

Genetically Modified Living Organisms and the Precautionary Principle

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Executive Summary:

Genetically modified organisms (GMOs) are presently released into the environment in numerous regions of the world, including the United States of America and the European Union. There are not yet global provisions which regulate such releases. International trade law contains a number of provisions which regulate prohibitions or restrictions of GMO releases which were adopted in order to protect human health or the environment.

The study examines United States and European Union law and practice with regard to bans or restrictions concerning the release into the environment of GMOs. It concludes that existing scientific uncertainties, in particular as regards the long-term effects of GMOs in the environment, clearly allow States or the EU in application of the precautionary principle, to prohibit such releases; international trade law would not constitute an obstacle in this regard. In contrast, the precautionary principle does not reach so far as to impose on states or the European Union an obligation to prohibit GMO releases into the environment. Such a decision is of a political nature. It is dependent on the answer to the political question, how much risk a society can be asked to bear.

The decision-making function concerning releases of GMOs into the environment was transferred, in the EU, to the EU institutions. Therefore, EU Member States only have limited possibilities to prohibit such releases.

1. The questions raised

(1) The present study was asked to answer to the following questions:

1. Is a deliberate release (or an authorization) of genetically modified (or synthetically produced) organisms legally possible, when the spatial and temporal spread of the organisms cannot be controlled, or when their retrieval is not possible?

1.1 Within the EU, taking into consideration Directive 2001/18 which provides for a review of authorizations after ten years and thereby appears to presume the possibility of retrieving?

1.2 In the frame of the Convention on Biological Diversity - taking into consideration the Biosafety Clearing House for the most important crop plants?

1.3 In the USA, taking into consideration the regulatory provisions which prohibit the cultivation of genetically modified cotton in certain regions, where there is a risk of out-crossing with wild relatives?

2. What legal provisions shall be recommended or which legal possibilities exist already at present, when the EU or its Member States wanted to prohibit such releases?

2.1 Is the precautionary principle which based on the result of a risk assessment, in principle apt to address the problem?

2.2 Or could/should preventive measures be taken which apply already at a moment when it becomes known that organisms are persistent and/or invasive, independently of the question, whether there exists already a concrete risk for humans or the environment?

2.3 Which other legal possibilities exist?

2. Introduction

(2) Biotechnology¹ and synthetic biology² - which tries to design and construct new biological forms and systems that are not found in nature -, are very recent forms of science. Modern forms of biotechnology developed since the 1970s; synthetic biology is even younger. This means that only limited knowledge exists as regards the effects, and in particular the long-term effects on the environment and human health of the application in practice of this science. As impacts on the environment are in question, it should be clearly understood that “long-term effects” include effects which become apparent after several generations only.

(3) There are no uniform global legal provisions on genetically modified organisms (GMOs), their authorization, their deliberate release into the environment, their monitoring and their retrieval. Even the terminology differs: in the European Union (EU), the term “genetically modified organism(s)” is common. In the United States, the term “genetically engineered” substance or product, plant or animal is normally used. The Convention on Biological Diversity (CBD)³ and the Cartagena Protocol on Biosafety to the CBD⁴ use the term “living modified organisms”. In the following text, the term “genetically modified organism(s)” or GMO(s) will be used; also as regards other terms, the terminology which is commonly in use within the EU⁵ will be used.

(4) This study will examine the legal situation at international level, In the United States of America and within the European Union. As it is intended to analyze the present situation and to give legal answers to the problems raised, it

1 The Convention on Biological Diversity (CBD), Article 2 defines biotechnology as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”.

2 See EGE (2009); Then-Hamberger (2010). An internationally recognised definition of “synthetic biology” does not yet exist, EGE (2009), p.48.

3 The Convention on Biological Diversity (CBD) was adopted in Rio de Janeiro on 5 June 1992. It entered into force on 29 December 1993. The EU adhered to the Convention by Decision 93/626, OJ 1993, L 309 p.1. According to Article 216(2) Treaty on the Functioning of the European Union (TFEU), the Convention is binding on the EU institutions and on the Member States. The USA did not ratify the CBD.

4 The Protocol on Biosafety was adopted in Montréal on 29 January 2000 and entered into force on 11 September 2003. The EU adhered to the Protocol by Decision 2002/628, OJ 2002, L 201 p.48. The USA did not ratify the Cartagena Protocol.

5 In this author’s opinion, though, the term “genetically modified living organisms” would be more appropriate, because the main problem is the question, how the environment can be adequately protected against the introduction of such *living* organisms which are, by their characteristic as live beings, different from products. This different emphasis would have required to base the relevant EU legislation, and in particular Directive 2001/18 on the deliberate release into the environment of such organisms (OJ 2001, L 106 p.1) on Article 192 and not on the product-related Article 114 TFEU. The problems which are linked to the legal basis that was chosen by the EU, cannot be discussed in detail in this paper; for a short presentation of the problem see paragraphs 222 to 226, below.

will put a greater emphasis, in the analysis and the legal evaluation, on the situation within the European Union.

3. General overview of legislation

3.1 International provisions

(5) The Convention on Biological Diversity (CBD) of 1992 states as its principal objectives the “conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” (Article 1). Article 8 lists a number of obligations which the Contracting Parties should comply with. As regards GMOs, this Article provides: “Each Contracting Party shall, as far as possible and as appropriate... (g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health”; (h) Prevent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species”. The precautionary principle is indirectly referred to in Recital 9 of the Convention⁶.

(6) The Cartagena Protocol on Biosafety, elaborated under the auspices of the CBD, has the objective to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of GMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity; it specifically focuses on transboundary movements. Exports of GMOS for deliberate release into the environment must be notified to the importing State before the export takes place, in order to allow the importing State to take an informed decision on such imports. The precautionary principle is referred to in Recital 4⁷, Article 1⁸, Article 10(6)⁹Article 11(8) and Annex III no.4¹⁰.

⁶ CBD, Recital 9: “Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat”

⁷ Cartagena Protocol on Biosafety, Recital 4: “Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development”.The “Rio Declaration on Environment and Development” was adopted by the United Nations Conference of Environment and Development (3 to 14 June 1992, Rio de Janeiro). It laid down a number of principles. Principle 15 reads: “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation”.

(7) Article 2(4) gives the right to Contracting Parties to take actions that are more restrictive of the protection of biological diversity than under the Protocol, provided that such an action is consistent with the Protocol and “is in accordance with that Party’s other obligations under international law”.

(8) Article 20 establishes a Biosafety Clearing-House in order to facilitate the exchange of information and assist in the implementation of the Protocol. Parties are asked to communicate to the Clearing-House their decisions to allow or prohibit the import of GMOs (Articles 10(3) and 11(1)).

(9) At global level, also the Agreements on trade, elaborated under the auspices of the World Trade Organization, have to be mentioned. The Agreement on Technical Barriers to Trade (TBT Agreement) provides that “no country shall be prevented from taking measures necessary.. for the protection of human, animal or plant life or health, of the environment.. at the level it considers appropriate”, provided that such measures do not discriminate against other countries or constitute a disguised restriction in international trade¹¹. A similar statement is found in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)¹², except that the protection of the environment is not mentioned¹³. Article 5 states that States “shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into

8 Cartagena Protocol on Biosafety, Article 1: “In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is....”

9 Cartagena Protocol on Biosafety, Article 10(6): “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological Diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects”.

10 Article 11(8) is almost identical to Article 10(6), except that it refers to imports of GMOs “for direct use as food or feed. or for processing”.

11 World Trade Organisation (WTO), Agreement on Technical Barriers to Trade, Recital 5. The EU adhered to that Agreement by Decision 94/800, OJ 1994, L 336 p.1; the Agreement is published in OJ 1994, L 336 p.86.

12 The WTO Agreement on the application of sanitary and phytosanitary measures (SPS Agreement). The EU adhered to this Agreement by Decision 94/800, OJ 1994, L 336 p. 1. The Agreement is published in OJ 1994, L 336 p.40.

13 In the WTO Dispute Settlement procedures DS 291, 292 and 293 between USA, Canada and Argentina and the European Union - WTO Panel report of 29 September 2006, adopted by the WTO Dispute Settlement Board on 21 November 2006 - which concerned GMOs, the WTO Panel applied the SPS Agreement to GMOs, considering the omission to mention the protection of the environment in the SPS Agreement to be irrelevant (Panel Report, paragraphs 7.208 to 7.211). This appears erroneous, as the TBT Agreement does not apply, when the SPS Agreement applies (Article 1.5 TBT Agreement); therefore, the Panel’s understanding would make the mentioning of the protection of the environment in the TBT Agreement meaningless. Environmental issues would thus, in the Panel’s understanding, only have to be discussed under the SPS Agreement, though the protection of the “environment” is only mentioned in the TBT Agreement.

account risk assessment techniques developed by the relevant international organizations". The precautionary principle is alluded to in the Preamble (Recital 6), Articles 3(3) and in particular Article 5(7) of the SPS Agreement¹⁴.

(10) There are no other specific provisions for genetically modified organisms under the Convention on Biological Diversity or under the Cartagena Protocol on Biosafety. Decision VI/23 of the Meeting of the Parties of the CBD adopted "Guiding principles for the prevention, introduction and mitigation of impacts of alien species". However, nothing in that Decision or in the Guiding principles themselves refers explicitly to GMOs, so that it would have to be established first that a genetically modified plant or animal constitutes an invasive species under the Convention, before these Guiding principles could find application.

(11) The Guiding principles, laid down in the annex to Decision VI/23¹⁵, are not binding. They contain recommendations and suggestions to the Contracting Parties of the CBD, how to approach the problem of invasive species. Principle 1 in particular suggests the application of the precautionary approach¹⁶. Principle 2 suggest to prevent the generation of invasive species; if that is not possible, measures should be taken to eradicate invasive species and where that is not possible either, to try to control (contain) the invasive species.

(12) The General Agreement on Tariffs and Trade (GATT), part of the WTO Trade Agreements, and the TBT Agreement contain provisions which have the objective

14 SPS Agreement, Article 5(7): "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant International organizations as well as from sanitary or phytosanitary measures applied by other members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time". The EU Commission, Commission (2000), section 4 p.11) rightly pointed out that the term "provisionally" referred to the development of scientific knowledge, not to a time limit.

15 The 15 Guiding principles are: 1. Precautionary approach 2. Three-stage hierarchical approach (prevention, eradication, containment) 3. Ecosystem approach 4. Role of the States 5. Research and monitoring 6. Education and public awareness 7. Border control and quarantine measures 8. Exchange of information 9. Cooperation and capacity building 10. Intentional introduction 11. Unintentional introduction 12. Mitigation impacts 13. Eradication 14. Containment 15. Control

16 CBD, Guiding Principles for the prevention, introduction and mitigation of impacts of alien species that threaten ecosystems, habitats or species, Guiding Principle 1: "Given the unpredictability of the pathways and impacts on biological diversity of invasive alien species, efforts to identify and prevent unintentional introductions as well as decisions concerning intentional introductions should be based on the precautionary approach, in particular with reference to risk analysis.; in accordance with the guiding principles below. The precautionary approach is that set forth in principle 15 of the 1992 Rio Declaration on Environment and Development and in the preamble of the Convention on Biological Diversity. The precautionary approach should also be applied when considering eradication, containment and control measures in relation to alien species that have become established. Lack of scientific certainty about the various applications of an invasion should not be used as a reason for postponing or failing to take appropriate eradication, containment and control measures".

to ensure free international trade. The provisions establish in particular that Contracting Parties treat 'like products' in the same, not in a different way. The answer to the question, whether GMOs are "like products" as conventional products depends on the question, whether their physical characteristics, the tastes and habits of consumers, the end uses of the products and their tariff classification point into the same direction; these criteria were successively developed by the WTO dispute settlement bodies in cases involving different Contracting Parties. In the United States, GMO products and conventional products are considered and treated as "substantially equivalent" which would probably classify them as 'like' products. However, as the main economic objective of companies which develop GMOs, is to create a difference with regard to conventional products which then is protected by intellectual property law, and as such investments normally reach millions of euros, it is difficult to accept that conventional and GMO products have the same characteristics. Also the risk which is linked to the use and cultivation of GMOs is quite different. Consumers, at least in Europe, do not consider GMOs and conventional products to be 'like', but request a label, in order to be able to better choose their preferred product. For reasons of all this, according to the above-mentioned criteria, GMOs are not products like conventional products¹⁷. Therefore, the GATT provisions do not prevent States of the EU to adopt specific provisions concerning GMOs.

3.2 United States legislation

(13) The United States of America (USA) do not have specific legislation which addresses genetically modified organisms. Genetically modified plants or animals are considered to be substantially equivalent to organisms which were not genetically modified (conventional plants or animals), so that general legislation applies. Responsibility for the protection of human health and the environment with regard to GMOs is shared between the Environmental Protection Agency (EPA) which monitors in particular the federal Insecticide, Fungicide and Rodenticide Act (FIFRA)¹⁸; the US Department of Agriculture's Animal and Plant Health Service (APHIS) which monitors the provisions of the Plant Protection Act 2000¹⁹; and the Food and Drug Administration (FDA) which deals in particular with genetically modified pharmaceutical products²⁰. The different authorities are obliged to prevent unreasonable adverse effects on the environment²¹ and/or the spread of plant pests or noxious weeds²². They have a large range of possibilities to refuse or restrict the marketing of a product or to impose conditions on its release into the environment.

(14) As the USA legislation is much more general than in the EU; because of the absence of specific legislation on genetically modified organisms, greater

¹⁷ See also Perez (2005), p.166.

¹⁸ Federal Insecticide, Fungicide and Rodenticide Act, 7 USC 136 (FIFRA).

¹⁹ Plant Protection Act, 7 USC 7701.

²⁰ The FDA is also responsible for authorizing the marketing of genetically modified salmon, for which an authorization was introduced, based on tests that were ongoing since 1996.

²¹ FIFRA (Fn.18), Section 3.

²² Plant Protection Act (Fn 19), paragraph 7701.

discretion is left to the administration dealing with GMOs (EPA and APHIS). The EPA shall accept a genetically modified organism, when it is satisfied that it does not have an “unreasonable adverse effect on the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide”²³. Where it is necessary to prevent unreasonable adverse effects on the environment, EPA may limit the distribution, sale or use of the organism²⁴. The Department of Agriculture (APHIS) has, under the Plant Protection Act, the task to control the spread of plant pests or noxious weeds and may prevent such spread or eradicate or suppress such plant pests²⁵. For this purpose, it establishes plant pest risk assessments ; its decisions shall be based on “sound science”²⁶.

3.3 European Union legislation

(15) Under EU policy and law, the term “environment” includes the protection of human health²⁷. As the questions which are being dealt with in this study, refer to the problems which GMOs may cause in the environment, but do not refer to problems related to human health, human health issues will not be separately examined in this study.

(16) The release into the environment of GMOs in the EU is mainly regulated by the general provisions of Regulation 178/2002²⁸ and more specifically by Directive 2001/18²⁹ and Regulation 1829/2003³⁰. Their transboundary movement is regulated by Regulation 1946/2003³¹

23 FIFRA (Fn 18), Article 2 (bb).

24 FIFRA (Fn 18), Article 3(a).

25 Plant Protection Act (Fn 19), Article 7701 and 7CFR part 340: A plant pest is defined *ibidem* as “any living stage that can directly or indirectly injure, cause damage to or cause disease in any plant or plant product (a) A protozoa (B) a nonhuman animal. (C) A parasitic plant (D) A bacterium (E) A fungus (F) A virus or viroid (G) An infectious agent or other pathogen (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs”.

26 Plant Protection Act (Fn 19), Article 7701(4) and Article 7711(b).

27 See Article 191(1) TFEU: “Union policy on the environment shall contribute to pursuit of the following objectives...: - protecting human health..” See also EU Court of Justice, case C-28/09, Commission v. Austria, judgment of 21 December 2011, paragraph 122: “the protection of human health is one of the objectives of Community policy on the environment. Those objectives are closely linked.. The protection of health is therefore already incorporated, in principle, in the objective of protection of the environment”.

28 Regulation (EC) No 178/2002 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, OJ 2002, L 31 p.1.

29 Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, OJ 2001, L 106 p.1.

30 Regulation (EC) No 1829/2003 on genetically modified food and feed, OJ 2003, L 268 p.1.

31 Regulation 1946/2003 on the transboundary movement of genetically modified organisms, OJ 2003, L 287 p.1.

Reg. 178/2002 on general principles and requirements of food law

(17) Regulation 178/2002 establishes the objectives, common principles and responsibilities for EU food legislation in order to reach, within the EU, a high level of protection of human health and consumers' interest. Articles 5 to 8 provide for the general principles of EU food law. Article 7 explicitly defines the precautionary principle³². Article 6 stipulates that food law shall normally be based on a risk analysis which consists of risk assessment, risk management and risk communication³³.

(18) Articles 22 to 49 establish the European Food Safety Authority (EFSA) with the task to provide scientific advice and scientific and technical support to the EU institutions in all fields of food and feed safety. EFSA "shall contribute to a high level of protection of human life and health and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market" (Article 22(3)).

Directive 2001/18 on the release into the environment of GMOs

(19) Directive 2001/18 which replaced an older directive³⁴, concerns the deliberate release into the environment of GMOs and the placing on the market of GMOs as or in products. It explains that "(L)iving organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member State. The effects of such releases on the environment may be irreversible"³⁵. Therefore, the Directive provides for a control of the deliberate release of GMOs.

(20) Recital 8 states: "The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing

32 Regulation 178/2002 (Fn 28), Article 7: "1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment. 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment".

33 See the definition of risk analysis in Regulation 178/2002 (Fn 28), Article 3 no.10. Risk assessment is defined Article 3 no.11 as: "a scientifically based process consisting of four steps, hazard identification, hazard characterization, exposure assessment and risk characterisation". According to Article 6(2) it "shall be based on available scientific evidence and undertaken in an independent, objective and transparent manner".

34 Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, OJ 1990, L 117 p.15.

35 Directive 2001/18 (Fn29), Recital 4.

it". Also Article 1 of the Directive states that its objectives are pursued "(I)n accordance with the precautionary principle"; and Article 4(1) asks Member States, to avoid, "in accordance with the precautionary principle", adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. The Directive does not contain a definition of the precautionary principle.

(21) The only explicit substantive requirement which is laid down in the Directive, is that an authorization should only be granted, after the competent authority "has been satisfied that the release will be safe for human health and the environment"³⁶. However, this requirement is also a consequence of the provision in Article 4(1) which requires Member States to "ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs". Also the explicit and detailed reference in Annex II to direct and indirect, immediate, delayed and cumulative effects which a GMO might have on human health and the environment, indicates that the Directive attaches great importance to ensuring optimal safety for human health and the environment.

(22) The deliberate release into the environment requires an authorization - a written consent - which is normally granted by the competent authority of the Member State which had received the application³⁷; the authorization is granted for a specific period of time. Where the application for a placing on the market of GMOs as or in products is objected by another Member State or the Commission, the decision on the application is taken at EU level, either by the Commission or the Council. The Member State to whom the first application had been made, is then obliged to execute a favourable decision by the EU institution and grant the authorization³⁸. When new or additional information becomes available after the authorization which increases the risk of the GMO, a Member State may recur to the so-called safeguard clause of Article 23³⁹ and take measures to restrict or prohibit the release of the GMO; such a national measure is controlled by the European Commission. Otherwise, Member States may not prohibit, restrict or impede the placing on the market of GMOs which comply with the requirements of Directive 2001/18 (Article 22). With regard to the safeguard clause in Article 23, the burden of proof that a restrictive measure is necessary is on the Member State invoking the Article.

