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Applying Precaution in Community Authorisation of Genetically Modified Products

Challenges and Suggestions for Reform

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Maria Weimer is PhD researcher in law at the European University Institute. E-mail: maria.weimer@eui.eu

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Centre for European Studies
University of Oslo
P.O.Box 1143 Blindern | 0317 Oslo | Norway
Tel: +47 22 85 87 00 | Fax +47 22 85 87 10
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Abstract

In this paper, I endeavour to examine concrete challenges, which arise with regard to implementation of the precautionary principle in the field of European Community regulation of GMOs. Developed by the European Courts into a general legal principle, precaution requires EU regulators to strike a balance between scientific and political legitimacy when taking decisions on risk-entailing products. Following this understanding the current GMO legislation creates precautionary governance structures, which allow for a broad input into the authorisation process not only of scientific, but also of 'other legitimate factors.' At the same time, it can be criticised for narrowly defining precaution as a decision rule, which, if applied correctly, will lead the decision-maker to the 'right' decision. I argue that this misconception is one of the reasons why in the current authorisation practice the Community institutions fail to apply the principle in a balanced way, falling into the extremes of either purely science-based decision-making or a highly politicised precautionary rhetoric. I suggest that in order not to be paralysing, precaution should be understood as a procedural principle that provides for precautionary governance, thus, enabling regulators to make appropriate risk choices.

Keywords

Legitimacy – Multilevel Governance – Regulatory Politics – Risk Regulation

Introduction

> In forcing public decision makers to think carefully about the scientific uncertainties involved in health and environmental decision-making, the precautionary principle is perhaps one of the most significant principles of the contemporary era.[1]

The existing academic literature on the meaning and possible interpretations of the precautionary principle is abundant and covers various academic disciplines.[2] The objective of this paper is not to contribute to this discussion by providing yet another abstract definition of the principle, or another argument either in favour or against its application. Despite the ongoing controversy surrounding it,[3] the precautionary principle has become a reality of public regulation all over the world.[4] In the European Union it is today an established principle of EU environmental and health law, and as such has been implemented in many concrete regulatory frameworks of risk regulation. Under European law the question is therefore not whether to implement the precautionary principle, but *how* to implement it. It is with regard to these concrete challenges arising from the application of precaution in particular areas of risk regulation that I hope to make a useful contribution.[5]

EU regulation of genetically modified organisms (GMOs) provides an interesting field for such a case study. GMOs are currently perceived as one of the main examples of new technological risks with potentially irreversible and unforeseen consequences, the occurrence of which has motivated Ulrich Beck to proclaim the advent of the risk society.[6] It is therefore the classic case for applying precaution. At the same time, in no other field of EU regulation do the shortcomings of the practical use of the principle in regulatory decisions become more apparent than in the authorisation of GMOs.

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[1] E. Fisher, J. Jones and R. von Schomberg, 'Implementing the Precautionary Principle: Perspectives and Prospects', in E. Fisher, J. Jones and R. von Schomberg (eds), *Implementing the Precautionary Principle*, Cheltenham, Edward Elgar Publishing, 2006, at pp. 1, 11.

[2] See R. Harding and E. Fisher (eds), *Perspectives on the Precautionary Principle*, Annandale, Federation Press, 1999; T. O'Riordan, J. Cameron and A. Jordan (eds), *Re-Interpreting the Precautionary Principle*, London, Cameron May, 2001; J. Morris (ed.), *Rethinking Risk and the Precautionary Principle*, Oxford, Butterworth-Heinemann, 2001; I. Forrester and J. C. Hanekamp, 'Precaution, Science and Jurisprudence: a Test Case', *Journal of Risk Research* 9, No. 4, (2006), pp. 297-311; A. Wildavsky, *But is it True? A Citizen's Guide to Environmental Health and Safety Issues*, Cambridge, MA, Harvard University Press, 1997, 3rd ed.; E. Fisher, 'Opening Pandora's Box: Contextualising the Precautionary Principle in the European Union', in E. Vos and M. Everson (eds), *Uncertain Risks Regulated*, Oxon, Routledge-Cavendish, 2008; C. R. Sunstein, *Risk and Reason*, Cambridge, UK, Cambridge University Press, 2002; C. R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle*, Cambridge, UK, Cambridge University Press, 2005; G. Majone, 'What Price Safety? The Precautionary Principle and its Policy Implications', *Journal of Common Market Studies* 40, No. 1, (2002), pp. 89-109; I. S. Forrester, 'The Dangers of too Much Precaution', in M. Hoskins, D. Edward and W. Robinson (eds), *A True European*, Oxford, Hart Publishing, 2003; N. de Sadeleer, *Environmental Principles: From Political Slogans to Legal Rules*, Oxford, Oxford University Press, 2002; T. Christoforou, 'The origins and content of the precautionary principle in European Community law', in C. Leben and J. Verhoeven (eds), *Le Principe de Precaution: Aspects de Droit International et Communautaire*, Paris, Editions Pantheon Assas, L.G.D.J. Diffuseur, 2002.

[3] See Sunstein, 2002, 2005, *supra*, note 2.

[4] See examples in Fisher et al., *supra*, note 1; Harding and Fisher, *supra*, note 2.

[5] Other scholars have already paved the way for this type of research on the precautionary principle. See Fisher et al., *supra,* note 1.

[6] See U. Beck, *Risk Society: Towards a New Modernity*, London, SAGE Publications, 1992.

Although the current regulatory framework, which was officially based on the precautionary principle,[7] was overhauled not long ago,[8] it is now the object of further criticism.[9] During summer 2008 the French EU presidency established a working group of member state representatives. The objective was to reflect upon possibilities of improving the authorisation procedures for GM products in the EU, and if necessary, to induce a new reform of the legislative framework.[10] In December 2008, following tough negotiations, the Environmental Council presented the first results of this reflection process by identifying several problem areas in the implementation of the GMO legal framework.[11] In the meantime, many member states have issued national bans on GMOs,[12] and some even demand a halt on authorisations until the current framework has been reformed.[13] The conditions under which the precautionary principle is applied in these procedures, are therefore highly politicised. Political deadlock and delays concerning decision-making are almost a daily occurrence. This situation nourishes the criticism often voiced to reject precaution as a meaningful concept to guide administrative decisions, namely that it just offers no guidance at all, is paralysing and leas to the stagnation of technological innovations.[14] By studying the application of precaution in the GMO framework, I will examine the pertinence of such criticism and, thus, contribute to the ongoing reflection process on the reform of the framework.

The research interest that guides this examination is to determine how the precautionary principle is defined under the current legal framework for GMO authorisation and subsequently, to look at the way this definition is applied by Community institutions in the practice of authorisation. The main hypothesis to be confirmed is that the GMO legislation establishes a notion of the precautionary principle closely following the precedent interpretation of the principle by the European Commission, which has also been confirmed in the jurisprudence of the European Court of First Instance. Under this interpretation, public decision making on risk-entailing products needs to have a strong scientific basis. However, it also

[7] See analysis below under; 'The definition of precaution under the GMO legal framework'.

[8] Between 2001 and 2003.

[9] See interview with M. Weimer for GMO-Safety on the reform debate from 12 September 2008, available at <http://www.gmo-safety.eu/en/debate/657.docu.html> (accessed 26 november 2009).

[10] See the French presidency proposal, available at <http://66.102.9.132/search?q=cache:mOddKHsaDR4J:register.consilium.europa.eu/pdf/en/08/st07/st07128.en08.pdf+7128/08+GMOs:+Exploring+the+way+forward&hl=en&ct=clnk&cd=1&gl=be&client=firefox-a> (accessesed 26 November 2009); Another parallel reflection group was set up by Commission President Jose Barroso, see article on EurActiv, available at <http://www.euractiv.com/en/environment/france-propose-concrete-solutions-eu-gmo-muddle/article-174002> (accessed 26 November 2009).

[11] See the 'Environment' Council conclusions on Genetically Modified Organisms from 5 December 2008 , available at <http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf> (accessed 26 November 2009).

[12] For lists of national measures see the DG Environment website, available at http://ec.europa.eu/environment/biotechnology/safeguard_measures.htm (accessed 26 november 2009).

[13] See interview with then German minister for agriculture Horst Seehofer from 9 May 2008 in Frankfurter Allgemeine, available at <http://www.faz.net/s/Rub0E9EEF84AC1E4A389A8DC6C23161FE44/Doc~EA0C9FFFA5E61499985B56F08D3909BB8~ATpl~Ecommon~Scontent.html?rss_googlefeed> (accessed 26 November 2009); see also 'OGM, l'Italia chiede il bando Ue "Basta autorizzazioni facili"', La Repubblica, 31 October 2007.

[14] See Sunstein, 2005, *supra*, note 2.

recognises the limitations of scientific assessment when faced with new technological innovations. In situations of scientific uncertainty, therefore, the Community institutions can apply the precautionary principle, which allows them to exercise their political responsibility in taking other factors than science into account. Understood in this way, precaution under EU law combines both a scientific and a political rationality, and it grants the Community institutions a wide discretion in balancing the two in case-by-case decision-making. Nonetheless, in the administrative practice of GMO authorisation, the institutions fail to find such a balance. Above all, the Commission does not seem to follow a coherent approach to precaution, when falling into the extremes of either a purely science-based decision-making or a highly politicised precautionary rhetoric. The failure to use the precautionary principle in a comprehensive way in GMO authorisations can be explained by the lack of political acceptance of the Commission's activities in the field on behalf of the member states, together with certain shortcomings of the current legislative provisions that should be corrected in the future. However, the main impediment to useful application of the precautionary principle identified in this analysis, is the misconception of the principle as a decision rule for dictating particular outcomes when certain conditions are fulfilled. I will conclude the examination by arguing that the understanding of precaution as a decision rule misconceives the nature of the principle as a *legal principle* that provides for institutions and procedures of precautionary governance and allows making appropriate risk *choices*. As such precaution can never guarantee a particular *right outcome*, it can only help structure the decision-making process; providing procedural guarantees for ensuring the *right input*, and, thus, enable the Community institutions to use a broad basis of knowledge for their decisions.

The precautionary principle in the EU legal system

The implementation of the precautionary principle in the legislative framework for GMO authorisation cannot be explained in a meaningful way without placing it into the broader context of EU law.[15] Following the development of precautionary approaches in several national as well as in international legal frameworks,[16] the EU has officially recognised the precautionary principle as the basis for its environmental policy by incorporating it into the EC Treaty.[17] Article 174 II EC states:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay […].

However, the treaty did not provide for a definition of the principle. At the same time, the concurrent development of precautionary approaches in different legal

[15] See Christoforou, *supra*, note 2. On the existence of different approaches to precaution under the EU legal system, see E. Fisher, *Risk Regulation and Administrative Constitutionalism*, Oxford, Hart Publishing, 2007.

[16] For an overview, see Harding and Fisher, *supra,* note 2*;* O'Riordan et al., *supra,* note 2.

[17] However, the EC has already adapted a precautionary approach in a number of directives and policy documents before the introduction of the principle in the treaties, see examples in A. Jordan, 'The Precautionary Principle in the European Union', in O'Riordan et al., *supra*, note 2, 143, 148ff.

regimes on a global scale, has brought about a variety of definitions and understandings of precaution. The EU could not adopt a pre-existent concept of precaution, simply because such a generally defined concept did not exist.[18] It was therefore left to other EU institutional actors to develop a definition capable of being applied within the EU legal order. The European Commission and the European Courts together have played an important role in this respect.

But before I can describe the respective contribution of these actors to the development of the precautionary principle, I will try to identify the 'core' idea behind the term *precaution*. Despite the lack of a common legal definition, a shared meaning behind the different variants of the principle does exist; incidentally, without such shared meaning there would hardly be any way to explain the rapid advancement of the principle in regulatory regimes all over the world, nor the transboundary academic and political discourse instigated by this advancement.[19] This 'core' idea states that 'where there is a threat to human health or environmental protection a lack of full scientific certainty should not be used as a reason to postpone measures that would prevent or minimise such a threat.'[20] Thus, it expresses that in cases of scientific uncertainty, 'no evidence of harm' should not be equated with 'no harm.'[21] The intuition behind this idea is that public decision makers should exhibit a 'healthy skepticism' towards the completeness of scientific knowledge; they should be aware of the limitations of science when identifying risks and pay more attention to the scientific uncertainties involved in public health and environment regulation.[22]

The Commission Communication on the precautionary principle

In 2000 the Commission has published a Communication on the Precautionary Principle (hereinafter Communication).[23] This document, albeit lacking any legally binding effect, has significantly influenced the discussion as well as the application of the principle in the EU. On the one hand, this policy document has attracted much attention in legal academic literature, and it seems to have become a necessary part of almost every commentary on the use of the precautionary principle in the EU.[24] On the other hand, it has had considerable influence on the interpretation of the principle by the Court of First Instance,[25] which has relied on the Communication in order to

[18] On the dependence of precautionary definitions upon the jurisprudential and jurisdictional context, see Fisher, *supra*, note 2; Harding and Fisher, *supra*, note 2.

