# The New Law on Plant Engineering: European framework – National Implementation – Scientific Issues

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*The new Deliberate Release Directive on plant engineering was to be implemented into national law on 17 October 2002. As the EC Commission recently gave notice to Germany, that some provisions of the new German implementation law may not comply with EC law, the following article emphasises the painstaking scrutiny of the legal leeway the EU has granted to its Member States in the law of plant engineering. To facilitate the ongoing discussions on implementation in the Member States the possible provisions are divided between (from the European perspective) the mandatory and the optional. In particular, the liability rules for farmers using GMOs, the rules safeguarding biodiversity in protected zones and the good professional practice rules are both politically and legally fiercely controversial and these topics are not only covered from the legal perspective but also the scientific, as assessed by a molecular biologist.*

## I. Preface

On 12 March 2001 the European Parliament and the Council adopted the new Deliberate Release Directive 2001/18/EC[1] based on Article 95 EC thus establishing a new legal framework for experimental releases and the marketing of genetically modified organisms (GMOs) used in agriculture[2]. The new Directive terminated the moratorium on GMOs introduced in 1999 due to the lack of scientific knowledge on their direct and long term effects on human health and nature[3]. Under Article 34 (1)[4] the Directive had to be implemented into national law at the latest by 17 October 2002. At the end of 2004 more than half of the EU Member States were still in default of this obligation. The following analysis lays out the European law to be complied with by the implementing Member States and then in an interdisciplinary approach outlines the relevant scientific issues.

## II. Requirements of European law

For the current discussion it is helpful to differentiate between what is mandatory EC law and those other provisions which grant discretionary powers to the Member States[5]. With this in mind, the following legal presentation will first detail binding law and then in a second part outline the optional provisions[6].

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1 OJ 2001 L 106/1, in the following to be refered to as "The Directive".

2 Not be mistaken for the Regulation 1829/2003/EC on GE food and feed concerning the consumer which kicks in later in the food chain after the GMOs already have been processed, OJ 2003 L 268/1.

3 See protocol of the 2194. session of the EU Council consisting of the ministers for the environment, 24/25 June 1999; see also Opinion of Advocate General Mischo in Case C-6/99 [2000] ECR I-1651.

4 In the following provisions without further specification are provisions of the Directive/EC.

5 To the precedence of European law in general see Hartley, The Foundations of European Community Law, 2003, p. 227.

6 With special reference to the German legal system see also Palme/Schlee/Schumacher, "Das neue Recht der Grünen Gentechnik: Europarechtliche Vorgaben und fachliche Praxis", EurUP 2004, p. 170.

## 1. Binding European law on plant engineering

### a. General remarks

In this section the pivotal European provisions that the Member States are obliged to implement without any discretion are presented. In the event that a Member State does not comply with these rules, the respective parts of the Directive may under certain circumstances apply directly or incur state liability[7]. In each area EU law provides for compulsory rules for the national legislators and for other provisions where the Member States may choose from among different options. Any respective leeway depends on what exactly EC law stipulates[8].

In the event that no EU-legislation exists, in terms of regulations or directives (secondary EC law)[9], the national legislator is bound „only" by the rules of the European Constitution which are predominantly laid down in the EC Treaty (primary EC law)[10]. To be mentioned here, are the free movement of goods laid down in Article 28 EC which, in principle, guarantee genetically engineered (GE) products European wide marketing and such fundamental economic freedoms as the freedom of profession, property rights, the right to invest capital and freedom of scientific research[11]. On the other hand there is something like a „European Environmental Constitution", Article 174 EC[12], comprising the precautionary principle, the obligation to protect biodiversity mandated by the Convention on Biological Diversity[13] and the property rights of the GMO-free-crop farmers to till their soil the intended way. Apart from these fundamental values the national legislator is free in its policy on GMOs.

The situation is completely different insofar as the EU has legislated on the respective issue either in the form of a regulation or directive. As the EU, in 2001, adopted the above mentioned Directive on Deliberate Releases, each Member State now has to comply with its provisions, leaving discretional powers only to those issues where the Directive explicitly or implicitly so empowers them to do so[14] or where the Directive has not legislated at all. In this situation European constitutional law only plays a role in two contexts. Either it represents theyardstick secondary law has to comply with or it serves as an interpretative aid for secondary law.

### b. Risk assessment

Compared to its repealed predecessor Directive 90/220 EEC, the new Directive has tightened risk assessment standards due to rising scientific concerns in terms of human health and biodiversity. This is why Articles 1 and 4 provide for a comprehensive assessment of the adverse effects caused by GMOs. This assessment has to be updated by the latest scientific research to be provided by independent scientific advice[15]. In Germany this is important for the composition of the Central Commission for Biological Safety, an advisory body which has a decisive influence in shaping the decisions of the German authorities supervising GE[16]. Any dominance by the industry or other conflicts of interest has to be strictly avoided. The risk assessment must not be limited to the direct and immediate effects caused by GMOs but also has to take account of its potential indirect and long-term impact on human health and biodiversity[17]. Furthermore, Article 4(3) prescribes the assessment of adverse effects occurring through gene transfer from GMOs to other organisms.

### c. Authorisation and surveillance

The Directive provides for two kinds of consent – one for the deliberate release of GMOs for field trials laid down in part B and the other for placing GMO produce on the market, regulated in part C. The field trials usually precede the placing on the market as they yield the scientific knowledge nec-

7 For further details, see Palme, "Staatshaftung wegen Nichtumsetzung des Europäischen Gentechnikrechts", EuZW 2005, p. 109.

8 To this Middeke, "Nationale Alleingänge", in: Rengeling, Handbuch des europäischen und deutschen Umweltrechts, 1998, § 32.

9 Article 249 EC.

10 Hartley, footnote 5 above, p. 103.

11 As for the development of fundamental rights see Lenaerts, "Fundamental Rights in the Euopean Union", ELR 2000, p. 575.

12 As for the Environment in the Future European Constitution see Beyer, "The Environment in the Future European Constitution", JEEPL 2004, p. 143.

13 OJ 1993 L 309/1.

14 As for the derogation powers of the Member States in European environmental law in general see Middeke, footnote 8 above, § 32.

15 See reasonings 20 and 21 and appendix II, part B, indent 4.

16 As for the introduction of scientific knowledge in authorization processes see also Fischer, "Current Scientific and Technical Knowledge in the Authorization Process for Plant Protection Products", JEEPL 2005, p. 135.

17 Article 2 No. 8 and App. II.

essary for a marketing decision. As to part C, here there is the necessity of regulating two conflicting issues, those of deregulation and the acceleration of the authorisation procedures[18] and the efficient safeguarding of safety standards. Matching up these two issues in an appropriate way will be the central issue in European GMO legislation.

