed in the media.

e) The Competent Authority sends the objections to the participating authorities (see above, Theme 2) and to the applicant.

f) The decision is sent to the applicant and to all persons who made objections. When the number of objectors exceeds 300, the delivery of the decision can be replaced by an announcement in the public register and in the newspapers or can be ordered within the next two weeks.[40]

g) Only persons who have participated in the above-outlined procedure can appeal to the courts against this decision.[41] But the suit is only recognized if the person can claim that he or she is a 'participant' (*Beteiligter*) according to §13 of the Administrative Procedures Act (APA), i.e. that his or her constitutional rights on health or property are directly affected. Claims on behalf of the environment in general are excluded on this legal base; however, a neighbouring property, e.g. an ecologically managed farm or a privately owned forest, may represent a part of the overall environment. The communal or *Länder* authorities may challenge the decision if their territory is affected. Anyone recognized as a participant has the right to examine the files, according to §29 APA.

6.2 Field trials: simplified participation procedure

---

[40] **See §10 of the Emission Control Act (Bundes-Immissionsschutzgesetz), to which reference is made in §18 of the GEA.**

[41] **Before the 1993 deregulation, an objection against the decision could be sent to the Competent Authority; this provision was abolished by §16, paragraph 7 of the present GEA.**

It is provided[42] that the Competent Authority's final decision — not its justification and the peripheral restrictions (*Nebenbestimmungen*) - must be published in the official register (*Bundesanzeiger*) and in the local newspapers, along with an indication of the deadline to raise objections. 'Participants' are therefore invited to request the whole text of the decision. But the common question will be then: Who may be a 'participant' according to §13 APA. A commentary (*Gesetzeskommentar*) on the APA states that the authorities must permit participation on demand if the possibility exists that the demanding natural[43] person is impeded in his or her constitutional rights to health and property.[44] If the person is recognized as a participant, then he or she must also have the right to examine the files, according to §29 APA.

After having received the text of the decision, in due course one may raise an objection and send it to the Competent Authority. The Competent Authority then decides whether or not to follow the objection. One may bring a lawsuit to the administrative court against this decision (see above). As in the case of the more elaborate participation procedure, all steps are 'precludent'; that is, they can be taken only if the person has followed the whole sequence of the prior steps, having substantiated from the very start that his or her constitutional rights to health or property might be affected. From this perspective, legal participation may serve to streamline administrative procedures by excluding objections which have been raised too late, thus giving the applicant more legal certainty for planning investments.[45]

So far, no experience exists with the simplified participation procedure for field tests. This procedure also applies to the approval of research laboratories and of most production plants by the competent authorities of the *Länder*. When people requested the text of laboratory decisions there, some *Länder* tried to restrict the participation by formal measures.[46]

6.3 Field trials: practical access

In practice there is one person at the *Gen-ethische Netzwerk* (GeN), an NGO with its office in Berlin, who gathers all information on field trials under

---

[42] In §12 of the Genetic Engineering Procedure Ordinance (GenTVfV) which refers to the Administration Procedure Act §69, paragraph 2, clauses 3 and 5.

[43] In contrast to organisations as juridical persons, which have no access.

[44] W. Clausen in: Knack, H.J. et.al., Verwaltungsverfahrensgesetz (Kommentar), Köln 1993, p.214f

[45] Based on the elaborate participation procedure, §23 GEA restricts also civil suits against field trials.

[46] For example, by denying participation until the demanding person had consulted a lawyer who dictates the standard formal sentences.

preparation[47]. The latter are often discussed within the interested scientific community, from where the information comes to the NGO network. Normally the organisation which plans to undertake a release (*Betreiber*) also informs the neighbours of the test fields and the local authorities far in advance, i.e. before the application is officially sent to the Competent Authority. The Competent Authority knows in advance, while informally discussing the modalities with the applicant, before the official application is delivered. There is some communication between the Competent Authority and the NGOs, even though the Competent Authority cannot give official information about applications which are not yet delivered officially.

Therefore the field trials normally become known before they are formally announced in the daily press (see above). The coordinator at GeN then informs the other NGOs which may have a local branch where the field trial is to be sited; or he may be informed by local people, already-alarmed. Often the applicant too tries to gain the support of the public, e.g. by organising local information and discussion meetings.

When a local citizen or a person from the NGO network asks the applicant for detailed information, the applicant normally delivers one or more copies in order to show his openness and cooperation. These copies will be then circulated throughout the network. Therefore the official disclosure procedure is not very relevant in practice. The popular summary of the application, as provided for in the law, seems to have no practical relevance; I have never heard it mentioned.

Nevertheless people from local initiatives told me that they had met difficulties when requesting a copy of the application from the local authorities. Some charged 1 DM (0.5 ECU) per copied page. Two cases (Northeim, Ahrensburg) were reported where the authorities refused to supply copies.

The applications are normally rather informative, containing approximately 120 pages and a further 100 pages with copies of the cited scientific literature. The claim for 'commercial secrets' seems not to be extensively used. From the two applications (KWS 1993, TU München 1993) I have studied, the one from a private applicant withheld the detailed sequence data of the transgenic construct. Apart from such details, NGOs and independent experts can obtain the same information as the Competent Authroity — at least officially.

Is this information adequate to make a judgement on safety? This is a contentious issue between the Competent Authority and NGOs. The answer may depend upon the interpreting the statutory criteria, that is: does the information represent 'the state of the art in science and technology'? And

---

47 He also updates the cumulative list.

does 'the state of the art in science and technology' allow a judgement of safety?