36 Directive 2001/18 (Fn 29), Recital 47.

37 Directive 2001/18 (Fn 29), Article 6(8) and Article 19.

38 Directive 2001/18 (Fn 29), Article 18(2). See for details of the procedure Articles 15 to 19. See also EU Court of Justice, case C-6/99 Greenpeace, ECR 2000, p.I-1651.

39 Directive 2001/18, Article 23: "Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.."

(23) The application for an authorization must be accompanied by a number of documents, amongst others by an environmental risk assessment which is made by the applicant. An environmental risk assessment is defined in Article 2 no.8 as “the evaluation of risks to human health or the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II”. This Annex II to directive 2001/18 details the requirements for an environmental risk assessment. It again refers to the precautionary principle (section B) and describes the objective of the environmental risk assessment (section A)⁴⁰, the general principles which apply (section B), the methodology (section C) and contains conclusions (section D).

(24) The decision, if and which risk *management* measures shall be adopted in order to avoid harm to human health or the environment, is taken by the authority which is responsible for granting the authorization.

(25) Article 4(1) of Directive 2001/18 requires Member States to ensure, by taking “all appropriate measures” that adverse effects on the environment which might arise from the deliberate release or the placing on the market of GMOs, are avoided. This objective is confirmed in Recital 48 of the Directive which requires that an authorization shall only be granted when the release of GMOs “will be safe for.. the environment”. In the event of a “severe risk”, means should be sought for providing possibilities for the retrieval of GMOs (Recital 45). This provision is further specified in Annex III V.D which requires the establishment of an emergency response plan with a specific minimum content⁴¹ . Also Article 4(5) of the Directive may be mentioned here which asks a Member State, when a GMO was released into the environment or placed on the market without authorization, to take, if necessary, “remedial action”, without specifying what such remedial action should consist of.

(26) Reading these different provisions together, it is not entirely clear, what the Directive tries to achieve. On the one hand, it stipulates that GMOs must be “safe” for the environment and that all appropriate measures shall be taken to avoid adverse effects of GMOs on the environment. As the precautionary principle is explicitly mentioned in Article 4(1), the provision requires the taking of steps as soon as there is an uncertainty, whether a GMO has an adverse effect on the environment. Moreover, the uncontrolled spread⁴² of an GMO in the

40 Directive 2001/18 (Fn 29), Annex II, section A: “The objective of an environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may have. The environmental risk assessment should be conducted with a view to identifying if there is need for risk management and if so, the most appropriate methods to be used”.

41 Directive 2001/18 (Fn 29), Annex III V.D requires the plan to contain: “1. methods and procedures for controlling GMOs in case of unexpected spread, 2. methods for decontamination of the areas affected, for example eradication of the GMOs, 3. methods for disposal or sanitation of plants, animals, soils etc, that were exposed during or after the spread, 4. methods for the isolation of the area affected by the spread, 5. plans for protecting human health and the environment in case of occurrence of an undesirable effect”.

42 Spread (French: propagation; German: Ausbreitung) of GMOs in the environment has to be distinguished from their controlled release (French: dissémination, German:

environment is itself seen, according to Annex II C(1), as an adverse effect. It follows from this that Article 4(1), together with Recital 45 aims at a zero level tolerance: GMOs should not be allowed to spread in an uncontrolled way in the environment.

(27) Where a GMO has already received an authorization to be released into the environment and then a risk of adverse effects appears, the Member State which has granted the authorization shall evaluate the information and may then suspend or terminate the deliberate release (Article 8(2)). Where a GMO has already received an authorization to be put on the market and then information becomes available which “could have consequences for the risks ..to ..the environment” (Article 20(3)), the Member State may provisionally restrict or prohibit the use and/or sale of the GMO in question on its territory, when the Member State is of the opinion that the GMO constitutes a risk to the environment; where the risk is severe, the Member State shall apply emergency measures such as the suspension or termination of the placing on the market of the GMO (Article 23(1)). In this case, any EU-wide measure is taken by the Commission or the Council (Article 23(2)).

(28) On the other hand, Member States and, where appropriate, the Commission shall ensure that adverse effects of a GMO are “accurately assessed on a case-by-case basis” (Article 4(3)). Furthermore, measures for the retrieval of GMOs shall be available, according to Recital 45, only in the event of *severe* risk. These provisions rather point into the direction of a risk management decision on a case-by-case basis, whether the risk of a GMO that has spread into the environment, was considered acceptable or unacceptable by the legislator of Directive 2001/18.

(29) This ambiguity of Directive 2001/18 is confirmed by a closer examination of its annexes. Annex II, C 1 to Directive 2001/18 identifies characteristics which may cause adverse effects and requires the risk assessment to identify any characteristic of the GMO that may result in adverse effects, emphasizing that it “is important not to discount any potential adverse effect on the basis that it is unlikely to occur”. It enumerates by way of example:

“Adverse effects may occur directly or indirectly through mechanisms which may include:

- the spread of GMOs in the environment;
- the transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not;
- phenotypic and genetic stability;
- interactions with other organisms;
- changes in management, including, where applicable, in agricultural practices”.

(30) Annex III to the Directive specifies the information which the applicant for an authorization – “the notifier” in the words of the Directive – shall submit together

Freisetzung) which is organized by the Directive.

with his application. This information concerns the GMO itself, the receiving environment, the conditions of the release and the interaction between the GMOs and the environment. They include the genetic transfer capability of GMOs into other organisms or from other organisms to the GMOs (Annex IIIA IV B.3), the potential for excessive population increase in the environment (Annex IIIA IV B.8) competing advantage of the GMOs in relation to the unmodified recipient of parental organism (Annex IIIA IV B.9), or the interaction with non-target organisms (Annex IIIA IV.B.14).

(31) Where genetically modified higher plants are to be released, Annex IIIB requires, among others, information on the reproduction (IIIB.B.2) survivability (Annex IIIB.B.3) potential interactions with organisms in the environment (IIIB.B.7), genetic stability (IIIB.D.5), interaction with target (IIIB.D.9) and non-target organisms (IIIB.D.10), the abiotic environment (IIIB.D.11), and the presence of sexually compatible wild relatives or cultivated plant species (IIIB.E.3).

(32) The wording in Annexes II and IIIC does not specify, whether any of the adverse effects mentioned in these annexes of a GMO are acceptable for the legislator - or for the society which has established the legislative provision - or not. However, as the environmental risk assessment is made on a case-by-case basis and has the objective to identify and assess the effects of GMOs on the environment, this approach is logical. It is confirmed by other provisions in Annex II C which require the assessment of the adverse effects, assuming that such adverse effects will occur⁴³ ; this procedural step would be unnecessary, if each identified adverse effect would be unacceptable to the legislator/society.

(33) Generally, Directive 2001/18 is mainly interested in the gene transfer from genetically modified plants and animals⁴⁴ to other wild relatives or conventional plants or animals in the environment, and to the effect of the GMO on non-target species⁴⁵. Indirect environmental effects which include agricultural practices such as the use of pesticides or herbicides, or the resistance of pest species or weeds, appear to be of less strong interest.

(34) Some provisions of Directive 2001/18 point into the direction that Member States shall be obliged to take *all* measures in order to avoid any impact of GMOS on the environment, as this is an adverse effect of the GMO and may lead, directly or indirectly, to other adverse effects. Other provisions, in particular

43 See in particular Annex II C 4 to Directive 2001/18 (Fn 29): „An estimation of the risk to human health or the environment posed by each identified characteristics of the GMO which has the potential to cause adverse effects should be made as far as possible, given the state of the art, by combining the likelihood of the adverse effect occurring and the magnitude of the consequences, if it occurs”.

44 Directive 2001/18 (Fn 29) is not limited to genetically modified plants, though genetically modified animals have not yet been authorized in the EU. For the United States, ESA(2005) p.383 listed, apart from microbes, the following “current and planned” genetically modified animals: Pink bollworm, Mouse, Atlantic salmon, Zebra fish, Pig, Goat and Sheep. In other parts of the world, attempts are made in particular to generate genetically modified mosquitos.

45 Non-target species are species that are not the direct target of pest control measures, for example beetles, bees, flies, wasps, bats, butterflies, birds, moths, soil organisms, endangered species etc.

those which require an environmental risk assessment on a case-by-case basis, rather suggest that the concrete adverse effect of the GMOs to the environment is assessed and monitored.

Regulation 1829/2003 on genetically modified food and feed

(35) Regulation 1829/2003⁴⁶ deals with genetically modified food and feed, covering also the cultivation of plants from which food or feed is produced. It details the provisions on the authorization procedure which differ in several parts from those of Directive 2001/18. In particular, the risk assessment of a genetically modified food or feed is made by EFSA; in the case of seeds, EFSA shall request a Member State to carry out the environmental risk assessment (Article 6(3)(c)). The decision on the authorization of a genetically modified product is taken, under the so-called comitology procedure, by the Commission or, under certain circumstances, by the Council. The Member States are in a more assistive role. Authorizations shall be valid throughout the EU for ten years and shall be renewable.

(36) The Regulation does not explicitly mention the precautionary principle. However, its Article 1 states that the objectives of the Regulation shall be pursued “in accordance with the general principles laid down in Regulation 178/2002”. As Regulation 178/2002 explicitly establishes the precautionary principle as one general principle of EU food law, the conclusion is that also under Regulation 1829/2003, the precautionary principle applies.

(37) Article 4(1)(a) requires that genetically modified food “must not have adverse effects on human health, animal health or the environment”; Article 16(1)(a) repeats this requirement for feed. No restriction – such as “significant adverse effect” – is made to this requirement. And the applicant for an authorization must “adequately and sufficiently” demonstrate that his product complies with this requirement⁴⁷. For the rest, Regulation 1829/2003 largely refers to the objectives and principles of Directive 2001/18. It provides for the risk evaluation (assessment) by EFSA to be a “scientific evaluation of the highest possible standard” of “any” risk which genetically modified food or feed presents for the environment⁴⁸. The risk assessment under the Regulation shall follow the principles of the environmental risk assessment of Annex II to Directive 2001/18⁴⁹. The risk management decision is to be taken by the EU (Commission or Council). As it “is recognized that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based”⁵⁰, this EU management decision shall be taking into account

46 Regulation 1829/2003 (Fn 30).

47 Regulation 1829/2003 (Fn 30), Article 4(3) and 16(3).

48 Regulation 1829/2003 (Fn 30), Recital 9.

49 See Regulation 1829/2003 (Fn 30), Article 2 no.4: “the definitions of ‘organism’, ‘deliberate release’ and ‘environmental risk assessment’ referred to in Directive 2001/18/EC shall apply”.

50 Regulation 1829/2003 (Fn 30), Recital 32.

EFSA's risk assessment opinion, as well as "any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration"⁵¹.

(38) Once a genetically modified product is authorized by or in accordance with Regulation 1829/2003, and it becomes evident that it is likely to constitute a "serious risk" to the environment, the EU or the Member States may take emergency measures according to the procedural and substantive provisions of Articles 53 and 54 of Regulation 178/2002⁵². However, where a Member State intends to take such measures, that Member State has the burden of proof that new evidence shows this serious risk.

(39) In 2009, the Commission published guidance notes regarding the monitoring plans for genetically modified plants⁵³. According to that Decision, cultivation of a genetically modified plant should in particular monitor

- the persistence and invasiveness and the selective advantage or disadvantage of the plant, including the increased occurrence of volunteers, the increased establishment of genetically modified plants outside of the fields, an increased spread, persistence and accumulation of the genetically modified plant in the environment including out-crossing with wild relatives, increased spread of genetically modified plant products in the environment,
- the development of resistance in target organism;
- the development of secondary weeds.

4. The practice

4.1 International level

(40) At International level, the Cartagena Protocol on Biosafety instituted a "Biosafety Clearing-House"⁵⁴. This Clearing-House has to objective to facilitate the exchange of scientific, technical, environmental and legal information on genetically modified organisms, and to assist Parties to the Protocol in its implementation. The Clearing-House aims at facilitating access to information and asks Contracting Parties to submit national legislation, summaries of their risk assessments on genetically modified organisms and the final decisions on the authorization or the import of genetically modified plants and/or animals. By December 2012, the Register of national communications contained 565 decisions on the release of GMOs⁵⁵.

51 Regulation 1829/2003 (Fn 30), Article 7(1).

52 Regulation 1829/2003 (Fn 30), Article 34. As regards the details of Member States' possibilities and the relationship of Article 34 to other provisions, see Court of Justice, case C-36/11, Pioneer Hi Bred, judgment of 6 September 2011.

53 Decision 2009/770, OJ 2009 L 275 p.9.

54 Cartagena Protocol on Biosafety (fn.4), Article 20.

(41) The Biosafety Clearing-House does not take decisions and does not either interfere with the national decision-making or risk assessment process. The summaries of the national risk assessments - only exceptionally has a Contracting Party sent the full risk assessment or the full, reasoned decision - are normally so succinct that a clear evaluation of the assessment or the conditions which accompany an authorization is not possible. Decisions, where authorizations are refused, are either not sent to the Biosafety Clearing-House or are only very exceptionally taken⁵⁶.

4.2 United States

(43) In the USA, cultivation of genetically modified plants is far-spread. Already in 2005, Soybean cultivation was based to 87 per cent on GMOs, Corn (including maize) to 52 per cent and cotton to 79 per cent. These percentages have further increased since then.

(44) The risk assessments for genetically modified plants - there are not yet any authorizations for the release of genetically modified animals into the environment - are performed by EPA or private applicants for authorizations; APHIS examines, whether a GMO may constitute a pest for a plant or an animal. Its activities will therefore not be examined in detail. EPA worked out guidelines for ecological risk assessments⁵⁷. These guidelines are not specific for genetically modified organisms, as there is not either specific legislation in the USA. The risk management decision is taken by EPA. The risk assessments principally concern the question of the herbicide tolerance or pest resistance of a GMO plant. They are largely based on studies which the applying company submits. These studies are not made public. It is difficult, on the one hand, to examine the content of these studies and on the other hand the question, whether all studies which the applying company made were submitted. The risk assessments themselves are apparently carefully made and complete.

(45) In 2000/2001, EPA decided to prohibit commercial production of BT-cotton in those parts of or regions belonging to the United States, where wild or feral⁵⁸ cotton plants were known to exist⁵⁹. The decision was based on concerns with regard to the development of weeds the protection of biodiversity and the gene transfer to feral or wild relatives. The available data for Hawaii, the Virgin Islands and Puerto Rico caused EPA to prohibit

55 258 decisions on releases on the American continent (including the USA, though the USA are not a Party to the Convention or to the Cartagena Protocol), 179 in Europe, 74 in Asia, 5 in Oceania and 4 in Africa.

56 The Register contained, in December 2012, only one decision from Colombia, where an authorization was refused, and one information from Norway on a prohibition of a release of a GMO into the environment, taken in 1997. See, however, also Convention on Biological Diversity (2008) section V which enumerates a number of further examples.

57 EPA, Guidelines for ecological risk assessments of 14 May 1998, Federal Register 63(93):26846-26924; <http://www.epa.gov/raf/publications/pdfs/ECOTXTBX.PDF>

58 A feral plant is a plant which has changed from being domesticated to being wild.

59 EPA (2001), p.III 1 ss.

- cultivating Bt-cotton south of route 60 (near Tampa) in Florida;
- commercial cultivation of Bt-cotton in the State of Hawaii;
- commercial cultivation of Bt-cotton in Virgin Islands and of another sort of genetically modified cotton in Puerto Rico.

(46) The applicant was asked to supply supplementary data and studies in this regard. For the rest of the USA, Bt-cotton was authorized with a number of conditions, such as the establishment of refuges, a program for insect resistance management, measures against resistance of pest animals etc.

(47) For a number of decisions concerning the cultivation of genetically modified plants producing insecticides, EPA regularly requests that around the field or in the immediate vicinity, between 5 and 20 per cent of the plants consist of conventional, non-modified plants (refuge). This measure has the objective of slowing down a possible development of resistance by pest insects to the insecticidal trait. Benbrook reports, based on other publications that “compliance with mandatory Bt corn refuge requirements in the U.S. has slipped to only 59% in 2011”⁶⁰

(48) In a case concerning the authorization of genetically modified corn, EPA allowed a conditional deliberate release⁶¹, but added: “the Agency is requesting supplementary studies that will evaluate the persistence of Cry3A in the soil and the long range effects of cultivation of Cry3A on the invertebrate community structure in corn fields. This will facilitate identification of potential adverse effects which may result from long-term use of this product”. Thus, the genetically modified plant was authorized, before the long-term effects of the GMO were known.

(49) Unauthorized use of GMO material also happens, as the following two examples show:

Syngenta Seeds Company (USA) sold, since 2004, at over 1000 occasions non-authorized genetically modified corn seeds in the USA, in South America and in Europe. In 2006, it paid a penalty of 1.5 million dollars to the Environmental Protection Agency in the USA⁶².

In 2010, Monsanto Company (USA) paid a penalty of 2.5 million dollars to EPA, because EPA had prohibited the sale and the cultivation of genetically modified cotton in a number of Texan provinces, in order to protect the regional environment. Monsanto had, between 2002 and 2007, disregarded this

60 Benbrook (2012) p.12.

61 EPA, Modified Cry3A protein and the genetic material necessary for its production (via elements of pZM26) in event MIR604 corn SYN-IR604-8 (2010).
<http://www.epa.gov/opppbpd/biopesticides/pips/mary3a-brad.pdf>.

62 See <http://www.epa.gov/compliance/resources/cases/civil/fifra/syngenta.html>. The fine which EPA had originally requested, was reduced by 75 per cent, because Syngenta had itself revealed the case. EPA accepted that the places, where the seeds had been sold, constituted confidential business information which was not revealed.

prohibition. The genetically modified cotton had been sold and probably been cultivated in Texas on more than 1700 occasions⁶³.

(50) What is striking in the United States is the fact that as regards the phase during which there are field trials with genetically modified plants or when genetically modified plants are cultivated, there is a limited monitoring of the results – or, at least, the monitoring results are not made public. Whether the sale or use restrictions imposed by EPA in the authorizations are actually followed, appears not to be monitored. Publications on escapes of genetically modified plants, on resistance of pest animals or plants, on the establishment of populations of feral plants or on cross-pollination with wild plants are not made by the Environmental Protection Agency or the US Department of Agriculture (APHIS), but, when they are made, by academic researchers; results can, though, not be generalized, in view of the large-scale cultivation of genetically modified plants. The absence of data is nevertheless remarkable. Also, the development of agricultural practice and its effects, such as the generation of Bt resistant pest insects and herbicide resistant weeds, appears neither to be the subject of risk assessments nor of monitoring by EPA. Benbrook reports of twenty-three glyphosate resistant weeds species in up to 23 States of the USA⁶⁴.

(51) During the last five years, more publications reported of outcrossings of genetically modified crops in the United States⁶⁵. This phenomenon does not appear to have led to reactions from the United States public authorities.

(52) Negative decisions by EPA – decisions, where an authorization of a genetically modified organism was refused – are not known.

4.3 European Union

(53) By end 2012, there existed 49 authorizations granted under Regulation 1829/2003⁶⁶. In five cases, the Commission had taken a decision to request the withdrawal of all genetically modified products from the EU market, because the notifier had decided not to request a renewal of an earlier authorization which had elapsed⁶⁷. Based on Directive 2001/18, the Commission took nine authorizing decisions, on potatoes (1), maize (5), flowers (2) and oilseed rape (1). The Register set up under the Cartagena Protocol lists for the EU Member States –

63 See <http://www.epa.gov/compliance/resources/agreements/fifra/monsanto-cafo.pdf>.

64 Benbrook (2012), p.30s.

65 See Gilbert (2010); Munier-Brittan (2010); Schafer and others (2011); Munier-Brittan-Lanini (2012).

66 EU Register for authorized GMOs, http://ec.europa.eu/food/dyna/gen_register/index_en.cfm. The authorizations concerned cotton (8), maize (27) microorganisms (2), oilseed rape (3), potato (1), soybean (7) and sugar beet (1).

