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Nature Protection and the Introduction into the Environment of Genetically Modified Organisms: Risk Analysis in EC Multilevel Governance

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Genetically modified organisms (GMOs) are usually introduced into the environment through experimental releases or extensive cultivation. The risks involved are controlled via both the authorization for deliberate release and the authorization for the placing on the market of a GMO. In these two steps, the core issues of legal protection are public health and the environment. GMO-free agriculture has been introduced as a third – economic – protected good. This has triggered coexistence measures keeping GM and non-GM agriculture separated. Given the fact that much has already been said about risks of GMOs to human health, this article will rather focus on the environmental dimension, and more precisely on aspects of nature protection. It will accordingly explore whether nature is adequately protected through the authorization for the release and the authorization for the market placement of GMOs. While these questions concern regimes aiming at preventing environmental damage, co-existence, if related to natural ecosystems (rather than to the protection of a variety of agriculture), raises the question of whether ecosystems can be considered as protectable goods even if no traditional damage is caused.

OVERVIEW OF RELEVANT LEGAL REGIMES

Nature protection as a concern for the release of genetically modified organisms (GMOs) can be covered by two different but overlapping legal regimes: genetic modification law and nature protection law. Genetic modification law (GM law) adopts a causal view. It focuses on a particular path of impact – genetic modification – and considers its effects on a broad array of objects of legal protection, including nature (see Figure 1). In contrast, nature protection law (NP law) adopts a functional approach. It focuses on a particular object of legal protection – such as nature – and, starting from there, considers various paths of impact, among them genetic modification.

This twofold approach is part of both EC and Member State laws. While Member State and EC GM laws are almost congruent in scope, EC NP law has a narrower scope than Member State NP law because of its focus on particularly threatened species and habitats of species. Nature protection beyond such level remains largely the domain of national law.

In the context of the above-raised questions, this article examines whether the inclusion of nature protection into GM law supersedes NP law, or whether a domain remains for NP law, such as a procedure ensuring the compatibility of projects with Natura 2000 sites or national protected areas.

To answer this question, four competitive relationships of laws have to be distinguished. Such relationships can be: (a) 'horizontal' between Community law on genetic modification and nature protection; (b) 'vertical' between European and national GM law on one side and European and national NP law on the other; (c) 'diagonal' between European GM and national NP law; and (d) again 'horizontal' between national GM and NP law.

The horizontal competition between GM and NP law – national as well as European – has to be resolved *prima facie* by the speciality rule that admits priority to more specific norms. Speciality means that the particular facts of a case are a subclass of another.[1] However, on one hand, genetic modification is a subcase of risks to nature (and hence more particular); on the other hand, protection of particular species and habitats under NP law is a subcase of protecting nature under the GM law (and hence, in this respect, more specific). Hence, the principle of speciality is not helpful here. We should, instead, question the spirit and purpose of both norms and decide by interpretation how concordance between them can be achieved.

[1] K. Larenz, *Methodenlehre der Rechtswissenschaft* (Springer, 1960), at 174 *et seq.*

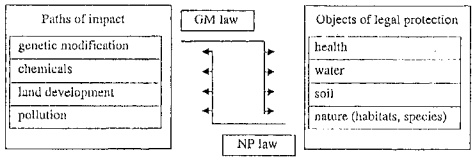

FIGURE 1 REGULATION DIRECTIONS OF GM AND NP LAW

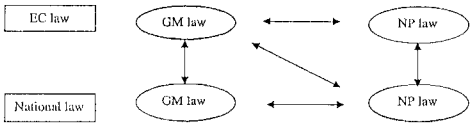

FIGURE 2 THE COMPETITIVE RELATIONSHIP BETWEEN GM LAW AND NP LAW

Besides horizontal competition at the level of Community law, vertical competition between Community law and national law can emerge. Community norms of genetic modification and nature protection can conflict with national rules. In order to resolve such collisions we need to ask whether a regulation (the superordinate) handles a subject matter exhaustively, or whether it leaves room for another norm. Such analysis will be especially tricky in the case of diagonal competition between European GM law and national NP law. Here, two steps might be required: first, the interpretation of EU GM law in concordance with EU NP law, followed by an assessment of the impact of this interpretation for national NP law.

REGIMES FOR THE PREVENTION OF ENVIRONMENTAL DAMAGE

First the instruments of authorizing deliberate release and market placement of GMOs will be sketched out. The situation in Germany will be used as a case study. Then the way in which risk assessment and management of GM law already take nature protection into account will be outlined. Finally, we will investigate whether any room for the requirements of NP law remains.

INSTRUMENTS OF AUTHORIZATION

The deliberate release and the placing on the market of GMOs is regulated by Directive 2001/18/EC.[2] This directive was transposed into German law by the Act on Genetic Modification (Gentechnikgesetz – GenTG).[3] The placing on the market of GM food and feed is separately regulated by Regulation (EC) 1829/2003.

For deliberate release, the procedure is as follows.[4] First, the notification is submitted to the national authority – in Germany the Federal Agency of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)). The BVL invites comments from other specialized agencies including the Federal Agency for Nature Protection (Bundesamt für Naturschutz (BfN)) as well as the Expert Commission for Biological Safety (Kommission für Biologische Sicherheit (ZKBS)). It also sends a summary to the European Commission, which forwards it to the other Member States for possible comments. On the basis of the submitted information the BVL produces an assessment report and makes a final decision on the application.

For the market placement of GMOs (more specifically for products that consist of, or contain, GMOs) the procedure is somewhat more Europeanized.[5] The notification must also be submitted to the BVL. The BVL forwards a summary to the Commission. It checks the completeness of the notification documents and invites comments of further specialized authorities including the BfN. It produces an assessment report based on the submitted information. If the BVL's conclusion is negative, the application is declined; if positive, the BVL forwards the assessment report to the Commission, which distributes it to the other Member States. The other Member States can raise their objections. If these objections are not dispelled, the Commission shall consult 'the relevant scientific committee(s)',[6] i.e. the European Food Safety Agency (EFSA) and its committee for GMOs,[7] to produce a scientific report, and takes a decision by committee procedure.[8] The national authority has to implement

[2] Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2001] OJ L 106/1.

[3] Law of 20 June 1990, Bundesgesetzblatt 1990 I, at 1080, last amended by law of 1 April 2008, Bundesgesetzblatt 2008 I, at 499.

[4] See GenTG, ibid., Article 16(3)–(5) and Directive 2001/18/EC, n. 2 above, Articles 6 and 11.

[5] See GenTG, ibid., Article 16(3)–(5) and Directive 2001/18/EC, n. 2 above, Articles 13–15.

[6] See Directive 2001/18/EC, n. 2 above, Article 28.

[7] Cf. Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] OJ L 31/1, Article 22(5)(c), which extends the EFSA's mission to 'scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC'. In terms of expertise this means that the agency, although concentrating on matters of food and feed, will be called on to also assess GMOs of any other application, including, e.g., micro-organisms used for water or soil purification and plants for energy use.

[8] See Directive 2001/18/EC, n. 2 above, Articles 30 and 18. The committee consists of representatives of the Member States. The procedure allows Member States to veto the Commission proposal.

the decision, in a favourable case, by approval of the market placement, or in a negative case, by rejection of the application.[9] The authorization is a transnational administrative act, i.e. it allows the introduction of the GMO into the environment in all Member States.