*Facilitation of procedures/deregulation*

The Directive prescribes short decision making periods regarding the authorisation procedures for placing products on the market[19]. Those products not yet permitted but benefiting from a favourable risk evaluation may be released without consent, provided they contain GMOs in a proportion no higher than 0.5 % and that this presence is accidental or technically unavoidable and the applicant is in a position to demonstrate that the appropriate steps have been taken to avoid the presence of such materials[20]. Procedural acceleration is also the intent of Article 6(3) and Article 13(4) allowing the notifier to refer, under certain circumstances, to data or results from notifications previously submitted by other notifiers. Article 8 lays down that only significant new information emerging after the written consent leads to its review[21]. Article 6(2) No. 7 and Article13(2)(h) require the applicant to include a summary of the dossier for facilitating the manifold consultation processes required during the authorisation procedure[22].

*Higher safety standards*

Article 6(9) stipulates that a GMO stemming from experimental releases may only be placed on the market after it has obtained a marketing permit. Or to put it in other words, a consent under part B of the Directive does not imply the right to place the plants on the market. It requires the Member States to safeguard two things. Firstly, GMOs originating from the plot of the experimental release may not be sold without the additional consent for marketing. Secondly, a GMO crossed out from field trials and contaminating adjacent GMO free plots may also not be sold without permission pursuant to part C. The reason for those strict rules lies in the step by step permission system of the Directive. Only after the successful conclusion of experimental releases and the comprehensive assessment of these trials may GMO produce be placed on the market[23].

Article 9 prescribes comprehensive consultation with and information for the public on proposed field trials. To this end Article 25(4) indent 1 exempts the purpose of the release from confidentiality, as it is only in this way, that a thorough public discussion on the project becomes possible. Under special circumstances, where sufficient experience of GMOs has already been obtained, the differentiated procedures under Article 7 allow for less public involvement[24]. Article 19(3 ) sets out the mandatory specifications to be included in each written consent, such as the identity of the GMOs to be placed on the market, its period of validity, the availability of samples, labelling and monitoring requirements and other further conditions, for example, handling, packaging and protection of particular ecosystems and geographical areas[25].

*Derogation*

The consent to place GMOs on the market takes the effect of a transnational administrative act with EU wide validity so that once the consent has been granted by one Member State it has to be accepted by all the other Member States[26]. This conception, in principle, rules out any review of the consent by other Member States as otherwise the intended EU wide free circulation would be thwarted. This is why Article 22 prohibits any impediments against legally marketed GMO products. It is only in exceptional cases where the safeguard clause of Article 23 allows for restrictions by other Member States[27]. A prerequisite is additional information or

18 As for the need for deregulation see Graf Vitzthum/Geddert-Steinacher, Standortgefährdung, 1992.

19 For instance Articles 13(1)(3), 14 (2), 15(1), (3), 16(3), 17(9)(1), (4-8) and 18.

20 Article 12a Directive/EC and Article 47 Reg. 1829/2003/EC (OJ 2003 L 268/1).

21 For further details regarding german law see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (173).

22 See for instance, Article 13(1) sentences 1, 15 and 18. For more examples of deregulation in the the Directive/EC see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (173).

23 See also Palme/Schlee/Schumacher, footnote 6 above, p. 170 (174).

24 Ibid.

25 Especially the item "geographical areas" might play an important role in protecting ecologically sensitive areas, see the following Chapter 1.g. and 2.d. For further provisions shaping up higher safety standards see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (173-174).

26 Articles 13(1) sentence 1, 19(1).

27 For further details with special regard to german law see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (173).

scientific knowledge on risks to human health or the environment. But even if that can be demonstrated, Member States are only empowered to take provisional measures and immediately have to inform the EU-Commission which ultimately has to decide on the measures[28].

### d. Labelling

Article 19(3)(e) introduces the labelling of GMOs[29] with the words „This product contains genetically modified organisms" thus ensuring freedom of choice for farmers and customers[30]. The corollary for the Member States is that each consent issued has to include labelling specifications. Furthermore, Article 21(1) requires that Member States take all the necessary measures to ensure that at all stages in the placing on the market labelling is secured[31]. This poses some difficulties as only the operator placing the product on the market is the holder of the consent and so a way has to be found to make sure that all the other persons handling the product like wholesalers, retailers, seed companies, farmers, transport companies and the food industry also comply with the labelling obligations[32].

### e. Monitoring and reporting obligations

Articles. 4(5), 13(2), 19(3) and 20 require operators and authorities to constantly monitor GMOs and if need be report new developments. The Member States have to implement this system completely and the only leeway they enjoy is in how they do it[33]. The financial burden of monitoring might be shared between the authorities and operators in that the authorities conduct general monitoring and the operators specific monitoring of the GMOs they have placed on the market[34]. Besides, Article 8(1)(b) prescribes certain obligations to inform the authorities in the event of any new information. The authorities themselves also have duties to provide information, especially vis-a-vis the public, for instance in the event where GMOs are released without consent[35]. The same is true if any new information comes to light during field trials[36].

### f. Site registers

Article 31(3) requires that Member States establish public registers recording the locations of GMOs. Those registers play an important role in safeguarding coexistence between GMO and GMO free farming[37], as only by knowing the location of GMO sites are the respective farmers able to cooperate in the exchange of information on the plants concerned, thus allowing for minimum distances between GMO and GMO free fields, the building up of pollen barriers etc. For reasons of data protection, the register should be divided into a generally accessible part and a further part containing personal data accessible only where a legitimate interest can be shown[38]. As Article 31(3) aims to protect GMO free farmers, Member States permitting the release of GMOs without establishing the site registers are liable for any contamination caused to adjacent GMO free plots[39].

### g. Biodiversity/protected areas

By adopting the Directive the EU has decided to permit GMOs and against an overall ban. On the other hand the EU is also a contracting party to the Convention on Biological Diversity and in Article 32 committed to implementing the Cartagena Protocol on biosafety[40]. Article 6 EC states that environmental protection requirements must be integrated into other Community policies with a view to promoting sustainable development[41].

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28 Article 23(1) subpara. 3(2).