As regards the first point, I have not heard serious complaints,[48] whereas the second point is the central issue in the risk debate among NGOs, the Competent authority and the applicants. As mentioned above, the GEA only demands an assessment on the basis of the *current* state of the art in science and technology; at least formally, it does not provide for further restrictions, e.g. moratoria, on grounds of ignorance about the GMO and the ecological aspects of the test site.

Also contentious has been the question of specifying the type of product, e.g. when a herbicide-resistance gene (linked to a virus-resistance gene) was inserted: Was it used only as a marker, as the applicant claimed? Or was a herbicide-resistant plant the aim, as the NGOs argued? This argument about intentions cannot be clarified by information disclosure.

To raise a substantiated objection, which perhaps gains some recognition from the authorities, one must assess scientifically the consequences which the field trial may have on one's own health or property. But the discussion over causal hypotheses of potential harm is so complex that a person who wants to assess it must read the full application. Thus the juridically, scientifically narrow procedure excludes all broader political-ethical claims which are in the centre of public debate. The participation procedure follows traditional juridical provisions and is not suited to a discussion of the socially relevant concerns. Hence the procedure does not have the capacity to democraticise and intentionally shape the technologial development.

---

48 An 'effective scientific examination' would not be possible, according to Hartmut Meyer of the *Arbeitskreis gegen Gentechnologie* (AK) of Göttingen, speaking at the EC conference on public participation in 1994 (VROM, p.35). However, that claim is overgeneralized, according to my own observations and conversations with opponents. It refers to some objections at the hearing in 1993 in Northeim, where the AK criticized some irregularities in the presentation of laboratory research findings in the application.

6.3 Field trials: information uses

Field trials in Germany meet a socially broad range of opposition — from distinguished conservative people to radical young anarchists. Most of the opponents are well educated. Most of them are pupils, students or graduates. Many of them are studying or have studied disciplines which relate to with genetic engineering, e.g. agriculture, biology, medicine. The number of people involved is not easy to assess because numbers fluctuate, as in most voluntary political action. Perhaps 100-200 are continually active. Only two or three people are engaged on a full-time paid basis in the field trials issue; more paid activists are involved in genetic engineering in general.

6.3.1 Oppositional groups

One can discern different organisational levels within the network of NGOs:

Small central NGOs, e.g the GeN, which are specific to the genetic engineering issue.

Small NGOs whose issue is affected by genetic engineering, e.g. an initiative against the use of pesticides.

Large nationwide NGOs with a broader range of aims, e.g. environmental protection groups which can be partly mobilized against genetic engineering or field trials.

Small local NGOs which may be specific to genetic engineering or even the field trial at issue. Many of them are subgroups of nationwide NGOs with a broader range of aims, eg.religious groups, farmer groups, nature conservationists etc..

German initiatives against genetic engineering and GMO field trials seem more radical than their European counterparts. This is true for German NGOs in general (Hey & Brendle 1994). The German political system gives many chances for expressive, adversarial forms of protest but restricts the opportunities for instrumental, policy-orientated environmental lobbying.[49]

---

49 A detailed explanation would include the following reasons:

- The more radical parts of the 1968 left-wing movement could not integrate into a socialist or communist party as e.g. in France. Radical impetus was channelled into the early environmentalist movement, which in France is more non-socialist.

- The state responded with vigorous police deployment, thus reinforcing the militant black-white outlook of the environmentalists.

- The administrative culture is not integrative to civil interests, at least, if they are new and unconventional, i.e. non-hierarchically organized.

- The corporatist system of interest participation is well organized but not integrative. The two large parties are connected with capital and labour, thus excluding the new environmentalist positions.

- The voting system in Germany guarantees proportional representation (with a 5% entry threshold). Thus the Greens could enter the national, regional and local parliaments. But they could participate in government only on the local level, and later sometimes on the regional level. Hence oppositional thinking remains dominant. When the Greens entered the first parliaments in the late 1970s, they portrayed this as 'to continue the demonstration by other means'; thus they alluded to a famous slogan of Clausewitz, that war would be 'the continuation of politics by other means'

For the first field trial in Cologne in 1990, there was intensive coverage and discussion in the national media. Since then, the coverage in the national media has declined but has shifted to the affected localities as field trials increase. Nationwide discussion was restricted to media-experienced experts and counter-experts, while at the local level there is more direct mobilization, with more concrete imaginations and involvement. From the local level, new recruitment and stimulation for this issue is channelled to the more central levels of NGOs. In the local press the resonance is high because the issue of a field test is always 'news' if it is the first GMO in the locality. Genetic engineering proponents may have expected that the mere proliferation of field trials would desensitize and accustomed the public to GMOs in the environment, but so far this is not the case in Germany.

The opponents' aims may differ and shift according to their social and organizational backgrounds. For religious groups, the main argument against the field trials is that 'Man should not play God', thus tampering with nature. For farmer groups, the main issue is the overall socio-economic impact of GMOs. Anarchist and feminist groups classify genetic engineering as a means of dominance of men over women, capital over labour, North over South, and man over nature. Concepts of 'genetic pollution' or 'reducing biodiversity' are not very prominent among the arguments against field trials. The Öko-Institut as an independent scientific institute focus intensively on the special effects of the trangenic constructs, e.g. the possibility of horizontal gene transfer; they argue that ignorance and uncertainty prevail, and emphasize the 'incalculable risks of genetic engineering'.

The relevance of the Öko-Institut and its activities is reinforced by the regulatory system, which responds only to the more scientific arguments. But in general the scientific risk issue is only one point within the broader range of counter-arguments. In most of the field trials, herbicide resistance is used as a marker or an explicit development aim. Hence the slogan death in the maize field' is directed more against herbicide use than against the associated GMO, which is criticized for promoting and stabilizing socially and environmentally unacceptable forms of agriculture. Therefore the aim of the opponents is not to make the GMO 'safer' — as is the aim of the EC Directive and the GEA — but rather to prevent its development, as a symbol and an instrument of the 'wrong' way of life. Opposition seems particularly strong at sites near large cities where postmodern-inspired people settle and ecologically-working farmers find their local markets. Hence many people are at least ready to sign petitions against GMOs. The number of objections amounted to 18,000 against one field trial in the outskirts of Munich.