67 Commission, Decisions 2007/304, OJ 2007, L 117, p.14; 2007/308, OJ 2007, L 117 p.25; 2007/305, OJ 2007, L 117 p.17; 2007/306, OJ 2007, L 117 p.20; 2007/307, OJ L 117 p.23; Decision 2012/69, OJ 2012, L 34 p.12.

Belgium, Germany, Romania and Spain are the only States that are mentioned – 178 national decisions on the deliberate release of GMOs into the environment⁶⁸.

(54) At EU level, the deliberate release of genetically modified animals into the environment and the cultivation of genetically modified plants has, until now, only been authorized at few occasions:

(55) Since 1998, the Commission authorized the cultivation of different lines of genetically modified maize (pest-resistant maize – Bt maize – and herbicide-tolerant maize)⁶⁹. The Decisions only stated that the cultivation or the placing on the market would not have any adverse effects on the environment, without giving any details. These two decisions are still in force. The Commission Register⁷⁰ indicates that the renewal of the authorizations is ongoing.

(56) In 2010, the Commission authorized the cultivation of a genetically modified potato (*solanum tuberosum* L. line EH92-527-1) for starch production for industrial purposes⁷¹. This Decision was preceded by a risk assessment of EFSA which had concluded that there was no indication that the growing of that potato would create adverse effects to the environment⁷².

(57) Decision 2010/135 referred to the EFSA Opinion and found that no further conditions should be imposed on the cultivation. The Commission decided, though, that some additional measures for monitoring the cultivation should be imposed, in particular the monitoring of potato-feeding organisms in the cultivation fields and their vicinity.

(58) All other decision taken by the EU until now excluded the cultivation of genetically modified products. The reason for this is that either the applicants did not ask for such an authorization, but limited their application to a request for the placing on the market, including the import, of genetically modified products; or in some cases, the original request for an authorization to cultivation was withdrawn⁷³ or was refused by the Member State to whom the application had been addressed⁷⁴.

68 Cartagena Protocol, Biosafety Clearing-House, <http://bch.cbd.int/database/results/?searchid=563961>. The communications from the EU were not included. The national notifications concerned in particular maize, wheat, potatoes, sugar beet, oilseed rape, gray poplar, cotton and soybean. It is not clear, though, whether the database is complete, whether the national authorizations continue to be in force and whether there is some overlapping with EU data.

69 Decisions 98/293, OJ 1998, L 131 p.30 (maize T 25); 98/294, OL 1998, L 131 p.32 (maize MON 810).

70 See fn 66 above.

71 Decision 2010/135, OJ 2010, L 53 p.11.

72 EFSA Opinion of 7 December 2005, EFSA Journal 2006, 323 p.1.

73 See for example Decision 2006/47 on maize, OJ 2006, L 26 p.17.

74 See for example Decision 2007/232, OJ 2007, L 100, p.20, where Belgium to whom the application had been made, had refused the cultivation.

(59) The other EU decisions concern the placing on the market of genetically modified products which are either tolerant to a herbicide or resistant to some pest animals⁷⁵. The EU decisions are systematically preceded by a risk assessment made by EFSA (since its establishment) which are published; earlier risk assessments were made by other scientific committees of the Commission. The EFSA risk assessments examine the impacts on human, animal and plant health and on the environment. For the environmental impact, they normally discuss questions of plant fitness, gene transfer, interaction with target organisms and non-target organisms, interaction with the abiotic environment and the impact on agricultural practices. The assessments are occasionally updated, either on request of the European Commission or on a decision by the EFSA authorities themselves. It is striking, though, that EFSA opinions - besides the dossiers presented by industry which are normally not peer-reviewed - mostly take into consideration only peer-reviewed literature. As the sector of biotechnology is of recent age and very largely dominated by large private companies, the limitation to peer-reviewed research considerably reduces the possibility to become aware of unforeseen, unexpected or emerging effects which a genetically modified organism may have on the environment.

(60) EFSA practice on risk assessment will be examined in three examples which are not necessarily representative of EFSA's practice, but which illustrate the legal implications. Following this, the EU's risk management decisions which are in practice all taken by the Commission, will shortly be discussed.

(61) In its opinion on drought tolerant maize (MON 87460) for food and feed uses⁷⁶, EFSA examined, as regards the environmental risk assessment, in particular the plant to bacteria gene transfer and the plant-to-plant gene transfer. As regards plant to bacteria gene transfer, it relied on additional information from the commercial applicant to state that in maize gluten feed and meal, dregs from brewing and distilling and maize oil, the plant DNA was "not detectable or intensively degraded to fragments" and concluded that the possible source of full-length genes would "mainly be limited to unprocessed whole grain, partially digested or spilled during transit, and to maize flour" (section 6.1.1.2 (a)(i)). This conclusion is neither taking into consideration unlikely events nor assuming the realization of a worst-case scenario, as requested by Annex II to Directive 2001/18. The subsequent conclusion that further degradation would take place in the human or animal body by host and microbial factors and that a full-length gene sequence would persist in the lower intestinal tract is not carried by the previous statement, as nothing in the Opinion allows the conclusion that fragments (larger than 1500 bp) would not also be able to contain the gene sequence. Finally, EFSA's statement that "the vast majority of plant DNA is expected to be degraded after soil entry by microbial DNases in the soil environment" does again not assume a worst-case scenario.

75 Two Commission decisions deal with genetically modified flowers for ornamental purposes, Decision 2007/364 and Decision 2009/244. Furthermore, in 2009, an application was made to the European Commission for the placing on the market of genetically modified drought tolerant-maize, on which EFSA delivered an Opinion on 18 October 2012 (EFSA Journal 2012, 2936). The EU has not yet decided on this application.

76 EFSA Opinion of 18 October 2012, EFSA Journal 2012; 10(11):2916.

(62) Uncertainties also were part of the following parts of the assessment, as the following statements demonstrate:

- “The fate of this single stranded DNA in the cell after transformation is still unclear”;
- “because chromosomal insertion of P1 or P1-like bacteriophages at the loxB site is rarely encountered, it is assumed that recombination of the loxP-nptII-loxP fragment would also preferentially occur into the loxP site of the P1 circular bacteriophage”;
- “Excision would lead to a circular small molecule encoding nptII that is expected to be lost during bacterial replication”;
- “Integration of the loxP-nptII-loxP into the genome would be unlikely because of the preferential insertion into the loxP site of the P1 or P1-like bacteriophage..”;
- “The nptII and expB genes in maize MON 87460 are derived from E.coli and B.subtilis, respectively and their presence in environmental bacteria with homologous DNA sequences of both genes can be expected, so that theoretically recombination between these genes from maize MON 87460 and members of natural microbial communities could take place”;
- “If the nptII cassette from maize MON 87460 is transferred to bacterial cells, the expression of the gene cannot be excluded because the 35S promoter (Section 3.1.1) has been shown to be functional in some bacteria..”;
- “there is limited information about the spatial and temporal variability in the selective conditions that would favour antibiotic-resistant bacteria, and in the occurrence, transferability and distribution of nptII genes in different environments. Also, there is a lack of experimental data on horizontal gene transfer from maize MON 87460”;
- “For the nptII gene of maize MON 87460, owing to the alternative gene transfer scenarios described above, both gene substitution and acquisition of the gene by recipients with the nptII gene would be possible”;
- “the acquisition of the nptII gene by bacteria without nptII genes (scenarios 1 and 2, see above) could confer resistance to kanamycin or neomycin, and thus provides a selective advantage in habitats in which these antibiotics would be present, i.e. the gastrointestinal tract of animals receiving kanamycin or neomycin orally (EFSA, 2009), or soils supplied with faecal matter containing antibiotic residues in sufficient concentration..”;
- “the EFSA GMO Panel considers that the stabilisation of the loxP-nptII-öoxP fragment due to the Cre recombination system present in bacteria containing a P1 or P1-like bacteriophage is unlikely. Even in the case that integration would occur, as the main action of Cre recombinase is excision, this would result in the formation of a circular small molecule encoding nptII, which would be expected to be lost during bacterial replication owing to the absence of an origin of replication”;

- “as for any other maize varieties, GM maize plants would survive in subsequent seasons only in warmer regions of Europe and are not likely to establish feral populations under European environmental conditions”.

(63) It is not argued here that EFSA’s statements and conclusions are wrong, but only that there is a considerable amount of scientific uncertainty which is covered by words such as “likely” or likelihood – which appear at least eleven times on six pages (p.28 to 34).

(64) EFSA’s Opinion of 15 June 2009 concerned the safeguard clause invoked by Austria on oilseed rape MS8, RF3 and MS8xRF3 according to Directive 2001/18⁷⁷. The Opinion stated that in regions where oilseed rape seeds are imported and transported, feral oilseed rape populations are likely to occur in non-natural disturbed ecosystems such as ports, processing facilities, margins of agricultural fields, roadside verges, railway lines and wastelands. “These populations can be large and show significant variation in size from one year to the next”⁷⁸. The Opinion continued to argue that in *most* non-agricultural areas, oilseed rape lacks the ability to establish stable populations due to the absence of competition-free gaps, and that populations *often* become extinct after 2 to 4 years⁷⁹, though it stated that in France such populations had been found to exist for eight years. The Opinion then stated that the presence of herbicide tolerance in oilseed rape does not confer a fitness advantage “*unless the respective herbicide is applied. Because glufosinate-ammonium-containing herbicides are not widely used in ruderal ecosystems in the European Union (EU), feral oilseed rape plants ensuing from spilled seeds of oilseed rape MS8, RF3 and MS8xRF3 would not show any enhanced fitness and would thus behave as conventional plants. Only where and when glufosinate-ammonium-containing herbicides are applied, is oilseed rape MS8, RF3 and MS8xRF3 expected to have a fitness advantage*”.

(65) The Opinion admitted that feral oilseed rape plants derived from spilled seeds may survive, outcross and eventually disperse genes to cross-compatible plants such as Brassica rapa and Raphanus raphanistrum, and even reported that in Canada feral oilseed rape populations were shown to actively outcross with cultivated populations of GM oilseed rape and to accumulate transgenes. However, the Opinion considered that the contribution of feral oilseed rape plants in vertical gene flow “*is expected to be limited*”, as such populations are small compared to cultivated populations. And the Opinion found that “*there are no compelling data*” to suggest that the presence of an herbicide tolerance trait in a wild relative changes the behaviour of the wild relative “*so far*”. “*If needed*”, the use of other herbicides and/or adequate mechanical practices could be used to solve the problem of feral populations. The Opinion concluded that imports of genetically modified oilseed rape grains is anticipated to be low. Some of the transport to Austria “*are likely*” to be by boat, others by road or rail. The Opinion thus found that Austria had not submitted “any new data subject to scientific scrutiny or scientific information” that would change previous risk assessments.

77 EFSA Journal (2009) 1153, p.6; A similar Opinion was adopted on 15 June 2009 for oilseed rape GT 73, EFSA Journal (2009) 1151, p.1. The Commission did not yet take a decision in this case.

78 Opinion (Fn 77), section2.2.1.

79 Here and in the following text, in all texts put into italics, the emphasis was added.

(66) The Opinion did not with one word address eventual specificities of the Austrian environment, though Austria – as well as the EU – is Party to the Alpine Convention which declared the Alps to be an “outstanding unique habitat”⁸⁰. Moreover, Austria ratified the Protocol on the “Conservation of Nature and the Countryside” under this Convention⁸¹ and is thus bound by its provisions. The EU signed this Protocol in 1994. Under Article 18 of the Vienna Convention of the Law of the Treaties 1969, the EU is thus obliged “not to defeat the objective and purpose” of the Protocol. The Protocol mentions that the Alps constitute “extremely sensitive ecosystems⁸²” and states that “in huge areas, the ways and intensity of using the Alpine territory in recent decades have caused, and will continue to cause if perpetuated, irrevocable losses of elements of the landscape, biotopes and species worth preserving”⁸³. It argues that “the limited tolerance of the Alpine territory requires regulations and measures of a specific character for conservation and the restoring of the correct natural balance”⁸⁴.

(67) Article 9(1) of the Protocol obliges Parties to ensure that “any avoidable impairments do not occur”. Article 17 requests that no wild plant species are introduced that were not previously present naturally. And Article 18 of the Protocol provides for the release of genetically modified organisms only, when such release will not lead to any risk for the environment. Though the Alps do not cover the whole of the Austrian territory, the EFSA Opinion should have addressed potential specificities and in particular the question, whether there is not an increased risk for the fragile Alpine environment in Austria. The Opinion dismissed such an examination with the words that the “Austrian submission did not supply scientific evidence that the environment or ecology of Austria was different from other regions of the EU, sufficient to merit separate risk assessments from those conducted for other regions in the EU”⁸⁵. It is necessary to mention that the previous EFSA Opinion on a specific situation in Austria had only discussed, in a very summary form, the situation in the Land Upper Austria (Oberösterreich)⁸⁶. As the EFSA Opinion of 15 June 2009 discussed the ways of transport of genetically modified oilseed rape to Austria, it would have been

80 Alpine Convention of 7 September 1991. Austria ratified the Convention on 8 February 1994, the EU on 26 February 1996 (OJ 1996, L 61 p.31. All texts and data in footnotes 79 to 83 are taken from the website of the Alpine Convention, <http://www.alpconv.org/en/convention/protocols/default.html>.

81 Ratification of 10 July 2002.

82 Nature Protocol (n.80), Recital 3.

83 Nature Protocol (n.80), Recital 6.

84 Nature Protocol (n.80), Recital 12.

85 Opinion (fn 77), Overall conclusions and recommendations. The judgments of the EU General Court in case T-366/03, Land Oberösterreich und Österreich v. Commission, ECR 2005 p.II-4005 (paragraphs 65-67), and the EU Court of Justice in case C-439/05P, Land Oberösterreich und Österreich v. Commission ECR 2007 p.I-7141 (paragraphs 61-67) are not relevant, as they only discuss the question, whether the small size of farms and the organic production in the Land Oberösterreich constituted features which would require a specific risk assessment concerning GMO releases. The uniqueness of the Alpine environment is a much broader issue.

86 EFSA Opinion of 4 July 2003, EFSA Journal (2003), 1 p.1. EFSA Opinion of 8 July 2004 (EFSA Journal (2004) 78. 1-13) did not at all discuss the specificity of the Austrian environment, though this issue had been raised by Austria.

obliged, in this author's opinion, also to discuss the uniqueness of the Austrian Alpine environment.

(68) The environmental risk assessment of Directive 2001/18 requires that a worst-case scenario be assessed⁸⁷. In this sense, the Opinion should have assumed that there was a considerable amount of seed spillage in Austria, that a large population of feral oilseed rape populations spread into the environment which is "unique" at least as regards the Alpine parts of Austria, that the oilseed rape was able to establish stable populations for eight years or more, that the treatment of the affected land took place with glufosinate-ammonium-containing herbicide, that the feral oilseed rape thus gained a fitness advantage compared to conventional weeds, that the plants outcrossed and dispersed genes to Brassica rapa plants and that the populations served as reservoir which held and returned transgenes to cultivated populations in Austria at different places and at different times.

(69) As the risk management decision is to be taken by the EU institutions (the Commission), this worst-case-scenario⁸⁸ might have the potential of influencing the final decision on the Austrian decision to recur to a safeguard measure under Article 23 of Directive 2001/18, though such a decision had, until September 2013, not been taken.

(70) On 6 September 2012, EFSA adopted an Opinion on the prolongation of prohibition of the placing on the market of genetically modified oilseed rape event GT 73 for import, processing and feed uses in Austria⁸⁹. In section 4.2, EFSA examined the imports of viable oilseed rape seeds to Austria. It found that "because it is uneconomical to transport imported viable seed inland., it is mainly transported by boat to river-located ports". However, the question, whether a transport is uneconomical, does not yet determine that it does not take place. In the same way, EFSA's argument that viable oilseed rape is "mostly" processed on-site and has little travelling distance between the points of entry and processing does not allow any conclusion on the magnitude of the transport distance.

(71) EFSA stated that Austria imported, in 2010/2011 304.000 (274.705) tons of viable oilseed rape seeds, of which, according to a trade association, 5000 tons came from outside the EU. These figures omit to indicate how much of these seeds that came from other EU Member States were previously imported from third countries; such an indication would have been necessary, as the overall EU imports were over 9 million tons and Germany, Belgium, France and the

87 Directive 2001/18 (Fn 29), Annex II, C.2.2: "The magnitude of the consequences of each potential effect should be evaluated. This evaluation should assume that such an adverse effect will occur. The magnitude of the consequences is likely to be influenced by the environment into which the GMO(s) is (are) intended to be released and the manner of the release".

88 In the summary of its Opinion adopted on 6 September 2012, EFSA agrees in that Opinion that it is requested to assume a worst case, but does not take any consequence in this regard.

89 EFSA Journal (2012) 10(9): 2876. The Commission did not yet take a decision in this case.

Netherlands were the main importers. It cannot be excluded that genetically modified seeds were first imported to another EU Member State and then to Austria. For all these reasons, EFSA's conclusion that "(M)ost of this (viable oilseed rape seeds) was imported in bulk containers for processing in the main ports on the river Danube and connecting waterways. Little, if any, imported viable seed is currently transported overland away from these main ports and processing facilities" is not based on facts and not presented as a worst case scenario. Apart from that, the transport means and hence the possibilities of seed spillage may change.

(72) In section 5, EFSA examined the possibility that oilseed rape GT 73 seeds will escape through spillage. It stated that in areas where genetically modified oilseed rape is cultivated, widespread occurrence of feral genetically modified oilseed rape plants were found, along field margins of agricultural fields, as well as along transportation routes. It stated in particular that some of these plants had exhibited the presence of not only one tolerance trait, but of two (glyphosate *and* glufosinate-ammonium), though no genetically modified plant containing these two tolerance traits together was placed on the market in the USA or in Canada; these findings mean that the plants have outcrossed by themselves and transferred the tolerance trait to other plants.

(73) EFSA confirmed that also in Japan, where genetically modified oilseed rape is currently not cultivated commercially, up to 100% of the feral oilseed rape plants contained one of the two tolerance traits, "and to a lesser extent both traits". It continued by stating that extensive monitoring reports as those performed in Japan had not been reported for EU countries, and called for caution to extrapolate the Japanese data to the EU, where the receiving environment might be different.

(74) EFSA concluded that "(A)s the import volumes of viable oilseed rape seeds from outside the EU are minimal (section 4.2.2), the occurrence of feral GMHT oilseed rape resulting from seed import spills is likely to be low and mostly confined to port areas. Therefore, the environmental exposure due to GMHT oilseed rape seed imports is anticipated to be low"⁹⁰.

(75) As EFSA's EU import data are incomplete, this conclusion is not confirmed by the facts. Furthermore, a worst-case scenario would have required⁹¹ to fully apply the Japanese data to the Austrian situation.

(76) In section 6, EFSA examined the persistence of spilled oilseed rape GT 73 seeds outside agricultural fields as feral plants. It first stated, based on studies in Denmark, Germany, France and the United Kingdom, that the size of feral populations of oilseed rape varied, most populations containing 100 plants or less, but some ranging until over 1000 plants. Normally, the lifetime of populations was between one and four years, but could be longer, where human activities (mowing, herbicide application or soil disturbance) occurred. The persistence of a population in one location depended on the replenishment with fresh seed spills, the recruitment from seed emerging from the soil seedbank or the redistribution of feral seed from one location to the other. EFSA agreed that

90 GMHT means "genetically modified herbicide tolerance".

91 See Directive 2001/18 (Fn 29), Annex II, C.2.2.

the respective contribution of these input sources was unclear, and that few studies had been able to define the proportion of populations derived from fresh spills. The persistence of secondarily dormant seed might reach ten years or more. Though the data were not entirely consistent, EFSA accepted that feral populations in Europe were sufficiently consistent in their presence and abundance to act as a genetic bridge between past and present oilseed rape varieties. Though feral populations normally have a smaller seed yield than crop plants, the yield may reach up to 30-48% of that of crop plants and thus contribute to the replenishment of the seedbank.