29 Provided a threshold of currently 0,9 % is exceeded, Article 21(2), (3).

30 Food labelling provisions are laid down in Article 12 Reg. 1829/2003/EC (OJ 2003 L 268/1).

31 Palme/Schlee/Schumacher, footnote 6 above, p. 170 (174).

32 As for the German approach on this question see Palme, "Die Novelle zur Grünen Gentechnik", ZUR 2005, p. 123.

33 Eor further details see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (175).

34 For further details as regard the German law see Palme, footnote 32 above, p. 125.

35 Article 4(5).

36 As for more reporting obligations see Palme/Schlee/Schumacher, footnote 6 above, p. 170 (175).

37 To this Palme, footnote 7 above, p 109.

38 As for the German implemantation of this obligation see Palme, footnote 32 above, p. 123.

39 Palme, footnote 7 above, p 109.

40 Qureshi, "The Cartagena Protocol on Biosafety and the WTO – Co-Existence or Incoherence?", International and Comparative Law Quarterly 2000, p. 835.

41 As for the Environment in the Future European Constitution see Beyer, footnote 12 above, p. 143.

Furthermore paragraph 3 of Article 95 EC – the legislative power that the Directive is based upon – requires the EU Commission to take as a base a high level of environmental protection when taking account any new scientific development. Even though these environmental standards leave leeway when weighing up against the basically positive decision for GMOs, there is an established and binding minimum biodiversity standard. The main pillars of this standard are laid down in the provisions of the European Ecological Network „Natura 2000“ and in Article 8(g) of the Convention on Biological Diversity. „Natura 2000“ is a network of ecologically sensitive areas throughout Europe supervised by the EU Commission. These are supported by the Flora, Fauna and Habitats Directive (FFH Directive) and the Bird Protection Directive[42]. Article 6 FFH Directive and Article 4 Bird Protection Directive provide for a comprehensive protection system to secure these selected areas[43]. A central part of this protection regime is an impact assessment for all projects in or close to „Natura 2000“ sites which may lead to a refusal of those projects likely to have a significantly adverse effect upon the sites concerned[44]. This regime also applies to GMOs, except under Article 6(4) FFH-Directive, since GMOs unlike other projects such as airports, roads, mining facilities etc. are not dependent on a special location and there is therefore no need to consider „imperative reasons of overriding public interest“: There is always the „alternative solution“ of another location within the meaning of Article 6(4) FFH-Directive so this paragraph makes little sense in project assessments concerning GMOs[45]. As for Article 8(g), this provision of the Convention on Biological Diversity requires the EU to control the risks of GMOs on biodiversity. As one of the main risks of GMOs is random contamination of natural sites the main responsibilities of the national legislators will be to make sure that whoever cultivates, handles, stores and transports GMOs takes precautionary action to ensure that the above mentioned activities do not lead to contamination. The best way of implementing this is through the introduction of „good professional practice“ via the flexible instrument of an ordinance[46].

### h. Coexistence

According to the EU Commission, no form of agriculture, be it conventional, organic or GMO should be excluded[47]. Therefore the ability of farmers and consumers to make a practical choice between conventional and GM crop production must be guaranteed. This is especially true in the case of organic farming, since the EU, in the aftermath of manifold food scandals, officially tried to strengthen this agricultural sector. To this end, the accidental presence of GMOs in non-GMO crops has to be averted. The EU Commission only issued the above mentioned non-binding recommendation leaving the actual legislation to the Member States. A new Article 26(a) was inserted into the Directive enabling the Member States to „take appropriate measures to avoid the unintended presence of GMOs in other products“. Even if the details of matching the needs of both GMO and non-GMO crops are currently part of an ongoing battle between the EU Commission and the Member States, there is at least emerging some kind of direction along which national legislation should go[48]. For reference, it is again helpful to note the difference between mandatory rules for the protection of GMO free crops as required by the European primary law[49] and secondary law [50]and further, optional law the respective Member State is free to introduce or not.

As far as the mandatory rules are concerned they have to safeguard a minimum protection for GMO free farmers. This standard has to ensure that GMO free farmers do not run the risk of being compelled to label their produce as containing GMOs. As there is currently a 0.9 % threshold of GMO presence before the labelling obligation is activated the

42 For an updated overview see Kratsch/Schumacher, Naturschutzrecht, ein Leitfaden für die Praxis, 2005, p. 133.

43 See also Article 8a Convention on Biological Diversity.

44 See Schumacher/Fischer-Hüftle, Bundesnaturschutzgesetz, 2003, § 34.

45 With regard to the German Law see Palme, footnote 32 above, p. 124.

46 As for Article 8 CBD see Beyerlin, “Erhaltung und nachhaltige Nutzung als Grundkonzept der Biodiversitätskonvention”, in: Wolff/Köck (eds.), 10 Jahre Übereinkommen über die biologische Vielfalt, 2004, pp. 55, 61.

47 EU-Commission, recommendation on coexistence of 29.7.2003, OJ 2003 L 189/36.

48 For further details see Palme/Schumacher/Schlee, footnote 6 above, p. 170 (176 and 179).

49 Esp. Articles 6 and 174 EC.

50 Article 5(3)(h) Reg. 2092/91 on organic farming prohibits the use of GMOs in this production system.

national law has to guarantee that at least this amount of accidental GMO never occurs in GMO free produce. To this end, the Member States have to pass the following legislation[51]:

- insert „coexistence“ as a new aim into national law on plant engineering;
- set up rules on good farming practice with a view to preventing contamination of GMO free produce;
- make available defensive remedies in case GMO farmers do not comply with good professional practice;
- acknowledge that contamination by GMO material exceeding the threshold of 0.9 % represents a material adverse effect within the meaning of national nuisance law triggering compensation claims;
- establish rules on the burden of proof, including joint and several liability in cases where it cannot be proven which of several neighbouring farmers caused the contamination;
- set up compensation schemes to be financed by the GMO industry as only this allocation complies with the polluter pays principle set out in Article 174(2) sentence 2 EC.

## 2. Optional European law on plant engineering

In this section some of the rules the Member States are free to introduce or not will be assessed[52], and although there is a plethora of possibilities for the Member States to legislate on[53], only the following two and currently most controversial issues will be dealt with – the protection of sensitive areas and coexistence.

### a. Extended protection of sensitive areas

It goes without saying that EU law must provide for the protection of all the special areas the EU itself set up via its Ecological Network „Natura 2000“. But what about all the other ecologically sensitive areas? Does EU law allow to extend protection against GMOs beyond „Natura 2000“ areas or does this constitute an infringement of the free circulation of GMO goods within the meaning of Article 22 Directive and Article 28 EC? By and large, this conflict can be discussed either in the context of the safeguard clauses[54] or within the concept of „measures having equivalent effect“ under the regime on free movement of goods.