6.3.2 Specific protests

Until now three field trials have been prevented through local initiatives:

i) In 1992 in Ahrensburg near Hamburg a site to test a bacterium resistant potato was chosen unintentionally in the direct neighbourhood of an ecologically working farmer. This farmer was the largest farmer in the locality and strongly opposed the field test. He argued that the bacterium is only a problem if potatoes are cultivated in an ecologically unsound manner and, moreover, that the image of his goods would suffer if the field test took place. The Competent Authority received 8000 objections to the field trial, among them the objection of the local authorities. The farmer and the local authorities announced that they would start law suits if the field test were to be approved by the Competent Authority. There was also strong opposition from within the Hamburg government, which as the land-owner had once engaged the opposing farmer to cultivate the land ecologically, and from within Hamburg University, the organizational background of the applicant. The applicant subsequently withdrew his application before a public hearing took place.

ii) In 1994 in Harthausen, a village in a more remote region in southern Germany, local protest influenced a farmer, the owner of the intended release site, to withdraw his permission for a field test.

iii) In 1994 in Wickstadt near Frankfurt-am-Main, an applicant got permission for a field test from a farmer who was the tenant of the land. When the land-owner, a count, was informed, he intervened and denied permission for the trial.

Several other field test have been attacked while the plants were growing. In the more severe cases, so many plants were damaged that the scientific evaluation of the trials was impeded.

There have been several lawsuits against field trials. They have to be brought to the administrative law court in Berlin because the Competent Authority is located there. In contrast to other law courts in Germany — the insulin production plant of Hoechst was stopped by the courts in Hessen several times — the competent chamber of the Berlin court is known to be friendly to the Competent Authorities' decisions. The court often decides not to admit the lawsuit, on grounds that the plaintiff's home is too far from the field where the GMO is to be released. In other cases, the judge states that he cannot see any serious procedural fault on the part of the Competent Authorityt.[50] Until now no suit against a field trial has been successful.

[50] It is clear from the jurisdiction that the court must only control the procedure but not reassess the content of the CA's decision.

6.4 Market approval: information access

6.4.1 Formal rules

According to the Robert Koch-Institutch Institut, not even the simplified participation procedure applies to market approval.[51] Only the minimal requirements of the Environmental Information Act may give everybody the right to obtain some information — after the final decision is settled.

6.4.2 Practical access

Several EU market approvals have been agreed by the Robert Koch-Institutch Institut, e.g. for a vaccine to protect pigs against Aujezsky disease. None of these approvals has met with any public reaction.

Insofar as the German Competent Authority has been involved in decisions with other EU Competent Authorities, e.g. the PGS oilseed rape decision, has adopted a stance of making no public comment until the decision is finally settled — even though the Competent Authorities voted in February 1995. Furthermore the Competent Authority states that the task of informing the public lies with the Competent Authority in the country where the application was filed (letter from Robert Koch-Institutch Institut, 7 June1995). According to Germany's Environmental Information Act (EIA) §7, the authority *can* refuse a request for information about the decision if the procedure is not yet closed.[52] That Robert Koch-Institutch Institut refusing all comment can be taken as a sign that it has voted for the the UK proposal to grant market approval, and wants to avoid any public debate.

No experience exists with lawsuits against a market approval. But the UBA — unlike the Robert Koch-Institutch Institut — responded to my question about the legal possibilities. Jurists at the *Umweltbundesamt* gave me the following information, with the cautionary hint that courts may decide differently:[53]

Generally the EU-member states can bring an action against decisions of the Commission at the European Court of Jusice in Strasbourg. Furthermore, a judge can bring a clause to the Court if s/he suspects that there is an inconsistency between national and EC law.

Against a decision taken by the national Competent Authority, the possibility of bringing an action depends on the national law. In the German

---

[51] One could question whether this is a correct interpretation of §12 of the Genetic Engineering Procedure Ordinance (GenTVfV), but until now nobody has argued that point.

[52] Another question is whether this German regulation is in accordance with the corresponding EC Directive 90/313 (see Turiaux 1994, p.2323). According to verbal information, the German Natur Conservation Alliance (BUND) plans to bring a suit against this paragraph.

[53] Letter from 21.7.1995 and letter 10.8.1995

law for consumers, it is probably impossible to bring an action because the suit is not admitted by the court, because of the legal logic that no *certain and definite* group of citiziens, e.g. the neighbourhood in the case of field tests, is affected. This is not a special provision in the GEA but a general feature of the German administrative law, which denies everybody the right to take action against any decision taken by the administration.[54]

However, anyone may bring an environmental complaint to the Commission on the basis that EU standards have not been correctly applied. The defendant is then the member state, not the Competent Authority. The infringment of personal rights is not necessary. It is adequate to give detailed and concrete reference to an objective violation of EC standards. The Commission then may take action against the member state, according to Article 169 EWG, or dismiss the complaint.

Against a decision taken by the Commission according to Article 13, paragraph 3, and Article 21 of Directive 90/220, theoretically a suit can be brought at the ELC. But the person must be affected by the decision, directly and individually. With a normal market approval these preconditions are probably not fulfilled because no clearly defined number of persons are affected, but rather the consumers in general.

A liability suit — in the case of actual damage to health or property — can be brought under civilian law against the producer. If the damage happens in Germany (or if the harmed person is living in Germany), or if the damage was probably caused by a German producer, then the suit can be brought to a German court. The German law — with the strict liability provisions of the GEA - would then apply. (See Section 1.1.)