[19] See *supra*, note 2.

[20] See Fisher, *supra*, note 15; see also, albeit in stricter terms, the Rio Declaration.

[21] E. Fisher, 'Precaution, Precaution Everywhere: Developing a "Common Understanding" of the Precautionary Principle in the European Community', *Maastricht Journal of European and Comparative Law* 9, No. 1, (2007), pp. 7-28, referring to the independent expert group on mobile phones (IEGMP), Report – Mobile Phones and Health, (HMSO, 2000), 6.16.

[22] See Fisher et al., *supra,* note 1, at p. 11.

[23] See Communication from the Commission on the Precautionary Principle COM (2000) 1, available at <http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf> (accessed 26 November 2009).

[24] See for example Fisher, *supra*, note 15; P. Craig, *EU Administrative Law*, Oxford, Oxford University Press, 2006; J. Scott, 'The Precautionary Principle Before the European Courts', in R. Macrory (ed.), *Principles of European Environmental Law*, Groningen, Europa Law Publishing, 2004, pp. 51-67; J. Scott and E. Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO', in C. Joerges and R. Dehousse (eds), *Good Governance in Europe's Integrated Market,* Oxford, Oxford University Press, 2002.

[25] See below under 'The EU Courts: the rise of a new general principle of Community law'.

determine the legal scope of application of the precautionary principle in the Community legal order.[26]

In the Communication the Commission pursues an ambitious goal, namely to build a 'common understanding of the factors leading to recourse to the precautionary principle and its place in decision making, and to establish guidelines for its application based on reasoned and coherent principles'.[27] This formulation already indicates an understanding of the precautionary principle as a decision rule; it is assumed that one can define factors triggering the application of the principle as well as factors, which will guide its application in decision-making. This is confirmed by the further content of the Communication.

The Commission begins by, for the first time in an official EU document, defining the legal status of the principle in EU law. Basing itself on the legal text of the Treaty provisions, EU case law and the relevant policy of the EU institutions the Commission arrives at the conclusion that the precautionary principle is a *general principle* that should in particular be taken into consideration in the fields of environmental protection and human, animal and plant health.[28] This constitutes a considerable extension of the validity of the principle, which, as Article 174 II EC states, was originally defined as a principle applicable in the field of EU environmental policy.

Further, the Commission describes the constituent parts of the principle. It distinguishes between two types of decisions required under the application of the principle: Firstly, there is the political decision to act or not to act as such, which is linked to the factors triggering recourse to the principle. Secondly, a decision on *how* to act needs to be taken. The decisions mentioned above are taken by the decision maker within the context of a risk analysis of a certain risk-entailing product or activity. The Commission approach to the precautionary principle is therefore strongly interconnected with its understanding of risk analysis, and both principles should be considered together.

The Commission defines what it calls a structured approach to risk analysis, under which the distinction between two phases of decision-making is crucial - between risk assessment and risk management.[29] The precautionary principle is said to apply only to the second stage, the management of risk.[30] This means that the principle shall guide the decision makers in their *political* decision of whether or not to act. Risk managers shall take into consideration the potential consequences of inaction and the uncertainties of the scientific evaluation. At the same time, all interested parties

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[26] See Case T-13/99, *Pfizer Animal Health SA v Council* (2002) ECR II-3305; Case T-70/99, *Alpharma v Council* (2002) ECR II-3495; see also Harding and Fisher, *supra*, note 2, who compares EC case law before and after the publication of the Communication.

[27] The Commission, *supra*, note 23, at p. 9.

[28] Ibid., at p. 10.

[29] The Commission, *supra*, note 23, at p. 3. The third element of risk analysis mentioned there is risk communication, which is defined as involving 'the interactive exchange of information, both within and beyond risk analysis as a whole, with an emphasis on 'the explanation of risk assessment findings and the basis or risk management decisions', see A. Stirling, O. Renn and P. van Zwanenberg, 'A framework for the Precautionary Governance of Food Safety: Integrating Science and Participation in the Social Appraisal of Risk' in E. Fisher, J. Jones and R. von Schomberg (eds), *Implementing the Precautionary Principle*, Cheltenham, Edward Elgar Publishing, 2006.

[30] The Commission, *supra*, note 23, at pp. 3, 13.

should be involved in this process 'to the fullest extent possible', and the process itself should be as transparent as possible.[31] The risk management measures are 'thus the result of a political decision, a function of the risk level that is "acceptable" to the society on which the risk is imposed'.[32] However, the factors triggering the application of the precautionary principle in risk management, are identified in the precedent stage of the risk assessment. Thus, the circumstances under which the principle can be applied, are

> Where scientific evidence is insufficient, inconclusive or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.[33]

It can be concluded from the Commission's explanation that the precautionary principle is supposed to govern risk decision-making in a direct way. Before the principle is triggered, the decision maker needs to ascertain that certain conditions, such as inconclusive scientific evidence and objective indications of risk, are fulfilled. The fact that, according to the Commission, the principle only applies in the phase of risk management; that the following political decisions are subject to certain requirements, such as proportionality, non-discrimination and cost-benefit analysis;[34] and finally, that the precautionary measures are described as a function of the risk level 'acceptable' to society; all these conditions show that the Commission aims at rationalising the application of precaution in the sense of a decision rule. The purpose of such an approach seems to be ensuring, or at least publicly stating the will to ensure, the non-arbitrary use of the principle in decision-making. This is illustrated by the iterate statement in the Communication saying that action based on the precautionary principle is not arbitrary.[35] The strategic character of the Communication in this regard has been described as follows:

> The communication may be seen not only as a contribution to the ongoing debate at international level, but also as a public relations exercise designed to calm the fears of those who perceive that the precautionary principle serves, in the case of the EU, to legitimate decisions which are irrational, other than in terms of their capacity to serve protectionist goals.[36]

Finally, the Commission interpretation of precaution seems to indicate the need to combine rational decision-making with the inclusion of non-scientific, political considerations when taking decisions on risk-entailing products. However, a tension remains between the requirement to base decision-making on rational, objective and non-arbitrary grounds yet at the same time provide for broad participation and responsiveness to public opinion.[37] We will see at a later stage that this tension also

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[31] Ibid., at p. 17.

[32] Ibid., at p. 16.

[33] Ibid., at p. 10.

[34] See ibid., at p. 18ff.

[35] The Commission, *supra*, note 23, at pp. 2, 8, 12, 15, 21.

[36] Scott and Vos, *supra*, note 24, at p. 278.

[37] See ibid., at p. 278.

becomes noticeable in the practical application of the principle in GMO authorisations.[38]

The EU courts: the rise of a new general principle of community law

The European courts played a crucial role in the legal evolution of the precautionary principle in the Community legal order; a considerable body of bright academic commentary has already been dedicated to the analysis of this evolution.[39] I will therefore confine my account of the case law to the essential elements, in order to demonstrate that the approach taken towards the precautionary principle in the Commission Communication was, in principle, also confirmed in the case law.[40]

The climax in the European case law with regard to precaution, was the promotion of the principle to a general principle of EU law, which applies not only to environmental policy, but also more generally to risk regulation activities in fields such as environmental, health, animal or plant health protection. The ECJ paved the way for this development in its Bovine spongiform encephalopathy (BSE) case.[41] In this case it has endorsed the application of the principle in the area of human health protection by accepting that the Commission could use the principle in order to justify a decision to ban export of beef from the UK to reduce the risk of BSE transmission.[42] The ECJ stated: 'Where there is 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 become apparent.'[43]

In consequence of this and other similar ECJ judgments,[44] the Court of First Instance assumed a leading role in the further development of the precautionary principle in the EU by explicitly recognising the precautionary principle as a general principle in several judgments.[45] It has thus confirmed the Commission view, which it has already expressed in its Communication.[46]

As a consequence of such promotion as a general legal principle, the precautionary principle constitutes a hierarchically superior source of EU law. Thus, it serves as an instrument for the interpretation of existing EU law and has to be respected whenever new legal norms are to be construed. At the same time, it plays a crucial role in the

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[38] See below, under 'Application of the precautionary principle in the praxis of GMO authorisation'.

[39] See *supra*, note 25.

[40] For a detailed analysis of the case law before and after the Communication, see Fisher, *supra*, note 15.

[41] Case C-180/96, *UK v Commission* (1998) ECR I-2265.

[42] The reasoning of the ECJ was based on a combined reading of Art. 174 (1) and Art. 174 (2) EC, see ibid., par. 100; for a more detailed explanation of the Court's legal reasoning, see Craig, *EU Administrative Law*, *supra*, note 24, at p. 718.

[43] Case C-180/96, *UK v Commission* (1998) ECR I-2265, par. 99.

[44] See Case C-157/96, *The Queen v Ministry of Agriculture, Fisheries and Food, Commissioners of Customs & Excise, ex p National Farmers' Union* (1998) ECR I-2211; with regard to actions brought against member states see Case C-174/82, *Officier van Justitie v Sandoz BV* (1983) ECR 2445; Case 247/84, *Criminal proceedings against Leon Motte* (1985) ECR 3887; Case 54/85, *Ministère public against Xavier Mirepoix* (1986) ECR 1067; Case C-473/98, *Kemikalieinspektionen v Toolex Alpha AB* (2000) ECR I-5681.

[45] See Case T-13/99, *Pfizer Animal Health SA v Council* (2002) ECR II-3305; Case T-70/99, *Alpharma v Council* (2002) ECR II-3495; Cases T-74, 76, 83-85, 132, 137 and 141/00, *Artegodan GmBH v Commission* (2002) ECR II-4945, par. 184.

[46] See the Commission, *supra*, note 23, at p. 10.

judicial review of the legality and validity of secondary norms, as it constitutes a benchmark against which these norms are assessed.[47] Most importantly, with regard to the main subject of this paper, is the binding effect the precautionary principle has on the Community institutions[48] whenever they take regulatory decisions on risk-entailing products without there being a need for an explicit mention of the principle in the respective provisions of secondary law. The role of the principle as an integral part of such decision-making has been confirmed by the ECJ in its Monsanto judgement, in which it found that the principle must be taken into account in the decision-making by the Community institutions for the purpose of deciding whether a product may be placed on the market without danger for the consumer.[49]

With regard to the definition of the precautionary principle and the conditions of its application in administrative decision-making, it is remarkable that the Court of First Instance widely endorses the interpretation of precaution as a decision rule as expressed in the Commission Communication. In *Pfizer*, the Court of First Intance found that 'certain aspects of the communication could reflect the law as it stood at the time when the contested regulation was adopted in relation to the interpretation of the precautionary principle', as enshrined in Article 130 r (2) (Article 174 (2)) of the Treaty.[50] Although it is not entirely clear what the Court of First Instance means by stating that the Communication reflects the law as it stood, it seems that it is willing to attribute an important interpretative value to the Commission guidance. As a consequence, not only the Commission definition of the precautionary principle itself, but also its approach to the entire process of risk analysis, and thus the risk assessment/risk management divide have become 'ubiquitous' in the European Courts' case law.[51]

With regard to the risk assessment, the Court of First Instance has described it as being founded on the principles of excellence, transparency and independence, as such being 'an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'.[52] The Court, therefore, has placed a strong emphasis on the quality of the scientific assessment. Accordingly, the application of precaution can only be triggered when this assessment has identified a potential risk that is not founded on mere hypothesis.[53] Yet at the same time, the Court has allowed the public authority as the risk manager to derogate in certain cases from the opinion of the scientific experts, justifying such derogation with the political and democratic legitimacy of the

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[47] J. Scott, 'The Precautionary Principle Before the European Courts', in R. Macrory (ed.), *Principles of European Environmental Law*, Groningen, Europa Law Publishing, 2004, at p. 54; see also P. Craig and G. De Burca, *EU Law: Text, Cases and Materials*, Oxford, Oxford University Press, 2008, at p. 178ff.

[48] As a general legal principle of EU law the precautionary principle is also binding upon the member states when they are acting within the scope of Community law. See Scott, *supra*, note 24, at p. 54; Craig, *supra,* note 24, at p. 731.

[49] See Case C-236-1, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri* [2003] ECR I-8105, par. 133.

[50] See *Pfizer*, *supra* note 45, pars 123 and 149.

[51] See Case C-192/01, *Commission v Denmark*, AG Mischo par. 89; see also Fisher, *supra,* note 15, at p. 231.

[52] See *Pfizer*, *supra,* note 26, par. 172.

[53] Ibid., par. 147; for criticism of the notion of risk underlying this jurisprudence, see Fisher, *supra,* note 15, at p. 229ff.; more generally on limitations of traditional risk assessment with regard to new technologies, see J. Holder and M. Lee, *Environmental Protection, Law and Policy*, Cambridge, UK, Cambridge University Press, 2007, at p. 18.

