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ROLE OF SCIENCE IN EU ENVIRONMENTAL DECISION MAKING
A Study of EU Regulation of GMOs

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Contents

Preface

I am grateful to Dr. Sanja Bogojević for help and stimulating suggestions. Thank you for giving me an insight into a new research field.

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Summary

According to Article 2 UN Convention on Biological Diversity, biotechnology is "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use".[1] Biotechnology is widespread in agriculture, food production and medicine.

Agricultural biotechnology has been extensively applied in field crop production. It is one of the fastest adopted crop technology in recent history. 2012 marked a hundredfold increase in genetically modified crops from 1.7 million hectares in 1996 to 170 million hectares in 2012.[2]

The term 'genetically modified organism' refers to an organism in which the genetic material has been altered in a way that does not occur naturally through fertilisation and/or natural recombination[3]. GMOs may be plants, animals or microorganisms, such as bacteria, parasites and fungi. In spite of the fact that the application of GMOs in agriculture has grown rapidly, the issue of socio-economic and environmental benefits of agricultural biotechnologies is rather controversial. There are conflicting arguments as to the implications of further commercialisation of GMOs.

The research is important because the EU "remains far from speaking with one voice on agricultural biotechnology".[4] The purpose of research is to examine how science impacts EU decision-making in the field of GMOs, and how the law should deal with limitations of science. It is aimed at

[1] Article 2 UN Convention on Biological Diversity, retrieved from http://www.cbd.int/convention/text/

[2] The data retrieved from the International Service for the Acquisition of Agri-biotech Applications (ISAAA) Executive Summary on Global Status of Commercialized Biotech/GM Crops: 2012, available online on http://www.isaaa.org/resources/publications/briefs/44/executivesummary/

[3] There are slightly different definitions of the term 'geneticall modified organism', e.g., 'an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' (Article 2(2) of Deliberate Release Directive).

[4] Lee, M. (2008). *EU Regulation of GMOs. Law and Decision Making for a New Technology*. Edward Elgar Publishing, p. 63.

examining the issue of interaction between the law and science. The research will focus on EU regulation of GMOs. The research will define and analyse the scientific features influencing EU regulation of GMOs, as well as the challenges and limitations posed by these features to the freedoms of internal market.

Abbreviations and acronims

AG	Advocate General
Codex	Codex Alimentarius Commission
CVMP	Committee on Veterinary Medicinal Products
Deliberate Release Directive	Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC [2001], OJ L 106/1
EC Treaty	Treaty Establishing the European Community
ECJ *or* the Court	Court of Justice of the European Union
EFSA	European Food Safety Authority
EMEA	European Agency for the Evaluation of Medicinal Products
EU courts	Court of Justice of the European Union *and* General Court of the European Union *and* Court of First Instance
FAO	Food and Agriculture Organization of the United Nations
Food and Feed Regulation	Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L 268/1
GC	General Court of the European Union
General Food Regulation	Regulation 178/2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002], OJ L 31/1
GM	genetically modified/genetic modification
GMO	genetically modified organism

IARC	International Agency for Research on Cancer
JECFA	Joint FAO/WHO Expert Committee on Food Additives
NGO	non-governmental organisation
TFEU	Treaty on the Functioning of the European Union
Traceability and Labelling Regulation	Regulation 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed products Produced from Genetically Modified Organisms and amending Directive 2001/18/EC [2003] OJ L 268/24
UN	United Nations
WHO	World Health Organization
WOAH	World Organization for Animal Health

CHAPTER ONE

Introduction

The proposed research arises from the rapid development of agricultural biotechnology and its social and economic implications. The proposed research area is technical and complex. EU policy on health and the environment relies heavily on scientific evidence. According to paragraph 3 Article 114 TFEU, European Commission aims at a high level of protection of human health and environment, taking into account new developments based on scientific facts. Integration of science in law through public policy brings on the science-based model of governance. The interrelation between scientific knowledge, economic interests and non-economic values is worthy of detailed research and explanation because law and science interpret facts in different ways.[5]

The new technologies set up a specific, complicated, and essentially politicized problem for EU policy on health and the environment. This problem created by agricultural biotechnologies is that they bring about new environmental and health risks, which are of peculiar properties because of the uncertainty about their potential risks. This uncertainty hinders policy makers from application of 'routine decision-making procedures for risk assessment and management. It impedes the application of standard scientific approaches and pushes regulatory decision-making into a more political direction'.[6] In the area of agricultural biotechnologies, national differences in risk regulation might set off political and trade conflicts (discussed in Chapter III). Indeed, EU environmental law involves various

[5] Brosnan, D. (Fall 2007). Science, Law, and the Environment: the Making of a Modern Discipline. *Environmental Law*, Vol. 37 Issue 4, pp. 987-1006.