For *foodstuffs and animal feed* that contain, consist of, or are produced from GMOs, an even more Europeanized procedure applies under Regulation (EC) 1829/2003.[10] While the application is still submitted to the national authority (the BVL), the BVL forwards it to the lead authority – the EFSA. The EFSA informs the other Member States about the application and publishes a summary of the application dossier. It produces an 'opinion' (which contains the assessment report of the other notification procedures) with the support of its committee for GMOs allowing authorities of other Member States to submit their comments.[11] It also has the discretion to ask Member States to produce an environmental risk assessment (ERA).[12] An obligation to do so exists for foodstuffs and animal feed that are used as seeds of other propagating material.[13] The opinion is forwarded to the Commission, the Member States, as well as the applicant, and is published.[14] The public can make comments within 30 days.[15] Finally, the Commission grants permission or rejects it by committee procedure.[16]

The main differences between the procedures for market placement of general GMOs and of modified food/feedstuffs are that (other than in Regulation (EC) 1829/2003) according to Directive 2001/18/EC:

- a national authority can reject an application autonomously;[17]
- a national authority is competent to conduct the ERA;[18]
- the final decision, even in case of a conflict decision by the Commission, rests with the national authority,[19] which is, however, obliged to implement it;[20] and
- complaints challenging the legality of the decision must be addressed to the national courts which, if they find the primary Commission decision unlawful, must ask the European Court of Justice (ECJ) for a preliminary ruling.[21]

It is not quite clear whether Regulation (EC) 1829/2003 can also be applied to *seeds*. Up until now, GM seeds have required an approval under national seed law[22] as well as an approval under national GM law.[23] For the latter approval, the national authorities have been competent, in line with the Directive 2001/18 procedure. At first sight, seeds are not food and feed and thus not subject to the Regulation (EC) 1829/2003 procedure. However, the current practice of authorities is different. The list of notifications pending at EFSA indicates that notifications concerning seeds for food and feed have been transferred from the less to the more Europeanized procedure and thus are handled under Regulation (EC) 1829/2003.[24]

This practice might be grounded on the term 'GMO for food use', for which Article 4(2) of Regulation (EC) 1829/2003 requires authorization by the Commission. The term is defined as a GMO 'that may be used . . . as a source material for the production of food'. This could imply an understanding of seeds as a source material. Moreover, Article 6(3)(c) of Regulation (EC) 1829/2003 – the obligatory risk assessment of food as plant propagating material by competent national authorities – can be interpreted in a similar vein, because it speaks of GMOs used as seeds or other plant propagating material making it obligatory that EFSA mandates a national authority to conduct the ERA.

I have doubts about such reasoning. The 'source material' for foodstuffs and animal feed is the crop – as material

The final decision, however, falls back to the Commission if the committee does not, within 3 months and by a qualified majority, reject the Commission proposal. See Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, [1999] OJ L 184/23, Articles 5 and 7. Cf. B. Sheridan, *EU Biotechnology Law and Practice: Regulating Genetically Modified and Novel Food Products* (Palladian Law Publishing, 2001), at 58–62.

[9] The commitment results from Article 249(4) of the Treaty Establishing the European Community (TEC). Based on Article 18(2) of Directive 2001/18/EC, n. 2 above, it does not follow that national authorities are free to decide according to their own discretion in cases of a negative decision. Rather, Article 18(2) arranges only for a time limit in case of a positive decision.

[10] Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, [2003] OJ L 268/1.

[11] See Regulation (EC) 1829/2003, ibid., Article 6(4).

[12] Ibid., Article 6(3)(c).

[13] Ibid., Article 6(3)(c), last half sentence.

[14] Ibid., Article 6(6)(2).

[15] Ibid., Article 6(6)(2).

[16] Ibid., Articles 7(1)–(3), 35(2).

[17] See Directive 2001/18/EC, n. 2 above, Article 15(2).

[18] Ibid., Article 14(2).

[19] Ibid., Article 18.

[20] In the context of the so-called moratorium in the late 1990s, national authorities sometimes delayed authorization, see Th. Christoforou, 'The Regulation of Genetically Modified Organisms in the EU: The Interplay of Science, Law and Politics', 41:3 *CMLR* (2004), 637, at 689.

[21] See ECJ 21 March 2000, Case C-6/99 *Greenpeace France v Ministère de l'Agriculture et de la Pêche*, [2000] ECR I-1676.

[22] Saatgutverkehrsgesetz of 20 August 1985, Bundesgesetzblatt 1985 I, at 1633, Article 30, as amended by Law of 21 March 2002, Bundesgesetzblatt 2002 I, at 1146.

[23] See GenTG, n. 3 above, Article 14.

[24] See the lists with pending proceedings, and in particular the applications EFSA-GMO-Nos UK-2005-17, NL-2005-28, UK-2006-30 and NL-2007-46 in Summary of the Application for the Authorisation of Genetically Modified 1507xnk603 Maize and Derived Food and Feed in accordance with Regulation (EC) 1829/2003 including Authorisation for Cultivation in accordance with Directive 2001/18/EC (undated), available at: <http://www.efsa.europa.eu/EFSA/DocumentSet/gmo_uk_2005_17_en1,0.pdf>.

to be processed – and not the seed. The obligatory involvement of national authorities in the ERA has to be understood as aiming to avoid a divergence in the risk assessment for one and the same GMO – used as foodstuffs and animal feed on the one side, and seed on the other side.[25] Hence, the national authorization of seeds under GM law remains, even if the GMO is used as food or feed as well.

In sum, two different procedures exist for market placement: a highly Europeanized one for food and feed with the EFSA in charge, and a less Europeanized one with the competent national authority in charge for all other GMOs, including seeds for food and feed. As current practice subsumes GM seeds for food and feed under the Regulation 1829/2003 procedure, I will in what follows assume that this is legally correct.

SUBSTANTIVE CRITERIA OF AUTHORIZATION

Nature protection can be ensured by substantive criteria, as specified by rules on the submission and assessment of risk information. To the extent that they do not ensure nature protection in the post-authorization phase, monitoring requirements must be considered as additional controls. Although the core issues are fixed by EC law, national law must also be consulted because the bulk of relevant EC legislation is framed as transposable directives. German GM law shall again be taken as an example.

Substantive Criteria of Risk Assessment

According to Article 16(1) (No 3) of the German GenTG, the substantive criterion is that the authorization is to be given if 'considering the state of science and the aim of the release, unjustifiable adverse effects on objects protected under Article 1(1) are not to be expected'. The indicated objects under protection of Article 1(1) are, *inter alia*, 'the environment with its interacting subsystems, fauna, flora and material assets'. The same requirements exist for the authorization to place products on the market according to Article 16(2) of GenTG.

Article 4(1) of Regulation (EC) 1829/2003 phrases the standard for the market placement of food and feed somewhat differently. It states, in part: 'Food referred to in Article 3(1) must not: (a) have *adverse effects* on human health, animal health or the environment . . .'.

Different again is the standard in Article 4 of Directive 2001/18/EC. This is the most important one because it informs both the national laws and Regulation (EC) 1829/2003.[26] It states, *inter alia*, that:

> 1. Member States shall, in accordance with the *precautionary principle*, ensure that all appropriate measures are taken to avoid *adverse effects* on human health and the environment . . .
> 3. Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur *directly or indirectly through gene transfer* from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment. [emphasis added]

The ERA required by Article 4(2) of Directive 2001/18/EC is defined in Article 2(8) of the same directive as:

> . . . the evaluation of risks to human health and the environment, whether *direct or indirect, immediate or delayed*, which the deliberate release or the placing on the market of GMOs may pose and [which is[27]] carried out in accordance with Annex II. [emphasis added]

According to Article 13(2a) of Directive 2001/18/EC, the necessary information provided with an application:

> . . . shall take into account the *diversity of sites of use* of the GMO as or in a product . . . [emphasis added]

Of particular interest here is the *precautionary principle*.[28] Generally, this allows the denial of permission if there is scientific uncertainty about adverse effects.[29]

[25] Of course, if a notifier aims at both an authorization for consumption and for cultivation, he can submit one application dossier to the national authority, which must then split the further proceeding as indicated. The model is 'two doors, one key' not 'one door, one key' as supposed by E. Tsioumani, 'Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments', 13:3 *RECIEL* (2004), 279, at 286.

[26] See Regulation (EC) 1829/2003, n. 10 above, Article 6(4), which states: 'in the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs . . .'. See also Article 7(8): 'References made in parts A and D of Directive 2001/18/EC to GMOs authorized under part C of that Directive shall be considered as applying equally to GMOs authorized under this Regulation'. Article 4 can be found in Part A of Directive 2001/18/EC and refers to the release and market placement in its section 1.

[27] These two words appear to be missing in the English version if compared with the German version.

[28] See, in the context of GM law, also Chr. Callies and S. Korte, 'Das neue Recht der Grünen Gentechnik im europäischen Verwaltungsverbund', 59:1 *Die öffentliche Verwaltung* (2006), 10, at 11. Stressing the uncertainty in application of the precautionary principle, see B. Sheridan, n. 8 above, at 263–280.

[29] See ECJ 5 May 1998, Case C-180/96, *United Kingdom v. Commission*, [1998] ECR I-2265 (*BSE*), para. 99; and CFI 11 September 2002, Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, [2002] ECR II 3305 (*Pfizer*), para. 139.