Community institutions. In Pfizer it states referring to a scientific committee of the Commission:

> Whilst the Commission's exercise of public authority is rendered legitimate, pursuant to Article 155 of the EC (now Article 211 EC), by the European Parliament's political control, the members of SCAN, although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority.[54]

It is worth mentioning that whilst the Court of First Instance defines the specific conditions under which the principle is to be applied to risk management, the possibility of judicially ensuring that these conditions are complied with is limited. This is so because the scope of judicial review is confined to assessing whether the Community institutions have committed a manifest error of appraisal when applying the precautionary principle.[55] The institutions are therefore granted a wide scope of discretion that extends not only to their choice of appropriate precautionary measures, but also to the establishment of the factual circumstances.[56] It lies in their discretion to ascertain whether or not there is a situation of scientific uncertainty to trigger the application of precaution. The Court is not, in principle, allowed to substitute this assessment.[57]

To conclude the analysis of the approach taken to precaution under the Community legal order, it can be stated that it has been mainly developed by the European jurisprudence, which granted it the status of a general principle of Community law. The relevant case law, to a large degree, reflects the interpretation of precaution adopted by the European Commission in its Communication. Accordingly, the principle is understood as a decision rule to guide risk management under situations of scientific uncertainty. The Community institutions are obliged to take it into account, under certain conditions set out in the case law, whenever they are regulating products that might entail risks to human and animal health and/or the environment. When doing so they enjoy a broad political discretion.

The legislative framework for GMO marketing authorization

Today there is a complex body of legislative provisions of EU law concerning the regulation of GMOs. Several legal acts lay down a legislative framework that regulates nearly all aspects of GMOs, such as the import, production, marketing, traceability and export of GM products in the Community. The objective of this section is not to offer a comprehensive overview of all these provisions.[58] The administrative law perspective followed instead concentrates on those aspects of the

[54] See *Pfizer*, *supra,* note 26, par. 201.

[55] Ibid., par. 166 and other judgments stated therein; also Scott, *supra*, note 24.

[56] See *Pfizer*, *supra,* note 26, par. 168 and other judgments cited therein.

[57] However, despite using the same formula of 'manifest error of appraisal' in *Artegodan*, *supra*, note 45, the Court of First Instance went on and nevertheless reviewed the consistency of the scientific assessment; see par. 197ff. of the judgement.

[58] For a substantial overview of existing GMO legislation, see T. Christoforou, 'The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics', *Common Market Law Review* 41, No. 3, (2004), pp. 637-709; M. Lee, *EU Regulation of GMOs*, Cheltenham, Edward Elgar, 2008.

legislative framework which determine the way the Community institutions decide upon marketing authorisations for GMOs. For that purpose, I will describe the main legal instruments that govern these procedures including their legal basis, objectives and their scope of application. This will set the scene for the following analysis of how the precautionary principle is embedded within this framework.

Directive 2001/18 and Regulation 1829/2003

There are mainly two EU secondary laws that set out the structures of the marketing authorisation for GM products, and which have to be viewed as interrelated. Together, they establish a general system of prior notification and authorization for the placing on the market of GMOs.

The first is a 'horizontal' measure, Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms (hereinafter 'Deliberate Release Directive').[59] It constituted the first step of the regulatory reform in the area by repealing in 2002 the Council Directive 90/220/EEC,[60] the first Community measure regulating deliberate release into the environment of GMOs. The Directive has as its legal basis Article 95 EC, one of the key internal market provisions,[61] and it pursues a dual objective, as stated in Article 1: on the one hand, to approximate the laws, regulations and administrative provisions of the member states and, on the other, to protect human health and the environment when releasing GMOs into the environment or placing them on the market.[62]

The second measure is the 'vertical' Regulation 1829/2003 on Genetically Modified Food and Feed (hereinafter 'GM Food Regulation')[63] that applies only for use of GMOs in food or feed products. This piece of legislation came into force two years after the Deliberate Release Directive, establishing an authorisation procedure specifically for GM food and feed, which was supposed to include the new principles introduced in the Directive.[64] However, with regard to both the legal basis and the legislative objective, the GM Food Regulation is broader than the Deliberate Release Directive. It is not only based on the internal market provision of Article 95 EC, but also on Article 37 and Article 152 (4) (b) EC, and therefore on provisions for the common agricultural policy and public health respectively. Accordingly, to ensure the effective functioning of the internal market is only one of several objectives mentioned in Article 1 (a) of the Regulation. In addition, 'the Regulation shall also ensure a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed'.

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[59] Council Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, OJ 2001 L 106/1.

[60] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, OJ 1990 L 117/15.

[61] Holder and Lee, *supra,* note 53, at p. 188.

[62] This dual objective is also expressed in recitals 5 and 7 of the preamble of Directive 2001/18/EC.

[63] Regulation (EC) 1829/2003 on genetically modified food and feed, OJ 2003 L 268/1.

[64] See recital 9 of the preamble of Regulation 1829/2003; the previous authorisation procedure for GM food was governed by Regulation 258/97 concerning novel foods and novel food ingredients.

With regard to their scope of application, both the Directive and the Regulation are supposed to cover different uses of GMOs, thus complementing each other.[65] On the one hand, as a 'horizontal' measure, the Deliberate Release Directive applies to all use of GMOs that involve deliberate release into the environment of the organism.[66] Such a deliberate release can be either the placing on the market of a GMO[67] or its deliberate release for any other purpose[68] such as, for instance, for experimental purposes in field trials. The main area of application of the marketing authorisation procedure under the Deliberate Release Directive is the commercial use of GM seed, such as, for example, GM maize or cotton, for agricultural cultivation. As a consequence, the environmental impact of such cultivation plays a crucial role in the authorisation procedure, where approval is conditioned by the positive outcome of an environmental risk assessment of the product.[69]

On the other hand, as soon as the product to be authorised for marketing is a GMO for food use, or a food product containing or consisting of GMOs or which is produced from GMOs,[70] the authorization procedure of the GM Food Regulation shall apply.[71] As becomes obvious from the multiple objectives of this Regulation, as stated above, the issues to be tackled in the decision making on the authorisation of such products, go beyond environmental concerns. Whereas under the Directive the competent authorities shall avoid adverse effects on human health and the environment potentially arising from the placing on the market of GMOs, under the Regulation GM food is moreover required not to have adverse effects on animal health, mislead the consumer or differ from conventional food to such a degree as to be disadvantageous for the consumer.[72] These differences can be explained by the fact that the GM Food Regulation, albeit specifically covering GMOs, is also part of a broader framework of EU legislation on food. It follows the general principles of Regulation 178/2002,[73] also known as the General Food Law Regulation.[74]

In accordance with the somewhat different nature of the GM products dealt with by the Directive and the Regulation respectively, both legal acts also establish two

[65] It should be noted that in practice, there is a strong overlapping of the scopes of application of both laws. In fact, companies that want to place on the market a food/feed product containing GMOs or consisting of them, have the choice of submitting either a single application under Regulation 1829/2003/EC thus obtaining a single Community authorisation including cultivation of the product; or they submit applications under both Directive 2001/18/EC and Regulation 1829/2003/EC. See further in the European Commision press release from 22 March 2005 entitled 'Questions and Answers on the Regulation of GMOs in the European Union', available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/05/104&format=HTML&aged=0&language=EN&guiLanguage=en>.

[66] 'Deliberate release' is defined in Art. 2 (3), Directive 2001/18/EC as 'any intentional introduction into the environment of a GMO or a combination of GMOs for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment'.

[67] Part C of Directive 2001/18/EC.

[68] Part B of Directive 2001/18/EC.

[69] See Art. 13 (2) (b) and Annex II of Directive 2001/18/EC.

[70] Similar observations apply to the authorization of GMOs as feed products, dealt with in Chapter III of Regulation 1829/2003/EC. For the sake of simplification I will confine my explanations to GM food.

[71] Art. 3 (1), Regulation 1829/2003/EC.

[72] See Art. 4 (1), Regulation 1829/2003/EC.

[73] See Art. 1 and recital 9 of the preamble of Regulation 1829/2003/EC.

[74] Regulation (EC) 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 31/1.

different types of authorisation procedures. The GM Food Regulation has created a centralised authorisation procedure at Community level, establishing the so-called 'one door – one key' principle. Unlike under the old regime of the Novel Foods Regulation, the role of the national competent authorities in granting GMO authorisations has been limited and it is now the Commission and the Council who decide upon the marketing approval by addressing their final decision directly at the applicant. Once an authorisation has been granted it is valid and enforceable vis-à-vis all the member states, the GM product being able to circulate on the entire common market.

The Deliberate Release Directive has, in principle, preserved the 'old' system of the Directive 90/220, whereby national authorities decide upon GMO applications. The company that applies for marketing authorisation under the Directive has to submit its application to the competent national authority (CNA) of the member states where it wants to market the product for the first time.[75] The CNA prepares an assessment report, in which it evaluates whether or not the product in question should be placed on the market.[76] It is thus primarily responsible for assessing the results of the environmental risk assessment. Subsequently, according to the standard procedure foreseen in the Directive[77] the CNA can, in principle, take the final decision on the marketing of the product, but only if no reasoned objections have been raised and upheld by the member states or the Commission. In case of such objections, the application procedure is elevated to the Community level[78] and is in this case very similar to the centralised procedure under the GM Food Regulation. In fact, since the entering into force of the Directive, such objections have been the case in every single application for commercial release;[79] bearing in mind the contestations around GMOs this comes as no surprise. As a consequence, in practice, the role of the NCA is reduced to the initial assessment report and it is, as under the Regulation, the Commission and the Council who together are responsible for granting or rejecting the approval of the GM product. As I am interested in the application of the precautionary principle by the Community institutions, in the following, I will limit my analysis of the Directive to the Community procedure.

Regulation 178/2002

There is a third legal instrument that plays an important role in legally structuring the decision-making process of GMO authorisations, which is Regulation 178/2002 laying down the general principles of food law and establishing the European Food Safety Authority (hereinafter 'GFL Regulation').[80] It was already briefly mentioned above in relation with the GM Food Regulation[81] which in fact, refers back to the GFL

[75] See Art. 13, Directive 2001/18/EC.

[76] See Art. 14, Directive 2001/18/EC.

[77] See Art. 15, Directive 2001/18/EC.

[78] See Arts 18 and 28 (1), Directive 2001/18/EC.

[79] See M. I. Kritikos, 'Institutions and Science in the Authorization of GMO Relesases in the European Union (1990-2007): The False Promise of Proceduralism', PhD Thesis, London School of Economics, 2007, at p. 166.

[80] Regulation (EC) 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 31/1.

[81] See above under 'Directive 2001/18 and Regulation 1829/2003'.

Regulation[82] and integrates it into the overall GMO framework. The enactment of the GFL Regulation was the result of a reform process in EU food safety law[83] that took place concurrently with that in the area of GMOs, both being part of the general overhaul of risk regulation at EU level.[84] The legal basis chosen for the GFL Regulation is particularly broad encompassing four different Treaty provisions, namely Articles 37, 95, 133, 152 (4) (b) EC concerning the common agricultural policy, the common market, the common commercial as well as the public health policy. The main objective of the GFL Regulation was to establish common general principles and procedures underpinning regulatory decision-making in the area of food safety.[85] As will be explained more detailed in the following sections, it introduced a major innovation by providing a general framework for risk analysis to be used in all areas touching upon food safety issues. Moreover, the Regulation undertakes to provide a 'uniform basis throughout the Community' of the use of the precautionary principle.[86] Accordingly, for the first time in a binding EU legal text, an actual definition of this principle is laid down.[87]

Furthermore, the GFL Regulation is the establishing legal act of the European Food Safety Authority (hereinafter EFSA), which is the main scientific authority to provide advice also in decision-making of GMO authorisation.[88] By establishing the organisation of EFSA, the composition of its organs and the procedures of its work, the GFL Regulation constitutes the legal backbone of the risk assessment process that is an essential part of every GMO authorisation. The impact of this Regulation on the way the authorisation decision-making is carried out is therefore crucial, and needs to be investigated in detail in the following sections.

To conclude, the EU legislation described above establishes a system of prior-authorisation for GM products, in which the decisions are mainly[89] taken at Community level within the comitology procedure.[90] The main institutional actors of authorisation are therefore the Commission and the Council. The legal acts pursue a variety of legislative objectives, which are not confined to the protection of health and environment, but also include the free circulation of GM products on the EU market, consumer protection, and animal health and welfare. Together they determine the structures, in which regulatory decisions on GMO authorisation take place. It is now time to examine how the precautionary principle is legally introduced into these structures.

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[82] See Art. 1, Regulation 1829/2003/EC.

[83] See White Paper on Food Safety, COM (1999) 719.

[84] For an overview of the historical developments leading to this overhaul, i.e. the BSE and other food scandals of the 1990s, see C. Shaffer and M. Pollack, 'Agricultural Biotechnology Policy in the EU: Between National Fears and Global Disciplines', in H. Wallace, W. Wallace and M. Pollack (eds), *Policy-Making in the European Union*, Oxford, Oxford University Press, 2005, 5th Edition.