As regards the former, it seems to be clear that the protection of areas only designated by the Member States can neither be justified by Article 176 EC nor by Article 26(a) Directive, as both safeguard clauses in this context simply do not apply[55]. The situation is slightly different when referring to the clauses the Member States can resort to in the event of new or additional information or knowledge: Article 23 Directive and Article 95(5) EC are, in principle, applicable but their conditions will not be met in every case, as the exigencies the EU-Commission demands for acknowledging new facts or new scientific research are usually high[56]. Furthermore, both safeguard clauses seem to be tailored for emergency situations and thus may not be the remedy of first resort for protecting ecologically sensitive areas.

The other approach would be not to consider the regimes protecting the designated sites as „measures having equivalent effect as quantitative restrictions“ within the meaning of Article 28 EC, Article 22 Directive. This legal peg could be significant given the departure from earlier case law performed by the ECJ[57]. Whilst the Court held for a long time that „any measure which is capable of directly or indirectly, actually or potentially, hindering intra Community trade constitutes a measure having equivalent effect“ it, in the widely discussed Keck decision departed from this strict concept and in doing so, created more leeway for national policies[58]. According to this new tenet, obstacles resulting from national provisions regulating only selling arrangements in a non-discriminatory way do not

51 As for the new German law see Palme, “Die Novelle zur Grünen Gentechnik”, ZUR, 2005, p. 119.

52 For further details see Palme/Schumacher/Schlee, footnote 6 above, p. 170, 177.

53 A detailed presentation of the various optional provisions established by the new German law at Palme, footnote 32 above, p. 119.

54 As for the system of the safeguard clauses in European environmental law in general see Middeke, footnote 8 above, § 32.

55 Article 176 EC does not apply to secondary law based on Article 95 EC and Article 26a Directive only deals with ”economic coexistence”.

56 See Commission Decision of 16.9.2003, OJ 2003 L 230/34 ”Upper Austria”.

57 See Weatherill/Beaumont, EU-Law, 1999, pp. 608-619.

58 Epiney, “Zu den Rückwirkungen der neuen Rechtsprechung des EuGH zu Article 30 EGV im Bereich des Umweltrechts”, ZUR 1995, p. 24.

fall within Article 28 EC Treaty, even if such legislation may restrict the volume of sales. The protection regimes for designated areas are similar to the „only selling arrangements“ the ECJ identifies in its new „Keck-concept“[59]. They do not aim to prevent the marketing of GMOs altogether, but have the character of directing them in order to ensure biodiversity. Furthermore, as only a very small percentage of the surface of the Member States not already included in ”Natura 2000” has been designated as nature protection areas, the obstacles for marketing GMOs probably run toward zero.

### b. Further rules on the concept of coexistence

Are the Member States empowered to introduce coexistence rules exceeding the above mentioned compelling EU standard?[60] In this context, two measures in particular are currently under discussion. These are the establishment of GMO free regions in order to secure coexistence and the prevention of GMO contamination even where the current EU threshold of 0.9 % has not been attained. Both measures, at least in individual circumstances might in one way or another be justified by the precautionary principle laid down in Article 174(2) EC. As for GMO free regions, a general discussion concerning the erosion of the regions´ competences due to the legal system of the EU[61] could also bolster activities in this direction. On the other hand too much leeway runs the risk of being exploited by those European governments that disapprove, in general, of GMOs. These Member States might feel encouraged to obstruct the introduction of GMO by resorting in an extensive way to the concept of coexistence. Here again, the newly inserted Article 26(a) concerning measures to avoid the unintended presence of GMOs is critical, i.e. measures must be „appropriate“ for safeguarding coexistence. At least one aspect can be considered settled – an overall ban on GMOs is illegal as only a case by case approach can live up to the principle of proportionality, which the word „appropriate“ in Article 26(a) ultimately refers to[62].

## III. Biological aspects of environmental law questions

### 1. Is there a possibility of the coexistence of GMOs with conventional crops?

The concept that there could be the possibility of coexistence between either unaffected wild species or conventionally bred crop within stands of GMOs[63] has its clear limitations within basic perceptions of natural science[64]. In principle, the transfer of gene constructs will always be possible and has often been demonstrated within labs though it is certainly more rarely seen in field conditions[65].

Principally, there are two main types of gene transfer. The vertical gene transfer is the direct transduction of DNA to the next generation of the same or a closely related species. Hybridisations are widespread in plants but are rarely to be found in animals. On the other hand, the importance of horizontal gene transfer has now been under scrutiny for about thirty years, describing transductions of DNA beyond species and even kingdom levels of organisms. These facts, however, are part of modern evolutionary concepts (i.e. theory of endosymbionts)[66]. The existence of at least 8 % of human endogenous retroviruses (HERVs) within the

59 ECJ, Judgment in Cases C-267/268/91 [1993] ECR I-6097.

60 See Palme/Schumacher/Schlee, footnote 6 above, p. 170 (179).

61 Bourne, ”The impact of European Integration on Regional Power”, Journal of Common Market Studies 2003, p. 597.

62 To the ongoing discussion see Herdegen, Koexistenz und Haftung, 2004; Palme, footnote 32 above, pp. 119, 128; Schmieder, “Die Neuregelung der Folgen von Auskreuzungen im Gentechnikrecht”, Umwelt und Planungsrecht 2005, p. 49.

63 Reflect the ongoing debate on ”when is it a GM?”, Fedoroff, ”Prehistoric GM corn”, Science 2003, Vol. 302, pp. 1158-1159; letters to ”The difficulties of defining the term ‘GM’”, from Grun, Ramsay, and response from Fedoroff, Science 2004, Vol. 303, pp. 1765-1767.

64 For general methodical questions on transformation of plants, see e.g. Jackson/Linskens (eds.), Genetic transformation of plants = Molecular Methods of Plant Analysis, 23, 2003.

65 E.g. see examples from Whitton/Wolf/Arias et al., ”The persistence of cultivar alleles in wild populations of sunflowers five generations after hybridization”, TAG 1997, Vol. 95, pp. 33-40; Kleihauer, Umweltfolgenabschätzung bei der Freisetzung gentechnisch veränderter Pflanzen – Ermittlung und Bewertung der Auswirkungen im internationalen Vergleich, 1998; Chèvre/Eber/Darmency et al., ”Assessment of interspecific hybridization between transgenic oilseed rape and wild radish under normal agronomic conditions”, TAG 2000, Vol. 100, pp. 1233-1239; Messeguer/Fogher/Guiderdoni et al., ”Field assessments of gene flow from transgenic to cultivated rice (Oryza sativa L.) using a herbicide resistance gene as tracer marker”, TAG 2001, Vol. 103, pp. 1151-1159; Lu/Kato/Kakihara, ”Destiny of a transgene escape from Brassica napus into Brasssica rapa”, TAG 2002, Vol. 105, pp. 78-84;

66 Margulis/Olendzenski (eds.), Environmental evolution: Effects of the origin and evolution of life on planet earth, 1992, especially pp. 149-172.

human genome[67], conjugations and the exchange of bacterial plasmids, uptake of microorganisms in cells of insect guts or uptake of fungal cells by plant cells – each giving the opportunity for an assembly of DNA components – demonstrate the enormous importance for the (co-)evolution of organisms.