Yet in such a case, indications for adverse effects are required: 'merely hypothetical considerations of a risk' do not suffice.[30] If such indications exist, Article 4(1) of Directive 2001/18/EC grants not only the authority but also the obligation to refuse permission.

Two circumstances make the refusal of approval, a radical solution, a rare event: first, the step-by-step concept of risk assessment[31] – spanning from the closed system to the experimental release and market placement – ensures that the available knowledge enables distinguishing between negligible and unacceptable risks. Second, the obligations of monitoring allow testing open hypotheses about remaining risks in the post-authorization phase.

Furthermore, the distinction between *direct and indirect effects* is essential. Annex II of Regulation (EC) 1829/2003 defines indirect effects as follows:

> 'indirect effects' refers to effects on human health or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management.

This implies that not only do adverse effects of GMOs through direct contact with the GMO by human beings or non-targeted organisms consuming GMOs have to be avoided, but also adverse effects mediated by the introduction into nature, by vertical or horizontal gene transfer and even by changes in management practices. Across direct and indirect effects one might distinguish between natural (food chain, return to the wild, gene transfer, food chain, etc.) and societal (changed applications of chemicals, rotation of crops, etc.) causation chains.

Effects may occur *immediately* or *late*, yet what counts as 'late' is left unspecified. The Commission guidance notes for the ERA according to Annex II of Directive 2001/18/EC provide illustrations:[32]

- where reducing the target population of insects affects the population of other insects; or
- where the development of multiple resistance or systemic effects will require assessment of long-term interaction.

In addition, the above-quoted Article 13(2a) of Directive 2001/18/EC requires that *different sites of use*, which are exposed to GMOs, are considered. This aspect is specified by the Commission Guidance:

> For each adverse effect identified, the consequences for other organisms, populations, *species or ecosystems* exposed to the GMO have to be evaluated. This requires detailed knowledge of the environment into which the GMO is to be released (site, region) and the method of release.[33] [emphasis added]
>
> Moreover, there may be a *broad range of environmental characteristics (site-specific or regional-specific)* to be taken into account. To support a case-by-case assessment, it may be useful to classify regional data by habitat area, reflecting aspects of the receiving environment relevant to GMOs (for example, botanical data on the occurrence of wild relatives of GMO plants in different agricultural or natural habitats of Europe).[34] [emphasis added]

Is this profile of substantive criteria adequate to cover effects on nature? The answer must distinguish between experimental release and market placement of GMOs. For experimental releases, the affected species and ecosystems are identifiable because in these cases the location of the release is fixed. In contrast, an authorization for market placement can result in the introduction into the environment of GMOs across Member States. If one applies the above-quoted wordings to procedures for the authorization of market placement, they give the impression that all European species and ecosystems possibly affected by the introduction of GMOs are included in the ERA. This is, however, neither the case *de facto* nor at all possible. A competent authorization procedure would have to be limited to relevant areas and this would need to be stressed by defining the particular application area of the GMO within the authorization. Species and habitats not covered by the authorization need to be handled by subsequent procedures of risk assessment and decisions based on NP law. We will return to this after discussing the adequacy of risk assessment methodology.

The Methodology of Risk Assessment

The ERA is aimed at preparing the decision on whether a given project fulfils the above-mentioned substantive criteria. Although our focus is on risks for nature, we need to broaden the perspective here because the methodology of ERA applies to all kinds of risks.

Steps of ERA

According to Annex II of Directive 2001/18/EC and the already mentioned Commission guidance, the ERA consists of six steps.

Step 1 identifies a GMO's *inherent characteristics* that might cause adverse effects, and the potential causation chains. Examples for risk factors are the potential to

[30] See *Pfizer*, ibid., para. 143. The court requires that 'the risk . . . appears nevertheless to be adequately backed up by the scientific data available at the time' (para. 144).

[31] Cf. Directive 2001/18/EC, n. 2 above, consideration (24).

[32] Commission Decision 2002/623/C of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, [2002] OJ L 200/22, chap. 2.

[33] Ibid., chap. 4.2.2, para. 3.

[34] Ibid., chap. 3., indent 3, sec. 4.

impact on population dynamics, on the genetic diversity of the receiving milieu or on agricultural practices.

In *step 2*, the magnitude of the potential *adverse effects* of GMOs on other organisms, populations, species or ecosystems shall be evaluated. The evaluation of adverse effects is carried out according to four categories:[35]

> 'high level consequences' might be significant changes in the numbers of one or more species of other organisms, including endangered and beneficial species in the short or long term. . . . Such changes would probably not be readily reversible and any recovery of the ecosystem that did take place would probably be slow; 'moderate consequences' might be significant changes in population densities of other organisms, but not a change that could result in the total eradication of a species or any significant effect on endangered or beneficial species. Transient and substantial changes in populations might be included if likely to be reversible; 'low level consequences' might be non-significant changes in population densities of other organisms, which do not result in the total eradication of any population or species of other organisms and have no negative effects on functioning of the ecosystem. The only organisms that might be affected would be non-endangered, non-beneficial species in the short or long term; 'negligible consequences' would mean that no significant changes had been caused in any of the populations in the environment or in any ecosystems.

Step 3 evaluates the *likelihood of the identified potential adverse effects to occur*. Here, risk factors, the number of released GMOs, the likelihood and frequency of genetic transfer, the receiving milieu and the circumstances for release have to be taken into account. For each identified adverse effect, the relative likelihood of occurrence shall be expressed in the qualitative terms of 'high', 'moderate', 'low' or 'negligible'.

Step 4 relates different categories of harm to the different levels of likelihood. Additionally, the extent of uncertainty has to be identified, taking into account the assumptions and extrapolations of the previous steps, as well as different scientific assessment and viewpoints.

In *step 5*, strategies for the management of risks arising out of deliberate release or market placement have to be worked out. The risk management has to be designed in such a way that identified risks are controlled and uncertainties are accounted for. Precautionary measures such as discard strips, safety margins, etc., have to be proportionate to risk and uncertainty. The risk management has to be flexible and adapt to the current state of science.

Step 6 assesses the *overall risk*. This includes an aggregation of risks and uncertainties arising out of an application, considering the amount of damages, the likelihood of harm as well as those protection measures mentioned in step 5.

Commentary

It is beyond my competence to propose how the ERA conception could be developed further.[36] I will only stress three points below that catch the eye of someone outside of the subject area.

First of all, one has to emphasize positively that the ERA not only inquires into its objects, but that it also reflexively assesses the (un)certainty of its own judgements.[37] Given the infancy of research into risks of genetic modification, this is of crucial importance.

Second, more critical is the structuring of risk assessment along the distinction 'characteristics of GMOs – magnitude and likelihood of effects'. This resembles the method of risk assessment for chemicals, which distinguishes between hazard assessment (focusing on the potentially harmful properties of a substance) and exposure assessment (focusing on the actual exposure of organisms to the substance).[38] This method aims to compare potentially harmful doses of chemicals with actual doses of exposed organisms. By contrast, GMOs are not always harmful *per se*. For example, the ability of a herbicide-resistant GMO to survive chemical herbicides is certainly not a *per se* harmful property. Whether it may nonetheless cause adverse effects depends on complex chains of causation, for example, if the 'vertical' transfer of the transgene to wild relatives and conditions is inducive of making them dominant in an ecosystem. Therefore, it appears that the focus should rather be on the analysis of causation chains, an exercise falling between steps one and two of the ERA for GMOs. The methodology suggesting this would be event and fault tree analysis.[39] By that methodology,

[35] Ibid., chap. 4.2.2, para 5. The examples in the Commission Guidance are mainly phrased in the subjunctive ('could . . . be'). This indicates that the Commission leaves room for Member States to find their own criteria.

[36] For the academic debate, see R.A. Hill, 'Conceptualizing risk assessment methodology for genetically modified organisms', 4 *Environ. Biosafety Res.* (2005), 67–70.

[37] The distinction between statements about the amount and likelihood of damages on the one hand and the (un)certainty of the underlying knowledge is stressed by the German Scientific Advisory Board on Global Environmental Change (WBGU) in its 1998 annual report: see WBGU, *Welt im Wandel–Strategien zur Bewältigung globaler Umweltrisiken: Jahresgutachten 1998* (Springer, 1999), at 53f.

[38] Cf. Ad hoc Kommission, *Neuordnung der Verfahren und Strukturen zur Risikobewertung und Standardsetzung im gesundheitlichen Umweltschutz der Bundesrepublik Deutschland, Abschlussbericht* (Bundesamt für Strahlenschutz, 2003).