6.4.3 Information uses

So far the German NGOs have hardly engaged with the market approval procedure. Many activists are so involved with the field trials that they have not given much attention to the next step. Because the market approval procedure offers no opportunity for participation, they must wait until they can mobilize opinion directly against the products.

Products so far approved, e.g. animal vaccines, are too esoteric for mobilizing public opinion. The market approval for rape and tobbacco do not mean that the products have already reached the consumer markets. The real test case may be the situation, when it becomes known by declaration or investigation, that a food product (e.g. Calgene's Flavr Savr) is being marketed.

GMO-based food has great resonance in the mass media. According to opinion polls, more than 75% of Germans do not want to eat food from GMOs. The antagonistic and therefore undecided style of German regulation has been accentuated by the German Health Minister is a surprising vote for

---

54 § 42 Verwaltungsgerichtsordnung

a far-reaching labelling requirement within the Novel Food Regulation, even though this was strongly opposed by the German Christian-Democrats beforehand.

6.5 Germany's risk communication culture

In the context of the protests against GMO field tests, formal information and objection rights seem peripheral. Thus it is obvious, and it may be evident just from the history of the GEA (see Section 1), that the conflict existed beforehand. The GEA resulted from the conflict — not the other way around. The provisions of the GEA may shape the conflict in a certain way, but conflict would exist even without such a law or an EC Directive.

6.5.1 Responses to objections

Most opponents do not believe that their objections will be taken seriously by the Competent Authority. The more educated and experienced opponents know that the Competent Authority can only respond to arguments that deal with the specific field tests and their ecological risks — not with product development, nor with complementary technologies, e.g. herbicides, nor with the social consequences, nor with genetic engineering in general. Hence the objections are seen, and meant more as a public demonstration of protest, than as an attempt to communicate with the authorities in a 'discursive way'[55]. The Competent Authority gives the impression that it does not respond substantially to objections even those within its remit; such an image is fostered when its representatives state that no new arguments will be found among the objections.

Even if both the opponents and the Competent Aauthority believe that the objections make no difference to the outcome of the decision, there are several reasons to doubt this belief:

---

55 'Discursive way' means that the communicators try to persuade each another by the evidence and logical strengh of arguments, not by resources of power.

i) When I looked at the administrative file of the first field test, I was surprised to see that the Competent Authority and the other authorities reacted seriously to external arguments which I thought they would dismiss. For example, opponents had claimed that horizontal gene transfer between the antibiotic-resistance gene of the petunia and soil microbes could occur. According to the file, the Competent Authority therefore asked an antibiotic expert about the medical relevance of the corresponding antibiotic and any additional spread of the resistance. In the final decision this reaction was not mentioned and therefore not visible to the opponents.

ii) It is difficult to assess exactly the deterrence effect, both on the applicant and the Competent Authority, of the information and objection rights.[56] This effect is invisible to the opponents because the informal bargaining between applicant and Competent Authority takes place without the participation of NGOs. When the applicant and the Competent Authority have come to a conclusion, both will defend the result and they will therefore be seen as united.

One may ask why representatives of the Competent Authority, and of administration in general in Germany, seem eager to appear unresponsive to the ecological objections of citiziens. The traditional self-image of the German civil servant is that he or she is not open to political influence, but rather follows the law and his own scientific expertise. Expertise is seen as neutral and objective. If the Competent Authority and the applicant reach the same assessment, this results not from bargaining or capture but rather from a neutral expertise which leads all experts to the same conclusions; by contrast, the opponents are irrational, emotional laypeople and therefore come to other conclusions.

The more the officials come under fire, the more they have to pretend that they rely on objective knowledge. This claim — in their belief — seems to be more legitimate, the more they narrow the scope of the issue by juridical and scientifical means, thus excluding the public. If civil servants were to admit that they respond to objections then they would be admitting that they had

---

[56] **The lag of the German biotech industry behind its competitors is often explained by this deterrence effect of the regulation. But there are several factors which are hard to discern:**

i) the internal discussion in large companies, where most directors are educated as chemists and not as biologists, whether or not to invest in in biotechnological developments;

ii) the perceived and the actual stringency of the regulatory authorities;

iii) the low degree of public acceptance or high degree of public opposition.

For example, one may ask why the *Hoechst* company has done a series of field trials in Canada before starting them in Germany. It is not very probable that *Hoechst* has greater resources (factor i) in Canada. But it is probable that *Hoechst* (now *AgrEvo*) feared more the general public opposition (factor iii) than the regulatory procedure (factor ii) when protesters tampered with the releases in Germany.

not noted or considered the points raised.. Hence they would be acknowledging that they were biased or that they were not experts. The more their own expertise is at stake, the more they have to deny the expertise of the people putting the arguments.

This discourse strategy, which is deeply rooted in the tradition of the German administration (Mayntz 1986), works only to over-rule feebly organized opponents and to convince authoritarian-thinking people. But it works as a self-reinforcing trap in conflicts typical of the 'risk society' (Beck 1986). Mediation and compromise is not possible on the basis of objective knowledge.

The opponents, educated in the norms of democracy in Western Germany after the Second World War, become angry when they are told that they are too silly to understand the issue. And the more narrow and therefore precise the claims are, the more easily they can be falsified, thus deconstructing the credibility of the administration.[57]

Given these dilemmas, why did the German legislators guarantee information and participation at all? The legislator clearly is not the administration. Yet the need for consistency with the legal tradition has an important influence. This must be taken into account in all countries which follow the top-down approach of continental law, but which is perhaps respected most in Germany.