(77) EFSA concluded that oilseed rape is capable of establishing self-perpetuating populations outside agricultural areas.

(78) In section 7 EFSA examined the gene flow from feral oilseed rape to other oilseed rape varieties. It agreed that oilseed rape was an outcrossing species with a potential to cross-pollinate other oilseed rape types. It was of the opinion that cross-fertilization levels “usually” decline very steeply with distance from one field to an adjacent or nearby field, but occurred at low frequency over several kilometers. Furthermore, EFSA resolved that feral plants can be cross-fertilized by commercially grown oilseed rape and have the potential of accumulating transgenes in areas where genetically modified oilseed rape is grown. It also accepted that stacking – this is the cumulative presence of two different tolerance traits in one plant – of herbicide tolerance traits in both volunteer⁹² and feral plants may take place. However, EFSA concluded then that “the most plausible source” for stacking under an import scenario was the cross-fertilization between plants having different herbicide tolerance traits in the country of origin (Canada, USA). This conclusion is once more in contradiction with the requirement to assume the worst-case scenario. And EFSA did not explain with one word, why such cross-pollination could not occur in the EU or in Austria, where also oilseed rape with different herbicide tolerance traits is placed on the market.

(79) EFSA concluded section 7.2.1.3 by stating that “it does not consider pollen dispersal and consequent cross-pollination as environmental hazards in themselves”. It is correct that the reaction to the potential of cross-pollination of plants is a question of risk management: the risk managers will have to decide, whether they accept that there are populations of plants in the environment that contain one or two – or one day several⁹³ – herbicide tolerance traits and which may cross-pollinate with other organisms⁹⁴. However, a wild plant that is, through genetic manipulation, tolerant to some herbicides, is a persistent plant: it has the capacity to survive in the environment.

92 A volunteer plant is a plant that moves from cultivated stage to an uncultivated stage, or from a controlled stage to an uncontrolled stage.

93 Benbrook (2012) p.1 reports that already at present companies place on the US market genetically modified plants which are herbicide-tolerant to eight different herbicides.

94 This problem reaches very far. The tolerance trait could also concern resistance to drought, to cold or to other characteristics. In the German public discussion, the “eierlegende Wollmilchsau” (a genetically modified pig that produces eggs, milk and wool) has reached some notoriety. This animal is not yet in our environment, as the present state of science is not yet that far, but the question is, where a stop should be made (“*principiis obsta*”).

(80) The feral-to-crop gene flow, according to EFSA, should be negligible compared to that from crop plants and volunteers. “The only exceptions to this might be where occasionally very large populations of feral plants (e.g., >10.000 plants) occur in derelict fields or around major construction work, adjacent to very small oilseed rape crop fields or oilseed rape certified seed production fields”. And the import scenario of the EU would make it “unlikely” that herbicide tolerance traits would enter agricultural fields and thus become cultivated unintentionally. A worst-case scenario would thus be, according to EFSA, a persistence of the initial introduced genetically modified herbicide tolerant oilseed rape plants with the consequences of an unintended cultivation of unapproved genetically modified plants, the subsequent gene flow to crop plants and stacking of herbicide tolerance traits and harvest admixtures. Nevertheless, EFSA followed some publications which conclude that “feral genetically modified herbicide tolerant plants resulting from seed import will have little relevance as a potential source of pollen or seed genetically modified admixture in conventional oilseed rape crops”. Once more, this conclusion did not take into consideration the worst-case scenario instruction of annex II to Directive 2011/18.

(81) In section 8, EFSA discussed the gene flow from feral oilseed rape to wild relatives. EFSA quoted one study to conclude that exposure under real conditions was likely to be negligible, and the probability of transgene introgression was extremely small in most instances, “with the exception of B.rapa to take place when oilseed rape and B.rapa grow in close proximity over successive growing seasons”. EFSA mentioned that incidences of hybrids and backcrosses with B.rapa had been found in fields in Denmark and the United Kingdom and a glyphosate tolerance trait persisted in Canada over a period of six years in a population of B.rapa. In Japan, where no cultivation takes place, transgenes were not detected in seed collected from wild relatives, and EFSA stated that very few other attempts were made to measure the transfer of genetic material from feral plants to wild relatives. This possibility “is likely to be very low”.

(82) In section 9, EFSA discussed the impact of herbicide tolerance traits on fitness persistence and invasiveness of feral oilseed rape and hybridizing wild relatives. It confirmed from tests in the United Kingdom that herbicide tolerant traits in oilseed rape did not confer a fitness advantage, unless the herbicide for which tolerance is obtained was applied. Whether this finding would be confirmed for other climatic conditions or situations is not indicated. EFSA found no evidence that genetically modified oilseed rape was more likely to survive, be more persistent or more invasive than conventional oilseed rape, or that herbicide tolerance traits in a wild changes its behaviour.

(83) As glyphosate herbicide is frequently used for the control of vegetation along railway tracks and in arable land, open spaces pavements or industrial sites, the glyphosate tolerance trait was likely to increase the fitness of plants which contain this trait. EFSA concluded: “Even in the worst case, considering data on gene flow, persistence and invasiveness, derived from cultivation, where exposure and potential impact are expected to be the highest, the EFSA GMO Panel could not identify scientific evidence to indicate any significant and imminent risk to the environment arising from the authorized uses of oilseed rape GT 73”. It needs to be mentioned though, that Article 23 of Directive 2001/18 does not allow safeguard measures to be taken only in the case of “significant

and imminent risk”, and that Article 34 of Regulation 1829/2003 mentions “serious risk” which need not be “imminent”, as EFSA pretends.

(84) EFSA’s conclusion does not either take into consideration that according to Directive 2001/18, the environmental risk assessment shall not only examine the immediate effects, but also the delayed effects, including the cumulative long-term effects⁹⁵. Seen from this perspective, EFSA would not only have to look at “scientific evidence”, but also at the possibility of the occurrence of worst-case scenarios.

(85) Such a worst-case scenario would include: there is a considerable spillage from genetically modified seeds during road and railway transport to Austria. The feral plants do develop persistence, as the herbicide to which they are tolerant, is largely used along roads and railways tracks. Some populations of feral plants are very large and generate gene flow to other varieties, including to wild varieties (*Brassica rapa*). The feral plants developed tolerance traits not only to one herbicide, but spontaneously also to other herbicides which was genetically introduced into plants. They developed thus considerable fitness advantage in the environment and became a significant weed.

(86) In conclusion⁹⁶, the EFSA risk assessment did not assess the potential impact of genetically modified oilseed rape GT 73 under a worst-case scenario and did not include in such a scenario all delayed and cumulative effects which might occur.

(87) A look at the Commission’s risk management decisions shows that the Commission relies very heavily on the risk assessment performed by EFSA. It is correct that Annex II to Directive 2001/18 explicitly suggests that EFSA also comments on risk management measures⁹⁷. EFSA is also asked to comment on the monitoring plan which the applicants submit. However, the fact remains that risk management measures do not come into the responsibility of EFSA, but into that of the EU institutions.

(88) In Decision 2009/184⁹⁸, the Commission’s decision to authorize genetically modified oilseed rape T 45 under Regulation 1829/2003 simply stated that “it is unlikely that the placing on the market (of T 45).. will have any adverse effect on human or animal health or the environment”⁹⁹, a statement which was a risk assessment statement that was up to EFSA. The Commission then took up the recommendation of EFSA to modify the monitoring plan submitted by the applicant¹⁰⁰ and declared finally “the EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific

95 Directive 2001/18 (Fn 29), Articles 4 and 13, and Annex II, Introduction.

96 Section 10 of the EFSA Opinion which deals with management issues, will not be discussed here.

97 See Directive 2001/18 (Fn 29), Annex II, C2 (5) and (6); Regulation 1829/2003 (Fn 30), Articles 6(5) and 18(5).

98 Decision 2009/184, OJ 2009, L 68 p.28

99 Decision 2009/184 (Fn 98), Recital 6.

100 Decision 2009/184, Recital 8.

conditions/restrictions for the use and handling, including post-marketing monitoring requirements, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas”¹⁰¹. No further explanation was given. The worst-case scenario was not taken into consideration and the precautionary principle was not mentioned.

(89) The Commission’s reasoning in Decision 2010/135 which concerned the authorization of a genetically modified potato¹⁰², was even shorter. The Commission only suggested that additional measures to monitor potato-feeding organisms in the fields and their vicinity should be put in place as part of the monitoring programme. Again, neither a worst-case scenario nor the precautionary principle was discussed.

(90) In Commission Decision 2008/495, where the Commission had to decide, whether it could accept a safeguard measure taken by Austria on genetically modified maize¹⁰³, the Commission did not with one word give any explanation as regards risk management, but only referred to the EFSA opinion and then asked Austria to repeal its safety measure.

(91) Commission Decision 2011/354 concerned the authorization for genetically modified cotton¹⁰⁴. The Commission referred in detail to the opinion of EFSA and then concluded, without any further assessment of that opinion its own: “Taking into account these considerations [of EFSA], authorization should be granted for the products”¹⁰⁵.

4.4 Comments

(92) A general consideration of legislation and practice will have to exclude the Convention on Biological Diversity and the Cartagena Protocol on Biosafety from the outset. Indeed, under both international Agreements, there are no decisions on GMOs taken. The Biosafety Clearing-House collects information on decisions which are taken by the Contracting Parties and the USA. The CBD has adopted a decision on guidelines concerning invasive species, but has not yet taken any decision, whether genetically modified plants or animals would fall into this category.

(93) Neither in the USA nor in the European Union does the possibility of retrieval play any role in day-to-day practice. Both regions accept implicitly that GMOs, once they are released into the environment, cannot be retrieved. The lack of the possibility of retrieval might influence decisions in the United States, for example on the authorization of deliberate releases of genetically modified animals (salmon); however, if such considerations play a role within the decision-making authorities, nothing is made public in this regard. In some of its risk assessment

101 Decision 2009/184 (Fn 99), Recital 13.

102 Decision 2010/135, OJ 2010, L 53 p.11.

103 Decision 2008/495, OJ 2008, L 172 p.25.

104 Decision 2011/354, OJ 2011, L 160 p.90.

105 Decision 2011/354 (Fn 104), Recital 7.

opinions, EFSA argues that genetically modified feral plants would not survive long in the wild; it recognizes, though, that such a survival was found to take eight to ten years; and in view of the overall limited time-span since GMOs in Europe were released into the environment, such statements are not necessarily final.

(94) In both the United States of America and the European Union, there is a general concern that genetically modified organisms should not harm human health or the environment, though the wording which is used differs. Genetically modified organisms are assessed before their release into the environment is authorized, and rules for the risk assessment are laid down in both regions. The provisions on risk assessment differ: in particular, the USA risk assessment is requested to also look at the economic advantage which the release of the GMO would bring, whereas the EU risk assessment does not contain any such provision. Moreover, the EU risk assessment explicitly requests the risk assessors to assume that unlikely events will occur, thus requiring an assessment of a worst case scenario. A corresponding provision is not found in the USA provisions.

(95) Both risk assessments examine in particular

- the potential escape of GMOs into the wild and a possible gene transfer to feral or wild relatives. According to EFSA, this risk appears low for herbicide tolerant maize or soybean or for Bt maize which do not have wild relatives in Europe. Also potato has no sexually compatible wild relatives in Europe¹⁰⁶. Though the risk of escaping into the wild and of gene transfer to feral or wild relatives is high for oilseed rape and sugar beet, EFSA also considered this risk to be very unlikely, in particular, because such genetically modified plants are not authorized to be cultivated within the EU.

(96) In the USA, EPA prohibited the sale and cultivation of genetically modified cotton in some regions, in order to avoid any gene transfer to feral plants or wild relatives¹⁰⁷. EPA apparently attached no attention to the escape into the wild of other genetically modified plants.

(97) Neither the risk assessments of EFSA nor those of EPA address the question, whether the prohibition of cultivating genetically modified plants or the construction of refuges is actually observed by farmers. Both bodies are of the opinion that a ban or a restriction will be respected by the persons concerned, though there are some – admittedly rare – examples that existing prohibitions were not respected¹⁰⁸.

(98) Neither in the USA nor within the EU is there any assessment of the risk of illegal exports of GMOs to third countries, where they could transfer gene traits to wild relatives. It is true that Regulation 1946/2003¹⁰⁹, the intellectual property rights of the company that markets the GMO and its contractual relations with farmers who use GMOs all have the objective to prevent such exports. However,

106 BEETLE (2009), p.50.

107 See above, paragraph 45.

108 See above, paragraph 49.

109 Regulation 1946/2003 (Fn 31, above).

to what extent such provisions are in practice fully respected, is unclear; no information exists in this regard. Outside the GMO sector, numerous cases are known of illegal exports of products, such as of pharmaceuticals, luxury consumer products, wastes, nuclear waste, endangered species, timber, ozone depleting substances, weapons and high-tech material. For this reason, it can never be completely excluded that GMOs, once they are released into the environment, are exported illegally and then escape into the environment. Indeed, the notion of “environment” is not limited to the EU environment; and the requirement of Directive 2001/18 that the release of a GMO into the environment must be “safe” for the environment, extends to the global, not to the EU environment¹¹⁰.

(99) - A gene transfer to microorganisms; such a transfer could also occur within the gastro-intestinal tract of animals that eat genetically modified feed, as EFSA continuously acknowledges itself. However, in the different assessments, EFSA considers the likelihood of such an event as low or very low. It is remarkable that when experts and representatives of stakeholders were asked on this likelihood, thirteen per cent were of the opinion that the existing data base was not sufficient to allow a conclusion, whether such gene transfer could occur and that this could have long-term negative effects¹¹¹. It is obvious that this divergence of view is to be solved by a risk management decision.

(100) - the effect of GMOs on target organisms; this aspect includes in particular the question, whether a plant pest may become resistant to the gene which was inserted into the plant. Both EFSA and EPA regularly consider this possibility. EPA provides for measures to slow down the development of resistance of pest animals, in particular by imposing as a condition of the authorization the installation of “refuges”¹¹². EFSA considers this risk as very low, as most authorizations in Europe are not granted for cultivation¹¹³. It is likely, though, that in long-term, pest insects will develop resistance also to genetically modified plants, in the EU thus in particular to genetically modified maize (Bt maize) which is cultivated in the EU.

(101) - The effects on persistence and invasiveness; this aspect includes in particular, whether feral plants or wild relatives to which the gene was transferred, obtain a fitness advantage with regard to other plants or weeds. It also includes the question, whether such an advantage can exist, when a feral or wild population has acquired two or several genes, for example on a tolerance towards a specific herbicide and on drought. Neither EFSA nor EPA were of the opinion that genetically modified plants had lasting negative effects with regard to persistence and invasiveness.

(102) Neither EPA nor EFSA considered the fact that feral plants or wild relatives to which a gene trait had been transferred, became herbicide tolerant, as a negative environmental effect, except in those cases, where the relevant herbicide is used

110 For the sake of doubt, it may be assumed here that the USA measures only have to ensure the safety of the US environment.

111 BEETLE(2009), p.79. Norway(2000), section 2.1 based its decision to prohibit the marketing of a genetically modified product also on the possibility of such a transfer.

112 See above, paragraph 47.

113 See above, paragraph 56.

outside the cultivated fields. This may lead to herbicide-resistant plants which create new problems: in the context of cultivation of GMOs, Benbrook reports of about two-dozen weeds in the United States that are herbicide-resistant and cause concern in anti-weed measures, increased use of new pesticides etc¹¹⁴. Moreover, the EFSA and EPA opinion is arguable: supposed, for one reason or the other, a genetic modification would lead to all trees having blue leaves, or all cows and pigs green eyes: such changes would interfere with the environment, without being a “harm” or constituting a loss of biodiversity or of other environmental advantage. In this author’s opinion, human-made interventions in the environment cannot be only assessed according to the question, whether the modification will bring about an ecological enhanced fitness. Rather, the risk management decision will have to take position on such other questions, all the more, as it is known how the traits might evolve and interact with the environment in future. This point will be further discussed below¹¹⁵.

(103) - the effects of changed agricultural practice. Where a genetically modified plant is herbicide-tolerant, the farmer may be inclined to cultivate more of this plant, because of the expectation of higher yields; or he may use the herbicide which created the tolerance more generously. Fields may also become larger, reducing thus biological diversity. In the case of insect-resistant crops (Bt maize), this may accelerate the resistance of pest animals; with herbicide-tolerant plants such practices may lead to increased herbicide use and to herbicide-resistant weeds¹¹⁶. In their risk assessments, neither EPA nor EFSA explicitly assess the long-term effects - extending over several generations - of such changes in agricultural practice, though EFSA has issued a number of general statements in this regard.

(104) The environmental risk assessment under Directive 2001/18 is very wide; it explicitly requires the assessment of direct and indirect, immediate and delayed effects, furthermore an analysis of the “cumulative long-term effects”¹¹⁷, and as the Directive provides that any risk that “might arise” should be “avoided”, implies that the presence of indirect risks should not be tolerated¹¹⁸.

(105) In the USA, all these effects are also assessed, though no explicit legislative provisions exist.

(106) On a more general point, the EU does not really follow its own law on the risk analysis of genetically modified organisms. Indeed, as regards the risk analysis, the General Court stated¹¹⁹: “[149]Risk assessment includes for the

114 Benbrook (2012) p.1.

115 See below, paragraphs 107 and 187.

116 See Benbrook (2012).

117 Directive 2001/18 (Fn 29), Annex II, introduction. This obligation also applies to environmental risk assessments under Regulation 1829/2003 (Fn 30), see Regulation 1829/2003, Article 2 no.4.

118 Christoforou (2007), p.202.

119 General Court, case T-13/99 Pfizer Animal Health v. Council, judgment of 11 September 2002, ECR 2002, p.II-3305, (emphasis added). It should be noted that this judgment concerned a human health issue. Thus, with regard to the present study, the words “human health” should be read as referring to “environment”.

competent public authority, in this instance the Community institutions, a two-fold task, whose components are complementary and may overlap but, by reason of their different roles, must not be confused. Risk assessment involves, first, *determining what level of risk is deemed unacceptable* and, second, conducting a scientific risk assessment of the risks. [150] As regards the first component, it is appropriate to observe that [151] *it is for the Community institutions to determine the level of protection which they deem appropriate for society. It is by reference to that level of protection that they must then, while dealing with the first component of the risk assessment, determine the level of risk - i.e. the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects - which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty. Therefore, determining the level of risk deemed unacceptable involves the Community institutions in defining the political objectives to be pursued under the powers conferred on them by the Treaty. [152] Although they may not take a purely hypothetical approach to risk and may not base their decisions on a 'zero-risk'..., the Community institutions must nevertheless take account of their obligation.. to ensure a high level of human health protection. [153] The level of risk deemed unacceptable will depend on the assessment by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge".*

(107) This statement, made with reference to the Commission's Communication of 2000 on the Precautionary Principle¹²⁰, clearly requires a political decision by the EU institutions what degree of risk related to GMOs is acceptable to the EU¹²¹. This decision is to be made, either *before* a risk assessment begins or at the stage of the risk management decision - i.e. on a case-by-case basis¹²². And it is important to emphasize that this basic political decision is an autonomous decision which is independent from the risk management decision which is taken in a specific case. Rather, the management in a specific case follows and has to follow the basic political decision what is an acceptable risk for society.