[39] Event trees represent a method of risk analysis starting with the normal state of a system and assuming non-regular events which initiate chains causing (or blocking) further non-regular events, which may finally result in a harmful accident. In contrast, fault tree analysis starts with a hypothetical harmful accident and traces this back to chains of non-regular events and finally the normal state of the system. Both approaches help to identify critical points in the causation chains which can be targeted by risk abatement measures.

FIGURE 3 LINKING RISK VARIANTS WITH BENEFITS

STATE OF KNOWLEDGE	*PROBABILITY OF HARM*	*MAGNITUDE OF HARM*	*LEGAL CONSEQUENCE*
Sufficient	High	Significant	Rejection
Sufficient	Low	Significant	Balancing with benefit
Insufficient	Uncertain	Significant or uncertain	Provisional rejection or approval on condition of knowledge generation
Sufficient	High or low	Minor	Balancing with benefit
Insufficient	Uncertain	Minor	Balancing with benefit
Sufficient or insufficient	High, low or uncertain	Negligible	Approval

intrinsic characteristics of GMOs, the conditions of release, paths of consequences and modes of impact are modelled into complex trajectories.[40]

Third, the fact that the substantive criteria of risk assessment and their specification in the ERA exclusively look at adverse effects can be questioned. In comparison, the German GenTG, by requiring that 'in relation to the purpose of release [or market placement] unjustifiable adverse effects are not to be expected', takes the benefits of the release (or market placement) into account. This means that adverse effects of a GMO may be acceptable if they can be justified in relation to the expected benefit of the release or market placement.

At first sight, such balancing of risks and benefits is incompatible with Article 4 of Directive 2001/18/EC, which simply requires Member States to ensure that all appropriate measures are taken to avoid adverse effects. However, I believe there is some leeway concerning the definition of adverse effect as a legal term. Given the unpredictability of ecosystems, there will always remain a risk of adverse effect. Deterministic assessments as they are used in matters of dangerous technologies are not appropriate in matters of biotechnology, because living systems are much more complex than technical systems. Therefore, some other criterion than harm avoidance is needed in order to determine what residual risk shall be tolerated or not. Such criterion could indeed be the benefit drawn from the release of the GMO.[41] The benefit would have to be of a kind that improves the overall environmental situation; for instance, if a fungicide GMO renders the use of chemical fungicides superfluous, one may conclude that the residual risk as weighed up against this benefit of avoided pesticides is overall no adverse effect on the environment in the legal sense of the term.[42]

Such balancing would require that during the authorization procedure not only risk but also benefit-related data must be submitted. Benefits are often simply postulated but would need to be rigorously scrutinized. Unfortunately, this is not provided by the relevant laws and ERA methodology.

The balancing of benefits needs to be related to different kinds of risks. Cases where the state of knowledge does not allow the rendering of conclusive assessments must also be taken into account. Figure 3 presents a model for such relationing. According to the model, authorization has to be denied if the state of knowledge is sufficient to render judgement and the harm is serious and likely; benefits are not to be considered in that case. The same is true in the inverse situation: the approval must be granted if the harm is predicted to be negligible, be its occurrence likely, unlikely or uncertain. For cost–benefit balancing, three constellations apply: cases of low probability, of significant harm and cases of predictably minor harm. The remaining constellation is one of precaution: if the occurrence of harm is uncertain and its magnitude predictably high or uncertain, the approval should only be granted on the condition that further knowledge must be generated, or it should be denied until better knowledge has emerged.(

[40] See, for example, the suggestions in US National Research Council, *Risk Assessment Models: Environmental Effects of Transgenic Plants – The Scope and Adequacy of Regulation* (National Academy Press, 2002), at 93–100.

[41] For a balanced discussion of benefits of GM green technology, see J. Holder and M. Lee, *Environmental Protection, Law and Policy*, 2nd edn (Cambridge University Press, 2007), at 72–84.

[42] This means that more general benefits such as the economic efficiency of agriculture or a reduction in consumer prices would not qualify as accountable benefits. For example, the notification dossier for an insect-protected cotton seed points to the following beneficial effect: 'Therefore, with the use of IPC 531 cotton with in plant *BT*-technology, endangered insect species are less likely to be harmed as they are with many broad spectrum insecticidal sprays. In fact, several studies have shown that non-target organisms can be more active in IPC cotton as biological control agents for secondary pests'. See 'Summary Notification Information Format (SNIF) for Products Containing Genetically Modified Higher Plants (GMHPs): Insect-Protected Cotton Line derived from Event 531' (EFSA document C/ES/96/2, undated), available at: <http://gmoinfo.jrc.it/csnifs/C-ES-96-02.pdf>.

In practice, however, administrative authorities avoid an open balancing of risks and benefits. In most cases, they posit that a GMO will not cause any adverse effects to non-target organisms, that the transgene is not spread vertically or horizontally, and that even if this occurs no or only negligible adverse effects would be caused.[43]

For instance, in a recent permission to experimentally release herbicide-resistant Bt-Maize, the German competent agency, the BVL, argued:

- that a spread of the transgene by pollen is not to be expected due to a lack of partners for crossing;
- that the spread to other kinds of maize can be minimized through covered seeds and safety margins;
- that a horizontal spread of genes is highly unlikely; and even if it occurred, would not significantly increase the natural frequency of gene transfer; and that ecologic consequences of such a gene transfer are unlikely;
- that the agricultural bacteria tumefaciens, used to produce the GMO, can spread in rare cases, yet that it is 'disarmed', i.e. unable to cause tumours in plants; and
- that the passing on of the transgene to uncultivated kinds of agricultural bacteria is also unlikely; yet, if it occurs and causes a tumour in a plant, no new plants are created that would be able to reproduce the transgene.

Something similar can be observed in the authorization procedure for the placing on the market of GM seeds. For instance, the summarizing dossier to the EFSA authorization proceedings for the cultivation of a transgene soy argues that the introduction has no direct adverse effects on non-target organisms, that the likelihood for the transgene to spread vertically or horizontally is very slim, and that an occurring gene transfer would cause only negligible adverse effects.[44]

Overall, therefore, practice often resorts to the notion of negligible residual risk. But it does not explain why such risk should be negligible.

In conclusion, although the substantive criteria and the ERA methodology for the release and market placement take the environment and thus species and habitat protection into account, the methodology could be improved in terms of fault or event tree analysis and risk–benefit balancing.

All this can be done at the stage of authorizing releases and the placing on the market of GMOs. However, considering the fact that at the stage of project authorization not all sites of introduction of GMOs and thus not all affected species and habitats are known, post-market site-related measures must be used to cope with this difficulty. This question will now be addressed.

Post-Authorization Measures On implementing Directive 2001/18/EC, national law must stipulate a differentiated monitoring and supervision system to be applied after the authorization for deliberate release or market placement has been granted.[45] The following obligations apply to the notifier and/or the user of the GMO. German law is again taken as an illustration of national implementation:

- the obligation of the notifier to comply with the authorization requirements, especially with regard to the implementation of the monitoring plan;[46]
- the obligation of the user to comply with good practice in order to prevent harm to health and the environment, especially through measures preventing cross-fertilization and the spread of transgenes through wild relatives;[47]
- the obligation of the user to continuously report to the competent authority (i.e. the BVL) on the unexpected threat of incidents during the deliberate release or market placement,[48] on case-specific and general observations according to the required monitoring scheme,[49] and generally, about newly emerging information about risks for health and the environment.[50]

These obligations for notifiers and users are accompanied by tasks and powers of the competent authorities:

- to supervise compliance with the conditions for the release or market placement;[51]
- to intervene in cases of established violations of conditions and legal requirements;[52]
- to take, in the event of severe risks, temporary emergency measures – the Commission has to be informed of these measures and takes a decision if necessary;[53] and
- to impose additional conditions[54] after initiating a cooperative procedure involving the Commission and the other Member States.[55]

While the duties of the notifier/user and the powers of the authorities are comprehensive, the concept is one of 'learning by doing': measures that may be taken to presuppose information generated while the GMO is introduced into the environment. The concept is not geared to once again require prognostic impact assessment before the GMO is introduced into the environment, in particular into nature protection areas. This is logical in cases of deliberate release because the location of release is then already known at the stage of the initial authorization. In the case of authorizing market placement, the precise location is not known at the authorization stage. An additional prognostic check may be appropriate in such cases. It will be seen that to do this is a matter of NP law.