[85] See Art. 1, Regulation 178/2002/EC.

[86] See recital 20, Regulation 178/2002/EC.

[87] See Art. 7, Regulation 178/2002/EC.

[88] See Art. 22, Regulation 178/2002/EC.

[89] Although the system under the Directive establishes a national authorisation procedure in principle, so far, every authorisation was in practice dealt with under the Community procedure.

[90] See Arts 18 (1) and 30 (2), Directive 2001/18/EC as well as Arts 7 (3) and 35 (2), Regulation 1829/2003/EC.

The definition of precaution under the GMO legal framework

Both EU legal acts regulating the marketing of GMOs, the Deliberate Release Directive and the GM Food Regulation, have been based on the precautionary principle. The Directive contains a direct reference to it by describing its objective in Article 1 as being 'in accordance with the precautionary principle.'[91] Also, in recital 8 it states, 'The precautionary principle has been taken into account in the drafting of this directive and must be taken into account when implementing it.' Although it does not directly mention the principle, the same applies to the GM Food Regulation. Art. 1 thereof states that it is based on the general principles of EU Food law as laid down in the GFL Regulation, one of these principles being the precautionary principle.[92] A combined reading of these provisions shows that the principle has been the guiding idea throughout the establishment of the new GMO framework.[93] However, apart from those provisions directly mentioning the precautionary principle, the legislator has also set up a whole set of principles, procedures and institutions, which together can be understood as an expression of that principle. In the following, I will therefore show that precaution has a role to play in two different contexts of the GMO framework. It has been employed as an *institutional* and *procedural principle* that guided the drafting of the legislation, and as such has influenced the institutional and procedural structures for the marketing authorisation process provided therein.[94] On the other hand, the principle has also been defined as a *decision rule*, because it shall guide the implementation of the legislative provisions, i. e. the case-by-case decision-making in single authorisation procedures.[95]

Institutionalisation of precautionary governance structures

In order to assess the nature of the precautionary principle as an institutional and procedural principle, we need to have a closer look at further principles on which the GMO regulatory system is based. Three principles are of particular interest in this regard: the principle of prior-authorisation of GMOs; the shift of the burden of proof to the applicant; and the principle of risk analysis to precede every authorisation decision. All of these principles can be understood as giving expression to precaution.

According to the principle of prior-authorisation[96], every GM product has to undergo a safety assessment by the public authorities before it can legitimately be placed on the market. This requirement is justified by the legislative assumption that GMOs are *a priori* potentially hazardous,[97] which calls for a precautious regulatory approach;

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[91] Art. 1, Directive 2001/18/EC.

[92] Defined in Art. 7, Regulation 178/2002/EC, see below in the foruth section, under 'Precaution as Decision Rule: Managing Scientific Uncertainty in GMO Authorisations '.

[93] See Z. K. Forsman, 'Community Regulation of Genetically Modified Organisms: a Difficult Relationship Between Law and Science', *European Law Journal* 10, No. 5 (2004), at pp. 580-81; Shaffer and Pollack, *supra*, note 84, at p. 342.

[94] See also R. von Schomberg, 'The Precautionary Principle and its Normative Challenges', in E. Fisher, J. Jones and R. von Schomberg (eds), *Implementing the Precautionary Principle*, Cheltenham, Edward Elgar Publishing, at p. 26, whom with regard to the GMO framework speaks of a 'particular design of a precautionary regulatory framework'.

[95] On these two meanings of the precautionary principle, see Fisher, *supra*, note 21; Stirling et al., *supra*, note 29.

[96] See Art. 13 (1), Directive 2001/18/EC and Art. 4 (2), Regulation 1829/2003/EC.

[97] See recitals 4 and 5, Directive 2001/18/EC.

accordingly, it has been confirmed by the ECJ that prior authorisation is one of the possible ways of giving effect to the precautionary principle.[98]

Furthermore, the shift of the burden of proof is considered to be an essential element of a precautionary approach to risk regulation.[99] As a consequence, the regulatory authority does not have to demonstrate a risk, but the applicant as the proponent of the risk-entailing product, has to adequately and sufficiently demonstrate its safety.[100]

Finally, the institutional set up, the course of the authorisation process and the role of actors involved are also governed by the principle of risk analysis as defined in Article 3 (10) and Article 6 of the GFL Regulation.[101] Accordingly, every authorisation decision has to be preceded by a risk analysis of the product in question. This process serves the purpose of evaluating whether the substantive requirements for authorisation[102] are fulfilled and it is divided in two main parts: risk assessment and risk management. Article 6 (2) and (3) of the GFL Regulation defines both processes as follows:[103]

> (2) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.
>
> (3) Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority (…), other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7 (1) are relevant, in order to achieve the general objective of food law established in Article 5.

The institutional embodiment of the above definitions was the creation of two main arenas of authorisation decision-making under the GMO framework. In the first one, that of risk assessment, actors such as scientific and administrative experts from all over the Union, the applicant company and civil society co-operate in a scientific expert network under the auspices of the EFSA. Legal scholars have already shown interest in the institutional set up and functioning of the EFSA.[104] Thus, the authority has been described as:

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[98] Case C-66/99, *Association Greenpeace France v Ministère de l'Agriculture et de la Pêche* (2000) ECR I-1651.

[99] See the Commission, *supra*, note 23, at p. 21; see also in the context of Australian administrative law, J. Jones and S. Bronitt, 'The Burden and Standard of Proof in Environmental Regulation: the Precautionary Principle in an Australian Administrative Context', in E. Fisher, J. Jones and R. von Schomberg (eds), *Implementing the Precautionary Principle*, Cheltenham, Edward Elgar Publishing, 2006.

[100] See Art. 4 (3), Regulation 1829/2003/EC; the Directive does not contain a similar explicit provision on the burden of proof, but the shift of burden follows from a combined reading of Arts 4 (2) and 13, Directive 2001/18/EC.

[101] By virtue of Art. 1, Regulation 1829/2003/EC, the principle of risk analysis directly applies to the GM Food Regulation although, as such, the principle is not mentioned in the Directive, the structured approach to risk analysis as formulated in the Commission Communication governs the administrative practice of the Commission also under the Community procedure of Directive 2001/18/EC, since the Commission Communication constitutes a self-binding commitment of the Commission to exercise its discretion in a certain way; see *Pfizer*, *supra,* note 45, pars 119 and 123.

[102] These requirements are formulated in Art. 4 (1), Regulation 1829/2003/EC for GM food; for GMOs to be placed on the market under the Directive, Art. 4 (1), Directive 2001/18/EC applies.

[103] See also the definitions in Arts 3 (11) and (12), Regulation 178/2002/EC.

[104] See for example D. Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life', *European Law Review* 30, No. 5 (2005), pp. 649-74; E. Vos and F. Wendler, 'Food Safety Regulation at the

> [...] a transnational governance regime which cuts across national/supranational and public/private distinctions, and which both guides and is accountable to scientific communities, national food authorities and civic society. As these networks inform its constitution, it cannot be seen as something starkly autonomous from them, but something that both contributes to their constitution and is constituted by them.[105]

For the purpose of this paper, it suffices to say that the mission of EFSA can be characterised as 'decentralised integration'[106] of national scientific authorities and other organisations carrying out similar tasks in the area of food safety and GMOs. Furthermore, it can be described as the integration of expert networks through which different actors of the GMO regime from different societal spheres are linked together and co-operate in order to generate knowledge and safety standards.[107] By integrating these networks EFSA itself constitutes an expert network providing for structures of scientific co-ordination within this area of the EU.[108]

In the second arena of authorisation decision-making, that of risk management, the political responsibility for taking the final decision is assigned to the Commission, a regulatory committee[109] and the Council, which are supposed to co-operate in the framework of the comitology procedure thus providing for a network[110] of transnational administrative co-operation and co-ordination between the Commission and national administrations.[111]

It follows that the regulatory committee procedure[112] applicable to GMO authorisation normally foresees that the Commission, the regulatory committee[113] as

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EU Level', in E. Vos and F. Wendler (eds), *Food Safety Regulation in Europe. A comparative institutional analysis*, Antwerp, Intersentia, 2006.

[105] See D. Chalmers, '"Food For Thought:" Reconciling European Risk and Traditional Ways of Life', *Modern Law Review* 66, No. 4 (2003), pp. 532-62.

[106] E. Chiti, 'Decentralisation and Integration into the Community Administrations: A New Perspective on European Agencies', *European Law Journal* 10, No. 4 (2004), pp. 402-38; see also T. Groß, 'Kooperation zwischen Europäischen Agenturen und Nationalen Behörden', *Europarecht*, No. 1 (2005), pp. 54-68.

[107] On the integrative institutional structures of EFSA, see M. Weimer, 'Legitimacy through Precaution in European Regulation of GMOs? From the Standpoint of Governance as Analytical Perspective', in C. Joerges and P. Kjaer (eds), *Transnational Standards of Social Protection*, ARENA Report No. 5, (2008), RECON Report No. 4, available at <http://www.reconproject.eu/main.php/RECONreport0408.pdf?fileitem=3522579>.

[108] The term network is understood as an analytical category in the sense of 'an entity in which different parts are loosely linked, but not fixed together. The single elements are autonomous from, yet not necessarily equal to each other.' See H. Türk and H. Hofmann, 'An Introduction to EU Administrative Governance', in H. Hofmann and H. Türk (eds), *EU Administrative Governance*, Cheltenham, Edward Elgar, 2006; See also G. Sydow, *Verwaltungskooperation in der Europäischen Union*, Tübigen, Mohr Siebeck, 2004, at p. 79.

[109] In case of a GM food product, it is the Standing Committee on Animal Health and Food Chain, see Art. 35, Regulation 1829/2003/EC; in case of an application under Directive 2001/18/EC see Art. 30.

[110] Ibid.

[111] C. Joerges and J. Neyer, 'Transforming strategic interaction into deliberative problem-solving: European Comitology in the foodstuffs Sector', *Journal of European Public Policy* 4, No. 4 (1997), pp. 609-25. On comitology as governance, see P. Kjaer, 'Between Governing and Governance: On the Emergence, Function and Form of Europe's Post-national Constellation', PhD Thesis, European University Institute, 2008.

[112] See Art 5 of Council Decision 1999/468/EC, OJ L 184/23. For an explanation of the regulatory procedure see Vos and Wendler, *supra*, note 104, at p. 89.

well as the Council adopt decisions on GMO marketing in co-operation. The comitology procedure could ideally be regarded as a compensation for the loss of national regulatory competences in this area, by serving as a forum for the member states to express their concerns, and to raise arguments about the ethical or socio-economic impact of GMO commercialisation on their national economies, agricultures, biodiversity etc.[114] We will see at a later stage of this examination that the practice of authorisation of GMOs does not quite match this normative ideal.[115]

To conclude, it becomes clear that the structured approach to risk analysis as described in the Commission Communication on the Precautionary Principle in the year 2000,[116] and later confirmed in the case law of the European Courts,[117] has provided for the model guiding the legislative setup of the GMO framework. It shall be recalled that the notion of precaution associated with this approach is one that distinguishes between two different rationalities underlying the precautionary principle; the scientific and the political rationality.[118] To use the Court's terminology, the precautionary principle is based on the idea that scientific legitimacy is not sufficient to underpin regulatory decisions on risk. It must be complemented by a political legitimacy provided for by a risk manager who is democratically accountable and has the discretion to take into consideration other factors than the results of the scientific risk assessment.[119] The institutional and procedural design of the GMO authorisation procedures established by the legislator seems to provide for participatory structures, which allow for the input of such other factors into authorisation decision-making. It can, therefore, be characterised as establishing precautionary governance of GMO risks.[120] However, as we will see in the following section, the conception of the precautionary principle also as a decision rule raises further questions and difficulties with regard to the inclusion of other than scientific factors into the authorisation process.

Precaution as decision rule
Managing scientific uncertainty in GMO authorisations

The Community institutions, above all the Commission and the Council, have the duty to implement the legislative framework set out for GMO authorisation.[121] As we have seen in the previous section, when doing so, they are acting within a precautionary framework. However, in this section I will show that the precautionary

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[113] In the case of the GM Food Regulation it is the Standing Committee on the Food Chain and Animal Health (SCFCAH), *supra*, note 109.

[114] See Sydow, *supr*a, note 108, at p. 221.

[115] See teh fifth section of thsi paper, under 'Application of the precautionary principle in the praxis of GMO authorisation'.

[116] See the Commission, *supra*, note 23.

[117] See the analysis in the second section of this paper, under 'The EU Courts: the rise of a new general principle of Community law'.

[118] See also T. Christoforou, 'The Precautionary Principle and Democratizing Expertise: A European Legal Perspective', *Science and Public Policy* 30, No. 3, (2003), pp. 205-12.