The question may be answered by examining to what extent the legislator used these options: Extended information and objection rights[58] are used only for industrial plants working on higher safety levels and for field trials, not for scientific laboratories on the one hand and not for market approvals on the other.[59] Scientific laboratories are excluded from extended disclosure by the constitutional right of scientific inquiry.

6.5.2 Market approval

The information rights for market approvals are in practice the weakest of all sections of the GEA. This striking difference is so far not debated in Germany, not even in the abundant juridical literature. None of the regulators I asked could or would answer the corresponding questions. Therefore I can only speculate about the reasons:

i) No distinct group of persons is affected. The German tradition of information and objection rights is constructed to protect the parties

---

57 See Eurobarometer 35.1. and 39.1 (Inra, 1991, 1993).

58 Following §10 Emission Control Act (BImSchG) and Genetic Engineering Hearing Ordinance (GenTAnhV).

59 For scientific laboratories, only §12 of the Genetic Engineering Procedures Ordinance (GenTVfV) must be followed (see below).

concerned (*Verfahrensbeteiligte*), i.e. neighbours of a plant and especially their property. The state, represented by the civil service, must protect the public in general. Also, no other product approval legislation provides for public participation. The Environmental Information Act, which gives such a right to everybody, is a new instrument which was — at last in 1994, two years after the deadline in 1992 — only possible because Germany had to implement EC Directive 90/313 (Turiaux 1994). The incompatibility with the German administrative culture is demonstrated by authorities trying to deter the use of this law, e.g. by charging very high fees for the information requests.[60]

ii) So far, no intense public protest has been launched against a market application, while the field test issue was controversial even before the formulation of the GEA. Controversy and silence clearly correlate to the existence and non-existence of information and objection rights in these areas. One may ask whether a causal relation exists: both possible directions would be plausible. But I would suggest a combined interpretation — i.e., that this process has an unintentional outcome: during the drafting of the GEA, public awareness pressed for far-reaching information and objection rights for field tests; in response, the authorities established an arena to focus public protest, thus distracting it from marketing applications.[61]

iii) One can see this difference also as an intentional attempt to treat and resolve the acceptance problem during the period of field tests and to smooth the economically more relevant procedure of the market approval. As regards the consent to other Competent Authorities' market approvals, it may be that one tries to keep out the domestic opposition from international affairs. Indeed, one regulator answered that perhaps it was hoped to resolve all relevant questions during the field tests, so that the market approval would be less problematic.

One must see some parallels at the EU level which may hint at an overall regulation pattern. The approval of biotechnological pharmaceuticals is very easy in the EC by comparison with the USA and Japan (Bienz-Tadmor 1993), whereas the regulation of the biotechnological development and production process is relativly strict (Hohmeyer et al. 1993).

---

[60] Tageszeitung, 9.9.1994, p.7; Süddeutsche Zeitung, 20.10.1994, p.II. The 'Zeit' headliine said, 'Like in old Prussia' (10.3.1995, p.35). Not only are high fees for photocopies calculated; more relevant are the fees that are requested that the civil servants pretend to have spent on the inquiry. The amount of time is not calculable in advance and can be very high because of the diverse exemptions provided for in the EIA. The civil servants cannot copy the whole file but must go through it to decide which pages are to be excluded and which names and sentences have to be blacked out in the copy.

[61] At an international meeting on public participation, the German NGO representative did not even mention the lack of information rights for marketing applications (VROM 1994).

6.5.3 State's rationale for access

Not all activities which could affect a neighbourhood, and for which an approval is necessary, are subject to extended information and objection rights.[62] Why did the legislator provide these rights for field tests? Before the GEA was enacted, the approval for production installations with GMOs was subject to the Emission Control Act § 10, which requires oral hearings. Whether or not to continue with this procedure, which was extensively used by genetic engineering critics, was a controversial point in drafting the GEA.

Deliberate release has been a strongly disputed issue since the Enquete-Commission on 'Risks and Benefits of Genetic Engineering' of the German Bundestag had demanded an five-year moratorium on the release of genetically modified microorganisms in 1986. It seems that in practice the regulators hoped that the participation procedure might contribute to a better acceptance of genetic engineering in Germany. This was indicated when Gernot Schubert, the civil servant responsible in the Ministry of Health, explained why the oral hearing procedure for field tests was abolished:

> The hearings lasted for several days in each case. All the administrative effort generated considerable costs and drove the competent authority to the brink of collapse _ New fact-situations and insights of relevance to the decision-making process were forthcoming in only a few of the objections expounded _ Very often the discussions which took place during the hearings were dominated either by general, fundamental issues which do not apply to the specific release project, or by procedural questions. The hearings did not succeed in achieving any perceptible increase in the acceptance of genetic engineering. Appeals were lodged against every decision taken, albeit so far without success.[63]

In fact, even with sympathy for the opponents, one may ask if the oral hearings make much sense (Drescher 1994, p.298). Information about the local context was at stake in the deliberations. The contribution of the 'neighbours' had a rather emotional and general style, not very specific to the concrete application and far beyond the scope provided by the GEA.

When discussion took place among the opponent experts, the regulators and the applicants, it was not clear how this exchange could influence the final decision. In the end all participants were frustrated, because neither did the proponents achieve their aim of gaining more acceptance, nor did the opponents achieve their aim of preventing the field test. If the intention was to smooth the innovation policy, one may speculate whether it would have been wiser to keep the field trials more invisible or, as the saying has it, 'to let sleeping dogs lie'. But 'the dogs' had already been awoken when the GEA was in the making. Therefore secrecy would probably have increased

---

62 See e.g. §19 Emission Control Act (BImSchG)

63 See Ministry of Housing 1994, p.29; Compare Bora 1994

suspicion and suspicion would have increased the demand for 'secret information'.