For GM *foodstuffs and animal feed*, the situation is similar. Articles 9(1) (resp. 21(1)) of Regulation (EC) 1829/2003 states that where post-market monitoring has been imposed on the authorization-holder, the latter 'shall ensure that it is carried out and shall submit reports to the Commission in accordance with the terms of the authorization . . .'. Furthermore, he or she must submit to the Commission all new scientific or technical information that could impact on food or feed safety.[56]

Article 10 (resp. Article 22) of Regulation (EC) 1829/2003 regulates authorities' reactions: if the monitoring or any other new information reveals unforeseen risks, the Commission, upon a proposal by EFSA and after consultation with the Member State and the public, may modify, suspend or revoke the authorization. In addition, there is the protection clause for emergencies according to Article 34 of Regulation (EC) 1829/2003, allowing the Member State to intervene and the Commission to react if GMOs are 'likely to constitute a serious risk to human health, animal health or the environment'.

In terms of the relevance of nature protection in post-market monitoring schemes, it becomes apparent that, as in the procedure under Directive 2001/18/EC, the obligations of operators are mainly bound to the authorization arrangements. Yet, the wording of the obligations neglects the need for preventive prognostic checking where nature protection areas that have not been tested in the authorization are affected.

Therefore, GM law does not prevent national area-specific measures, but neither does it encourage or stipulate them; hence, it must be asked what competences and obligations for action with regard to area-specific measures derive from NP law.

GENETIC MODIFICATION IN NATURE PROTECTION LAW

As stated above, while GM law takes a causal view, NP law is functionally orientated. It hedges valuable nature against a variety of impacts, including those caused by GMOs. The question is whether NP law can add anything to what GM law already ensures. As NP requirements are in parts differently designed, experimental release and market placement will be discussed separately. The focus will be on the protection of Natura 2000 sites,[57] although it must be kept in mind that EC law also protects certain species outside its habitat regime, and that the Member States run their own regimes protecting areas and species beyond the EC minimum.

Experimental Release First we need to clarify whether releases of GMOs are projects according to Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora (the FFH Directive)[58] requiring an FFH impact assessment (FFH-IA), and how these FFH-IAs have to be administered.

Requirement of FFH-IA

According to Article 6(3) of the FFH Directive 92/43/EEC:

> . . . any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, . . . shall be subject to appropriate assessment of its implications for the site in view of the site's conservation objectives.

The term 'project' has been defined by the ECJ based on the language in Article 1(2) of the Environmental Impact Assessment (EIA) Directive.[59] Article 1(2)

[43] A. Fisahn, 'Die Genehmigung der Freisetzung gentechnisch veränderter Organismen: Eine Fallstudie', in G. Winter *et al.*, *Die Prüfung der Freisetzung von gentechnisch veränderten Organismen. Recht und Genehmigungspraxis*, UBA-Berichte 4/98 (Erich Schmidt Verlag, 1998), 25 *et. seq.*

[44] For further examples see the opinions of EC scientific committees summarized in B. Sheridan, n. 8 above, at 66–77.

[45] For food and feed, see below.

[46] See GenTG, n. 3 above, Article 15(2) no. 4a and (3) no. 5a and Ordinance on GM procedures (Gentechnikverfahrensverordnung – GenTVfV of 4 November 1996, Bundesgesetzblatt 1996 I 1657), Article 6(1)(4a). The basis in Directive 2001/18/EC is Article 20(1) and Annex VII. According to Annex VII, sec. A, the aim of the monitoring plan is to: '– confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the ERA are correct, and – identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the ERA'.

[47] GenTG, n. 3 above, Article 16b(2) and (3) no. 1.

[48] Ibid., Article 21(3).

[49] Ibid., Article 21(4) and (4a).

[50] Ibid., Article 21(5).

[51] Ibid., Article 25.

[52] Ibid., Articles 26 and 38.

[53] Ibid., Article 26(5)(2). See also Directive 2001/18/EC, n. 2 above, Article 23 (protection clause procedure).

[54] See GenTG, n. 3 above, Article 19(2). See also Directive 2001/18/EC, n. 2 above, Article 20(3).

[55] Ordinance on EC and Member State participation in GM procedures (Gentechnikbeteiligungsverordnung – GenTBetV of 17 May 1995, Bundesgesetzblatt 1995 I 734), Article 3(7); see also Directive 2001/18/EC, n. 2 above, Article 20(3).

[56] See Regulation (EC) 1829/2003, n. 10 above, Articles 9(3) and 21(3).

[57] These are sites constituting an EU-wide network of valuable habitats. The protection regime is based on two directives: Council Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds, [1979] OJ L 103/1 (Birds Directive) and Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora, [1992] OJ L 206/7 (FFH Directive).

[58] Ibid.

[59] Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, [1985] OJ L 175/40.

states that the term encompasses 'other interventions in the natural surroundings and landscape' apart from construction works and other installations. With regard to the protective aim of both Directives, 'intervention' is conceived of broadly, and includes mechanical mussel fishing, which was the subject of an ECJ decision.[60] Releases of GMOs should also be regarded as an 'intervention'. This should apply both to releases in an FFH area and to external releases impinging on an FFH area.[61]

Only those projects that are likely to have a significant effect on an FFH area are, however, subject to the required FFH-IA. The likelihood of significant effect requires a preliminary screening. In doing this, the authority has, according to the ECJ, to apply the precautionary principle. The ECJ sets high standards in that respect. It should 'not be excluded' that the project may have significant effects on the site. If 'doubts' exist, an impact assessment must be carried out.[62]

Procedures

Two variants of the procedure of the FFH-IA are possible: an independent proceeding under NP law, or the incorporation of protection aspects into the authorization procedure for deliberate release of GMOs. In the first case, the conservation authorities make the decision and, in the second case, the authorities for genetic modification make the decision.

Procedural efficiency militates for an integrated solution. For a notifier, it would hardly be acceptable that the authorization for release, which is bound to a protected site, is followed by a further procedure examining FFH compatibility. However, Article 6(3) of Directive 92/43/EEC does not exclude such a solution.

However, the case is different if the authorization for introduction is granted under the simplified procedure of Article 6(5) of Council Directive 90/220/EEC and Commission Decision 94/730/EC.[63] The same applies to differentiated procedures under Article 7 of Directive 2001/18.[64] If the simplified or differentiated procedure leaves the site of release unspecified, as is possible under the above-mentioned decision, the applicant is obliged to provide 'additional information together with a statement indicating whether the original risk assessment remains valid and if not, provide further evaluation'.[65] Furthermore, it is prescribed that the competent authority 'may alter the conditions of the original consent or intervene to alter the conditions of specific subsequent releases on the basis of the results indicated in the reports or on the basis of information obtained during inspections'.[66]

In summary, in cases of GMO releases, the site-specific impact assessment should be linked to the procedure for release authorization. A particular procedure is only required in cases of simplified differentiated procedure in which the authorization of release leaves future sites unspecified. The FFH-IA for the site-specific release of GMOs would therefore be part of the ERA under GM law. This means that the ERA should be amended to include a step that would cover area characteristics, conservation aims, protection purposes and supporting elements of FFH sites. An operator who wants to pursue a release in or close to an FFH area has to provide documentation in order to allow a preliminary examination of the potential for serious harm. If a potential harm is approved, further information on impacts on the FFH area has to be submitted for the ERA. In terms of administrative competences, the integrative solution would imply that the authority that is competent for GM approvals should also obtain the competence for the FFH-IA. In Germany, this is the BVL. Considering that primarily environmental interests have to be taken into account, the participation of nature conservation authorities with their area-specific knowledge must be assured. In Germany, these are the nature protection authorities of the Laender and the BfN.

Market Placement

Pre-Market Requirements

NP law looks at the direct effects of GMOs on protected areas that are subsequent to the placing on the market, such as mechanical destruction, chemical contamination or biological modification. To that effect, NP law cannot be applied directly to the procedure authorizing a GMO's introduction.

Nevertheless, an indirect influence of NP on the effects of GM law exists. While, as shown above, the European GM law claims to also examine effects on different biotopes and species in its ERA, one could draw on the list of protected habitats and species set out in Directives 79/409/EEC and 92/43/EEC in order to provide a more differentiated picture. There is a self-interest of GM law to accommodate NP law as far as possible, because its exhaustive effect depends on it – as will be shown below.