[119] See *supra*, note 55.

[120] On precautionary governance structures, see Stirling et al., *supra*, note 29.

[121] Under the Directive, the member states have this duty, but only as long as the standard and not the Community procedure for marketing authorisation applies, see the third section of this paper, under 'Directive 2001/18 and Regulation 1829/2003'.

principle also guides the Community institutions in their decision-making in a more direct way, namely as a decision rule to be applied under certain specific conditions.

As briefly mentioned above, Article 7 of the GFL Regulation contains the first legal definition of the precautionary principle under Community law. It states:

> 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 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 matters 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.

This definition directly applies to the decision-making under the GM Food Regulation by virtue of Article 1. It does as such not apply to the Deliberate Release Directive, because the latter does not contain any reference to the GFL Regulation and its principles. Also, the above definition is confined to the application of the precautionary principle in the area of health protection, and it does not cover protection of environment, which is the main objective of the Directive.[122] However, one should bear in mind that the precautionary principle as defined in the case law of the European Courts is a general principle of Community law; it must therefore be taken into account, under conditions set out in the case law, in all regulatory decisions taken by the Community institutions on risk-entailing products.[123] As a consequence, under the Directive's Community procedure, the Commission and the Council are obliged to act in accordance with the precautionary principle.

If we compare the formulation chosen in the GFL Regulation with the Commission Communication, the significance of the Commission document becomes apparent once again. Firstly, as in the Commission Communication, the precautionary principle in Article 7 shall apply only to risk management measures, and only when the previous scientific assessment has indicated the possibility of risk as well as a situation of scientific uncertainty. Secondly, Article 7 (1) and (2) follow the distinction made in the Commission Communication between the political decision to act on the one hand, and the political decision on how the precautionary measures should be taken on the other; both being decisions of the risk manager.[124] Also the requirements of proportionality, non-discrimination, and the provisional nature of measures

[122] See the third section of this paper, under 'Directive 2001/18 and Regulation 1829/2003'

[123] See the second section of this paper, under 'The EU Courts: the rise of a new general principle of Community law'.

[124] See the analasys in the second section of this paper, under 'The Comission communication on the precautionary principle'.

following from the decision to act under the precautionary principle are included in Article 7.[125] Read together with the previous Article 6 of the GFL Regulation, which defines the principle of risk analysis, it is evident that the legislative approach taken here follows the one expressed in the Commission Communication. Seeing that the latter approach has mostly been confirmed in the case law of the European Courts,[126] it can be concluded that the definition of the precautionary principle to be applied by the Community institutions under both the GM Food Regulation and the Deliberate Release Directive, is essentially the same.[127] This is also consistent with the fact that the guidelines laid down in the Commission Communication constitute a commitment of the Commission to exercise its discretion with regard to the precautionary principle in the way expressed in this document. They therefore create an administrative practice, which the Commission has obliged itself to respect in all its activities.[128]

Let us now take a closer look at how exactly the definition of the precautionary principle in Article 7 of the GFL Regulation interacts with the decision-making process of GMO authorisation. To simplify matters, I will choose the example of a marketing application for a GM food product under the GM Food Regulation. Article 7 (1) of the GM Food Regulation determines the way in which the Commission has to adopt its risk management decision on authorisation. After receiving EFSA's risk assessment on a product, for which a marketing application has been submitted, the Commission shall submit to the regulatory committee its draft decision in respect of the application. When taking this draft decision the Commission shall take into account the opinion of the EFSA, any relevant provisions of Community law and other legitimate factors relevant to the matter under consideration. If the Commission decides to derogate from EFSA's risk assessment, it shall provide an explanation for the differences. [129]

If we interpret this provision in the light of the precautionary principle as laid down in Article 7 of the GFL Regulation, it follows that the Commission has to take into account this principle as one of the relevant provisions of Community law when preparing its draft decision. However, this does not necessarily mean that the principle will be applied in that particular decision-making process.[130] Only where the conditions triggering the application of the precautionary principle are given, will the Commission, firstly, decide on whether or not to act in accordance with the principle, and, secondly, on how to act. This means, that only where the scientific assessment has identified the possibility of adverse effects on health or the environment, thus a potential risk that is not of merely hypothetical nature; and where at the same time it has indicated that there is scientific uncertainty as to the

[125] See *supra*, note 23.

[126] See analysis in the second section of this paper, under 'The EU Courts: the rise of a new general principle of Community law'.

[127] The European Courts so far have only dealt with Art. 7, Regulation 178/2002/EC en passant confirming the view that it codifies the previous Community case law on the precautionary principle for the area of EU food law. See Case C-453/03, A*BNA Ltd and others v Secretary of State for Health and Food Standards Agence*, AG Tizzano; Case C-41/02, *Commission v Kingdom of the Netherlands*, AG Maduro.

[128] On the nature of the Commission Communication as a self-imposed limitation of the Commission's discretion, see *Pfizer*, *supra*, note 26, pars 119 and 123.

[129] See Art. 7 (1), Regulation 1829/2003/EC.

[130] See Art. 6 (3), Regulation 178/2002/EC that states that the precautionary principle shall be taken into account in a risk management decision only 'where the conditions laid down in Article 7 (1) are relevant.'

reality and extent of such risk;[131] only in this case can the Commission apply the precautionary principle by taking the above mentioned discretionary decisions whether and how to act in the face of the scientific uncertainty identified in the risk assessment.

It is important to note that EFSA does not have the prerogative to identify scientific uncertainty, and therefore, to trigger the precautionary principle. This follows from the provision that the Commission can depart from EFSA's opinion, provided it can appropriately justify such departure.[132] Moreover, EFSA co-ordinates the work of national scientific authorities, but it has not been placed in a hierarchical relation to them being able to overrule other scientific opinions.[133] As a consequence, the Commission is entitled and, by virtue of precaution even obliged to take into account other existing scientific evidence than that provided by EFSA.[134]

According to the understanding of the precautionary principle as expressed in the GFL Regulation as well as to the broader understanding within the Commission Communication and the case law,[135] the scientific evidence is not the only factor that shall be taken into account when drafting an authorisation decision. Both Article 7 of the GFL Regulation and Article 7 of the GM Food Regulation mention 'other legitimate factors' to play a role in the decision-making. The definition of such factors and their exact role in the decision process is, however, a highly contested issue. The relevant legislative provisions do not sufficiently clarify the role of such factors, the practical consequence being that the Community institutions have so far not explicitly based their decisions in respect of GMO marketing on such 'other legitimate' factors; I will further discuss this in the next section. Moreover, no discussion takes place as to how the inclusion of 'other legitimate factors' is connected with the application of the precautionary principle in the case-by-case decision-making on authorisation. However, both aspects are closely intertwined as the following analysis of the relevant legal provisions illustrates.

Under the GFL Regulation, both articles defining risk management mention 'other legitimate factors.' In Article 3 (12) risk management is defined as a process of 'weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors….' In Article 6 (3) it is stated further that risk management 'shall take into account the results of risk assessment, (…) other factors legitimate to the matter under consideration and the precautionary principle…' Under the GM Food Regulation Article 7 (1), already referred to above, stipulates that the Commission shall take into account 'other legitimate factors' when drafting its decision on the marketing of a GM food.

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131 See *Pfizer*, *supra*, note 26, pars 142-144; see also Case C-244, *France v Parliament* (2005) ECR I-4021, AG Geelhoed par. 107; see also Case E-3/00, *EFTA Surveillance Authority v Norway* (2001) 2 CMLR 47, where the EFTA Court has interpreted the required level of potential risk in restrictive, probabilistic terms, see pars 30-32.

132 On the requirements on this justification developed in the case law, see *Pfizer, supra*, note 45, par. 199.

133 This is demonstrated by provisions such as for example, Art. 30 and Art. 36, Regulation 178/2002/EC.

134 In *Pfizer*, *supra*, note 26 and *Artegodan*, *supra*, note 45, the Court of First Instance has admitted that the Community institutions can make recourse to other sources of scientific research, see for example *Pfizer,* pars 199 and 204.

135 See the second section of this paper, under 'The precautionary principle in the EU legal system'.

According to these provisions, therefore, it is part of risk management to take into considerations, not only science, but also 'other legitimate factors.' At the same time, the risk manager also has to take into account the precautionary principle in the way it was considered above. The question arises as to whether these two elements of risk management are in some way interrelated. The only provision, in which both are mentioned at the same time, is Article 6 (3) of the GFL Regulation. The wording of this provision enumerates the different factors to be considered in risk management decisions, and it seems to indicate that 'other legitimate factors' and the precautionary principle are treated as separate issues. The consequence of such a reading for authorisation decisions under Article 7 (1) GM Food Regulation would be that the introduction of 'other legitimate factors' would be possible irrespective of there being a situation of scientific uncertainty. In other words, even in situations where the risk assessment is conclusive and does not indicate any uncertainties in relation to possible risks to public health and the environment, the risk manager would be entitled to consider other factors than the scientific opinion. On the other hand, if interpreted in the light of the precautionary principle, Article 7 (1) would require the risk manager to include into the decision-making non-scientific aspects only in accordance with the precautionary principle; and that would mean, only in a situation of inconclusive scientific evidence and scientific uncertainty.

The latter interpretation seems to be confirmed when looking at the recitals of both Regulations. Recital 19 of the GFL Regulation states,

> It is recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account, including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

The word 'including' indicates that the enumeration of 'other legitimate factors' given here is not exhaustive. However, it becomes clear what type of factors is envisaged by the legislator, and that they must be other than scientific factors. This recital can be interpreted as implying that the situation, in which those factors become relevant is a situation, in which the risk assessment cannot provide all the information on which to base the risk management decision. The formulation that it is only in 'some cases' that this situation occurs, implies that normally the risk assessment is expected to be able to provide for all the relevant information, because it is conclusive, ie it either excludes the existence of risks or, on the contrary, it indicates such existence. Understood in this way, the situation described in recital 19 is identical with the situation that triggers the application of the precautionary principle; it is one of scientific uncertainty. This is further affirmed by the recital 32 of the GM Food Regulation, which is formulated in almost identical terms:

> It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account.

Here, the formulation '*may* be taken into account' expresses that the use of 'other legitimate factors,' as envisaged by the legislator, is confined to the particular cases of scientific inconclusiveness and uncertainty. However, indeterminacy as to the role of

such factors in the authorisation decision-making remains. On the one hand, one can imagine certain factors to be relevant for the authorisation decision, which should legitimately be taken into account even when scientific assessment is conclusive and does not indicate risk. An example could be the protection of certain especially sensitive zones, such as Natura 2000 zones, where biodiversity could be endangered although in other areas the release of a GMO would be considered as safe. On the other hand, the Deliberate Release Directive does not have any reference to 'other legitimate factors' causing incoherencies in the overall application of the GMO framework. It would, therefore, be desirable in the future to have a legal clarification of the role of such factors in decision-making.[136]

To conclude, the analysis of the legislative provisions shows that not only is the legal framework for GMO authorisation based on the precautionary principle, but the Community institutions also need to act in accordance with this principle when drafting risk management decisions on single marketing authorisations. This applies to both, decisions taken under the GF Food Regulation and those under the Deliberate Release Directive. In the implementation of the framework, the principle, thus, becomes a decision rule to guide decisions on concrete applications, when the precedent scientific risk assessment has identified the possibility of adverse effects on health and/or the environment, but scientific uncertainty as to the existence of the risk and its extent persists. Although EFSA is the main institutional actor responsible for delivering risk assessments on GM products to the Commission, a situation of scientific uncertainty can also result from there being scientific opinions from other national or international scientific institutions, which contradict EFSA.[137] Once the Commission ascertains that there is scientific uncertainty, and the Courts grant it a broad discretion in doing so also with regard to determining the factual situation, [138] it can, considering the level of protection chosen in the Community, adopt provisional precautionary measures taking into account 'other legitimate factors,' such as the socio-economic impact of the product to be marketed. One possibility in such a situation would be for the Commission to invoke the precautionary principle in order to deny authorisation of the product. Also here the Commission is granted a wide discretion in deciding what measures it considers most appropriate as a reaction to the scientific uncertainty and the possible risks.

Application of the precautionary principle in the praxis of GMO authorisation

Reality usually turns out to be by far more imperfect than normative ideas, and this is particularly true for the application of the precautionary principle in concrete cases of marketing authorisation. Challenges arise, above all, in the phase of risk management with regard to the way, in which the Community institutions exercise their political

[136] In the currently ongoing reflection process on GMO legislation this issue seems to be the bone of contention between the member states and the Commission, although, unfortunately, it is discussed without any reference to the precautionary principle, see *supra,* note 10. It remains to be seen whether this process will accomplish clarifying the way, in which the legislative provisions should be implemented.

[137] *Pfizer*, *supra*, note 26, pars 199 and 204; see also A. Alemanno, 'EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review', in E. Vos (ed.), *European Risk Governanc*e, Mannheim, Connex, 2008, at pp. 37, 49.