Furthermore the problem is not only the conducting of field trials — since large companies at least can do trials in foreign countries. With a perspective on marketing the products, one must accustom people to GMOs. In an interview, the coordinator of a partly destroyed field trial explained to me (afterwards) that he could have conducted the trial within a well-guarded military camp, but he decided to locate the test site on an open camp near a large city, just to familiarize people with GMOs.

Hence it is sensible to understand the step-by-step-and case-by-case principle in Germany also as a trial to test — and perhaps to tire — social reactions. This strategy means not only the sequence from the more harmless to the more uncertain steps or cases, but also the sequence from the more reputable to the more ill-reputed organisations. It seems not to be accidential that the first release applications came from the Max-Planck Institut in Cologne as an organisation of basic research, followed by the Kleinwanzlebener Saatzucht, a small company with a good public image (or no image at all), and followed by Hoechst, a multinational company often involved in negative environmental headlines and one of the three postwar offspring of IG Farben, known for its notorious role in the Nazi regime. In fact, as several independent sources confirmed, Hoechst had asked or even pressed several reputable members of the research community to start field trials in Germany.

REFERENCES

Beck, U., (1986): *Risikogesellschaft: Auf dem Weg in eine andere Moderne*, Frankfurt am Main.

Beck, U., (1993): *Die Erfindung des Politischen*, Frankfurt/M

Bienz-Tadmor, B. (1993): 'Biopharmaceuticals Go to Market: Patterns of Worldwide Development', *Bio/Technology* 11: 168-172

BMFT (1988-1994): Bundesministerium für Forschung und Technologie: *Biologische Sicherheit*, Bonn, 3 Bände: 1988, 1990, 1994

Bonß, W. et al., (1992): 'Risiko und Kontext. Zur Unsicherheit in der Gentechnologie', *Jahrbuch Technik und Gesellschaft* Nr.6, Frankfurt/M. S.141-174

Bora, A., (1994): 'Schwierigkeiten mit der Öffentlichkeit: Zum Wegfall des Erörterungstermins nach dem novellierten Gentechnikgesetz', *Kritische Justiz*, p.306-322

Brickman, R. et al., (1989): *Controlling Chemicals: The Politics of Regulation in Europe and the United States*, Ithaca: Cornell University Press

Buchholz, K., (1979): 'Die gezielte Förderung und Entwicklung der Biotechnologie', in:W.vanden Daele et.al., *Geplante Forschung*, Frankfurt/M., S.64-116

Daele, W.v.d. et al. (1994/3): *Verfahren zur Technikfolgenabschätzung des Anbaus von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz.* Heft 3. WZB-Bestell-Nr. FS II 94-303

Daele. W.v.d. et al. (1994/4): 'Risiken der Verwilderung von transgenen Pflanzen:Argumenationen des TA-Verfahrens', in *Verfahren zur Technikfolgenabschätzung des Anbaus von Kulturpflanzen mit gentechnisch erzeugter Herbizidresistenz.* Heft 4. WZB-Bestell-Nr. FS II 94-304.

Deutsch, E. (1982): 'Rechtspolitische Probleme der Gentechnologie', in *Medizin, Mensch, Gesellschaft* 7(2): 88-97.

Dolata, U. (1994): 'Internationales Innovationsmanagement: Die deutsche Pharmaindustrie und die Gentechnik', *Diskussionspapier 3-94 des Hamburger Instituts für Sozialforschung*, Hamburg

Drescher, R.D. (1994): 'Jurassic Park: Made in Germany?', *Zeitschrift für Umweltrecht*, pp.289-299

Finnegan, J. & McElroy, D. (1994): 'Transgene Inactivation: Plants Fight Back!', *Bio/Technology* 12: 883-888.

Gassen, G. et al. (1992): 'Gutachten zur Biologischen Sicherheit bei der Nutzung der Gentechnik' im Auftrag des Büros für Technikfolgen-Abschätzung des Dt. Bundestages (TAB)

Gill, B. (1991): *Gentechnik ohne Politik*, Frankfurt a.M.

Gill, B. (1993): 'Partizipative Technikfolgenabschätzung: Wie man Technology Assessment umwelt- und sozialverträglich gestalten kann', *Wechselwirkung* Nr.63 (Okt. 1993), p.41-44

Gill, B. (1995): Vorsorge vor hypothetischen Risiken, Vortrag anläßlich der DVPW-Tagung 'Politik und Biotechnologie' am 22.6.1995 in Wien (will be published in the proceedings of the meeting)

Gloede, F. et al. (1993): 'Biologische Sicherheit bei der Nutzung der Gentechnik', Endbericht des Büros für Technikfolgen-Abschätzung des Dt. Bundestages (TAB)

Goodwin, B. et al. (1993): 'Is Morphogenesis an Intrinsically Robust Process?', *Journal of Theoretical Biology* 163: 135-144

Gottweis, H. (1995): 'German Politics of Genetic Engineering and its Deconstruction', *Social Studies of Science* 25: 195-235.

Harwood, J. (1989): 'Gesellschaftsstruktur als Analogie: Genetiker stellen sich die Zelle vor', *Berichte zur Wissenschaftsgeschichte* 12: 157 ff.

Hasse, R. et al. (1994): Die Technologisierung der Biologie am Beispiel der Pflanzengenetik und Pflanzenzüchtungsforschung, BMFT-Forschungsbericht, Bamberg

Hasse, R. & Gill, B. (1994): 'Biotechnological Research in Germany: Problems of Political Regulation and Public Acceptance' in U. Schimank & A. Stucke, eds, *Coping with Trouble: How Science Reacts to Political Disturbances of Research Conditions*, Frankfurt/New York, Campus Vlg./St. Martin's Press, pp.253-292

Heins, V. (1992): 'Gentechnik aus der Verbraucherperspektive', *Soziale Welt* 43/4: 383-399.