(108) Until now, neither the Commission nor the Council have ever explicitly taken any such basic political decision on the amount of risk which they are ready to impose on society, neither in a general, abstract manner nor in the context of a management decision linked to a specific case, following the risk assessment made by EFSA and the provisions of Directive 2001/18 and Regulation 1829/2003. The issue of this basic political decision by the EU institutions will further be discussed below, paragraphs 162ss.

120 Commission (2000), in particular section 5 (p.12) where this approach is called "prudential approach": "The prudential approach is part of risk assessment *policy* which is determined *before any risk assessment takes place*" (emphasis added).

121 Christoforou (2007), p.202; Fauchald (2007) 239; In a similar context, the United States Government, used the term "societal value judgment", see below, paragraph 202.

122 Christoforou (2007), p.201.

(109) As regards the risk assessment itself, Directive 2001/18 is quite clear¹²³: “It is important not to discount any potential adverse effect on the basis that it is unlikely to occur...This evaluation [the evaluation of the potential consequences of each adverse effect, if it occurs] should assume that such an adverse effect will occur”.

(110) However, the risk assessments made by EFSA do not identify the occurrence of unlikely events that could happen and do not assume that unlikely adverse effects will occur. And the risk management decisions - taken by the EU (the Commission)¹²⁴ - do not proceed to an own evaluation of EFSA’s risk assessment, but simply refer to the evaluation of that body.

(111) With regard to the situation in the USA, EPA’s individual decisions to authorize a genetically modified plant which is herbicide-tolerant or insect-resistant, are not made public. As EPA acts as risk assessment and risk management body at the same time, its practice can only generally be evaluated.

(112) Overall, the situation in the USA and the EU differs in particular with regard to two aspects: in the USA, genetically modified organisms (food, feed, plants and probably animals) are not considered to be inherently more risky than conventional food, feed and animals. Therefore, there is no specific US legislation on GMOs. In the European Union, GMOs are considered to bear new risks that require specific assessment and regulation, in order to control these risks and to prevent indirect or long-term negative effects on the environment and on humans.

(113) Furthermore, the USA agriculture relies heavily on the cultivation of genetically modified products. As experience with such cultivation is relatively recent - about fifteen to twenty years - long-term effects on health and the environment, including changes in agricultural practice, only become progressively visible. Such long-term effects are not in the specific focus of the US public authorities which are responsible for health and environmental issues related to genetically modified organisms. This is also strengthened by the fact that the risk assessment performed by EPA is explicitly required to weigh the economic advantage which the genetically modified organism may bring, a criterion that favours short-term considerations.

(114) In the European Union, cultivation of genetically modified organisms is, until now, limited to maize and potatoes. This reduces practical experience with the effects of GMOs on the environment, on changes in agricultural practice and on human health.

123 Directive 2001/18 (Fn 29), Annex II, C 2.1 and C.2.2.

124 It is generally accepted that monitoring conditions are part of risk management decisions and that these fall outside the responsibility of EFSA, see for example EFSA Opinion of 30 January 2008 on glufosinate-tolerant GM T45 oilseed rape for food and feed uses, EFSA Journal (2008) 635, section 5.2.2: “Monitoring is related to risk management, and thus a final adoption of the general surveillance plan falls outside the mandate of EFSA”.

5. The precautionary principle

5.1 General observations

(115) Among lawyers at global level, it is argued, whether there is or whether there should exist, in law, a “precautionary principle”. Sometimes, there is mention of a “precautionary approach”¹²⁵, sometimes some elements concerning the avoidance of impairment are quoted¹²⁶, which then leads others to argue that these elements are part of the precautionary principle. In particular in the United States, considerable opposition exists among lawyers, economists and public authorities to accept the existence of a principle of law that provides for precautionary measures; and it was the United States that opposed, at the Rio Conference 1992, the use of the term “precautionary principle” and insisted in the use of “precautionary approach”.

(116) In practice, though, the difference between the United States, the EU and other parts of the world are not considerable. Also the USA take measures to prevent the realization of certain risks, before the reality and seriousness of such risks becomes fully apparent, to a degree that is not, quantitatively or qualitatively, significantly different from that of the EU¹²⁷.

(117) Trouwborst¹²⁸ listed, in 2006, 58 international legally binding agreements which referred to the precautionary principle; since then, a considerable number of new agreements would have to be added to that list. The formulation of the principle differs. For this reason, it does not make much sense to discuss the precise content of the precautionary principle (or approach) in detail at this stage. Rather, there will be some discussion of the EU and the US theory and practice with regard to GMOs.

(118) EU legislation on the release of genetically modified organisms into the environment is based on the precautionary principle. This principle is mentioned in Article 191(2) TFEU, but not defined there. Directive 2001/18 on the deliberate release of GMOs into the environment mentions it several times, but does not define it either. Regulation 1829/2003 refers indirectly to it. Regulation 178/2002 on food law contains a definition¹²⁹. This definition clearly places the precautionary principle in the context of a risk management decision (“following an assessment of available information, ..provisional risk management measures.. may be adopted..”). In this, it follows the EU Commission’s general approach, where the Commission stated in a Communication of 2000¹³⁰:

125 See, for example, the Rio Declaration on Environment and Development, quoted in Fn 7, above.

126 See, for example, the CBD Convention, Recital 9, quoted in Fn 6, above, and the Cartagena Protocol of Biosafety, Article 10(6), quoted in Fn 9, above.

127 See Morrison-Wolfrum (2000); Myers (2000); Raffensperger – Barrett (2001); Wiener (2004); Hammitt and others (2005); Montague (2006); Wiener (2007); Sunstein (2008); Montague (2008); Wiener and others (2010).

128 Trouwborst (2006), p7; see also de Sadeleer (2002) p.94.

129 See Fn 32, above.

130 Commission (2000) section 5, p.12.

“application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environment protection or of human, animal and plant health may be in jeopardy. The Commission considers that measures applying the precautionary principle belong in the general framework of risk analysis, and in particular risk management”.

(119) As to the content of the precautionary principle, the Court of Justice stated in 1998¹³¹: “Where there is scientific uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks becomes fully apparent”. This wording was taken up by a series of other judgments by the Court itself as well as by the General Court which called the precautionary principle a “general principle of Community law”¹³². As regards EU law, this wording can be understood to reflect the content of the precautionary principle. It is in almost identical words taken up in the legal literature, by Member State legislation and by court jurisprudence within the EU¹³³.

5.2 The possibility of prohibiting releases

(120) The first question for the application of the precautionary principle is therefore, whether there is scientific uncertainty as regards the risk of environmental harm caused by the release of genetically modified organisms into the environment. In this regard, the aspects raised in Directive 2001/18, mentioned above in paragraph 29, will be used hereafter as a guideline. The fact that this different information is expressly asked for by the legislation, is an indication that such events are considered to constitute an adverse effect on the environment. And it is generally accepted in legal literature that the spread of GMOs into the environment, the transfer of genes to and the interaction with other organisms, taken separately or cumulatively, do constitute some “harm” to the environment, as these factors coming from genetic engineering and interfere with the natural environment.

(121) *The spread of GMOs in the environment.* It is accepted that GMOs may spread into the environment. This is particularly the case, where GMO plants are cultivated, but is not limited to crop GMOs. Scientific uncertainties concern the questions, to what extent GMO plants that escape into the environment, are capable to survive on their own, to spread and thus become a weed. This might also depend on the climate and the regional environment. Also, it is obvious that a genetically modified animal may spread into the environment. Its behaviour there, its survival possibility, its food and breeding habits are unknown, as long as such a release into the environment has not taken place.

131 Court of Justice, case C-157/96, Ministry of Agriculture, ECR 1998, p.I-2211 paragraph 63; case C-180/96 United Kingdom v. Commission, ECR 1998, p.I-2265 paragraph 99.

132 General Court, cases T-74/00, T-76/00 a.o., Artogedan a.o. v. Commission, ECR 2002, P.II-4945, paragraph 184.

133 See generally on this Trouwborst (2003).

(122) GMOs may also spread into the environment, where cultivation is prohibited, as at present for most plants in the European Union. For such genetically modified plants, EFSA regularly examines the accidental release into the environment of viable seeds or grains during their transport and processing, as well as through the manure and faeces of animals that were fed with genetically modified feed. Uncertainty consists on the one hand, whether such accidental spillages take place, how frequent they are, whether they may generate wild populations of genetically modified plants whether these populations can survive and spread further. With regard from GMOs entering the environment through animal faeces and manure, the same uncertainties exist.

(123) *The transfer of the inserted genetic material to other organisms, or the same organism whether genetically modified or not.* It is well known and documented that genetically modified plants may cross with wild relatives. Within the EU, this is in particular the case with oilseed rape, where wild relatives exist. In other parts of the world, the transfer of gene traits from maize to wild relatives was observed¹³⁴; cotton was restricted from use in the USA, because of that risk. In the USA, also creeping bentgrass and sugar beet were observed to have escaped into the environment and transferred gene material to other organisms.

(124) *Phenotypic or genotypic stability.* There is little knowledge about phenotypic or genotypic stability of genetically modified plants. This is in particular due to the relatively short time of fifteen to twenty years that genetically modified organisms are released into the environment and the fact that a considerable amount of research is financed by the companies that are interested in biotechnology. At present, no certain statements can be made in this regard.

(125) *Interaction with other organisms.* It is claimed that genetically modified plants which are insect-resistant or herbicide resistant, produce greater yields, at least at short term. This may increase profits for farmers and biotechnology companies. However, it is certain that the development of herbicide resistance weeds and of pest insects leads to higher use of herbicides which takes away part or all of the profit of farmers. The precise evolution and speed of this resistance evolution is not known. Non-target organisms will also be affected, though it is uncertain which organisms (microorganisms, larvae, soil organisms, bees, wasps etc). Overall, biodiversity is at risk of being reduced, where genetically plants are cultivated, also due to a more extensive use of herbicides. Long-term effects are not well known.

(126) It may be presumed that genetically modified animals would interact with other animals, though no commercial release into the environment appears to have taken place until now.

(127) *Changes in management practice (land use), including in agricultural practice.* There is considerable uncertainty as regards changes in management practice, as such changes also depend on a number of socio-economic factors, such as the price of genetically modified seed, the price of herbicides, the presence of organic agricultural activity, consumer taste and preferences, climate

134 See Center for International Environmental Law – defenders of Wildlife (2003), Convention on Biological Diversity (2008); Global Citizens Report (2011); the observations are contested.

and regional specificities etc. Farmers appear to have a tendency to cultivate genetically modified plants in increasing quantities, for reasons of scale and increased profit; this may favour monocultures, the loss of biodiversity, promote resistance in weeds and pest animals, reduce organic farming activities.

(128) Overall, there is a very considerable amount of scientific, technical and factual uncertainty linked to the release of genetically modified organisms into the environment.

(129) This statement on uncertainties is confirmed by the present state of knowledge concerning long-term effects of GMOs in the environment. Long-term effects of GMOs were considered, by Directive 2001/18, to be of particular importance: “A general principle for environmental risk assessment is also that an analysis of the ‘cumulative long-term effects’ relevant to the release and the placing on the market is to be carried out. ‘Cumulative long-term effects’ refers to the accumulated effects of consents on human health and the environment, including, inter alia fauna and flora, soil fertility, soil degradation of organic material, the feed/food chain, biological diversity, animal health and resistance problems in relation to antibiotics”¹³⁵.

(130) As regards the existing uncertainties of potential *long-term effects* of the release into the environment of genetically modified organisms, the BEETLE study of 2009, made for the European Commission, is of particular importance¹³⁶. This study analyzed more than 700 scientific publications from all over the world about GMOs and their potential effects on environment including biodiversity, and received contributions to online surveys from 100 to 167 invited environmental experts representing a wide range of knowledge with a focus on the EU¹³⁷. The study declared:

(131) *Increased fitness of the GM plant* (section 5.1.1.1, p.50): “Data in the literature are scarce with respect to long-term effects on increased fitness (resulting in higher persistence) of GM crops or GM hybrids. Currently, information for the ERA [environmental risk assessment] needs to be derived from analogous data on the behaviour of conventional crop varieties selected e.g. for salinity or drought resistance... Based on the 31 publications evaluated, the likelihood for increased fitness for the currently used GM crops in the EU is: high for herbicide tolerant (HT) oilseed rape or HT sugar beet in complementary herbicide crop rotations and in non-agricultural habitats being applied with the herbicide, and negligible for HT maize, HT soybean, SM potato or BT maize..”.

(132) *Outbreeding depression after hybridization with wild relatives* (section 5.1.12, p.52)¹³⁸: “Data on the mechanisms of “outbreeding depression” are rarely found in the GM crop literature, as these are ‘natural’ phenomena of in crop breeding”.

135 Directive 2001/18 (Fn 29), Annex II, introduction, last subparagraph.

136 BEETLE (2009), in particular p.49ss.

137 BEETLE (2009), p.30.

138 “Outbreeding depression” means that the progeny from crosses between individuals from different populations have lower fitness than progeny from crosses between individuals from the same population.

- (133) *GM crop/feral/wild hybrid persistence* (section 5.1.1.3, p.53) “So far no clear rules can be derived concerning outcrossing between related species and the fate of a transferred GM trait”.
- (134) *Altered flower phenology* (section 5.1.2.2, p.55) “studies demonstrating an introgression of GM traits from oilseed rape or sugar beet into compatible wild relatives did not measure, report, or assess possible changes in pollination success up to now”.
- (135) *Altered fecundity increasing seed (gene) flow* (section 5.1.2.4, p.56): “For HT crops with wild relatives in our flora increasing fecundity could only occur if the herbicides would be applied outside of fields. However, there are no reports published on such a phenomenon”.
- (136) *Increased frequency of horizontal gene transfer (HGT)*(section 5.1.2.5, p.56): “this effect was not observed in the environment so far”.
- (137) *Resistance development of pests* (section 5.1.3.1, p.57): “It is likely that in the long-term pests or pathogens will also develop resistance against GM-crops designed to protect against pests and pathogens. Summarizing the available literature, resistance development by lepidopteran species against BT-protein was not observed in Europe until 2007”
- (138) *Effects on non-target organisms(NTO)* (section 5.1.4, p.59): “ an inherent uncertainty remains to extrapolate from short term ecotoxicological experiments on long-term environmental effects. In particular, the observed sublethal effect could have the intrinsic potential to affect NTO in the long run”.
- (139) *Effects on NTO due to altered nutritional composition of the GM plant* (section 5.1.4.2, p.60): “very few studies presently support any assumption for herbivorous insects favouring GM in contrast to non-GM plants.. Consequently, data regarding altered herbivore attractiveness of GM crops with changed nutritional composition are scarce.. Altogether, there is a lack of experience so that the knowledge of potential long-term effects remains poor, which results in identified uncertainty”.
- (140) *Effects on NTO due to accumulation of toxic compounds* (section 5.1.4.4, p.61): “short-term studies showed so far that fate of Bt proteins in the soil is not fully understood in the low concentration range... it is still unclear whether soil persistence processes could be more important and could lead to long-term effects on soil organisms and soil ecofunction”.
- (141) *Effects on rhizosphere microbiota* (section 5.1.4.5, p.61): “data are only available from short-term experiments and predictions of potential long-term effect are difficult to make. More than 10% of the experts emphasized that the available data basis is insufficient, in particular for the issue of rhizosphere organisms (17%) or mycorrhiza (17%). This is an important uncertainty”.
- (142) *Effects on symbiotic NTO* (section 5.1.4.6, p.62): “in several cases more than 10% of the experts emphasized that the available data basis is ‘insufficient’, for the issue of mycorrhiza 17% of the respondents were concerned about insufficient data”.

(143) *GM traits may cause changes on soil functions* (section 5.1.5.1, p.63): “From these limited studies, the impact of BT proteins on soil processes seems to be small. Because of the wide range of methodological techniques used and because many aspects regulating soil communities are still not sufficiently understood, it is difficult to extrapolate results of effects on special taxa or communities to whole ecosystem processes, and even more difficult to make predictions about long-term impacts. This is an important uncertainty”.

(144) *Effects on biological control* (section 5.1.5.2, p.63): “To what extent the ecological function, i.e. the control of a pest, is affected by slightly decreased population densities of the natural enemies, remains unclear and may not be simply deduced from abundance frequencies of the natural enemy species”.

(145) *Altered use of agrochemicals* (section 6.1.6.1, p.66): “GM plant cultivation and management could potentially cause increased/altered use of agrochemicals controlling herbicide tolerant weeds, and persistent GM crops (volunteers) with adverse effects on NTO and/or ecological functions.. The expert contributions were characterized by a high number of answers in the assessment option -‘insufficient data’ or ‘no expert’ in general. One reason could be that the data basis for the assessment is deficient... High uncertainty was expressed in particular for cases regarding the use of HT-GM plants with the complementary herbicide”.

(146) *Indirect changes in susceptibility of crops against plant pathogens* (section 5.1.6.2, p.67): “The expert contributions were characterized by a high number of answers in the assessment option ‘insufficient data’ or ‘no expert’ in general.. This indicates a high level of uncertainty”.

(147) *Adverse effects on agro-biodiversity* (section 5.1.6.3, p.68): “The expert contributions were characterized by a high number of answers in the assessment option ‘insufficient data’ or ‘no expert’ in general.. So there is still some uncertainty about this area”.

(148) *Indirect changes in fertilizer use* (section 5.1.6.4, p.68): “the expert contributions were characterized by a high number of answers in the assessment option ‘insufficient data’.. or ‘no expert’..”

(149) *Potential changes in landscape structure* (section 5.1.6.5 p.68): “The expert contributions were characterized by a high number of answers in the assessment option ‘insufficient data’ or ‘no expert’..”

(150) *Increased production of greenhouse gases* (section 5.1.7.1, p.69): “Literature data are very limited with respect to long-term impacts of GM crops on climate change”.

(151) *Increased mineral nutrient erosion and fertilizer leaching* (section 5.1.7.2, p.79): “Literature data are limited with respect to long-term impacts of GMN crops on soil mineral nutrients... a noteworthy number of experts (29%) felt that they did not have sufficient expertise to answer the questions in this category”.

(152) *Altered chemical attributes of soil fractions* (section 5.1.7.3, p.70): “available literature data are limited with respect to long-term impacts of GM crops on chemical soil attributes”.

(153) *Stacked events* (section 5.1.81., p.71): “ Although stacked events have been cultivated for about 10 years, very little research has been published and investigations addressing potential long-term effects are missing”.

(154) *Regional aspects* (section 5.1.9, p.72): “For each group of processes mentioned in the sections above [5.1.1 - 5.1.7], the experts were asked .. whether the assessment needs differentiation concerning geographical regions in Europe.. Within eight of 23 cases, the majority (>50%) of experts answered ‘yes. In 10 cases, the answers were ambiguous. Accordingly, there seems to be a need for more regional approaches within the assessment, since the expert majority agreed or felt uncertain. This is mainly true for invasiveness, persistence, seed survival, and hybridization issues”.

(155) The cumulative effect of these comments on the present state of knowledge about long-term effects - extending, be it repeated, over several generations - of releases of GMOs into the environment is that a positive affirmation, according to which the release of GMOs into the environment is “safe for the environment”, as Directive 2001/18 requires, is simply not possible. The main reason for this conclusion is that the time-span between the beginning of such releases and September 2013 is too short to gain sufficient scientific certainty on all potential long-term effects of GMOs. Also the unintended or cumulative effects of GMOs which lead to a slow and gradual effect in the receiving environment and which only become apparent after several years, must be taken into consideration. The situation of uncertainty is accentuated by the fact that numerous publications, studies and research on GMOs are financed by commercial companies or bodies; it cannot be excluded, therefore, that not all scientific findings which indicate negative effects of GMO releases are published and that research of some potential areas of concern is not being undertaken.

(156) In view of these uncertainties, the question which the EU institutions as risk management deciders will have to answer, is the question which kind of risk they consider acceptable for the (EU) society which mandated them to take management decisions¹³⁹. In other words, are the uncertainties, sketched out in the preceding paragraphs, so relevant that GMO releases into the environment or GMO placing on the market should not take place?