[138] See *supra*, note 56.

responsibility to adopt final decisions on GMO marketing. The practice of authorisation, as will be shown in this section, does not seem to follow a coherent approach with regard to which factors should be decisive in granting GMO authorisations; it is characterised by a lack of transparency, a confusion of political and scientific arguments as well as by contradicting, and even antipodal, interpretations of the precautionary principle.

Since the restarting of authorisations in 2004, the Community institutions, above all the Commission, seem to be determined to demonstrate that the new authorisation procedures are functioning by adopting a science-based approach to GMO authorisation as well as building a strong alliance with EFSA, the newly established scientific authority. Thus, so far, all new applications for GMO authorisation[139] have been approved by the Commission that based itself in every case on a positive risk assessment from EFSA.[140] Even so, the decision-making process in each case was highly politicised and accompanied by strong opposition on the part of the member states within the comitology procedure. All the Commission draft decisions were referred to the Council and could be adopted only because, under the regulatory procedure in comitology, the lack of qualified majority either in favour or against the Commission draft decision entitles the latter to adopt the final decision.[141] Empirical studies on the work of the comitology committees in this field[142] have shown that no debate usually took place among the members. A vote was always called for and national representatives came to the meetings already with instructions or a strict mandate from their ministries.[143] When the matter proceeded to the Council, no qualified majority could be reached either in favour or against the Commission,[144] although there was always a simple majority opposing the authorisation.[145] It has been stated that

> The authorisation of GMOs is precisely the sort of controversial decision in which the Council will find it difficult to muster a qualified majority vote in either direction, such that national and political involvement in the final decision on GMOs is undermined by disagreement. The restarting of authorisations for GMOs in 2004 depended on Commission decision in the face of member state inability to reach a qualified majority in either direction. [146]

[139] Submitted under either the Directive 2001/18/EC or the Regulation 1829/2003/EC.

[140] See Community register on authorisation, available at <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm> (accessed 3 December 2009).

[141] See Art. 5 (6), Council Decision 1999/468/EC.

[142] See Vos and Wendler, *supra*, note 104, at p. 116; Chalmers, *supra,* note 104, at p. 656.

[143] See Vos and Wendler, *supra,* note 104, at p. 89.

[144] So far, the Council reached a qualified majority against the Commission only in procedures concerning the lifting of national cultivation bans on GMOs; in June 2005, it opposed the Commission proposal to lift eight bans invoked by five member states; and in March 2009 the Council rejected the Commission's recommendation to lift cultivation bans upheld in Austria and Hungary. See <http://www.gmo-compass.org/eng/news/422.cultivation_ban_gm_maize_austria_hungary_remains.html> (accessed 3 December 2009); see also Holder and Lee, *supra*, note 53, at p. 197.

[145] Vos and Wendler, *supra*, note 104, at p. 129.

[146] Holder and Lee, *supra,* note 53, at p. 195.

This situation shows clearly that the Commission authorisations granted so far lack the political acceptance of at least a majority of the member states.[147] Ever since the Commission started approving GMOs after the halt of authorisations under the de-facto moratorium, new national bans on the marketing and/or cultivation of biotech products came into force in several member states.[148] Around half of all member states seem to oppose GMO commercialisation in the Union at the moment.[149]

At the same time there is no indication that the Commission, before drafting its decision, took into account 'other legitimate factors' besides of the risk assessment. The decisions for authorisation taken so far usually refer to the fact that EFSA has 'concluded that it is unlikely that the placing on the market of the products […] will have adverse effects on human or animal health or the environment;'[150] and, 'taking into account those considerations, authorisation should be granted for the product.'[151]

This authorisation practice shows a purely science-based approach to GMO authorisation. Risk management by the Commission appears to have been based on no more than the scientific opinion of EFSA, the expertise of which has in no case been questioned or departed from. This seems to be in accordance with the understanding of the precautionary principle as a decision rule under the legislative framework, because in no case has the EFSA indicated that there is a possibility of risk to human health or the environment. Therefore, following EFSA, the Commission so far had no reason to assume a situation of scientific uncertainty under which it would have been obliged to apply the precautionary principle. It is notable that this authorisation practice was from the beginning accompanied by critical media publicity and public protests in the member states.[152] As a reaction to this, protest from the national governments followed promptly, calling for another revision of the GMO legislation and the improvement of the functioning of the authorisation procedures; some governmental officials even suggested another moratorium on GM products until the regulatory system is improved.[153]

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147 According to the Eurobarometer *Europeans and Biotechnology in 2005: Patterns and Trends* published in May 2006, only an average of 27 per cent of the European population encourages the technology of GM food.

148 See list of national measures on the DG Environment website, available at <http://ec.europa.eu/environment/biotechnology/safeguard_measures.htm> (accessed 3 December 2009). A recent example is the invocation by Germany of a safeguard measure under Directive 2001/18/EC against the MON 810 Bt maize, see GMO Compass, 'Germany: Minister Aigner bans MON810 Bt maize', available at <http://www.gmo-compass.org/eng/news/432.docu.html> (accessed 3 December 2009).

149 See La Repubblica from 31 october 2007, 'OGM, l'Italia chiede il bando Ue "Basta autorizzazioni facili"'. See also Chalmers, *supra*, note 104, p. 663, who emphasises the ambiguous role member states play in the comitology voting.

150 See for example Commission Decision 2008/280/EC of 28 March 2008 authorising placing on the market of products from maize GA21, Preamble (4); For other GM food and feed authorisations see the Community register available at <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm> (accessed 3 December 2009).

151 Ibid., Preamble (6).

152 See, for example, press article by The Independent from October 2008 at <http://www.independent.co.uk/environment/green-living/europes-secret-plan-to-boost-gm-crop-production-973834.html> (accessed 3 december 2009).

153 See references, *supra*, note 13.

This situation appears to be a 'déjà-vu'; one should, however, not forget the double role of the member states in this controversy. A qualified majority of the member states approved the GMO legislation in its current form,[154] including the science-based approach to the precautionary principle taken therein. However, the member states have been voicing criticism with regard to the quality of EFSA's risk assessment as well as the lack of consideration of other legitimate factors in the Commission's risk management decisions.[155]

Such strong public opposition and the lack of support for its authorisation methods has started to show first effects on the Commission's work. In fact, the science-based approach to GMO authorisation described above is only one part of the picture. Although there have been no refusals of marketing authorisations so far, there are cases, in which the Commission, despite of several positive EFSA opinions, was not, or only after a long period of time, able to take action at all. Two of such cases[156] are of particular interest, because the applicant companies concerned have filed an action against the Commission at the Court of First Instance asking the it to condemn the Commission for failure to act according to Article 232 EC;[157] it was the first time that biotechnology companies took a Community institution to Court in relation to the GMO authorisation procedures.[158]

The first case concerns the placing on the market of a GM maize 1507 for cultivation under the Deliberate Release Directive.[159] The product is a insect-resistant maize produced by Pioneer Hi-Bred International containing the so-called Bt-toxin, the environmental impacts of which are currently disputed among the member states and the Commission.[160] In 2001 the company submitted an application for cultivation of maize 1507 to a Spanish competent authority under the Deliberate Release Directive. According to the assessment report of the national authority, there was no scientific evidence indicating risks to human health or environment posed by the maize. Since other member states raised objections in the standard procedure under the Directive,[161] the authorisation decision was elevated to the Community level and was now to be taken in the framework of the comitology procedure according to Article 18

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[154] Art. 251/EC.

[155] See references, *supra,* note 10.

[156] See for lists of all pending cases for authorisation, available at <http://ec.europa.eu/environment/biotechnology/authorised_prod.htm> (accessed 3 December 2009).

[157] See Case T-139/07, *Pioneer Hi-Bred International v Commission*, application published in OJ from 7 July 2007, C 155/28; and Case T-293/08, *BASF Plant Science and Others v Commission*, OJ from 25 october 2008 C 272/28.

[158] Even under the so-called de facto moratorium there was no direct legal action against the Commission. The European Courts, so far, only had to assess national safeguard measures issued under the GMO legislation or under Art. 95 (5) EC. See Monsanto, *supra,* note 49; also Joined Cases T-366/03 and T-235/04, *Land Oberösterreich and Republic of Austria v Commission* and Joined Cases C-439/05 P and C-454/04 P, *Land Oberösterreich and Republic of Austria v Commission*.

[159] See the status of application at <http://www.gmo-compass.org/eng/gmo/db/75.docu.html> (accessed 3 december 2009). See also Pioneer press statement at <http://www.pioneer.com/web/site/portal/menuitem.646ebc4966a3a245abfe06e2d10093a0/> (accessed 3 December 2009).

[160] Several member states have invoked safeguard clauses under Directive 90/220/EEC and Directive 2001/18/EC in order to ban other maize products containing the Bt-toxin, notably maize Bt-176 and MON810. See the Commission list, *supra,* note 148.

[161] See on this procedure in the third section of this paper, under 'Directive 2001/18 and Regulation 1829/2003'.

of the Deliberate Release Directive. As foreseen in such cases, EFSA was asked to evaluate the product and it delivered a positive opinion in January 2005 finding that the cultivation of maize 1507 was safe.[162] Despite the positive risk assessment the Commission did not proceed by submitting a draft proposal concerning the authorisation of this product to the regulatory committee. Instead, following objections from the member states with regard to the quality of EFSA's risk assessment, the Commission referred the matter back to the Agency twice asking it to reassess certain aspects of its previous opinion.[163] In the meantime, after having waited more than two years for a draft decision on its product, Pioneer filed a complaint to the Court of First Instance in Mai 2007 arguing that the Commission has infringed its obligation under Article 18 (1) of the Deliberate Release Directive, because it did not adopt a decision in the timeframe foreseen in this provision. It was not until beginning of 2009 that the Commission submitted a draft decision recommending the authorisation of the maize 1507 to the regulatory committee.[164] As in previous cases, in February 2009 the standing committee failed to reach a qualified majority necessary to approve the Commission proposal, after which the matter was referred to the Council.

The circumstances of the second case are similar. This time the product in question is the so-called Amflora potato, which was genetically modified in order to produce large amounts of starch for industrial purposes. The first approval request for the potato was made by Baden Aniline and Soda Factory (BASF), its producer, already in 1996 under the old legislative framework. After the introduction of Directive 2001/18, BASF resubmitted its application for cultivation of the potato under this Directive. In addition, because of the possible use of the industrial residuals in animal feed, in 2005, the company also submitted a parallel application under the GM Food Regulation.[165] Both applications are dealt with by the Commission within the comitology procedure. The Amflora potato contains a so-called antibiotic resistance marker gene, which creates particular concerns with regard to possible transmission of antibiotic resistance to humans and animals.[166] Article 4 (2) of the Deliberate Release Directive obliges the authorities to take GMOs containing such marker genes into particular consideration when carrying out an environmental risk assessment. However, EFSA has delivered a positive risk assessment with regard to both applications finding the Amflora potato as safe as conventional potatoes.[167] In contrast to the *Pioneer* case, the Commission has initially adopted a draft decision approving the Amflora potato and submitted it to the regulatory committee. Neither the committee nor the Council have found a qualified majority either in favour or

[162] See EFSA opinion from 15 January 2005 with annexes in The EFSA Journal (2005), 181, 1.

[163] See ibid., the annexes of the EFSA opinion as well as its opinion from 29 October 2008 in The EFSA Journal (2008), 851, 1.

[164] See the text of the draft decision as well as the status of the procedure in the Commission's comitology register, available at <http://ec.europa.eu/transparency/regcomitology/index.cfm> (accessed 15 December 2009).

[165] See the status of the applications at <http://www.gmo-compass.org/eng/gmo/db/16.docu.html> and at <http://www.gmo-compass.org/eng/gmo/db/17.docu.html> (both accessed 3 december 2009); see also BASF press statement, available at < http://www.basf.com/group/corporate/de/content/products-and-industries/index> (accessed 15 December 2009).

[166] See EFSA Opinion from 2 April 2004 in The EFSA Journal (2004) 48, 1.

[167] See EFSA opinion from 7 December 2005 on the placing on the market for food/feed uses, The EFSA Journal (2006) 324, 1-20; and EFSA opinion from 7 December 2005 on the placing on the market for cultivation, The EFSA Journal (2006), 323, 1-20.

against the authorisation and it was for the Commission to adopt the final decision.[168] However, unlike in other authorisations, the Commission did not move forward with the approval process. Instead, in May 2008 it addressed EFSA once again asking it to prepare a consolidated opinion on the use of antibiotic resistant marker genes used in GM plants. The Commission has stated to act only after this third EFSA opinion has been issued.[169] In July 2008, BASF filed an action at the Court of First Instance presenting a similar argument as Pioneer a year before, namely that the Commission has failed to act under Article 18 (1) of the Deliberate Release Directive. In the meantime, EFSA has published the requested consolidated opinion in June 2009 confirming its previous assessment that the use of antibiotic resistant marker genes in GM plants is unlikely to have any adverse effects.[170] At the time of writing this article, however, the Commission did not adopt a final decision on the authorisation of the Amflora potato.