Post-Market Measures

As already detailed above, the introduction into the environment of GMOs is a project in the sense of Article 6(3) of Directive 92/43/EC, which by a preliminary investigation must be tested as to its likelihood of significant effects on an FFH area.[67] This also applies to the introduction after authorization of market placement.

If, however, the type of habitat into which the introduction is intended was already examined during the authorization procedure and proven to be harmless, this can be seen as a preliminary investigation precluding further examination.

Other than in the case of experimental releases, the FFH-IA cannot be combined with the ERA in the authorization procedure because at the stage of market placement the location of introduction of the GMO is yet unknown. The FFH-IA must therefore stand on its own.

For the impact assessment, it would be helpful if those legal acts establishing an FFH area specified conservation aims, protective purposes and regulations with regard to the release of GMOs.

Pre-Emption of Area-Related Measures?

Post-market controls based on NP law could be objected to based on the argument that the EC provisions on the authorization of market placement are conclusive and thus pre-empt area-related measures of a Member State.

In relation to Natura 2000 sites, this question is first of all one of the horizontal compatibility of EC NP law on the one side and GM law on the other. One may consider solving the conflict between these laws by applying the *lex specialis* rule. It has, however, been argued above that both laws address specialities: NP law addresses the specificity of Natura 2000 sites and GM law addresses the specificity of genetic modification. It was suggested above that in this event of 'horizontal' conflict, concordance should be attempted by looking at the spirit and purpose of the two regimes. Should the result be (as it is) that NP measures are allowed to add on to GM law, it is by implication clear that national NP measures implementing EC NP law are allowed as well. If, however, national NP law, by protecting sites and species beyond the scope of Natura 2000, goes further than EC NP law, a constellation of 'diagonal' conflict arises, because EC GM is then not relativized by EC NP law.[68] In this case it must be inquired as to whether EC GM law pre-empts national NP measures.

For the sake of simplifying this rather intricate doctrinal task, it is submitted that the analysis of concordance in relation to 'horizontal' conflicts and of pre-emption in relation to 'diagonal' conflicts can draw on the same criteria. Therefore, looking from the perspective of EC GM law, we can answer both questions at the same time.

When studying whether an EC legal act exhausts a matter, the ECJ has applied the following criteria:[69]

- the scope of application of the legal act;[70]
- its conclusiveness;[71]
- its objectives;[72]

Concerning existing case law, it is striking that most cases refer to the issue of whether a Member State is allowed to regulate the market placement of products differently from Community law.[73] There seems to be no jurisprudence on whether post-market regulations of product use are allowed after the authorization of market placement. This is astonishing, as there are obviously a plethora of such post-market rules of use, both at the EC and Member State levels, such as, for example, the ban on the introduction of licensed fertilizers or pesticides in water protection areas.[74]

[60] ECJ 7 September 2004, Case C-127/02, *Landelijke Vereniging v. Staatssecretaris van Landbouw, Natuurbeheer en Visserij*, [2004] ECR I-7448, paras 28 and 27; ECJ 10 January 2006, Case C-98/03, *Commission v. Germany*, [2006] ECR I-75; and see S. Lütkes, 'Anpassungserfordernisse des deutschen Artenschutzrechts', 16:11 *Zeitschrift für Umweltrecht* (2006), 513, at 515.

[61] M. Gellermann, *Natura 2000: Europäisches Habitatrecht und seine Durchführung in der BRD*, 2nd edn, (Blackwell Wissenschaft, 2001), at 71; this is also implicit in ECJ 10 January 2006, Case C-98/03, *Commission v. Germany*, [2006] ECR I-75, para. 43.

[62] See *Commission v. Germany*, ibid., para. 44.

[63] Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC, [1994] OJ L 292/31.

[64] See n. 2 above.

[65] Decision 94/730/EC, n. 63 above, sec. 7.

[66] ibid., Annex sec. 7 and 10.

[67] National nature protection legislation (including the German legislation) commonly does not require an impact assessment for GMOs in protected sites outside FFH areas. Yet the national legislator is free to establish similar rules. It is recommended that the introduction of such regulations follow the relevant rules for FFH areas.

[68] See Figure 2 above. It is this constellation only (and not the horizontal conflict between EC laws) which is addressed by the free circulation clause in Article 22 of Directive 2001/18/EC.

[69] On the following, see the comprehensive study by A. Furrer, *Die Sperrwirkung des sekundären Gemeinschaftsrechts auf die nationalen Rechtsordnungen* (Nomos Verlag, 1994).

[70] For instance, in the *Galli* case, Italy had taken measures against the rise in prices for grain based on legally granted emergency powers. Under preliminary procedure, the ECJ declared that the pricing system of the market only applied to the production and wholesale level, but left the retail and consumer level untouched. See ECJ 23 January 1975, Case 31/74, *Galli*, [1975] ECR 47, at paras 32–34.

[71] The ECJ, for example, adjudicated that for substances not included in Directive 76/769/EEC, no exhaustive effect arises. For these substances, the regulative powers of the Member State remain intact. See ECJ 11 July 2000, Case C-473/98, *Chemikalieninspektionen v. Toolex*, [2000] ECR I-5681.

[72] In the above-mentioned *Galli* case, the Community measure was aimed at establishing a common market for grain. In contrast, the Italian measure aimed at remedying a supply shortage. See *Galli*, n. 70 above, para. 8 et seq.

[73] See A. Furrer, n. 69 above.

[74] Article 19(1)(3) of the Federal Water Law (Wasserhaushaltsgesetz of 19 August 2002, Bundesgesetzblatt 2002 I 3245). This is supported by Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, [2000] OJ 327/1, Article 7(3).

Furthermore, we need to consider that the issue of exhaustive regulation may sometimes not be identifiable at the level of laws, but only at the level of individual acts of implementation. The foundational norm then needs to be interpreted so as to basically allow an exhaustive effect, which can, however, only be decided upon in the individual case.

We will now proceed to apply the criteria having in mind both constellations: the horizontal concurrence of EC NP and GM law and the diagonal concurrence of EC GM law and national NP law.[75]

Scope of application: Community GM law focuses on the market placement of GMOs, while NP law focuses on their use. Nonetheless, the introduction is authorized in order to allow usage. In this respect, the scopes of application overlap not completely but partially. Whether this leads to incompatibilities has to be measured against other yardsticks such as the different objectives.

Objectives: As emanates from the competence foundation in Article 95 TEC and its recitals, Regulation (EC) No 1829/2003 primarily serves the Single Market, i.e. free trade in GMOs.[76] Directive 2001/18/EC is also based on the Single Market competence, yet it does not primarily regulate free trade but potential transborder risks.[77] In contrast, post-market NP measures strive to protect locally limited areas relevant for nature protection. Neither the exchange of products nor the transborder effects are paramount here. Hence, the objectives differ. They do not collide with each other; on the contrary, the NP measures support the objectives of the two EC GM legal acts because both of them are also concerned with the protection of health and the environment.

Conclusiveness: Above, I have substantiated that the ERA in the authorization procedure cannot cover all potentially affected species and habitats existing in the EU. Therefore, both Directive 2001/18/EC and Regulation 1829/03/EC must be interpreted to shift the decision on conclusiveness to the individual authorization. To the extent that the ERA in the individual case has checked potentially affected species and habitats, it is conclusive. Concerning the remainder, it is not. Hence, use-related measures can be taken in that respect.

In summary, EC GM law does not hinder Member States from introducing NP measures concerning Natura 2000 areas, or going further.

In terms of future practice, an authorization should be restricted to those circumstances of introduction that have been checked in the ERA. This is also intended in both Directive 2001/18/EC and Regulation (EC) 1829/2003, where 'precise instructions and conditions for use' and 'conditions for the protection of particular ecosystems/environments and/or geographical areas' are recommended. In practice, conditions normally only relate to monitoring requirements. Authorizations that are granted unconditionally must therefore be teleologically reinterpreted in a reading that leaves post-market measures permissible.[78] If this were not to happen, the authorization would have to be seen as illegal.