Hey, C. & Brendle, U. (1994): *Umweltverbände und EG*, Opladen

Hobom, G. 'Erfahrungen aus der Arbeit der Zentralen Kommission für biologische Sicherheit', in Th.v.Schell & H.Mohr, eds, *Biotechnologie: Gentechnik, eine Chance für neue Industrien*, pp.422-431, Berlin.
Hohmeyer, O. et al. (1993): 'Gesetzliche Regelungen der Gentechnik im Ausland und praktische Erfahrungen mit ihrem Vollzug', Gutachten im Auftrag des TAB. Karlsruhe, typescript.
Hohn, H.W. & Schimanck, U. (1990): *Konflikte und Gleichgewichte im Forschungssystem*, Frankfurt/M.
INRA Europe (1991): 'Biotechnology and Genetic Engineering: What Europeans Think About It in 1991', Eurobarometer 35.1, Brussels: Commission of the European Communities, DGXII/E-1.
INRA Europe (1993): 'Biotechnology and Genetic Engineering: What Europeans Think About It in 1993', Eurobarometer 39.1, Brussels: Commission of the European Communities, DGXII/E-1.
Jasanoff, S. (1986): *Risk Management and Political Culture*, New York.
Katzek, J. & Wackernagel, W. (1991): 'Stand der Forschung im Bereich der Risikoabschätzung beim Umgang mit gentechnisch veränderten Organismen und Aufdeckung von Forschungsdefiziten', Brüssel & Oldenburg, typescript.
Lau, C. et.al. (1993): 'Risikodiskurse: Gesellschaftliche Auseinandersetzungen um die Definition von Risiken und Gefahren', Bamberg, Forschungsbericht, typescript.
Levidow, L. (1994): 'Biotechnology Regulation as Symbolic Normalization', *Technology Analysis & Strategic Management*: 16(3): 273-288.
Mayntz, R (1968) *Bürokratische Organisation*, Köln 1968
O'Riordan, T & Wynne, B. (1987): 'Regulating Environmental Risks: A Comparative Perspective', in P.R.Kleindorfer & C.Kunreuther, eds, *Insuring and Managing Harzardous Risks*, pp.389-410,Berlin.
O'Riordan, T. & Cameron, J. (1994): *Interpreting the Precautionary Principle*, London.
Ott, W. (1992): 'Zur Konkurrenzklausel in §2 Nr.4 des Gentechnikgesetzes', Natur und Recht, p.459-463
Schneider, V. (1988): Politiknetzwerke der Chemikalienkontrolle, Berlin
Simon, J. (1994): 'Gentechnik als Grundlage neuer Industrien unter den rechtlichen Rahmenbedingungen der EG und Deutschlands', in Th.v.Schell & H.Mohr, eds, *Biotechnologie: Gentechnik, eine Chance für neue Industrien*, pp.359-388,Berlin.
Tait, J. & Levidow, L. (1992): 'Proactive and reactive approaches to risk regulation' *Futures* 24(3): 219-231.
Tappeser, B. (1994): 'Der Perspektivenwechsel in der Risikodebatte oder Bewiesene Risiken sind natürliche Risiken sind keine Risiken', Vortrag anläßlich der Tagung 'Welche Entwicklung eröffnet die Biotechnologie', 10-11.Okt., Kiel.
Tiedje, J.M., et al. (1989): 'The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations', *Ecology* 70(2): 298-315.

Turiaux, A. (1994): 'Das neue Umweltinformationsgesetz', *Neue Juristische Wochenschrift* 36: 2319-2324.
Umweltbundesamt (1995): 'Konzept zur Riskioabschätzung von Freisetzungen gentechnisch veränderter Organismen'. Berlin, unpublished internal draft.
Vitzthum, W.G. (1993): 'Zur Gentechniknovelle: Eher Neuanstrich als Umbau', *Zeitschrift für Gesetzgebung,* pp. 236-247.
von Schomberg, R. (1993): 'Political Decision-making and Scientific Controversies', in R. von Schomberg, ed., *Science, Politics and Morality: Decision-Making and Scientific Uncertainty*, pp. 7-26. Dordrecht: Kluwer Academic.
VROM (1994): Public Information and Participation in the context of European Directives 90/219/EEC and 90/220/EEC, report of a seminar held on 6 July 1994, Heemskerk, Netherlands. The Hague: Ministry of Housing, Spatial Planning and the Environment:
Wahl, R. & Melchinger, H. (1994): 'Das Gentechnikrecht nach der Novellierung', *Juristenzeitung* 49/JG (20/94): 973-982.
Weidner, H. (1995): *25 Years of Modern Environmental Policy in Germany*. Berlin. WZB-papers No. FS II 95-301.

APPENDICES

Appendix I Institutional acronyms

APA: Administrative Procedures Act
BBA: Biologische Bundesanstalt (In the acronym list you should add as translation of "Umweltbundesamt" "Federal Environmental Agency" and of "Biologische Bundesanstalt" "Federal Biological Research Centre for Agriculture and Forestry", a research and administration unit within the authority of the Federal Ministry of Agriculture, Food and Forestry)
BGA: Bundesgesundheitsamt (former Federal Institute of Health, now dissolved)
BMFT: Bundesministerium für Forschung und Technologie (Federal Ministry of Research and Technology)
EIA: Environmental Information Act
GEA: Genetic Engineering Act
RKI: Robert Koch-Institutch Institut is the Competent Authority (Federal Environmental Agency, a research and administration unit within the authority of the Federal Ministry of Health, part of the former BGA)
UBA: Umweltbundesamt (research and administration unit within the authority of the Federal Ministry of Environment)
ZKBS: Zentrale Kommission für biologische Sicherheit (central committee for biological safety, see Part II B)

Appendix II Methods and materials

The report is mainly based on published material. Some interviews and background information comes from my role as a research scientist and former political activist in this field for many years.