As evolution is not a strict experiment being unfinished, unrepeatable and non-comparable[68], even if one day the sequencing of whole genomes is achieved this will not answer all of the remaining questions as there will always be uncertainty from the retrospective point of view due to extinction events and re-mutations. Parts of the genome can be removed, recombined or mutated in unpredictable ways within each individual. Another important fact is that some genes are only active within a distinct organ or time frame of development – while silenced or inactive in another[69].

As a result, no one can predict what will happen to GMOs or transferred genes during further evolution. The protection of so-called "evolutionary integrity" is in the meantime recommended[70], a protection of the self-organisation of the processes of an organisms' evolutionary dynamic. This has to be established over a long time as evolution is not retractable.

Critics mention that an engineered construct is more easily transferred to non-target organisms than wild species as they "are designed to cross species barriers and to jump into genomes, i.e., to further enhance and speed up horizontal gene transfer and recombination"[71]. Moreover, T-DNA of Agrobacterium, and bacterial or viral (CaMV promoter) transfer techniques are suspected of recombining more easily than their wild progenitors or during a natural uptake[72]. Critics therefore see the establishment of a more rapid and expanded transfer of gene constructs than could happen with a more moderate crop usage obtained via classical breeding or comparable to that obtained by an insert of neobiota in autochthonous environments as also leading to a change in genetic variability and the creation of differing ecologic or genetic selections. No matter what plants are grown, man's impact on natural evolution is generally caused by his influence on environmental factors and an increase of anthropogenic habitats, pollution and exploitation of ecosystems[73]. Crops, however, are definitely one of the most characteristic parts of our cultural landscape and are commonly thought to be worth protecting and imbedding within nature conservation concepts. Demarcation between old breeding lines often flows between crops that break through taxonomic boundaries or those that did not establish within historic epochs. Also important to many of mankind's crops heterosis effects (hybrid vigour) play a major role in natural and artificial hybridisation (breeding) and factor effects that are still not yet clarified[74] – the classification of hybrids' behaviour will always be incomplete.

An altogether more careful handling of the disposal of organisms[75] in order to avoid the establishment of non-autochthonous species would be – from the point of view of nature conservationists – a basis for a "putting into circulation concept" within which especial control of GMOs could be included. This could offer the possibility of bringing GMOs closer to the "exotic species model", though even then, not totally includable in this model[76].

Taken together, each sort of gene transfer is in principal possible. Which one occurs and of what importance depends on individual cases, though there is the likelihood that vertical gene transfer will play a major role and be detectable faster and more easily – though no higher or lower risk-assess-

67 Macfarlane/Simmonds, "Allelic variation of HERV-K(HML-2) endogenous retroviral elements in human populations", Journal of Molecular Evolution 2004, Vol. 59, pp. 642-656; "junk DNA" reflects only momentary non-utilisation, see Kidwell/Lisch, "Perspective: Transposable elements, parasitic DNA, and genome evolution", Evolution 2001, Vol. 55, pp. 1-24.

68 Breckling/Züghart, "Die Etablierung einer ökologischen Langzeitbeobachtung beim großflächigen Anbau transgener Nutzpflanzen", in: Lemke/Winter (eds.), Bewertung von Umweltwirkungen von gentechnisch veränderten Organismen im Zusammenhang mit naturschutzbezogenen Fragestellungen, Umweltbundesamt (ed.), = Berichte / Umweltbundesamt; 2001,3 (Berlin 2001), pp. 319-343.

69 Pedersen/Zimny/Becker et al., "Localization of introduced genes on the chromosomes of transgenic barley, wheat and triticale by fluorescence in situ hybridization", TAG 1997, Vol. 94, pp. 749-757.

70 Breckling/Züghart, footnote 68 above.

71 Ho/Ching (eds.), The case for a GM-free sustainable world, Independent Science Panel (ISP), 2003, p. 32.

72 Ibid., pp. 37-38, additionally, they considered transgenic DNA being different, referring to Bergelson/Purrington/Wichmann, "Promiscuity in transgenic plants", Nature 1998, Vol. 395, p. 25.

73 Sukopp, "Entwicklung der Kulturlandschaften Mitteleuropas und ökologische Risikobewertung des Anbaus transgener Kulturpflanzen", in: Lemke/Winter, footnote 68 above, pp. 195-223.

74 Birchler/Auger/Riddle, "In search of the molecular basis of heterosis", The Plant Cell 2003, Vol. 15, pp. 2236-2239.

75 Schumacher/Fischer-Hüftle, Bundesnaturschutzgesetz, Kommentar, 2003, § 41 para. 15.

76 Schell, Die Diskussion um die Freisetzung gentechnisch veränderter Mikroorganismen als Beispiel einer interdisziplinären Urteilsbildung, 1992.

ment results from a special mechanism. Monitoring efforts (see III. 3.) will not be able to reflect all possible consequences.

While there can be legally binding threshold values, keeping to them is not that easy – not least, due to the lack of methodical verification. It is certain that achieving a 0 % threshold value can no longer be realised[77].

## 2. Main features of a good technical practice for cultivation

The cultivation of GMOs will for the foreseeable future lead to the introgression of given constructs into wild species or other non-target organisms. This will cause questions of what the threshold value levels should actually be whilst the total number of uninfluenced areas will decrease. Fixing onto GMOs – due to a diaspore bank in the soil – could have lasting consequences that might also affect those neighbours who perhaps want to grow crops organically but find it impossible to keep the minimum distances[78]. Due to the lack of studies and verifiable regulations, only some non-representative cases will break through the breeders' walls of secrecy and those farmers fearing the destruction of their fields[79]. On the other hand, the necessity for the specific growth of non-modified breeding lines is also important for the GMO farmers themselves, as cross-breeding has to be ensured with non-resistant opposable partners[80]. Crop rotation and further treatment of the soil to eliminate crop residuals are important for minimising the possibility of gene transfer and abidance with the law. Despite applications of marginal seeds of conventional crops, gene transfer for some species is inevitable[81]. Studies of individual cases[82] show significant differences, not only within species, but even within several breeding lines. Many studies are said to be done in a too close an area, underestimating the possibility of transfers in excess of 1000 meters[83].