Procedures

For the procedures of the post-market FFH-IA, two routes can be considered: to involve the authorities in charge of GM supervision; or to establish an independent procedure under NP law under the responsibility of nature protection authorities. For experimental releases, I have suggested above that the impact assessment should be integrated into the authorization procedure, in which the involvement of nature protection authorities is anyway provided for. This is based on the fact that the authorization of release is geared towards concrete areas. Yet the monitoring system active after the authorization for the placing on the market of the GMO is just as site-unspecific as the authorization for market placement itself. Additionally, the biological knowledge concerning a relevant local area lies more with the NP authority and less with the GM authority. Therefore, the nature protection agencies should be responsible for post-market FFH-IAs.

For the competent nature protection authorities to learn about the post-market introduction of GMOs, operators must be required to report. As such, an obligation already exists in the context of the location register.[79] The authority in charge of the register (in Germany the BVL) should be made responsible to inform the nature protection authorities when the introduction of a GMO affects a nature reserve. Additionally, the nature protection authorities should be given the power to ask the operator to submit data for an FFH-IA, and to ban the introduction if the FFH-IA predicts significant adverse effects.

[75] On horizontal and diagonal concurrence, see Figure 2 above.
[76] See Regulation (EC) 1829/2003, n. 10 above, Recital (1).
[77] See Directive 2001/18/EC, n. 2 above, Recital (4).
[78] For similar conclusions, see F. Kerschner and E. Wagner, *Mögliche legistische Maßnahmen zum Schutz der biologischen und gentechnikfreien konventionellen Landwirtschaft in Österreich vor Kontaminationen und Veruneinigungen mit GVO unter Berücksichtigung des EU-Rechts und der WTO-Verträge* (unpublished legal study commissioned by Global 2000, September 2002), at 51, available at: <http://www.global2000.at/files/gutachten.pdf>.
[79] See Directive 2001/18/EC, n. 2 above, Article 31(3b). In Germany, this is transposed by GenTG, n. 3 above, Article 16a (3).

THE REGIME OF GM-FREE AREAS

GENERAL REMARKS

The policy of keeping particular areas GMO-free can be grounded in the principle of coexistence of the usage of land with and without genetic modification. The principle transcends considerations of concrete risks for health and environment. It is generally recognized and legally protected with regard to agricultural ways of production. According to Commission opinion, the reason for agricultural coexistence rests in the freedom of choice of both consumers and farmers.[80] The Commission stresses:

> It is important to make a clear distinction between the economic aspects of coexistence and the environmental and health aspects dealt with under Directive 2001/18/EC on the deliberate release of GMOs into the environment.[81]

The question posed here is whether the coexistence of areas with GM-free and GM cultivation can also be justified on the grounds of nature protection.

Before we examine the legal dimension of this question, some more general remarks are apposite. As has already been stressed, agricultural coexistence is based on the market principle, i.e. it is geared to ensure producers' and consumers' choice between GM and GM-free production and consumption. Ecosystems as the subject of NP law instead belong to the public sphere. Protection is not granted because individual users prefer it but because public policies and politics do so. Legitimized political priorities may require the exclusion in a particular area of even residual risk of GMOs because the originality (Eigenart) of nature shall be preserved; because GM knowledge is still considered to be insufficient to reliably assess risks; or because the indeterminacy of natural processes is seen as excluding any reliable prognosis. More pragmatically, GM-free reference areas could be considered to be necessary in order to better measure the effect of GMO releases in other areas. These reasons suggest GM-free areas as a means of protection not (as in the case of agricultural co-existence) of producers and consumers, but of nature as such. Therefore, it appears that based on those reasons it is justifiable to prohibit the introduction of GMOs – either specific ones or GMOs in general – into nature protection areas.

Turning now to the legal dimension, we proceed from the national to the EC level. Does national GM and NP law enable the establishment of GM-restricted areas for reasons of nature conservation, and is such authority compatible with both EC GM and NP law?

THE NATIONAL LEGAL FOUNDATIONS FOR GM-FREE AREAS

Such legal foundations can result from (a) GM law and (b) NP law. Germany once more serves as an example.

Genetic Modification Law The German GM law first of all aims to protect classical objects – in the given context especially the environment – against harm. Yet this is not the only protective aim. It is joined by the coexistence of the production and marketing with and without GMOs. This is stated in Article 1(2) of GenTG as follows:

> The purpose of this Act is . . . 2. to safeguard the possibility of producing and placing on the market products, notably foods and feedstuffs, produced according to conventional standards, organic standards or using genetically modified organisms . . .

Article 26a of Directive 2001/18/EC supports this rule. It is not made obligatory, yet it is recognized as a competence remaining with the Member State. The Article says:

1. Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.
2. The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, on the basis of the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.

However, the focus of both the national and the EC provisions is on production based on technology. The production and harvesting of wild products, as for instance the wild growing of mushrooms or berries, can, however, hardly be seen as resulting in a 'product' or 'crop' in the sense of the cited provisions. Although some product chains lead from nature to consumers (such as the picking and selling of wild fruits), this appears to be too weak of an argument to justify general GM freedom for natural areas. In conclusion, authorization for the establishment of GM-free natural areas cannot be derived from GM law.

Nature Protection Law The justification for keeping areas GM-free may result, as explained above, from the perception of nature as a good in itself. This perspective is

[80] Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, C (2003) 2624, at 6.
[81] Ibid., at 6.

indeed laid out in Article 1 of the Federal Law on the Protection of Nature (Bundesnaturschutzgesetz – BNatSchG),[82] which states:

> In view of their *own value* [eigener Wert] . . . , considering also responsibility towards future generations, nature and landscape . . . shall be conserved, managed, developed and, where necessary, restored, in order to safeguard . . . the *diversity, peculiarity and beauty [Eigenart]* of nature and landscape on a lasting basis. [emphasis added]

Although Germany almost exclusively consists of cultured landscapes, still different degrees of human intervention (the so-called hemeroby[83]) can be distinguished. Landscape ecology, for instance, suggests a typology of landscape types called 'untouched primordial', 'pre-industrial', 'urban-industrial' and 'artificial park and garden'.[84] Stressing the peculiar character of nature and landscape, the above-cited Article 1 of BNatSchG makes it easier for the competent authority to decide to preserve the naturally and socially grown genetic diversity of an area in its evolutionary dynamic, and to keep an area free from those organisms that did not 'grow along'. On such a ground, the introduction of GMOs – for individual or all organisms – could be banned.

This general enabling of measures ensuring the intrinsic value of nature is supported by the provisions on specific nature protection areas. Nature protection areas can be established in order to protect the 'peculiar character' (besondere Eigenart) of a natural site.[85] For national parks, the law aims to ensure 'an as much as possible uninterrupted course of natural events in their natural dynamic'.[86] Biosphere reserves shall among other things aim 'to conserve, develop or recreate a landscape characterized by traditional, varied use and the historical species and biotope diversity that has developed there, including wild and earlier cultivated forms of economically used or usable animal and plant species'.[87]

'Particular characteristics', 'natural dynamics', 'wild forms of species', 'earlier cultivated forms of species' – all these terms imply an area characteristic as a non-instrumental value, as something of inherent or intrinsic value,[88] not as something directly useful to people.

The protection of nature as an intrinsic value means that the competent authority can prescribe GM freedom when it establishes protected areas and defines protection aims. This applies to nature reserves, national parks and biosphere reserves.[89] FFH areas are also covered, because they are normally designated as nature reserves or national parks under national law.

COMPATIBILITY WITH EUROPEAN NP LAW

Is the permissibility under German law of establishing GM freedom in particular reserves compatible with European NP law?

With regard to FFH areas, we need to draw on Article 6(1) of the FFH Directive.[90] The Directive renders obligatory a minimum standard of protection according to the 'ecological requirements of the natural habitat types'; yet it remains geared to the notion of harm prevention. The intended protection level is also mirrored in the precept to ban the introduction of non-indigenous species as far as they harm natural habitats.[91] Beyond this minimum standard there remains leeway for the Member State. This follows from the open wording, 'for special areas of conservation, Member States shall establish the necessary conservation measures'.[92] It is true that according to its recitals the Directive follows an approach that qualifies its main aim, the protection of biological diversity, with societal interests in the use of nature,[93] but one cannot conclude that it strives to deny FFH areas an advanced protection, if Member States wish to go further and base protection on the intrinsic value of nature. In any case, Member States could take more far-reaching measures on the basis of Article 176 EC.