The described cases show a clear policy turn in the Commission's authorisation practice. Whereas before EFSA's opinions were considered as an authoritative source of expertise, in these two cases, the Commission decided to give more weight to the objections raised by the member states, discrediting EFSA by sending the scientific assessments back to the Authority for re-examination. As at the time of writing the cases are still pending at the Court, not much is known about the precise arguments invoked by the Commission for delaying the authorisation procedures. What can be grasped from public rhetoric on the part of the Commission, however, is that it seems to justify its action (or inaction) by recourse to the precautionary principle. In relation to both products mentioned above the Commission considers that not all possible long-term risks to the environment, public health or biodiversity are completely known.[171] Therefore, despite a positive assessment of EFSA, this time the Commission relies on the objections raised by the member states in order to assume a situation of scientific uncertainty. Thus, it seems to justify the delay in the authorisation procedure by making recourse to the precautionary idea, while interpreting it in a way as to require going back to EFSA as many times as doubts about the possibility of risk still remain. It remains open whether the Court will accept this argumentation in the light of the wording of Article 18 (1) of the Deliberate Release Directive, which clearly stipulates the time limits for the Community authorisation procedure. As far as the *Pioneer* case is concerned, the Court is likely to suspend a decision on the substance of the action since the Commission has submitted a draft decision recommending the authorisation of the Pioneer product after the opening of the Court proceedings. Thus, the subject matter of the Pioneer action, the Commission's failure to adopt such decision, has ceased to exist.[172] However, the question of whether or not

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[168] See GMO Compass, 'Commission to approve five GMOs' at <http://www.gmo-compass.org/eng/news/336.commission_approve_five_gmos.html> (accessed 3 December 2009).

[169] See GMO Compass, 'Zulassung Amflora-Kartoffel: BASF zieht vor Gericht' at <http://www.transgen.de/aktuell/957.doku.html> (accessed 3 December 2009).

[170] See EFSA opinion from 26 March 2009, The EFSA Journal (2009) 1108, 1-8.

[171] See statements of the EU Commissioner for Environment Stavros Dimas on GMO Compass, available at <http://www.gmo-compass.org/eng/news/messages/200710.docu.html#167> (accessed 3 December 2009) and on Transgen at <http://www.transgen.de/aktuell/957.doku.html> (accessed 3 December 2009); see also press article on EurActiv, available at <http://www.euractiv.com/en/environment/commission-hesitant-approve-gm-crops/article-172209> (accessed 3 December 2009).

[172] Thus, the Court is not longer able to bring about the effects of the action foreseen in Art. 233/EC. See Case 377/87, *Parliament v Council* (1988) ECR 4017 at 4048; Case 383/87, *Commission v Council* (1988) ECR 4051 at 4064.

the delay in the decision-making was unlawful remains relevant for a potential non-contractual liability of the Commission (Article 288 (2) EC) for damages incurred by Pioneer for not being able to market its product earlier; a question which the company might be interested in pursuing in the future by means of an action according to Article 235 EC.

Some critical observations and suggestions for reform

The difficulties encountered in the practical application of the precautionary principle in GMO marketing authorisations beg the question as to whether precaution can serve as a meaningful decision rule to guide administrative decision-making. In the previous sections we have seen that under EU law in general, and under the GMO legislation in particular, precaution is basically understood as a general legal principle that endeavours to combine both scientific and political rationality. Yet the practice of its application in the GMO authorisation fails to reconcile these two rationalities by following, on a case-by-case basis, either the one or the other extreme. In most cases under the new legal framework the Commission has adopted a purely science-based approach, in which it has granted EFSA the sole authority to determine whether or not there is scientific uncertainty about the risks of a particular GM product. As a result, following EFSA's positive assessment the Commission has not considered the precautionary principle to be applicable. In some cases, however, it has adopted the extreme opposite approach to precaution, by applying the principle even in the face of remote, long-term risks; it should be noted that it is almost impossible to exclude the possibility of such risks seeing that genetic engineering is a relatively new technology, the consequences of which we cannot fully foresee at the moment. This second approach to precaution seems to mirror the sentiment of disquiet about GMOs as well as, partially, their rejection in the member states' societies, at least in the way this is perceived by national governments represented in the Council. As a result, under the pressure from the member states, the Commission finds itself in a situation of inaction, which is precisely why some legal scholars strongly criticise the use of the precautionary principle as such, namely because it is paralysing and leading to the stagnation of technological innovations.[173]

Intricacies of the current authorisation system and possibilities of improvement

If one does not want to follow this criticism and to reject the usefulness of the precautionary principle in administrative risk decisions in general, one needs to identify what causes the difficulties of its application described above. This is important, in particular, in order to determine how legal frameworks can make better use of the precautionary principle and ensure that it is applied in a reasonable way.

To begin with, there is a legal and a pragmatic explanation of why the Commission usually tends to use a science-based approach when authorising GMOs. From the legal viewpoint, one should not forget that it is one of the main tasks of the Commission to ensure the proper functioning of the common market and, therefore, to promote the economic integration in the EU.[174] In the case of GMOs, the

[173] See Sunstein, 2002, 2005, *supra,* note 2.

[174] See Art. 211/EC.

Commission needs to ensure the implementation of the legislative provisions, which have as their objective, inter alia, the free circulation of GM products on the European market.[175] In addition, the way the Commission regulates GMOs is also strongly influenced by its obligation to comply with international trade rules, and, in particular, with WTO rules, which show a preference for scientific proof in the risk appraisal of globally traded products.[176] In fact, it is well known that problems of EU regulation in the area of biotechnology are deeply intertwined with the regulation of such problems in international trade law.[177] With regard to precaution it is stated that 'The ambivalence caused by the conditions attached to resorting to the precautionary principle cannot be explained other than by the Commission's concern with aligning Community practice with World Trade Organisation rules.'[178]

It follows, therefore, that the Commission adopts a science-based approach to GMO authorisation in order to be able to comply with the free trade objectives imposed upon it by both Community and International law. To put it in more drastic terms, one could claim that in authorising GMO products, and, thus, also in its application of the precautionary principle, the Commission is biased towards the objective of free trade disregarding other factors legitimate to the matter of GMO regulation, such as their long-term environmental or socio-economic impact.

The predominant reliance on science in the risk regulation of new technologies can, of course, be criticised. Social studies of the scientific process have amply shown the limitations of the traditional risk assessment in cases of scientific uncertainty as well as the value-laden nature of scientific investigation, especially when it is used in order to underpin regulatory politics.[179] As regards the pragmatic explanation for the Commission's tendency towards science, one should, however, acknowledge that if the Commission is to comply with the authorisation procedures and timeframes foreseen in the GMO legislation, it needs a clear set of factors that guide its decision-making. As has been described in one of the previous sections,[180] the only tangible factor on which the Commission can base its decision is the scientific opinion of EFSA. The role and definition of 'other legitimate factors,' is, on the contrary, far from being clear. One crucial objective for the reform of the legislative framework would, therefore, be to clarify the use of such factors in the authorisation process.[181] This

[175] See the third section of this paper, under 'Directive 2001/18 and Regulation 1829/2003'.

[176] See Arts 2.2 and 5.7 of SPS Agreement; Appellate Body Report, *Australia – Salmon* from 6 November 1998, WT/DS18/AB/R par. 125; see also Forsman, *supra*, note 93, at pp. 591-92 with further references to Codex Alimentarius rules.

[177] See J. Scott, 'European Regulation of GMOs: Thinking about "Judicial Review" in the WTO', Jean Monnet Working Paper, No. 4/04, 2004; see also C. Joerges, 'Sound Science in the European and Global Market: Karl Polanyi in Geneva', in E. Vos and M. Everson (eds), *Uncertain Risks Regulated*, Oxon, Routledge-Cavendish, 2008.

[178] Forsman, *supra*, note 93, at p. 591.

[179] See A. Stirling, 'On Science and Precaution in the Management of Technological Risk', An ESTO Project report, JRC, Institute for Prospective Technological Studies, Sevilla, 1999; B. Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm', *Global Environmental Change* 2, No. 2, (1992), p. 113; J. Steele, *Risks and Legal Theory*, Oxford, Hart Publishing, 2004.

[180] See the fourth section of this paper, under 'Precaution as decision rule: managing scientific uncertainty in GMO authorisations'.

[181] The Environmental Council in its declaration on GMOs from December 2008 stipulates an obligation for the Commission to submit two reports with regard to the socio-economic implications of the placing on the market of GMOs, one of them by January 2010. See Council conclusions, *supra*, note 11.

would also entail determining the relationship between the inclusion of these factors into decision-making and the application of the precautionary principle therein. In addition, if the legislative provisions are to be taken seriously, there is a need to provide the Community institutions with a methodology of how to include socio-economic factors into decision-making in a rational, transparent, and non-arbitrary way. At the moment such methodology does not seem to exist.[182] It is, therefore, not surprising that the Commission, in absence of other guidance, justifies its authorisation decisions by making recourse to the apparently objective and rational basis of scientific risk assessment.[183]

Against this background, the recent cases, in which the Commission did not follow the usual science-based approach and has delayed the authorisation of GM products despite of the positive EFSA assessments, appear to witness the weakness of the Commission to enforce its line against the political opposition of the member states. What is more, these cases can also be interpreted as signalling another immanent shortcoming of the authorisation system. If a large majority of the member states in the Council permanently votes against all the draft decisions submitted to it by the Commission, it begs the question as to whether the Commission should legally be granted the power to adopt the final decision against this majority.[184] If indeed, the authorisation of GM products is considered to be an essential political question of societal importance, than, eventually, it is for the member states in the Council to adopt the final decisions in this field and to be accountable for them towards their own citizenships. This would imply the necessity to change the current comitology procedure[185] together with the majority rules in the Council, at least as applied in the area of GMO authorisations.[186] An argument of favour of such change would be that the Comitology procedure has originally been designed to control the implementation activities of the Commission in very technical areas. In highly politicised areas, such as GMO regulation, comitology looses the consentive and deliberative character, which is the basis of its good functioning in other areas.[187]

Seeing the complexities and political controversy of GMO regulation, it seems that the challenges to applying the precautionary principle in this area are intractable. In one

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[182] First steps to develop such methodology are based on cost-benefit analysis techniques, which are mentioned as part of the application of the precautionary principle in the Commission Communication, *supra*, note 23, at p. 19; for critical views on cost-benefit techniques in the US context, see D. A. Kysar, 'It Might Have Been: Risk, Precaution and Opportunity Costs', *Journal of Land Use and Environmental Law* 1, No. 22, (2006), pp. 1-58; An example for a regulatory system, which includes the appraisal of socio-economic risks is the REACH framework, Art. 85 of Regulation 1907/2006/EC, establishing the European Chemicals Agency foresees not only a Committee for Risk Assessment, but also a Committee for Socio-Economic Risk Analysis. On the REACH framework, see P. Kjaer, 'Rationality within REACH? On Functional Differentiation as the Structural Foundation of Legitimacy in European Chemicals Regulation', EUI Working Papers Law, No. 18 (2007).

[183] On the misuse of science as justification for political decisions in the regulation of new technological risks, see Fisher, *supra*, note 21, at p. 9; Holder and Lee, *supra*, note 53, at p. 18.

[184] The Commission itself acknowledges the need to exercise political self-restraint in such cases, see statement concerning Art. 5 of Council Decision 1999/468/EC in OJ 1999 C 203/1.

[185] It currently follows Art. 5 of Council Decision 1999/468/EC.

[186] Calls for such reform have already been voiced; see an account in Vos and Wendler, *supra*, note 104, at p. 131.

[187] See Joerges and Neyer, *supra*, note 111; C. Joerges and E. Vos (eds), *EU Committes: Social Regulation, Law and Politics*, Oxford, Hart Publishing, 1999; on the malfunctioning of comitology in the GMO area, see Vos and Wendler, *supra*, note 104, at p. 130.

or another way the principle seems often to be (mis-)used for political rhetoric and it loses its credibility as a meaningful decision rule to guide administrative discretion in a non-arbitrary way.