Of high potential for risk minimisation is abandoning the recruitment of foreign genes via plasmids by horizontal gene transfer[84]. Debates on the risks of antibiotic resistances fit into this topic and the planned ban on antibiotic resistances in 2005 is long overdue. Linkage of the construct (target gene) to the resistance gene is done in order to facilitate the detection of the transfer. This, however, is also quickly and easily possible by the standard method of PCR (see III. 4.). Moreover, the inclusion of so called terminator genes[85] and the implementation of, e.g. the Cre/loxP-systems[86], could have a slight advantage. An outcross might be prevented in most plants if the target gene were to be coupled with plastid DNA instead of nucleus DNA, since plastid DNA is – in by far the most cases – only maternally inherited and therefore often not distributed via pollen[87]. Changes of sowing dates, crop usage

77 Eastham/Sweet, Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer, Environmental issue report 28, European Environment Agency, 2002, p. 59; see also Stokstad, "GM genes go to seed", Science 2004, Vol. 303, p. 1273; Macilwain, "US launches probe into sales of unapproved transgenic corn", Nature 2005, Vol. 434, p. 423.

78 Förster/Diepenbrock, "Use of genetically modified plants – consequnces for crop production", in: Senatskommission zur Beurteilung von Stoffen in der Landwirtschaft (ed.) / Deutsche Forschungsgemeinschaft, Schwellenwerte für Produkte aus gentechnisch veränderten Pflanzen, Mitteilung 7, 2002, pp. 50-57; Pessel/Lecomte/Emeriau et al., "Persistence of oilseed rape (Brassica napus L.) outside of cultivated fields", TAG 2001, Vol. 102, pp. 841-846.

79 For the situation in Germany see: Winter, "Verhasste Gen-Saat – Die Industrie nutzt eine Gesetzeslücke zum heimlichen Anbau von Gen-Mais…", Der Spiegel 2004, Vol. 58 (21), p. 44.

80 Kempken/Kempken, Gentechnik bei Pflanzen – Chancen und Risiken, 2nd edition, 2004, p. 193.

81 Ibid.; Lu/Kato/Kakihara footnote 65 above; Chèvre/Eber/Darmency et al., footnote 65 above; Reboud, "Effect of a gap on gene flow between otherwise adjacent transgenic Brassica napus crops", TAG 2002, Vol. 106, pp. 1048-1058.

82 Eastham/Sweet, footnote 77 above; Schmitz/Schütte, "Genübertragung zwischen verschiedenen Pflanzensorten und -arten", in: Schütte/Stirn/Beusmann (eds.), Transgene Nutzpflanzen – Sicherheitsforschung, Risikoabschätzung und Nachgenehmigungs-Monitoring, 2001, pp. 56-75.

83 Giddings, "Modelling the spread of pollen from Lolium perenne. The implications for the release of wind-pollinated transgenics", TAG 2000, Vol. 100, pp. 971-974.

84 SRU Gutachten 1998; Schütte/Oldendorf, "Horizontaler Gentransfer", in: Schütte/Stirn/Beusmann (eds.), footnote 82 above, pp. 76-81.

85 Meanwhile discussed as an additional risk with an advantage for patent purposes, Giddings, footnote 83 above; Masood, "Compromise sought on 'Terminator' …", Nature 1999, Vol. 399, p. 721; meanwhile, term is replaced by "Trait-specific Genetic Use Restriction Technology" (= "T-Gurt") – the "eco-friendly name" according to Stewart, Genetically modified planet – environmental impacts of genetically engineered plants, 2004, p. 85.

86 Kempken/Kempken, footnote 80 above; but see also Park/Lee/Kang/Chung, "Co-transformation using a negative selectable marker gene for the production of selectable marker gene-free transgenic plants", TAG 2004, Vol. 109, pp. 1562-1567.

87 Most recent studies show evidence that transfer of plastid transgenic DNA to the nucleus can happen; see Maliga, "Mobile plastid genes", Nature 2003, Vol. 422, pp. 31-32 and corresponding study from Huang/Ayliffe/Timmis, "Direct measurement of the transfer rate of chloroplast DNA into the nucleus", Nature 2003, Vol. 422, pp. 72-76.

before flowering, the establishment of male sterility (which on the other hand can increase cross-pollination with wild species)[88], as well as enhancing self-pollination or apomixis of inbreeding-lines[89] could also be ways of minimising risk.

## 3. Interference in Natura 2000 areas

As far as can be seen, studies on the effects of GMO influences in conservation areas (nature protection areas, "Natura 2000 areas") are still lacking. The consensus is that monitoring projects should start to improve the actual protection of these areas and highlight relevant discrepancies between crop and GMO biodiversity instead of being simple declarations of intent[90]. Monitoring means the observation and documentation of the consequences in a downstream process as not all parameters and eventualities are testable in the lab. This does not mean that risk assessment can be postponed to monitoring procedures after the product has been placed on the market[91]. The concepts for monitoring are even now far from proven[92], however, as hard data is still missing[93] and there is also often a tendency to concentrate on the use of model scenarios even though these remain interesting and important[94]. Necessarily, at first, recent monitoring has focussed on the detection of target genes. Studying the influences of the whole transfer itself, the whole re-composition of the genome during a plant's struggle within changing ecological conditions provides too many parameters and therefore remains too complex. Thus – even though it is also relevant to the biotechnology industry itself – the inclusion of ecology and the resulting activities in aspects of nature conservation came very late. There is, as well, a large financial discrepancy between the molecular biology establishment (though with a still considerable lack in basic research) and the underprivileged ecology[95]. Eco-systemic variations are not representative for other stands, and, therefore, even studies made on recent deliberate releases of GMOs are not necessarily comparable. In addition, the length of these studies is essentially too short and monitoring should, in theory, be extended until the new construct may be ingrained in a new context, though this, however, could last for an unmanageable amount of time – million years[96].

Only 1 % (in Germany, 15 %)[97] of the deliberate releases have been accompanied by detailed ecological studies – not a high significance up to now, since "risk assessments will need to be especially sensitive to temporal and spatial factors" on a "case-

88 Chèvre/Eber/Darmency et al., footnote 65 above.

89 Jefferson/Bicknell, "The potential impacts of apomixis: a molecular genetics approach", in: Sobral (ed.), The impact of plant molecular genetics, 1996, pp. 87-101.

90 Stirn, "Stand der Diskussion um Begleitforschung und Nachgenehmigungs-Monitoring", in: Schütte/Stirn/Beusmann, footnote 82 above, pp. 229-239.