(157) An answer to that question has not yet been given by the mere fact that the EU adopted Directive 2001/18 and Regulation 1829/2003, as this legislation explicitly requires that any such release must be preceded by a risk assessment and followed by a risk management decision. The fact that the EU allowed, during the last fifteen to twenty years, the release into the environment and the placing on the market, without cultivation, of a number of GMOs, is equally not a decisive factor.

(158) One issue to consider in this respect is, whether the fact that genetically modified plants may escape into the wild, survive there and build feral and later wild populations which could not be retrieved any more, could induce the EU management deciders to prohibit the marketing of GMOs altogether. EFSA declared on several occasions that “it does not consider the occasional occurrence of feral genetically modified herbicide-tolerant oilseed rape plants as

139 See paragraphs 107 and 187.

an environmental hazard in itself”¹⁴⁰. It had already been mentioned, though, that it is up to the risk managers to take a decision, whether the gradual change in the environment, caused by the introduction of genetically modified persistent living organisms might lead to a slow, but progressive change of the natural environment, with eventually possible unintended effects¹⁴¹.

(159) Any such decision by the EU management decision-making body is influenced by economic, social, cultural and in particular political considerations¹⁴². Legally, under Directive 2001/18 and Regulation 1829/2001, any answer is possible. EU legislation does not require that the release into the environment of a genetically modified plant or animal be authorized under all circumstances. Rather, the overriding consideration is, whether the GMO is safe for the environment and whether *all* measures are taken to *avoid* adverse effects on the environment¹⁴³. In particular Regulation 1829/2003 specifies in this regard that the management decision of the EU (Commission) shall take into account “the opinion of [EFSA], any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration”¹⁴⁴; the same considerations apply to decisions under Directive 2001/18.

(160) There can be no doubt that in view of the strong emphasis which EU law in general and the EU legislation on GMOs in particular put on the precautionary principle, the precautionary principle constitutes such a legitimate factor. It allows the EU institutions, in the case of uncertainties, to “err on the safe side” and to take measures in order to prevent a gradual progressive change in the natural environment through the introduction of GMOs.

(161) In conclusion the EU institutions are legally entitled to declare that there are numerous scientific and technical uncertainties concerning the release of GMOs into the environment which do not allow the affirmation that the release of GMO into the environment is “safe for the environment”. These uncertainties concern in particular the

- increased fitness of GM plants;
- outbreeding depression after hybridization with wild relatives;
- outcrossing between related species and the fate of a transferred GM trait;
- altered flower phenology;
- altered fecundity, increasing seed (gene) flow;

140 EFSA Opinion of 6 September 2012 on a request from the European Commission related to the prolongation of prohibition of the placing on the market of genetically modified oilseed rape event GT 73 for import, processing and feed uses in Austria; EFA Journal (2012) 10(9): 2876, with further references.

141 See also paragraphs 107 and 187.

142 Commission (2000), section 5.2.1; de Sadeleer (2002) p,197 : « The question of what society should do in the face of uncertainty regarding cause and effect relationships is necessarily a question of public policy, not science”; similarly p.178. Bachmann-Mansuy (2002), p.72.

143 See paragraphs 20 and 25, above.

144 Regulation 1829/2003 (Fn 30), Article 7(1).

- increased frequency of horizontal gene flow;
- resistance development of pests;
- effects on non-target organisms;
- effects on non-target organisms due to altered nutritional composition of the GM plant;
- effects on non-target organisms due to accumulation of toxic compounds,
- effects on rhizosphere microbiota;
- effects on symbiotic non-target organisms;
- changes in soil functions caused by GM traits;
- effects on biological control;
- altered use of agrochemicals;
- indirect changes in susceptibility of crops against pathogens;
- adverse effects on agro-biodiversity;
- indirect effects in fertilizer use;
- potential changes in landscape structure;
- increased production of greenhouse gases;
- increased mineral nutrient erosion and fertilizer leaching;
- altered chemical attributes of soil fraction;
- emerging of stacked events;
- the necessity of regional differentiation of risk assessments.

5.3 The obligation to prohibit releases

(162) The further question to be answered is, whether in view of the existing uncertainties, the precautionary principle *requires* the prohibition of releases of GMOs into the environment.

(163) It was mentioned above, paragraph 119, that the precautionary principle in the formulation of the EU Court of Justice *allows* the taking of action. The formulation of the Court does not *oblige* public authorities to take action. However, this might also be due to the fact that the Court was not yet confronted with a situation where an obligation to take action became relevant. Therefore, it is necessary to analyze in more detail the content and effects of the precautionary principle in EU law.

(164) Where States have a right to take action, they also have, under specific circumstances, the obligation to take action, mainly in situations, where the

discretion to act is reduced, because of the importance of the societal values which would be impaired when no action is taken. This concept of law, though, does not need be elaborated here in too great theoretical details. As regards the precautionary principle and the release of GMOs into the environment, the right and the obligation to take action in order to prevent the realization of harm to the environment depends on the questions, of how likely to realization of harm is and how serious or irreversible the environmental harm is, should it occur¹⁴⁵.

(165) Where harmful effects are certain, the public authorities of the EU and of the EU Member States have, under existing EU primary and secondary law, an obligation to prevent such damage. On the contrary, where harmful effects may practically be excluded, there is no such obligation, and even the right to take preventive action may be doubtful, as the proportionality principle allows the taking of measures that are *necessary* to reach an objective, but does not allow to go beyond.

(166) Practical experience all over the world shows that genetically modified plants can escape and do escape into the environment, build feral and later wild populations, transfer genes to other organisms etc. For the European Union, this risk exists – if it has not materialized already – in particular with regard to oilseed rape and sugar beet, plants which have wild relatives in Europe; there might be other genetically modified plants tomorrow – poplars, other trees, strawberries, tomatoes, rice – which will be released into the European environment. The likelihood of oilseed rape and sugar beet is, for the European environment, greater than for maize, cotton, or potatoes which do not have wild relatives or sexually compatible plants in Europe; however, until now, neither oilseed rape nor sugar beet were authorized to be cultivated in Europe.

(167) More generally, the likelihood of harm to the environment by GMOs becomes very obvious, when one thinks of genetically modified animals (salmon, fleas, bees, mosquitos etc), as obviously such genetically modified animals have even greater opportunities to escape into the environment than plants. The likelihood that GMOs will enter the environment also in Europe is thus relatively great, in particular, when a medium- or long-term perspective is taken.

(168) As regards the degree of risk, the existence of genetically modified plants or animals in the natural environment constitutes a *serious* risk. The spread of GMOs into the environment is not a local event, but is capable of having a wide geographical dispersion. Such organisms will have long-term effects on the environment, as they will persist in it and lead a life of their own. The duration of the risk is thus, theoretically unlimited. And the release into the environment, once it is achieved, is *irreversible*: the GMOs cannot be retrieved or taken back. Again, this is more obvious with genetically modified animals than with plants (weeds), though the principle is the same for both plants and animals.

(169) There appears to exist a relatively large consensus among lawyers and scientists that the spread of genetically modified plants and animals into the environment constitutes a serious and irreversible risk for the environment. Depending on the likelihood of the realization of this risk, the public authorities in the EU have thus the right or even the obligation to prevent its realization.

145 See for the following in particular Trouwborst (2006) p.287ss.

(170) In paragraph 164, above, it was noted that the precautionary principle allows and in certain circumstances even obliges public authorities to take measures, in order to prevent the realization of the perceived risk. However, this does not mean that once it is found that there is a serious and/or irreversible risk to the safety of the environment, public authorities are completely free to decide on measures which they apply. As the precautionary principle, in the present context, is a principle of EU law, its application also depends on a number of other general factors and principles of EU law which public authorities will have to respect¹⁴⁶. The reason for this interdependency of the precautionary principle with other principles of EU law lies in the fact that the precautionary principle is not a legal provision, but is a *principle* which is embedded in the general frame of EU law.

(171) The first aspect to be taken into consideration is that the measure must be capable of containing or eliminating the risk; it must be effective. This issue constitutes a difficulty, as genetically modified organisms are cultivated and released into the environment in all parts of the world. Even a measure by the EU to prohibit the cultivation and the import of genetically modified products would not be able to prevent that in other parts of the world, GMOs spread into the natural environment and form new phenotypes or genotypes, changing thus progressively the planet's environment.

(172) However, this reasoning does not prevent the public authorities in the EU from taking action. Indeed, as long as there is no global environmental decision-making institution, each society is in charge of taking the measures to protect the environment which it considers necessary and appropriate. The discussions on climate change, ozone-depletion, endangered species etc. are obvious examples for this present state of law in environmental matters. At the same time, these examples demonstrate that EU measures need not necessarily be limited to protect the EU environment. As the environment knows no frontiers, there is no limitation to the EU protecting elephants in Africa or taking measures to fight global climate change. It is irrelevant for the EU measures, whether other countries adopt similar measures or not.

(173) The management measure may not constitute an *arbitrary* measure. There must be a sufficiently great likelihood of a risk for the safety of the environment, if no measure were taken and to avoid any sort of protectionism in favour of indigenous farmers or plants. And the measures must be *consistent* with other measures taken by the competent public authorities in order to ensure the protection of the environment and human health. - From what was stated in paragraphs 166 above, this likelihood of risk to the environment caused by the uncontrolled spread of GMOs in the environment appears obvious and does not need further elaboration.

(174) The management measure must be *proportionate*. The proportionality principle is, as regards the actions by EU institutions, explicitly laid down in Article 5 of the Treaty on European Union (TEU)¹⁴⁷. However, it also applies to

146 Commission (2000), section 6.3 p.17ss.

147 Article 5(4) TEU: "Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the

actions by public authorities of the EU Member States, when - as in the present case of GMO law - they act in implementation or execution of EU legislation. The principle requires that the measures taken make it possible to achieve the appropriate level of protection, but do not go beyond of what is necessary to reach this objective. "(T)he potential long-term effects must be taken into account in evaluating the proportionality of measures in the form of rapid action to limit or eliminate a risk whose effects will not surface until ten or twenty years later or will affect future generations. This applies in particular to effects into ecosystems. Risks that are carried forward into the future cannot be eliminated or reduced except at the time of exposure, that is to say immediately"¹⁴⁸.

(175) Monitoring environmental effects of GMOs after their release is a measure which is less restrictive than an outright ban of their release. Directive 2001/18 provides for such monitoring in Article 20, but remains general: the notifier shall be obliged to monitor the release "according to the conditions specified in the consent" and shall report on the monitoring to the Commission and the Member States. Similar provisions are found in Articles 9 (food) and 21 (feed) of Regulation 1829/2003, except that the post-market monitoring is not compulsory under that Regulation. The monitoring reports under Regulation 1829/2003 shall be made public. Practice shows that the EU institutions - in almost all cases this is the Commission - normally follow the comments made by EFSA on the monitoring projects of the notifier. Apart from its monitoring reports, there is no real control, by inspectors or otherwise, of whether the monitoring plans were sufficiently comprehensive or whether they were complied with. Furthermore, the monitoring of the release of a specific GMO into the environment will not be able to discover all the existing uncertainties linked to such a release and which were mentioned in paragraph 29, above. It is therefore concluded that monitoring the release of GMOs into the environment does not systematically constitute an appropriate, but less restrictive alternative to a complete ban of releases.

(176) The Commission is furthermore of the opinion that the *advantages* and *inconvenients* of the measure or its omission need to be considered. This term "advantages and inconvenients" is broader than the term "costs and benefits" which is found, though in the English version only, in Article 191 TFEU. It includes all societal advantages and disadvantages¹⁴⁹, thus also aspects of human health, the interference of GMOs in the natural environment, the development of resistant weeds and animals, the dependency of farmers from the seed supplies by commercial companies, the fact that genetically modified food and feed does not lead to the elimination of hunger in the world which is a problem of food distribution rather than of food production, the already existing overproduction in EU agricultural products etc. It goes beyond the scope of this study to examine all these elements in detail. However, it is obvious that a risk management decision on GMOs has enough arguments to demonstrate that the inconvenients of GMO releases outweigh the advantages of this technology.

(177) With regard to EU measures it was already mentioned that there is a difference in the degree of risk of an uncontrolled spread of GMOs into the

Protocol on the application of the principles of subsidiarity and proportionality".

148 Commission (2000), p.17s.

149 De Sadeleer (2002), p.199.

environment. Such a risk is apparently highest, where genetically modified animals are concerned. Fish which is cultivated in aquaculture, regularly escapes into the wild, and land cultivation of fish or other containment measures do not appear able to limit the long-term risk of uncontrolled spreading of GMOs into the environment to a reasonable degree.

(178) For domesticated animals – cows, goats, pigs etc – the question is more difficult to answer, as such animals would not spread in an uncontrolled way in the environment. In legal terms, this difference between animals is expressed by EU law differentiating between “life and health of animals and plants” on the one hand, the “protection of the environment” on the other hand¹⁵⁰, though some overlapping between these categories exists. As domesticated animals are in closer relation to humans, the question, whether genetically modified domesticated animals should be allowed to be marketed, touches more closely also ethical aspects. For this reason, the proportionality principle would allow a decision according to which there should be a prohibition to allow a release of all genetically modified animals. However, it would also allow a differentiation between domesticated animals and other animals. The political question remains to what extent the EU society should accept genetically modified animals in the environment.

(179) With regard to plants, this last question is posed in the same way: shall society accept that genetically modified plants enter the wild environment and build populations? As mentioned, EFSA answered that such plants do not constitute an environmental harm¹⁵¹; however this is the answer of risk assessors which cannot substitute the risk management decision.

(180) It is questionable, whether a difference should or could be made between those genetically modified crops which have wild relatives in Europe (in particular oilseed rape and sugar beet) and other plants. Obviously, the risk of outcrossing is greater for the first category of plants; on the one hand, however, their cultivation is not yet authorized at EU level and the field trials in the EU Member States appear of a limited scale. On the other hand, genetically modified maize and potatoes have wild relatives in other parts of the world, so that gene transfer in the environment (beyond the EU borders) might occur, for example in the follow-up of authorized, incidental or illegal exports of GMOs.

(181) A number of legal writers are of the opinion that where there is a risk of serious or irreversible damage, the precautionary principle *obliges* public authorities to take action in order to prevent the risk to be realized¹⁵². The arguments which are advanced concentrate on the fact that the damage, once it occurred, cannot be repaired, but remains in permanence.

150 See for example Article 36 TFEU and the jurisprudence of the Court of Justice in this regard.

151 See the quotation in paragraph 79, above.

152 Unesco (2005) p.13; Bugge (2007), p.117 (“ duty for the authorities to avoid serious or irreversible risks”). Trouwborst (2006) p.158, p.276 and p.287 formulates as follows: „wherever, on the basis of the best information available, there are reasonable grounds for concern that serious and/or irreversible harm to the environment may occur, effective and proportional action to prevent and/or abate this harm must be taken, including in situations of scientific uncertainty regarding the cause, extent and/or probability of the potential harm“. See also de Sadeleer (2007b), p.35.

(182) These arguments were mainly developed in theory, without specifically addressing the questions of GMOs. They are not shared here as regards the release of GMOs within the European Union. Indeed, it was stated above, paragraph 106s, that the decision which level of risk is acceptable with regard to GMOs - be this a decision which is taken in general and in abstract, or be this a decision in the context of a specific case (risk management decision) - is a political decision which reflects a choice of society with which risk it wants to live. In the same way as a society may decide that it does not wish to recur to nuclear energy or that it does not wish to tolerate the drinking of alcohol - Saudi Arabia is such an example - it may decide that it does not wish to accept GMO releases into the environment. However, it is not possible, on the basis of the precautionary principle alone to appeal to a court of justice and claim that the use of nuclear energy or of alcohol drinking must be forbidden.

(183) There are other similar examples. Climate change and the rising temperatures, rising ocean levels etc constitute without doubt a serious and irreversible risk which might lead to the disappearance of a number of countries - in particular of island States -, to the rise of oceans and other irreversible adverse consequences for humans and for the environment. Yet it is not legally possible to recur to the precautionary principle and oblige a State or a Community of States to take specific, concrete actions in order to fight climate change. Another example is the loss of biological diversity, a global phenomenon: it is legally not possible to invoke as the only argument the precautionary principle - the need to prevent the serious and irreversible damage caused by the progressive loss of biodiversity - and ask a State or a Community of States to take a specific action to protect biodiversity.

(184) Rather, in all these examples, public authorities have to take a political decision which is embedded in a specific legal, social, economic and cultural context and depends on the choice which the respective society has made. The natural environment does not have rights in the EU or EU Member States' legal order which would allow it to defend its integrity against any interference of genetically modified animals or plants. The final decision on the authorization to allow the release of GMOs into the environment is thus a *political* decision, not a decision which is deduced from a legal rule or - as in the present case - from a legal principle¹⁵³.

(185) This reasoning also applies to the question, whether the precautionary principle obliges States - or the EU - to prohibit GMO releases into the environment. It is up to a policy decision, whether such prohibition shall be established. The EU Member States, by adopting the GMO-legislation at EU level, transferred this decision to the EU institutions. And up to now, the EU institutions considered that a restrictive practice of authorizations - few decisions on the cultivation, no authorization to release genetically modified animals, -, detailed

153 Commission (2000), section 7(p.21): "the decision to act or not to act... is of an eminently political nature, and the measures resulting from recourse to the precautionary principle, which must comply with the general principles applicable to all risk management measures". Daemen (2003) p.10; Scott (2004) p.72; Perez (2005) p.170; Fauchald (2007), p.238; Christoforou (2007), p.201; de Sadeleer (2002) p.178; de Sadeleer (2007b) p.32.

environmental risk assessments by a scientific body (EFSA), and the monitoring of GMO-releases would constitute a proportionate means to limit the risk.

(186) No argument for an obligation to prohibit the release of GMOs into the environment can be drawn from the fact that Directive 2001/18 and Regulation 1829/2003 both provide for a maximum authorization period of ten years¹⁵⁴. Indeed, where a substance or a product requires, under EU law, an authorization, this authorization is given for a limited time. Examples are pesticides¹⁵⁵, biocidal products¹⁵⁶, or chemical substances¹⁵⁷. Even for industrial installations which obtain a permit, the relevant EU legislation provides that the permit conditions are regularly updated¹⁵⁸. The 10-year delay in the EU biotechnological legislation was thus not introduced, because GMOs cannot be retrieved, but because they might cause – as any hazardous substance, product or activity – unforeseen effects on humans or the environment.

(187) As far as can be seen, the “error” in the present discussion on GMOs within the EU lies in the fact that there is, despite the existing and continuing uncertainties as regards the long-term, indirect and cumulative risks linked to releases of GMOs into the environment, no explicit, deliberate decision to authorize or not to authorize such releases. Directive 2001/18 started from the assumption that there would be no risk tolerated. However, the individual decisions which were taken later, in order to authorize the release or the placing on the market of GMOs accepted that there was a certain risk, though this was regularly qualified as “low” by the EFSA risk assessment opinions. And the political institutions of the EU did not see – or want to see – that a number of individual, ad-hoc decisions on the release would gradually change the reality of the releases itself; they did not take a political decision, how much risk they would be prepared to let the EU society bear. This assessment is confirmed by the fact that, as far as can be seen, no use was ever made of Article 7 of Regulation 1829/2003 which asks the Commission to take into consideration, in its individual management decisions, also any relevant provision of EU law – thus also the precautionary principle – and other legitimate factors relevant to the release of GMOs¹⁵⁹.

(188) The EU has thus not yet taken a political decision, what level of risk it deems unacceptable for the EU. This decision is, be it repeated, not a legal decision. It precedes the application of the precautionary principle, but is not a consequence of its application. Therefore, the precautionary principle does not reach so far as to legally oblige the Commission (the EU) to take a specific decision on GMO releases.