Precaution as a procedural principle

However, in the last part of this section I would like to dwell, once again, on the legal nature of the precautionary principle. In fact, the conception of precaution as a decision rule able to solve hard choices in environmental and health regulation might just be causing the problems arising in the practical application of the principle. In order to show this, I first need to go back to the core idea of the precautionary principle.[188] This idea emphasises the need for regulatory decision-makers to be aware of the limitations of science in the area of technological risk, where, because of the lack of knowledge about, and experience with the technology, traditional risk assessment is not always sufficient. The principle, therefore, opens up discretion for public decision-makers, to take precautionary measures to respond to situations of scientific uncertainty. It would, however, be excessive to expect the precautionary principle to give us a ready answer to the question of what to do with the uncertain information from science. The idea of risk[189] entails that we need to accept the possibility of losing something in order to win something else; and that because we dare, we do not know precisely what the future will bring us. Precaution, therefore, cannot be interpreted as allowing the decision-maker to know in advance what the right decision in relation to a new technological product, such as a GMO, is. This is why the precautionary principle is afflicted with so many difficulties when it is applied as a decision rule that dictates specific outcomes of regulatory decisions. Instead, it is suggested to recall the meaning of precaution as a *legal principle*. Legal scholars dealing with the precautionary principle rightly observe that as a legal principle it structures the process of legal reasoning, and 'states a reason that argues in one direction, but does not necessitate a particular decision.'[190] It can, therefore, not be understood as a 'bright line' or an autonomous rule that dictates a particular outcome in a certain set of circumstances. The strength of the principle, therefore, lies in its *procedural* nature and its ability to 'completely recast the ways in which public administration makes decisions.'[191] The procedural nature of precaution is described as follows:

> As the principle is concerned with process it requires decision-makers to reflect on how they justify their decision, what factors are relevant to a decision, how that decision should be made, and who should be involved in the decision-making process. In particular the principle is concerned with the reasons for a

[188] See the second section of this paper, under 'The precautionary principle in the EU legal system'.

[189] See D. Garland, 'The Rise of Risk', in R. V. Ericson and A. Doyle (ed.), *Risk and Morality*, Toronto, University of Toronto Press, 2003; P. L. Bernstein, *Against the Gods: the Remarkable Story of Risk*, Chichester, John Wiley and Sons, 1996; A. Giddens, 'Risk and Responsibility', *Modern Law Review* 1, No. 62, (1999), pp. 1-10; Beck, *supra,* note 6; Steele, *supra*, note 179.

[190] Fisher, *supra* note 21, at p. 16, with reference to R. Dworkin, *Taking Rights Seriously*, London, Duckworth, 1977, at p. 26; see also A. Herwig, 'The Precautionary Principle in Support of Practical Reason: an Argument Against Formalistic Interpretations of the Precautionary Principle', in C. Joerges and E.-U. Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and Social Regulation*, Oxford, Hart Publishing, 2006, at pp. 301-3.

[191] Lee and Holder, *supra*, note 53, at pp. 21, 22, 29.

> decision in that it states that in circumstances of scientific uncertainty a lack of certainty cannot be used as a reason for a decision.[192]

I argue that in the legal framework for GMOs such procedural understanding of the precautionary principle[193] entails the provision of institutional structures that would enable reflexive and justificatory risk discourses in relation to the product to be authorised, such discourses being carried out within regulatory public space of the procedure. These risk discourses, provided participation of all 'stakeholders' of GMO authorisation (ie regulatory, economic, and societal actors) is ensured, serve the purpose of bringing scientific rationales and socio-economic / ethical values affected by GMO regulation into 'a lasting equilibrium within stable institutional structures of governance', this being, as some authors convincingly submit, the primary function of modern risk governance.[194] Furthermore, I would like to stress the importance of deliberation[195] within such risk discourses. It has rightly been observed[196] that modern governance regimes beyond the state, or in other words, global bureaucracies (the EU's supranational executive making part of global executive arrangements), despite of their technocratic rational and their *Zweckrationalität,* are inexorably political in nature. As I have illustrated in this paper, seemingly technical fields of regulation, such as GMOs or food regulation in general, always touch upon issues of social and economic relevance and, moreover, have (re-)distributive effects.[197] The *problematique* of these supranational/global political bureaucracies is that they are not at the same time embedded in domestic/national contexts of political contestation, in which conflicts over social and economic issues are resolved within a wider public space,[198] and through national parliaments. I submit, therefore, that a procedural understanding of the precautionary principle requires the recognition of the political issues at stake in GMO regulation. Up until now, the Commission makes an effort to veil the value-laden as well as economically conflicted nature of agricultural biotechnology by recognising the scientific rationality as the only valid one within its decision-making on GMO authorisations. It seems that in order to re-embed the political activity of EU administration into a context, from which it would derive legitimacy, all rationalities involved in this field of regulation need to be brought to bear through deliberative processes; thus, through processes, in which there is no predominance of one rationality over the others; and, in which ideas of some sort of objectively identifiable substantive truths will be abandoned in favour of procedural notions of legitimacy. Precaution as a legal principle has, therefore, to be re-conceptualised in order to contribute to the procedural legitimacy of risk governance.

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[192] Fisher, *supra*, note 2.

[193] See in a similar vein M. Everson and E. Vos, 'European Risk Governance in a Global Context', in E. Vos (ed.), *European Risk Governance,* Mannheim, Connex, 2008, at pp. 7, 31.

[194] See Everson and Vos, *supra,* note 193, at p. 16.

[195] I use this term here in the 'Habermasian' sense of a discursive process based upon persuasion and the exchange of arguments, which provides an opportunity for open debate in which all the contending positions and interests in GMO regulation are included. See J. Habermas, *Between Facts and Norms*, Cambridge, MA, MIT Press, 1996; J. Black, 'Proceduralizing Regulation: Part I', *Oxford Journal of Legal Studies* 20, No.4, (2000), pp. 597-614.

[196] See Everson and Vos, *supra*, note 193; M. Everson, 'Three Intimate Tales of Law and Science: Hope, Despair and Transcendence', in E. Vos (ed.), *Uncertain Risks Regulated*, London, Routledge-Cavendish, 2009, at p. 347.

[197] See Lee, 'Living with GMOs (1): Coexistence, Liability and Labelling' in M. Lee, *EU Regulation of GMOs*, Cheltenham, Edward Elgar, 2008; Lee, 'Living with GMOs (2)' in ibid.

[198] On the term 'public space' (Öffentlichkeit), see Habermas, *supra*, note 195, at p. 435.

As one scholar has aptly put it, 'the principle must now be opened up as a site of political contestation.' And, the legal authority within such contestation 'must now be created by legal disavowal of substantive decision making, and the consequent dedication of law to procedural and forensic investigation of the robustness of social-political interaction and conflict within governance.'[199]

It follows that several suggestions for institutional improvement of the GMO authorisation procedure can be made. Firstly, following the findings of this paper it should be noted that the EU legislator has to a certain extent already given expression to a procedural concept of the precautionary principle by creating, *inter alia*, institutional structures of public consultation, stakeholder participation as well as a network of co-operation between different scientific experts involved in the risk assessment of GMOs.[200] These structures can be characterised as precautionary governance structures[201] that allow for the input of different actors into the decision-making. However, the participatory structures of the authorisation should be improved as they currently fail to enable deliberation on the risks at stake because the sole rationality admitted as valid in the discourse is that of a scientific expert. One way of showing a clear commitment to the consideration of socio-economic values in the authorisation decision-making would be the creation of an expert committee responsible for a socio-economic risk appraisal of the GMO product under scrutiny. The EU regulatory framework for chemicals, REACH, presents a first example of such inclusion into risk appraisal of not only scientific experts, but also those having a background in social sciences and economics.[202] Furthermore, I submit that a procedural understanding of the precautionary principle requires the Commission to abandon its approach of recognising the validity of the principle only in the phase of risk management.[203] A deliberative approach to precaution, understood as a procedural principle framing the entire process of risk appraisal, rather emphasises the principle's importance in the phase of risk assessment where it can serve as a tool to broaden the input of knowledge relevant to the assessment of GMO risks, thus including, for example, lay knowledge.[204] Some scholars also rightly point at the importance of stakeholder participation even before risk assessment begins suggesting the creation of committee structures at the interface between assessment and management, where risk issues to be dealt with by risk assessors are being framed.[205] Finally, any reflection on the reform of the framework should pay particular attention to the possibility of improving the justification requirements upon public decision makers, ie the Commission and the Council, in order to ensure that stakeholder input really counts in the final decision-making. One shortcoming of the

[199] See Everson, *supra*, note 196, at p. 356.

[200] For a more detailed account of these structures, see Weimer, *supra*, note 107, at p. 187.

[201] On precautionary governance in food regulation, see Stirling et al., *supra*, note 29.

[202] See *supra,* note 182.

[203] See the Commission, *supra*, note 23.

[204] See B. Wynne, 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs', *Science as Culture* 10, No. 4, (2001), at p. 445; On the application of the precautionary principle already in the risk assessment, see P. von Zwanenberg and A. Stirling, 'Risk and Precaution in the US and Europe: a Response to Vogel', in H. Somsen, T. Etty, J. Scott and L. Krämer (eds), *Yearbook of European Environmental Law* 3, Oxford University Press, Oxford (2004), at p. 47.

[205] For more detail and the distinction of different forms of public participation, see M. Dreyer and O. Renn, 'Some Suggestions for a Structured Approach to Participation in Food Risk Governance with a Special Emphasis on the Assessment Management Interface', in E. Vos (ed.), *European Risk Governance*, Mannheim, Connex, 2008, at p. 89.

present system seems to be that although there is the possibility for the public to make comments on the risk assessment, and to address them to the Commission,[206] there is no provision for a reason-giving requirement that would oblige the Commission to explain whether and how it has taken these comments into consideration.[207] Thus, the official declarations, including the Commission Communication on the Precautionary Principle,[208] that all interested parties should participate in the study of the diverse options in the area of risk assessment appear to be little more than 'lip service'. Yet without transparency about the reasons underlying an authorisation decision, and thus about 'arguments and science used, the values involved and the way they have been addressed as well as the procedure followed'[209] there can be no true accountability of the Commission and the Council for the decisions taken. I submit, therefore, that reason-giving requirements and justification obligations as to the input of stakeholders into decision-making should clearly be laid down in the legal provisions of the GMO framework.

Conclusion

The purpose of this paper was to identify concrete challenges arising from the application of the precautionary principle in the area of EU authorisation of GMOs. At the same time, I aimed at providing for an explanation of why these challenges arise as well as at suggesting some ways for making better use of the principle in regulatory legal frameworks.

The examination has shown that the current legislative framework that sets out the rules and procedures for GMO marketing authorisation in the EU has been based on a concept of precaution, which has already previously been defined by the European Commission and further confirmed and developed in the case law of the EC Courts. According to this concept precaution is a general principle of Community law, which, therefore, must be taken into account in the decision-making by the Community institutions for the purpose of deciding whether a product may be placed on the market without danger for the consumer. Moreover, the principle has been interpreted as a *rule* to guide public risk-management towards certain outcomes, assumed certain conditions, set out in the case law are fulfilled. Such an understanding has subsequently been taken over by the EU legislator in Article 7 of the GFL Regulation.

In the analysis of the legal provisions framing the decision-making on authorisation the main shortcomings identified concern the notion and role in decision-making of so-called 'other legitimate factors' as well as their relationship with the precautionary principle as a decision rule. The uncertainties of legal interpretation in this area call for improvement. It remains to be seen whether the currently at EU level ongoing reflection process on GMO legislation will lead to an effective resolution of these uncertainties.

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[206] See Art. 6 (7), Regulation 1829/2003/EC.

[207] On the false promise of public participation channels in the GMO authorisation, see M. P. Ferretti, 'Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union,' *Science as Culture* 16, No.4, (2007), pp. 377-95.

[208] See the Commission, *supra*, note 23, at p. 16.

[209] See Everson and Vos, *supra,* note 193, at p. 31.

Finally, the main difficulties with regard to the application of the principle have been identified in the practical use of it in case-by-case decision-making of authorisation where it is currently interpreted in terms of a decision rule being able to justify a particular decision outcome.[210] This makes it easy for the institutional actors involved, the Commission as well as the Council and the member states, to defend their political positions by recourse to precautionary rhetoric; especially in the Commission's use the principle seems to be incoherent partially revealing a situation of political paralysis between the opposition of the member states and its own free-trade motivated science-based approach. I have, however, argued that the only way to make reasonable use of the precautionary principle in risk decision-making seems to be providing for procedural safeguards that would structure the way in which decisions are made, thus hindering the arbitrary use of discretion as well as, to some extent, compensating for the lack of substantive judicial review. The European Courts have rightly stressed the fundamental importance of procedural guarantees conferred by the Community legal order in administrative proceedings.[211] Yet, so far, the only effective procedural guarantee established in the legislative framework is the requirement to base authorisation decisions on scientific risk assessment. The precautionary idea, however, requires the legislator to provide also for other procedural structures, such as, for example, public participation, the requirement to include a socio-economic appraisal of GMOs or reason-giving requirements, that would allow for a broader and more transparent input of knowledge into the authorisation system than the one based on science.[212] Thus, I have argued in favour of a procedural understanding of the precautionary principle pointing out its nature as a flexible legal *principle* that structures public decision-making on risk instead of allegedly determining it.

[210] For criticism to such an approach, see Fisher, *supra,* note 21; Id., *supra*, note 15.

[211] See *Pfizer*, *supra*, note 26, par. 172.

[212] On social appraisal of risk, see Stirling et al., *supra,* note 29.

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