91 Ibid.

92 For Germany: Breckling/Züghart, footnote 68 above; Züghart/Breckling, Konzeptionelle Entwicklung eines Monitoring von Umweltwirkungen transgener Kulturpflanzen, (Vol. 1 + 2), = UBA-Texte 50/03, Umweltbundesamt, 2003; Breckling/Brand/Winter et al. (eds.), Fortschreibung des Konzeptes zur Bewertung von Risiken bei Freisetzungen und dem Inverkehrbringen von gentechnisch veränderten Organismen, = Berichte 3/04, Umweltbundesamt, 2004; for Austria see Traxler/Heissenberger/Frank et al., Ökologisches Monitoring von gentechnisch veränderten Organismen. Studie im Auftrag des Bundministeriums für Umwelt, Jugend und Familie (Wien 2000); for Switzerland, obviously closely abutted to the EU Directives, see Sanvido/Bigler/Widmer et al., Umweltmonitoring gentechnisch veränderter Pflanzen in der Schweiz: Erarbeitung konzeptioneller Grundlagen, Eidgenössische Forschungsanstalt für Agrarökologie und Landbau (FAL), 2003.

93 Widest going data supply with predominantly critical results: Farm Scale Evaluations (FSE) in U.K., see 10 contributions out of the Theme Issue, edited by Zeki, "The Farm Scale Evaluations of spring-sown genetically modified crops", Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences, 2003, Vol. 358 (Number 1439), pp. 1775-1913; for summarizing comments see Stokstad/Vogel, "Mixed message could prove costly for GM crops", Science 2003, Vol. 302, pp. 542-543; Freckleton/Sutherland/Watkinson, "Deciding the future of GM crops in Europe", Science 2003, Vol. 302, pp. 994-996; Johnson, "Changing cropping systems is an important issue for GM crops", in: Breckling/Verhoeven (eds.), Risk hazard damage – Specification of criteria to assess environmental impact of genetically modified organisms, = Naturschutz und Biologische Vielfalt, 1, Federal Agency for Nature Conservation, 2004, pp. 229-237 (234).

94 Wilkinson/Elliott/Allainguillaume et al., "Hybridization between Brassica napus and B. rapa on a national scale in the United Kingdom", Science 2003, Vol. 302, pp. 457-459; see also models of Haygood/Ives/Andow, "Consequences of recurrent gene flow from crops to wild relatives", Proceedings of the Royal Society of London, Series B: Biological Sciences, 2003, Vol. 270, pp. 1879-1886.

95 Schell, footnote 76 above, p. 388; Lavigne/Klein/Couvet, "Using seed purity data to estimate an average pollen mediated gene flow from crops to wild relatives", TAG 2002, Vol. 104, pp. 139-145.

96 Breckling/Züghart, footnote 68 above; longterm observations showing abnormities only within generations and: Lu/Kato/Kakihara, footnote 65 above; Chèvre/Eber/Baranger et al., "Characterization of backcross generations obtained under field conditions from oilseed rape-wild radish F1 interspecific hybrids: an assessment of transgene dispersal", TAG 1998, Vol. 97, pp. 90-98; Tomiuk/Hauser/Bagger-Jørgensen, "A- or C-chromosomes, does it matter for the transfer of transgenes from Brassica napus", TAG 2000, Vol. 100, pp. 750-754.

97 Kempken/Kempken, footnote 80 above.

by-case" analysis[98]. Hence, there is a large deficit, having no de lege lata fixation, in the monitoring and reference areas within the GMO regulations. Codes of practice focus mainly on the "Natura 2000" areas, obviously due to most recent basic information evaluated there99, and therefore, there has been a lack of observation in most of the agricultural land and of old cultivars.

The complexity of the monitoring is resulting in the use of abiotic factors such as climate and habitat ecology whose influences must be determined over several years[100]. Moreover, within the soils, a variety of, in part, undescribed microorganisms with an unknown ecology, will lead to an unpredictable situation[101]. And it is still not clear, how – if at all – an "ecological damage" will manifest itself and be describable[102].

The simple transfer of the gene construct itself into another organism is – in all due consideration – not inherently a damage, rather an intervention in its "evolutionary integrity"[103] that is also needed for the protection of species and biotopes and not necessarily the status quo. On the other hand most environmental laws (should) include a progression and process idea that would allow a more dynamic conservation concept. This means, that, through change, when discussing GMO influences, the management of nature protection areas within the Central European cultural landscape has also to be debated. Eventually, we will then find it hard to subsume such different approaches as protection of cultural plants, protection of species, and protection of nature conservation areas under the same statute[104]. Thus, what is really possible to bring about in a defined protection area will have to be regulated by special decree. If the focus is on the protection of special wild crop ancestors, the effects of GMOs would definitely be of very high relevance[105].

## 4. Scientific evidence for outcrossings of GMOs in neighbouring areas

The qualitative detection of a known (!) construct is in principal easy to perform by standard molecular methods[106], such as the immunological detection of proteins, PCR (polymerase chain reaction, eventually realtime PCR for quantification), DNA blotting procedures (DNA hybridisations), FISH (fluorescence in situ hybridisation)[107] or the use of microarrays[108]. The latter, however, also demonstrates where the problems will arise if quantifications, e.g. the need to measure threshold values is of interest, as only a percentage of isolated DNA is known without being able to extrapolate on the total amount of DNA of the whole harvest or the marginal conventional crop. Problems will also occur if the gene construct is unknown to the controllers, due to the wish on the part of the producers or cultivators for secrecy so as to avoid competitors or patent theft. At least parts of the construct must be known for the PCR approach. In certain circumstances, some evidence of the biotechnical origin can be obtained indirectly, when detection of common antibiotic resistance genes or commonly used promoters (linked to the target gene,

98 Wolfenbarger/Phifer, "The ecological risks and benefits of genetically engineered plants", Science 2000, Vol. 290, pp. 2088-2093 (2090 and 2092).

99 Züghart/Breckling, footnote 92 above; Traxler/Heissenberger/Frank et al., footnote 92 above.

100 Kjellsson/Strandberg, Monitoring and surveillance of genetically modified higher plants: guidelines for procedures and analysis of environmental effects, 2001.

101 Schell, footnote 76 above, examples at pp. 322 et seq.; Giddings/Mytton/Griffiths et al., "A secondary effect of transformation in Rhizobium leguminosarum transgenic for Bacillus thuringiensis subspecies tenebrionis d-endotoxin (cryIIIA) genes", TAG 1997, Vol. 95, pp. 1062-1068; see Heissenberger/Unger/Wottawa/Schmidt, Möglichkeiten zum Monitoring des Einflusses transgener Pflanzen auf Bodenmikroorganismen, = Reports; R-160, Umweltbundesamt, 1999, pp. 13, 29-30, 33-34.