(189) A society may, of course, lay down in law that no nuclear energy shall be used, that alcohol drinking is prohibited, or that GMOs shall not be released into

154 Directive 2001/18 (Fn 29), Article 15(4); Regulation 1829/2003 (Fn 30), Article 7(5).

155 Regulation 1107/2009 concerning the placing of plant protection products on the market, OJ 2009, L 309 p.1, Article 5 (10 years).

156 Regulation 528/2012 making available on the market and use of biocidal products, OJ 2012, L 167 p.1, Articles 4 and 13 (10 years, renewal 15 years).

157 Regulation 1907/2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH), OJ 2006, L 396, p.1, Article 60 (8(“Authorizations shall be subject to a time-limited review..”).

158 Directive 2010/75, on industrial emissions, OJ 2010, L 334 p.17, Article 21.

the environment. However, any legal action to enforce such a decision would be based on the legal provision in question and not on the precautionary principle alone.

(190) This finding for EU law is not put in question by the fact that EU environmental policy shall aim at a “high level of protection” (Articles 3 TEU, 191(1) and 114(3) TFEU) and shall promote “sustainable development” (Articles 3 and 11 TEU). These terms are themselves not precise enough. The EU Court of Justice found that the high level of protection need not necessarily be the highest possible level¹⁶⁰. And the term of sustainable development - not defined in EU law¹⁶¹ - is in itself too general to *require*, in a given case, a specific action.

(191) While the abstract application of the precautionary principle does thus not require a specific set of decisions (not to authorize certain genetically modified plants or animals), the case-by-case weighing of the risk which is involved in the release into the environment of a genetically modified plant or animal is inevitably leads to results which come close to such an abstract prohibition. This may be illustrated by two examples: genetically modified salmon has wild relatives. When such a salmon is released into the environment, it may reproduce with wild relatives and thus become non-retrievable. Specific conditions for the release could limit this risk, for example the condition to only release sterile animals, and/or the condition to release salmons only in specific water tanks which are unconnected to open waters. Such conditions considerably reduce the risk of a spread of genetically modified salmon in the environment - though they do not altogether eliminate the risk, because of the possibility of human errors, unforeseen events, deliberate sabotage or other factors¹⁶². This means that the competent authorities within the EU will have to weigh this residual risk and decide, whether they could authorize the release into the environment of genetically modified salmon. In this author's opinion, the residual risk remains too high, so that a release of genetically modified salmon could not be allowed under either Directive 2001/18 or Regulation 1828/2003.

(192) Genetically modified oilseed rape species have the capacity to survive, pollinate and spread into the environment. Examples of such events, stemming from the transport of oilseed rape, not from its cultivation, were found within the European Union. Little is known, whether these populations are able to permanently survive and spread in the environment, though a survival during eight years was described¹⁶³. Therefore, a cultivation of genetically modified oilseed rape is likely to considerably increase this risk of this species spreading in the environment and no longer to be "safe" for humans and the environment. An authorization to cultivate oilseed rape within the European Union would thus not

160 Court of Justice, case C-233/94, Germany v. European Parliament and Council, ECR 1997, p.I-2405.

161 Often, recourse is made to the formulation of the UN Brundtland-Commission of 1987 which defined sustainable development as a “development which meets the needs of the present without compromising the ability of future generations to meet their own needs”.
162 This is the same problem as with the authorization of a contained use of a genetically modified animal or plant. also in such cases, it is not possible to consider that *any* risk is excluded.

163 See paragraph 64, above.

be compatible with Directive 2001/18 or Regulation 1829/2003, or, in other words: any decision to allow the cultivation of oilseed rape in the EU would be, in this author's opinion, incompatible with the precautionary principle.

(193) Generally, a "zero-risk" situation does not exist, when a genetically modified animal or plant is released into the environment. It is therefore up to the competent authorities to decide case by case, whether the risk is acceptable or not. Where a species is to be released into the environment that has wild relatives, or that may itself become persistent or invasive, the risk of an uncontrolled spread of the released species becomes too great, so that an authorization may not be granted.

(194) This conclusion aligns with the requirement of Recital 45 of Directive 2001/18, according to which measures for the retrieval of GMOs shall be available in the event of severe risk, as there is little or even no doubt that a spread of a genetically modified plant or animal in the environment constitutes such a severe risk.

(195) As a result, it has to be stated that the risk of genetically modified plants or animals not being retrievable after their release into the environment is a considerable risk. This risk is greater, when a species has wild relatives or when it is capable of becoming persistent or invasive. The competent authorities will have to weigh this risk in each specific case and decide, whether it is acceptable. The result may be different from one plant or animal species to the other.

(196) In the United States, the precautionary principle has not found explicit expression in legislation. However, the question, how to deal with scientific and/or technical uncertainty, has more or less the same importance as in the European Union¹⁶⁴. And the answers given in specific cases are not significantly different from those in the EU: confronted with uncertainty, decisions are taken with prudence and in order to err on the safe side. The most obvious example in the sector of biotechnology is the prohibition pronounced by EPA to cultivate genetically motivated cotton in regions of the United States, where a risk of outcrossing and gene transfer to wild cotton populations exists¹⁶⁵.

(197) Another example is that of genetically modified wild salmon, where the authorization procedure runs already since about fifteen years, without the public authorities – in this case the FDA – being able or being prepared to take a decision. According to media reports, the FDA issued, end of December 2012, a draft risk assessment, according to which genetically modified salmon does not constitute a risk for human health or the environment; this draft assessment is open to public consultation for two months. Critics of the draft appeal to the political authorities in the USA to stop – by a risk management decision – the release of genetically modified salmon.

(198) In view of the similarity of the basic situations, many of the conclusions made for the legal situation with the EU can be taken over for the United States. As within the EU, risk assessments are made. And as in the European Union, the management decision consists in answering the question, whether the risks

164 Wiener (2004); Hammitt and others (2005); Wiener(2010), etc.

165 See above, paragraph 45.

related to the release of GMOs into the environment are acceptable. Nevertheless, the basic point of departure between the United States and the EU is different. Whereas the United States do not see, in law, any difference between a pesticide which was by way of genetic engineering, implanted into a plant, and a conventional pesticide or between a conventional plant and a plant which was genetically modified in order to become herbicide-tolerant, the European Union legislation considers these GMOs as substantially different from conventional plants. This also influences the risk management decisions: in the United States, the decision on the authorization of a GMO is obliged to take into consideration cost-benefit considerations, in other terms, whether the release would be economically advantageous for the United States economy. In the European Union, such a consideration would not easily be accepted¹⁶⁶.

(199) The escape of genetically modified crops into the wild and the forming of feral populations, furthermore the spontaneous forming of several stacks in a plant do not appear to raise concern with the bodies which are responsible for taking the risk management decisions in USA. Even if there are criteria being applied by the authorities in the US to make a distinction between the cultivation of cotton and, for example, on oil seed rape, such criteria are not made public and no public explanation is given.

(200) All these aspects concentrate finally in the policy question, how much risk a society is ready to accept from the release of GMOs into the environment. In the USA, the cultivation of genetically modified crops is far-spread. In the European Union, only maize and potatoes were authorized; this reflects the greater concern for the environment of risk managers in the European Union.

(201) When EPA imposed the prohibition to cultivate genetically modified cotton in certain areas, it did not explain much in order to justify its decision. Also the prohibition "south of route 60 (near Tampa) in Florida"¹⁶⁷ is rather vague and shows the amount of discretion which public authorities have. The same is true for the conditions for refuge building in order to slow down the speed of resistance development of pest animals and weeds¹⁶⁸.

(202) It can thus be concluded that also in the United State, public authorities have the possibility, based on the uncertainty of risk - in Europe, the term "precautionary principle" would probably be used - that is linked with the release of genetically modified organisms into the environment, to pronounce prohibitions of such releases or to put far-reaching restrictive conditions on a release. The fact that they are more generous in granting authorizations for cultivation and less concerned with the environmental risks linked to such releases, is based on the greater risk which they are ready to impose on the United States society. Furthermore, no requirement to reassess authorizations for GMOs after a certain period of time is imposed by US legislation.

(203) This statement also answers the question, whether the United States authorities could be obliged to prohibit the release of GMOs into the environment.

166 See Trouwborst (2006), p.252ss; de Sadeleer (2007b), p.40s.

167 See paragraph 45, above.

168 See EPA (2012b).

As was stated above, it is a political, not a legal question, what amount of risk the risk manager may ask the society to bear. Apparently, the United States answered this political question in a way that grants large possibilities to the release of GMOs. The uncertainties linked to such releases are not perceived to be so great that more drastic measures are necessary. And as within the European Union, the uncertainty alone - the precautionary principle alone - which is linked with such a release, is not sufficient to oblige the US authorities to prohibit releases. No case brought before a court of justice in the United States and pleading for a prohibition of GMO releases, would, under the present state of law, be successful.

(204) At international level, the Convention on Biological Diversity does not provide for measures to authorize or prohibit the release of genetically modified organisms. The Convention simply invites the Contracting Parties to take appropriate measures against GMOs and invasive species, in order to protect biological diversity. Therefore, the question, whether the CBD allows or requires the prohibition of GMO releases into the environment, is not of relevance.

(205) Another question is, however, whether a prohibition of GMO releases is compatible with international trade law. A detailed examination of this issue goes beyond the scope of this study. Therefore, only some comments will be made.

(206) The World Trade Organization's Agreement on Sanitary and Phytosanitary Measures (SPS-Agreement) indicates that sanitary and phytosanitary measures should best be based on multilaterally-agreed, harmonized standards. It recognizes, though, that WTO Member States may adopt measures which are more stringent than international standards, by providing that countries may fix the appropriate level of sanitary or phytosanitary protection (Articles 3 and 5). This appropriate level is defined as the "level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory" (Annex A, paragraph 5)¹⁶⁹.

(207) It is noteworthy to quote the understanding of the United States government of this provision. The USA Government declared, at the moment of ratification of the SPS-Agreement by the USA that the provision in question "explicitly affirms the right of each government to choose its level of protection, including a 'zero risk' level if it so chooses. A government may establish its level of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific one"¹⁷⁰.

(208) This opinion is in conformity with the opinion expressed above with regard to the situation within the EU. It follows that a political decision made by the EU -

169 It was already mentioned that the SPS-Agreement does not cover environmental aspects, see paragraph 9, above.

170 Uruguay Round agreements Act, Statement of Administrative Action, at 89, reprinted in H.R.Doc.No 103.316, 103d Cong, 2d Sess.656, p.745, quoted according to Wirth (2004), fn 35.

or by any State¹⁷¹- not to allow the release of GMOs is compatible with international trade law. This evaluation is not in conflict with the findings of the WTO-Panel in cases DS 291, 292, and 293, mentioned above¹⁷², as these cases did not discuss and examine a policy decision by the EU on GMO releases, but the administrative execution and concrete application of that legislation in specific cases¹⁷³.

(209) Should the EU have the intention to prohibit or further restrict the release of GMOs into the environment, it has the possibility to take a political decision in that regard¹⁷⁴. Such a decision could, for example, consist in the elaboration of the provision of Article 4 of Directive 2001/18 and declare, that “safe for the environment” means that there is no risk of any release of GMOs into the environment. The declaration could also state that it is up to the applicant to prove that there would be no escape of GMOs for which he has requested an authorization, into the environment. Such elements could, of course, also be laid down in an amendment to the existing EU legislation (Directive 2001/18 and Regulation 1829/2003).

(210) Between such statements or provisions which provide for a “zero-risk” of releases, and the maintaining of the present status quo, the EU institutions dispose of a range of possibilities which take into consideration the greater or smaller risk which they perceive in the spreading of GMOs in to the environment. The policy decision could thus differentiate according to the perceived seriousness of the uncertainty. For example, the EU could decide

- the prohibition of allowing the placing on the market of genetically modified animals;
- the prohibition of allowing the placing on the market of genetically modified animals other than domesticated animals;
- the prohibition of any cultivation of genetically modified plants in the EU;
- the prohibition of the cultivation of those genetically modified plants which have wild relatives in Europe, thus, at present in particular oilseed rape and sugar beet;
- the prohibition of placing on the market of genetically modified plants which have wild relatives in Europe;
- the prohibition of cultivating genetically modified plants in “Natura 2000” areas, as well as in a buffer zone around them;
- the prohibition of cultivating genetically modified plants in other sensitive natural zones;

171 In Europe, Norway and Switzerland are countries, which have de facto a total prohibition of GMO-releases into the environment. In Norway, authorizations have just not been granted. In Switzerland, a referendum of 2005 provided for a five year moratorium for such releases which was, in 2010, prolonged until 2013.

172 Paragraph 9 and Fn 13, above.

173 See Bevilacqua (2007), p.321.

174 See paragraphs 107ss, above.

- the prohibition of cultivating genetically modified plants in agriculturally sensitive zones.

6. Possibilities for EU Member States

6.1 Amendment of Directive 2001/18

(211) The next question is, whether legal possibilities are available to EU Member States which want to prohibit GMO releases into the environment, especially if they are not retrievable.

(212) In 2010, the European Commission proposed to amend Directive 2001/18 and to give Member States the possibility to restrict or prohibit the cultivation of genetically modified organisms “on grounds other than those related to the assessment of the adverse effect on health and the environment”¹⁷⁵. The proposal was discussed in the European Parliament which proposed some amendments¹⁷⁶, in the European Economic and Social Committee¹⁷⁷ and in the Committee of the Regions¹⁷⁸.

(213) In the Council, a compromise text was discussed which would, at the request of a Member State, allow the notifier of a GMO to limit his application, before a decision on the authorization was taken, by exempting the territory of the Member State in question; after the decision on the authorization, Member States should be allowed to restrict the cultivation of the GMO, provided that this restriction was not in conflict with the risk assessment on the GMO. The Council could not find a common position on the Commission proposal. Since March 2012, the discussions on the proposal appear to have come to a standstill¹⁷⁹.

(214) The Commission Proposal intends to leave unchanged the issues concerning the spread of GMOs in the environment and the long-term impacts which this may have on the environment. It does therefore not address the questions discussed in the present paper. It might be that some possibilities for Member States to restrict or prohibit the cultivation of GMOs on their territory for reasons of protecting conventional and organic agricultural practice could be achieved. However, the *environmental* problems raised by the release of GMOs would not be solved.

6.2 Safeguards and Article 114 TFEU

(215) A possibility consists of invoking the safeguard clauses of, as the case may be, either Article 23 of Directive 2001/18 or Article 14 of Regulation 1829/2003. However, it was clarified by the EU Court of Justice that the field of action for

175 Commission, COM(2010) 375.

176 European Parliament, document TA/2011/314/P7.

177 European Economic and Social Committee, Opinion of 7 and 10 September 2011, OJ 2011, C 54 p.51.

178 Committee of the Regions, Opinion of 27 and 28 January 2011, OJ 2011, C 104 p.62.

179 Council, PRES/2012/99.

Member States in this regard is quite narrow¹⁸⁰. There must be new information which challenges the risk management decision that had been taken with regard to the GMO in question. Thus, a general prohibition of releases of GMOs cannot be based on the safeguard clauses. And the burden of proof that there is really a change in the risk situation with a specific GMO, lies on the Member State¹⁸¹.

(216) A similar situation exists, when a Member States intends to recur to Article 114(5) TFEU¹⁸². This provision allows a Member State to opt out of a common legislation, where it has “new scientific information relating to the protection of the environment”; furthermore, the problem in question must be “specific to that Member State” and must have arisen after the adoption of the EU legislation in question. Also in this case, the Court of Justice applied these requirements rather restrictively¹⁸³. As the burden of proof that there is new scientific evidence specific to one Member State, is again on the Member State, the general problems of releasing GMOs into the environment which are known and discussed since years, can hardly be qualified as new scientific information specific to one Member State. Therefore, the recurrence to Article 114(5) TFEU does not appear possible.

6.3 Swiss and Norway as models?

(217) It might also be interesting to examine more closely the national legislation by Switzerland and Norway; in both countries releases of GMOs into the environment do not or hardly take place.

(218) Switzerland went another, though similar way than the EU in approaching the problem of GMOs: the Swiss Federal Act on Biotechnology¹⁸⁴ provides in Article 6(1): “Genetically modified organisms shall be handled in such a way that they, their metabolites or wastes: (a) cannot endanger human health, animals or the environment; (b) do not impair biological diversity or the sustainable use thereof”¹⁸⁵. Article 6(3) then mentions, among others, that GMOs may only be

180 See ECJ, case 6/99, Greenpeace (fn. 38, above) and cases C-58/10 to C-68/10, Monsanto France and others v. Ministère, judgment of 8 September 2011.

181 See also the two cases mentioned in paragraphs 61 to 86, above.

182 Article 114(5) TFEU: „Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonization measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonization measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them“.

183 See in particular Court of Justice, case C-439/05P, Austria v. Commission ECR 2007, p.I-7141; furthermore Commission, Decision 2003/65, OJ 2003, L 230 p.34; Decision 2006/255, OJ 2006, L 92 p.14; Decision 2008/62, OJ 2008, L 16 p.17; Decision 2009/828, OJ 2009, L 294 p.16.

184 Swiss Bundesgesetz über die Gentechnik im Aussenbereich (Gentechnikgesetz), of 21 March 2003 (No.81.491). See generally Perez (2005).

185 Gentechnikgesetz (Fn 185), Artikel 6(1): “Mit gentechnisch veränderten Organismen darf nur so umgegangen werden, dass sie, ihre Stoffwechselprodukte oder ihre Abfälle:

authorized if experiments in contained systems or field trials have shown that they “do not cause severe or permanent impairment of the material balance of the environment”; “do not cause severe or permanent impairment of any important functions of the ecosystem in question, in particular the fertility of the soil”; “do not disperse, or their traits do not spread in an undesired way”; “do not otherwise contravene the principles of paragraph 1”¹⁸⁶.

(219) These provisions are far reaching and to some extent more stringent than the existing EU legislation. The words “cannot endanger.. the environment”, “do not impair” and the different restrictions of Article 6(3) of the Swiss Act demonstrate that the Swiss legislator wanted to exclude *any* possible risk to the environment. At the same time, in particular the term “do not spread in an undesired way” leaves large discretion to the competent authorities to authorize or not the release of a GMO into the environment. What constitutes an *undesired* spread of GMOs into the environment, an impairment of the material balance of the environment, an impairment of important functions of an ecosystem or a contravention of the principles Article 6(1) depends, at the end of the day, on the political risk management decision by Swiss responsible authorities.

(220) Even these provisions, though, were not sufficient in the eyes of the Swiss: in a referendum of 2005, a moratorium of five years for releases of GMOs into the environment was adopted; this moratorium was prolonged for further three years in 2010 and was, till September 2013 still in force.

(221) The Swiss legislation thus confirms the political character of the decisions to authorize, in general or on a case-by case basis, the release of GMOs into the environment. Even if EU or an EU Member State’s legislation were aligned to the Swiss legislation, the terms “undesired”, “severe”, serious, “cannot endanger” etc of that Swiss legislation would need interpretation.

(222) EU Member States would not be able to follow the Swiss example, as they do not have, at present, the possibility to adopt legislation that deviates from EU legislation. Moreover, a referendum on GMOs in an EU Member State would, in law not allow that Member State to disregard existing EU legislation and its application¹⁸⁷.

(223) A way similar to the Swiss way was taken by Norway. Norwegian legislation on GMOs¹⁸⁸ provides that GMOs shall be allowed to be released into the

(a) den Menschen, die Tiere oder die Umwelt nicht gefährden können; (b) die biologische Vielfalt und deren nachhaltige Nutzung nicht beeinträchtigen”.