[82] Federal Law on the Protection of Nature (Bundesnaturschutzgesetz) of 25 March 2002, Bundesgesetzblatt 2002 I 1193 ('BNatSchG'), last amended by Law of 10 May 2007, Bundesgesetzblatt 2007 I 666.
[83] From the Greek hemerosis (cultivation) and bios (life).
[84] H. Sukopp, 'Entwicklung der Kulturlandschaften Mitteleuropas und ökologische Risikobewertung des Anbaus transgener Kulturpflanzen', in M. Lemke and G. Winter, *Bewertung von Umweltwirkungen von gentechnisch veränderten Organismen im Zusammenhang mit naturschutzbezogenen Fragestellungen* (E. Schmidt Verlag, 2001), 195. See also I. Kowarik, 'Natürlichkeit, Naturnähe und Hemerobie als Bewertungskriterien', in W. Konold, R. Böcker, and U. Hampicke (eds), *Handbuch Naturschutz und Landschaftspflege: Kompendium zu Schutz und Entwicklung von Lebensräumen und Landschaften* (Ecomed, 1999 et seq.), Chap. V-2.1, looseleaf edition, at 1–18.
[85] See BNatSchG, n. 82 above, Article 23(1)(3).
[86] Ibid., Article 24(1)(3).
[87] Ibid., Article 25(1)(3).
[88] See for this distinction, Th. Potthast, *Die Evolution und der Naturschutz. Zum Verhältnis von Evolutionsbiologie, Ökologie und Naturethik* (Campus, 1999) who defines inherent value as a value due to a particular relation between valued object and valuing individual (e.g. an old apple tree in the garden) and intrinsic value as a value an object entails by itself and hence produces a *direct* moral obligation. There is no space here to discuss the philosophical underpinning of such theorems.
[89] For example, according to oral information from the Ministry for Environmental Protection, Kiel, in the German Land *Schleswig-Holstein*, GM freedom was routinely prescribed in all nature reserve regulations from 1996 until 2005.
[90] See n. 57 above.
[91] See Directive 92/43/EEC, n. 57 above, Article 22(b). See also F. Kerschner and E. Wagner, n. 78 above, at 56, who conclude from the regulation that a general ban for the introduction of GMOs is admissible.
[92] See Directive 92/43/EEC, n. 57 above, Article 6(1).
[93] Ibid., Recital (3), which states that the 'main aim of this Directive being to promote the maintenance of biodiversity, taking account of economic, social, cultural and regional requirements'.

EXHAUSTIVE EFFECT OF EUROPEAN GENETIC MODIFICATION LAW?

As developed above, national measures stipulating and implementing GM freedom in Natura 2000 areas or in other protected areas are neither mandated nor prohibited by European NP law. Hence, they are autonomous measures of the Member State. With regard to the vertical competition between national and European NP law, they are therefore permissible. However, in the 'diagonal' relation they could collide with European GM law. It must therefore be considered whether the fact that the market placement of GMOs was authorized precludes the Member State from categorically prohibiting their introduction into nature preservation areas. This depends on whether an exhaustive effect for post-market, area-related measures can nevertheless be assumed.

The question of such an exhaustive effect must be distinguished from the question of whether the Member State can go further in relation to Community law. The issue of going further has become relevant in the case of the ban of GMOs established by Upper Austria for its area of jurisdiction. The Commission[94] and the European Court of First Instance (CFI)[95] had interpreted the ban as a violation of Article 95 TEC. They argued that the prerequisites of Article 95(5) TEC – new scientific findings and regionally specific problems of a Member State – were not given. The Commission decision and the CFI verdict refer to Article 95(5) TEC as a yardstick for national leeway, which was logically consistent, as Austria had notified its measure according to Article 95(5) TEC based on the assumption that the GMO ban referred to a political subunit, a *Bundesland*.

The examination of whether further measures are permissible is, however, preceded by the question of whether the relevant Community legal act has preemptive effect. If this is denied, Member States do not need to invoke rules on more stringent measures. Only if this is affirmed must they do so. The above-mentioned decisions of the Commission and the CFI (as upheld by the ECJ) do not exclude the possibility that the authorization regime, due to its substantial design, can allow area-related measures and especially ones that refer not to politically defined territories but to smaller areas defined by specific land uses.[96]

On this issue, we must recall the criteria for the examination of exhaustive effects.[97] As outlined above, the *scopes of application* for EC GM law and NP law partially overlap. In relation to pristine nature, it can, however, be argued that this issue is exclusively addressed by NP law. As for the respective *objectives*, it was submitted that post-market measures protecting locally limited areas do not have an impact on the tradeability of GMOs; they thus do not collide with the purpose of laws on market placement. Finally, the criterion of *conclusiveness* leads to a closer examination of the authorization procedure and content. Above, I have substantiated that Community law does not exclude post-market, area-related measures for the *protection of nature against harm*, unless in the procedure for authorizing the market placement of GMOs it was determined that the risks of harm for affected habitats and species are negligible. The observation that Community law holds no exhaustive effect is therefore also valid for the safeguarding of coexistence between GM agriculture and nature protection sites.

In conclusion, for the aim of the *protection of nature as intrinsic value*, zones can be established, in which the introduction of any GMO or specific categories of GMOs is generally banned.

OVERALL RESULT

This paper has discussed to what extent nature protection is ensured when GMOs are introduced into the environment. Both GM and NP laws must be examined in this context.

While GM law takes a causal view, NP law adopts a functional approach. This generates potential overlaps and conflicts of laws both on the EC and national levels. The situation is complicated by 'diagonal' conflicts between EC GM law and national NP law. The conflicts can, however, be resolved by concordant interpretation and the analysis of exhaustive effects.

EC and national GM law provide substantive criteria and a methodology of environmental risk assessment that aim at nature protection in the procedure of authorizing the experimental release and market

[94] Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) ECT, [2003] OJ L 230/34.
[95] CFI 5 October 2005, Cases T-366/03 and T-235/04, *Republic of Austria v. Commission*, Rep. 2005, II-4009, upheld by ECJ 17 September 2007, Case C-439/05 P and C-454/05 P, not yet reported.
[96] C. Palme, 'Nationaler Naturschutz und Europäisches Gentechnikrecht', 28:2 *Natur und Recht* (2006), 76, at 79.
[97] The Commission considers the market placement to be categorically pre-emptive on any area-related measures: 'In particular, some Member States have proposed to prohibit or restrict GM crop cultivation in protected or ecologically sensitive regions. In these cases the Commission made it clear that national coexistence measures cannot introduce requirements to protect the environment which go beyond the provisions laid down in Community legislation'. See Commission Communication to the European Parliament and Council, *Report on the implementation of national measures on the coexistence of modified crops with conventional and organic farming*, SEC (2006) 313, at 5. I submit that this oversimplifies the relationships between laws of different sectors and levels.

placement of GMOs. Nonetheless, the environmental risk assessment could be fleshed out in view of nature protection law:

- by differentiating impacts on different types of habitats and species, in particular in the framework of the Natura 2000 network;
- by modelling complex causation chains from the introduction into the environment of GMOs to potential adverse effects;
- by more systematically integrating uncertainty into the calculus of decision-making;
- by balancing risks and (environmental) benefits when risks are of low probability or minor magnitude; and
- by precautionary measures when risks are uncertain.

An experimental release of GMOs is to be considered as a project under the FFH Directive, thus requiring a screening as to whether an FFH-IA must be conducted. In the affirmative case, reasons of administrative efficiency suggest that the impact assessment should be integrated into the authorization procedure for experimental release based on GM law.

With regard to market placement, the examination of the multitude of possibly affected areas of nature and species is constrained by administrative capacity. Therefore, the authorization should be limited to those uses of GMOs for which the relevant information was available and assessed in the authorization procedure.

After the authorization of market placement of GMOs and before their actual introduction into the environment, potential impacts on FFH areas/species must be screened and eventually assessed. The same may be required by national law concerning additional protected areas/species. EC GM law does not exclude such measures, unless in the procedure for authorizing market placement of GMOs it was concluded that the risks for specific habitats and species are negligible. Legal acts establishing nature protection areas should define conservation aims, protective purposes and use regulations with regard to the introduction into such areas of GMOs.

Measures keeping nature protection areas GMO-free can be based on a Member State's political discretion to preserve nature areas as of intrinsic value, to wait for more certain knowledge about effects of GMOs, or to regard effects as indeterminate. In Germany, measures preserving the intrinsic values of natural sites are enabled by the provisions for nature reserves, national parks and biosphere reserves. They are permissible under European nature protection law and not pre-empted by EC genetic modification law.

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