Difficulties

Access to interviews, in particular with regulators, was not easy. This is highly significant for the German controversy on this issue. The reasons are:

i) Some identified me with my former role as a political activist. But this seems only relevant to some extent because other researchers — even from other countries, e.g. Martine Kraus from Berkeley, USA — reported similar problems with research access in Germany. Interviews, at least for content beyond the already published information - are denied on both sides when the researcher acknowledges having contacts with the other side. He or she is then suspected to be possibly partisan for the other side, or at least not partisan for own side and of using the information in others ways, as intended by the respective interviewee. It is clear that the suspicious style of the German debate is reinforced by this kind of reaction.

ii) On account of the controversy, much published material exists. Actors may therefore feel they would be wasting their time — particularly if they are unwilling to say more than what is already published.

iii) I was not very tenacious in my attempts to obtain interviews because I too have had the experience of wasting time, when it becomes clear that actors are not allowed or not willing to give information beyond the scope of published material. And even if one gets this kind of information, it often cannot be used, at least not directly, and therefore may be of limited value for research purposes.

iv) In the debate on biotechnology in Germany, one cannot get much novel information by the interview method — or one cannot use it — but a lot of material is published anyway. The specific value of the interview method lies in the possibility to validate one's own interpretation of the published material.

Interviewees

The pecularity of the controversy, as sketched above, is also the reason why I cannot cite the interviews as openly as might be desirable for verification purposes. I made the following interviews:

Regulators: Umweltbundesamt (1) on 07.03.1995, Biologische Bundesanstalt (1) on 10.03.95. Answers from these regulators do not necessarily represent the opinion of the respective authority. The Robert Koch-Institutch Institut, the Competent Authority, declined to give me an interview and answered my questionnaire by a very short letter on 07.06.1995.

Applicants: Several interviews in autumn 1994 during another investigation project with a research group which is conducting a field test.

Critics: Öko-Institut (1) on 04.05.1995; participation at a meeting of opponents of deliberate release, organised by the Gen-ethische Netzwerk, on 20-22.-1.95 in Münster/Westfalen.

Appendix III Participation procedures

Approval procedure for field trials (elaborate participation)

applicant: advice by and informal negotations with the Competent Authority

«symbol SYMBOL "Wingdings"»

ZKBS/BBA/UBA etc. (participating authorities)	«symbol SYMBOL "Wingdings"»	Competent Authority informs other authorities		
		Competent Authority may ask for further information		
		«symbol SYMBOL "Wingdings"»		
«symbol SYMBOL "Wingdings"»		Competent Authority accepts application as complete		
		«symbol SYMBOL "Wingdings"»		
		Competent Authority informs European Commission and the public	«symbol SYMBOL "Wingdings"»	Brussels
		«symbol SYMBOL "Wingdings"»		«symbol SYMBOL "Wingdings"»
		«symbol SYMBOL "Wingdings"»		procedure according to Article 9 of 90/220

		end of objection deadline		«symbol SYMBOL "Wingdings"»
give consent	«symbol SYMBOL "Wingdings"»	«symbol SYMBOL "Wingdings"»	«symbol SYMBOL "Wingdings"»	remarks

decision

objectors / applicant

«symbol SYMBOL "Wingdings"»	administrative court decides on appeals

Approval procedure concerning field trials (simplfied procedure)

applicant: advice by and informal negotations with the Competent Authority

		«symbol SYMBOL "Wingdings"»
ZKBS/BBA/UBA etc. participating	«symbol SYMBOL "Wingdings"»	Competent Authority informs other authorities
authorities)		Competent Authority may ask for further information
		«symbol SYMBOL "Wingdings"»
«symbol SYMBOL "Wingdings"»		Competent Authority accepts application as complete
		«symbol SYMBOL "Wingdings"»
		«symbol SYMBOL "Wingdings"»
give consent	«symbol SYMBOL "Wingdings"»	«symbol SYMBOL "Wingdings"»
		decision
		result is published
participants can request text of the decision		

«symbol SYMBOL "Wingdings"»

Competent Authoritydecides on objections

«symbol SYMBOL "Wingdings"»

administrative court decides on appeals

applicant: advice by and informal negotations with the Competent Authority

«symbol SYMBOL "Wingdings"»

ZKBS/BBA/UBA etc. (participating authorities)	«symbol SYMBOL "Wingdings"»	Competent Authority informs other authorities
«symbol SYMBOL "Wingdings"»		Competent Authority may ask for further information
		«symbol SYMBOL "Wingdings"»
		Competent Authority accepts application as complete
		«symbol SYMBOL "Wingdings"»
		«symbol SYMBOL "Wingdings"»
give advice	«symbol SYMBOL "Wingdings"»	«symbol SYMBOL "Wingdings"»

	decision	«symbol SYMBOL "Wingdings"»	Brussels
			«symbol SYMBOL "Wingdings"»
			procedure according.to Article 13 of 90/220
	Competent Authority decides on other Competent Authority's objections	«symbol SYMBOL "Wingdings"»	
			procedure according to Article 21 of 90/220
			«symbol SYMBOL "Wingdings"»

Commission's
decision

anyone may ask for
the text of the
decision, according
to the Environmental
Information Act

if damage occurs in Germany,
or a German producer is involved,
or a German citizen is affected
a suit may be brought to a civilian court in Germany
and extended liability according to GEA may be applicable