186 Gentechnikgesetz (Fn 185), Artikel 6(3): “Gentechnisch veränderte Organismen... dürfen nur in Verkehr gebracht werden, ... wenn auf Grund von Versuchen im geschlossenen System und von Freisetzungsversuchen belegt ist, dass sie... den Stoffhaushalt der Umwelt nicht schwerwiegend oder dauerhaft beeinträchtigen.. keine wichtigen Funktionen des betroffenen Ökosystems, insbesondere die Fruchtbarkeit des Bodens, schwerwiegend oder dauerhaft beeinträchtigen.., sich oder ihre Eigenschaften nicht in unerwünschter Weise verbreiten.. nicht in anderer Weise die Grundsätze von Absatz 1 verletzen”.

187 Politically, though, a referendum would have a considerable effect.

188 Act No 38 of 2 April 1993 on the production and use of genetically modified organisms.

environment “in an ethically justifiable and socially acceptable manner, in accordance with the principle of sustainable development and without adverse effects on health and the environment”. Article 10 takes up this basic consideration and states: “In deciding, whether or not to grant an application, considerable weight shall be given to whether the deliberate release will be of benefit to society and is likely to promote sustainable development”.

(224) These provisions allow Norwegian authorities in particular to consider the long-term effects of a GMO on the environment (“sustainable development”) which might concern several future generations. Again, the risk managers are not bound into a legal straitjacket, but are requested to also consider the political dimension of releases of GMOs into the environment. It is obvious, though, that this wording alone does not guarantee a safe environment, as for example genetically modified feed is authorized in Norway for use in the fish industry. As in Switzerland, thus, the decisive factor is the political decision, whether to accept a risk – or some risk – which is linked to the release of GMOs into the environment.

(225) In EU legislation on GMOs, there is no reference to sustainable development. As “sustainable development” is a general objective of the EU¹⁸⁹, Member States could hardly be prevented from making a reference to sustainable development in their national GMO legislation, even where it transposes EU legislation. Where national legislation of an EU Member State contains such a provision, this would emphasize that Member States determination to take into particular consideration the effect of GMO releases into the environment for future generations. As such, though, such a reference would not put into question the existing EU decision-making procedure for GMOs, which puts the decisions on releases into the hands of the EU institutions. As such, the Norwegian legislation would therefore not be of help to an EU Member State.

6.4 Changing the legal basis of GMO legislation

(226) EU legislation on GMOs is not based on the environmental provision of Article 192 TFEU, but on the provisions of Article 114 TFEU on the internal market (Directive 2001/18) and on agriculture (at present Article 43 TFEU), internal market (at present Article 114 TFEU) and public health (at present Article 168 TFEU). It is submitted that these legal bases are not correct. Genetically modified organisms are *organisms*, in other words living beings. Under EU law, living beings are not the same as products. This follows from Article 36 TFEU which allows Member States to take measures which restrict or eliminate the free circulation of products, in order to protect the health and life of animals and plants; such a right does not exist to protect products. It is only a consequence of this basic decision in the EU Treaties that legislation concerning animals or plants is normally not based on the provision of Article 114 TFEU which concerns the establishment of an internal EU-wide market for products, but on either the environmental (Article 192 TFEU) or the agricultural provisions (Article 43 TFEU).

189 See Article 3(3) and Recital 8 TEU.

(227) The choice of the legal basis of EU legislation depends, according to the consistent jurisprudence of the Court of Justice, on the objective and content of the legislation (centre of gravity) and is subject to judicial control. Both pieces of EU GMO-legislation have as their primary objective the protection of human health and the environment, objectives which are both capable of being achieved by the provisions of Article 192 TFEU. The extensive provisions on the release of GMOs into the environment, the environmental risk assessment, the intervention of the European Food Safety Authority EFSA, the possibility to consult the EU Committee on Ethics¹⁹⁰, and the genesis of Directive 2001/18 which was adopted after a considerable dispute within the EU on the issues related to the release of GMOs into the environment, all show that the concern about the effects of GMOs on human health and on the environment were the main objectives of the EU GMO-legislation; these objectives also found their expression in the different provisions of the two pieces of legislation. For this reason, Article 192 TFEU would have been the most appropriate legal basis.

(228) In favour of this legal basis pleads a further argument: it is a fundamental decision of the EU Treaties that measures which directly affect the environment, should not be the subject of harmonizing legislation, but that EU legislation should respect the diversity of the environment within the EU – including the different approaches which EU Member States might be prepared to have in this regard. This fundamental decision found its expression in the insertion of Article 193 TFEU¹⁹¹ into the Treaties which existed since the moment -1987 -, when first environmental provisions were mentioned in the Treaties, and which allows EU member States to provide for a better protection of their environment than ensured by EU legislation. How EU Member States are prepared to protect – and even over-protect – their environment, is their decision. And the insertion of genetically modified living organisms is such a significant and important interference with the environment that Member States must be able to declare the EU level of environmental protection not to be sufficient and adopt more stringent provisions in this regard.

(229) A detailed examination of the legal basis of EU GMO-legislation goes beyond the scope of the present study and would require a study of its own. Under the assumption that a Member State were considering to challenge the actual legal basis of Directive 2001/18 and Regulation 1829/2003, it should be noted that an action under Article 263 TFEU against the EU legislator – the European Parliament and the Council – before the EU Court of Justice is not possible, as such an action would have had to be introduced within two months after the adoption of the respective legislation¹⁹².

(230) However, if a Member State were determined to challenge the legal basis of the existing EU GMO-legislation, it would have the possibility to adopt national

190 Directive 2001/18 (Fn 29), Article 29.

191 This provision of Article 193 TFEU is the core provision for suggesting the shift of the legal basis. It reads as follows: “The protective measures adopted pursuant to Article 192 shall not prevent any Member State from maintaining or introducing more stringent provisions. Such measures must be compatible with the Treaties. They shall be notified to the Commission”.

192 See Article 263(6) TFEU.

legislation which altogether prohibits or which restricts the release of GMOs into the environment – as if Article 192 TFEU were applicable. Should the Commission then take action against that Member State under Article 258 TFEU, the Member State could raise, in the case before the EU Court of Justice, all arguments in fact and in law which plead in favour of the legal basis of Article 192 TFEU.

(231) A similar control of the correctness of the actual legal basis by the EU Court of Justice could be reached, where a dispute is brought to a national court of justice between a Member State and a private company that sees itself prevented from cultivating a GMO in that Member State despite the authorization of that GMO by the EU authorities. The national court would then be entitled and, under the conditions laid down in Article 267 TFEU¹⁹³, be obliged to submit to the EU Court of Justice the question for a preliminary ruling, whether the EU GMO-legislation was based on the correct legal Treaty provisions.

7. Conclusions

(232) In summary thus, it appears that EU legislation on genetically modified organisms is already at present sufficiently robust to allow, on the basis of the precautionary principle, the taking of a decision according to which

- either, the release into the environment of genetically modified organisms is prohibited altogether, because there is an uncertainty, whether such releases are “safe for the environment”;
- or to decide on a case-by-case basis and following the different risk assessments by EFSA that as risk management measure the remaining risks, in particular as regards long-term and cumulative effects, are considered so relevant that an interdiction is necessary; this includes the possibility to decide that a release into the environment of a GMO shall not be authorized, because the likelihood that, at a later stage, it is not retrievable, is too great.

(233) In these cases, this constitutes a political decision which is to be taken by the relevant competent authorities at EU level.

(234) The situation is completely different, where it turns out, that a genetically modified plant has spread in the environment and has developed populations which are, in legal terms, considered to be an invasive alien species¹⁹⁴. When a feral or volunteer genetically modified plant survives in the natural environment outside the cultivated areas, this constitutes a new situation, as the authorization granted to the GMO did not refer to this. In the absence of EU legislation on

193 The condition is that against the decision of the national court “there is no judicial remedy under national law” (Article 267 (3) TFEU).

194 As there is, until now, no specific EU legislation on alien species, the terminology of the CBD will be used here. The CBD Guidelines on alien species (annex to CBD Decision VI/23) define as follows: „*alien species* refers to a species, subspecies or lower taxon, introduced outside its natural past or present distribution; includes any part, gametes, seeds, eggs, or propagules of such species that might survive and subsequently reproduce“; “*invasive alien species*” means an alien species whose introduction and/or spread threaten biological diversity”.

invasive species, each Member State may treat such wild populations of genetically modified plants as weeds and destroy them, without even being obliged to inform other Member States or the Commission.

(235) With regard to the genetically modified plants which had received the necessary authorization, the consequences for Member States follow from the application of the safeguard clauses of either Directive 2001/18¹⁹⁵ or Regulation 1829/2003¹⁹⁶. The Member State in question, on whose territory the wild genetically modified plant is discovered, is entitled to take safeguard measures under the conditions laid down in the different provisions¹⁹⁷. Such measures certainly include the possibility to prohibit the further sale, use or cultivation of the genetically modified plant on the territory of the affected Member State. For the rest, all depends on the dimension of the specific problem that was discovered, as also in such a case, the above-mentioned proportionality principle applies. The question of proportionality is also decisive for the question, whether also other EU Member States are entitled to use the safeguard clause and take measures with regard to the authorized genetically modified plant. Both safeguard procedures mentioned provide for an EU-wide procedure in order to reconcile the necessities of safety on the one hand, of the functioning of the internal, EU-wide market on the other hand¹⁹⁸.

(236) An examination of the existing legislation and practice in the EU, the United States of America and at international level leads to the following conclusions:

(237) The Convention on Biological Diversity and the Cartagena Protocol on Biosafety do not contain detailed provisions concerning risks for human health and the environment which stem from the release into the environment of genetically modified organisms. In particular the Biosafety Protocol provides for procedures to ensure appropriate international cooperation, but refers, as regards substantive law, back to the applicable law of the Contracting Parties.

(238) The United States consider genetically modified organisms as substantially equivalent to conventional organisms. Thus, they did not adopt specific GMO legislation. Existing provisions require the administration to prevent adverse effects of a GMO on the environment; however, also the costs and benefits of authorizing a GMO shall be weighed against the disadvantages.

195 Directive 2001/18 (Fn 29), Article 23: „Where a Member State, as a result of new or additional information made available since the date of the consent... has detailed grounds for considering that a GMO... constitutes a risk to human health or the environment, that member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory...”

196 Regulation 1829/2003 (Fn 30), Article 14: „Where it is evident that products authorized by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment.. measures shall be taken under the procedure provided for by Articles 53 and 54 of Regulation (EC) No 178/2002”

197 As to the relationship between the two safeguard provisions see Court of Justice, cases C-58/10 to C-68/10, Monsanto France (Fn 180). Member States’ rights under the safeguard provision of Directive 90/220, the predecessor of Directive 2001/18, are discussed in case C-6/99, Greenpeace(Fn 38).

198 See for details Article 23 of Directive 2001/18 Fn 29) and Articles 53 and 54 of Regulation 1829/2003 (Fn 30).

(239) The EU requires that GMOs may only be released, when they are safe for the environment; it did not yet have to decide, whether a GMO could be authorized to be released into the environment, where an increased likelihood existed that it would not be retrievable. At the moment of authorizing the release, cost-benefit consideration may not be taken into consideration. Any release must be preceded by an environmental risk assessment which must also consider unlikely events and shall, in the assessment, assume that the worst case scenario occurs. The management decision as to whether the GMO shall be authorized and what conditions shall eventually be inserted into the authorization, is to be taken by the EU institutions - normally by the EU Commission.

(240) In practice, Contracting Parties notify their national decisions on the authorizations concerning a release of a GMO or refusals to authorize to the Biosafety Clearing-House under the Biosafety Protocol. It is doubtful, whether all Contracting Parties comply with this obligation and, in particular, whether really all refusals are communicated.

(241) In the United States, authorizations were granted in great number, in particular also for the cultivation of genetically modified crops. Long-term effects and cumulative effects are only marginally discussed in the authorizations. Occasionally, prohibitions to cultivate genetically modified plants in certain regions - mainly outside the US mainland - were pronounced, in order to avoid the transfer of genes to wild relatives (cotton). To what extent compliance with such restrictions is controlled, is unclear. Also the detailed conditions attached to the individual authorizations are not made public, and the monitoring of such conditions is unclear. The outcrossing of genetically modified plants, which appears to have increased in recent years, does not appear to constitute concern for the public authorities.

(242) In the European Union, only the cultivation of genetically modified maize and potatoes are authorized so far. The risk assessments of EFSA do not appear to assume the arrival of a worst case scenario. EFSA opinions which should not interfere with risk management decisions, de facto classify the different forms of risk ("low", "small" etc). This classification is almost always followed by the EU Commission which does not take into account the broader elements that Article 7 of Regulation 1829/2003 put at its disposal. A detailed examination shows that there are a considerable number of uncertainties linked to the release of GMOs into the environment; these concern in particular long-term and cumulative effects.

(243) The precautionary principle addresses the question, how to act in the face of scientific uncertainty. Though the principle - rather the term - is disputed in the United States, in practice, the public authorities in the USA and the EU deal in a comparable manner with existing uncertainties. The practical difference lies more in the different reaction to the potential risk of GMOs. Furthermore, the EU requires the reassessment of authorizations after a fixed period of time (ten years).

(244) There is a large consensus in the literature on the precautionary principle that at the beginning of a risk analysis the question has to be answered, how much risk should be imposed on a society. The answer to this question is a political, not a legal question. For this reason, the precautionary principle *allows*,

in the presence of scientific or technical uncertainty, to take measures in order to restrict or altogether prohibit the release into the environment of genetically modified organisms. However, it cannot be used to answer the question, how much risk a society is to bear with regard to GMOs. Therefore, it is not an instrument to *impose* on the EU institutions or on Member States an obligation to prohibit, in the name of precaution, the release of GMOs.

(245) As there are numerous uncertainties as to the effects of a release of GMOs into the environment, existing EU law already allows at present that EU institutions altogether prohibit any release of GMOs into the environment, because it is not ensured, at present, that such releases are “safe for the environment”. It is also possible to take measures which reach less far, as for example a general prohibition to cultivate genetically modified plants within the EU, a prohibition to release genetically modified animals into the environment, or the restriction of the cultivation of genetically modified plants in certain sensitive areas. All these decisions are of a political nature. Science and law do not interfere in this.

(246) Until now, the EU institutions did not explicitly take such a policy decision as regards the risk which they consider appropriate for the European society to bear. Neither is there a general nor are there case-by-case decisions in this regard. The mere existence of EU legislation on GMOs is not sufficient, because this legislation stipulates that GMOs may only be released when they are safe for the environment, and the numerous existing uncertainties on the effects of GMOs just raise the question, whether the release is indeed safe.

(247) When the EU accepts biotechnology in principle and despite the existing and continuing uncertainties with regard to the long-term effects, as an acceptable technology, as it is the case at present, the precautionary principle will be applicable in the individual case-by-case decisions regarding risk management measures. In such a case, in particular the proportionality principle and the consistence with other, earlier decisions will be of importance. This does not mean that a risk management decision by the EU authorities could not come to other decisions than in the past. However, in such a case, a detailed and careful justification will have to be given, why the existing risks linked to the placing on the market of the GMO are considered unacceptable now.

(248) Should the EU take a policy decision to prohibit the release of GMOs into the environment (in part or in full), such a decision appears to be compatible with international trade law, as international trade law explicitly provides that each State (or regional organization as the EU) has the right to determine itself the degree of risk which it is ready to accept from products such as GMOs.

(249) Examples of legislation of Switzerland and Norway demonstrate that the legal terminology of GMO-legislation is not the decisive issue. Rather, all depends of what policy decision is taken as regards the risk coming from the release of GMOs into the environment. Another wording of EU legislation would therefore only marginally improve the present situation.

8. Answers to the questions raised

(250) In view of all this, the questions raised are answered as follows:

- 1.1 EU law, and in particular Directive 2001/18, allows but does not require a prohibition of the release of genetically modified organisms into the environment, based on the abstract application of the precautionary principle. Where there is, in a concrete case, a likelihood that genetically modified plants or animals cannot be retrieved, the legal obligation to ensure that any release must be "safe" requires the refusal to authorize such releases.
 - 1.2 The Convention on Biological Diversity combats, among others, invasive species. As, however, no genetically modified plant or animal was reported to be invasive until now, the provisions of the Convention are not relevant: no GMO was ever declared invasive species. Anyway the Convention refers to the legislation of its contracting Parties and is itself neutral as regards the treatment of genetically modified weeds or pest animals. And its guidelines on the handling of invasive species are non-binding anyway.
 - 1.3 USA legislation allows and even imposes the responsible authorities to prohibit the release of GMOs into the environment, when they are convinced that such a release has adverse effects on the environment. However, the legislation is drafted in a form which gives a very wide discretion to the responsible authorities to pronounce restrictions or prohibitions. Until now, the US authorities considered the risk of releases to be small and not to justify broad restrictions or prohibitions.
- 2.1 Where a release of a GMO into the environment was authorized by the EU - be it on the basis of Directive 2001/18 or of Regulation 1829/2003 - Member States have the possibility to recur to the safeguard clauses of both pieces of legislation which constitute the practical application of the precautionary principle. Furthermore, they may recur to Articles 114(5) TFEU and introduce new, deviating legislation. However, the EU Court of Justice put very strict conditions to the application of the safeguard clauses as well as to the application of Article 114(5) TFEU.
 - 2.2 The fact that a genetically modified organism which was released into the environment is persistent, was not considered by the EU Commission - which decided by way of the comitology procedure, and thus with agreement of the majority of the Member States - to be an environmental impairment. A Member State could reach another evaluation of such a situation by obtaining a change in the Commission's evaluation, or by recurring to the application of the safeguard provisions of Directive 2001/18 or Regulation 1829/2003. Whether the risk management decision by the Member State (to prohibit or stop the release) or by the EU (to allow the continued release) is correct, will have to be decided by the EU Court of Justice. A Member State does not have the possibility to take preventive measures on the basis of other legal provisions.
 - 2.3 Other legal possibilities consist of

- the introduction of national legislation on the prohibition of releases of GMOs into the environment, as if Articles 192 and 193 TFEU were of application. Should the Commission then bring the case before the EU Court of Justice under Article 258 TFEU, the Member State could raise all the arguments which plead in favour of Article 192 TFEU as the correct legal basis and try to persuade the Court of these arguments.
- a prohibition of releasing a GMO which had been authorized by the EU authorities at a national level. Should the ensuing dispute between the company that wants to place the GMO on the market and the prohibiting Member State be brought before a national court of justice, that court would be entitled and under certain conditions be obliged to submit to the EU Court of Justice the question for a preliminary ruling, whether the present legal bases for the two pieces of legislation are the correct ones (Article 267 TFEU). The Member State in question would then have the opportunity to raise all the arguments which plead in favour of an application of Articles 192 and 193 TFEU.
- an amendment of the present EU legislation on GMOs - Directive 2001/18 and Regulation 1829/2003 - by allowing Member States to maintain or introduce stricter provisions to protect the environment;
- an amendment of the legal basis of Directive 2001/18 and Regulation 1829/2003, as far as genetically modified living organisms (GMOs) are concerned and take Article 192 TFEU as the legal basis.

The difficulties in these two last procedures lie, though, in the fact that any initiative to change existing legislation would have to be initiated, under the TFEU, by the EU Commission. The Member States have no possibility, under the EU Treaties, to initiate environmental legislation. And as regards the first two possibilities, it is obvious that the outcome of eventual court procedures is not predictable.

The decision, whether the EU considers biotechnology acceptable for the EU environment, is, at the end of the day, a *political* decision which is not pre-determined by consideration of international trade law. The omission to take a basic decision in this regard, combined with the slow, but progressive change which the environment will incur in the short, medium and long term through the present adoption (“slicing”) of case-by-case decisions which authorize releases into the environment, is not capable of being solved by legal interpretations alone and in particular not by the precautionary principle.

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