102 Breckling/Züghart, footnote 68 above; Schlee, "Probleme der Erhaltung biologischer Vielfalt in der Kulturlandschaft – Ökologische Schäden durch verfehlte Pflegekonzepte", in: Potthast (ed.), Ökologische Schäden: Begriffliche, methodologische und operationale Aspekte. Jahrestagung AK Theorie und AK Gentechnik der GfÖ in Blaubeuren 2003, = Theorie in der Ökologie, Vol. 10, 2004, pp. 95-110; Wolfenbarger/Phifer, footnote 98 above, p. 2092.

103 Breckling/Züghart, footnote 68 above.

104 Schlee, footnote 102 above.

105 Celis/Scurrah/Cowgill et al., "Environmental biosafety and transgenic potato in a centre of diversity for this crop", Nature 2004, Vol. 432, pp. 222-225; Ellstrand, Dangerous liaisons: when cultivated plants mate with their wild relatives, 2003, p. 268; Baltazar/Jesús Sánchez-Gonzalez/Cruz-Larios, "Pollination between maize and teosinte: an important determinant of gene flow in Mexico", TAG 2005, Vol. 110, pp. 519-526.

106 A generell overview is given by Kempken/Kempken, footnote 80 above.

107 Pedersen/Zimny/Becker et al., footnote 69 above.

108 Aarts/Hoef/Kok, "The use of micro-array technology for the detection of GMOs", in: Senatskommission zur Beurteilung von Stoffen in der Landwirtschaft (ed.) / Deutsche Forschungsgemeinschaft, footnote 78 above, pp. 3-11; Breckling/Züghart, footnote 68 above.

usually CaMV p-35S promoter) is successful. The expectations within the scientific community were high, when Quist & Chapela described introgressions of transgenic DNA in several recent Mexican land races of maize[109]. Even if there still remains uncertainty as to how the results should be interpreted, a shadow is falling on the possibilities of independent scientific publications. It must be considered as wholly unsatisfactory that scientific research is not funded – and payable – by public institutions, as this situation may, in turn, lead to an enormous increase in the influence of the financial support given by companies[110]. In Germany, the blocking of the transposition of the new Deliberate Release Directive through the Federal Council has led and is still leading to secret start-ups of GMO sowing[111]. Research is therefore, de facto, impossible[112]. Even if a register for all possible gene constructs were to be established, not all areas and not all constructs could be found and monitored at the required sample size needed.

There is also an overall need for clarifying the question of cost benefit. Two solutions are feasible, on the one hand, costs could be imposed on the general public as the legislature of the EU has articulated a broad use of the green gene technology which could result in public benefits through risk management. On the other, a costs-by-cause principle could be seen to be assigning the benefits to the operators[113].

Whoever pays, a standard has to be established as to how often experiments should be repeated by independent institutions because the sensitive responses of, e.g. the PCR procedure, could easily lead to false-positive signals due to smallest of contaminations (in the lab). Such a risk of contamination is also possible in each phase of the transport of the probe, e.g. when pollen material is only overlying the probe and will be amplified during PCR. In the case of the use of microarray approaches – based on digitalised and the altogether higher requirements of computer analysis procedures – results are interpretable on various occasions.

Taken all together, these uncertainties result in the desirability of and need for the parallel usage of several methods to reduce misinterpretations – with even higher labour and overall costs. Otherwise, compliance with threshold values would just be a farce from the very beginning.

It would also be of interest in the identification of an emitter to have the possibility to detect a special sequence docked to the gene construct that would allow for the classification and coding of sufficient data of the producer[114]. DNA is a pretty good candidate for an integrating code[115] and it can therefore be assumed that this procedure is already being used secretly, e.g. for patent purposes[116] and proofs of misuses – but vice versa it can also be a risk if improperly transferred to non-target organisms just to discredit a company.

## IV. Summary

Though very belated, the implementation of the new Directive on Deliberate Releases is currently underway in most of the EU-Member States. The Directive contains very specific requirements to be implemented exactly, but it also allows for optional rules that leave discretionary powers to the Member States to decide whether to introduce them or not. From the viewpoint of nature conservation, there remains a lack of basic research which in turn leads to the insufficient predictability of risk assessment of gene technology. On the other hand, methods of monitoring are now already well established in theory and should eventually be used to overcome any data gaps within extensive practical monitoring projects. At the moment, this is necessary to avoid the greatest risk – the secret use of

109 Quist/Chapela, "Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico", Nature 2001, Vol. 414, pp. 541-543; for further references on the dispute see Rowell, Don't worry, it's safe to eat: the true story of GM food, BSE, and foot and mouth, 2003.

110 Snow, "Moving beyond 'industry vs ecologists' stereotype", Nature 2002, Vol. 420, p. 121.

111 Winter footnote 79 above.

112 Quist, "Transgene ecology: An ecological perspective for GMO risk assessment", in: Breckling/Verhoeven, footnote 93 above, pp. 239-244, 240-241.

113 Winter, Die Prüfung der Freisetzung von gentechnisch veränderten Organismen: Recht und Genehmigungspraxis, Gutachten im Auftrag des Umweltbundesamtes, Berichte/Umweltbundesamt, Vol. 4/98, 1998, p. 117.

114 Lemke, "Rechtliche Fragen der Verantwortungsverteilung zwischen Betreiber und öffentlicher Hand im Hinblick auf ein Langzeitmonitoring", in: Lemke/Winter, footnote 68 above, pp. 344-357; Kempke/Kempke, footnote 80 above.

115 Borchard-Tuch, "Lebendes Chiffriergerät – Kryptographie mit Hilfe von DNA", c't – Magazin für Computer-Technik 2001, Vol. 19(3), pp. 94-97.

116 Kondro, "Canada: Monsanto wins split decision in patent fight over GM crop", Science 2004, Vol. 304, p. 1229; Jayaraman, "Illicit GM cotton sparks corporate fury", Nature 2001, Vol. 413, p. 555.

transgenic crops that leads to a lack of control at all stages. Despite the collection of more and more detailed data however, politics, of course, has to classify scientific results[117] and uncertainties will always remain, since environmental law has too many deficiencies when it comes to safeguarding nature protection areas and the genetic integrity of those several wild species that are the ancestors of genetically modified crops.

117 Daele/Pühler/Sukopp, Transgenic herbicide-resistant crops: a participatory technology assessment, Summary report, Discussion Paper FS II 97 – 302, Wissenschaftszentrum Berlin für Sozialforschung, 1997.