[6] Falkner, R., & Jaspers, N. (2012, February). Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap. *Global Environmental Politics*, Vol. 12 Issue 1, pp. 30-55.

non-economical interests. The precautionary principle of EU policy on environment is linked up to the science-based model of governance. There are some gaps in the current research on the use of science in regulatory processes. This research aims to create a specialized and detailed legal account of the role of science in relation to GMOs.

European institutions governing the environmental issues have extensively used scientific knowledge in decision-making process. The Commission's officials deal with scientific data. The role of courts in shaping scientific expertise used in EU decision-making process cannot be underestimated. Contrary to common knowledge, EU environmental risk regulation is not a product of legislative interventions 'but the result of a rich and informed case-law developed by EU courts in recent years'.[7] Since the impact of scientific data on judicial decision making tends to increase, I will examine how the courts deal with measurement of scientific uncertainty.

In the field of environmental law, the doctrine of risk regulation is concerned with the governance of risks to health and safety, weighed up against economic interests such as the cost of regulatory measures and their potential negative impact on trade.[8] In other words, a health protection measure can affect trade negatively, as well as trade liberalisation can affect health protection interests.

The added value of the research will be the elaboration on the role of science in EU environmental decision making. The research is important since the environmental risk management and proper application of EU policy on environment depends on whether EU officials and judges handle these issues in a way that follows on objectivity provided by scientific evidence, 'over the more evaluative and more obviously manipulable political concerns provoked by GMOs'.[9] An essential requirement for effective environmental policy is knowledge about what sorts of scientific data is relevant and useful and how to interpret, evaluate, and draw

[7] Alemanno, A. (2009, January 1). The Shaping of European Risk Regulation by Community Courts. *The Jean Monnet Working Papers*, n. 18/2008.

[8] See, to that extent, Holder, J., Lee, M. & Elworthy, S. (2007). Environmental Protection, Law and Policy: Text and Materials. In *Law in Context* (2nd Ed.). Cambridge: Cambridge University Press.

[9] *Ibid*, p. 198.

conclusions from such data. There is an opinion that many lawyers typically do not have this knowledge[10], even though TFEU emphasizes the importance of available scientific and technical data in preparing EU policy on environment.[11] The current level of knowledge and development achieved in the research on the role of scientific evidence, uncertainty and the precautionary principle in regulation of GMOs has not been studied exhaustively and comprehensively yet.[12]

1.1. Purpose and main objectives of the research

The purpose of the research is to examine how the scientific expertise has been applied and how the scientific evidence has been interpreted by EU courts and policymakers in the field of EU policy on health and the environment. Generally, I aim to study what opportunities are offered by science to the law, how scientific risk assessment affects EU decision-making, and how the law should deal with limitations of science. Specifically, I will focus on the legal framework of EU regulation of GMOs with regard to the role of science in judicial decision making. The research will define and analyse the scientific features influencing EU regulation of GMOs, as well as the challenges and limitations posed by these features to the freedoms of the internal market.

[10] See Tanford, J.A. (1990). The Limits of a Scientific Jurisprudence: The Supreme Court and Psychology. 66 *Indiana Law Jornal* 137, 144-145; Dobbins, S. et al. (2002). Applying Daubert: How Well Do Judges Understand Science and Scientific Method? 85 *Judicature* 244, 247; Dobbins, S. et al. (2001). Asking the Gatekeepers: A National Survey Of Judges On Judging Expert Evidence In A Post- Daubert World. 25 *Law & Human Behaviour*, 433.

[11] First indent paragraph 3 Article 191 TFEU.

[12] For specialized research on the precautionary principle, science and uncertainty in the GMO debate and regulation of GMOs, see relevant works of M. Lee, B. Wynne, S. Jasanoff, J. Tait, L. Levidow, S. Carr, D. Wield, a list is available in bibliography of this thesis.

I aim to understand how scientific evidence has been interpreted and how scientific uncertainty has been weighed by EU courts against the internal market freedoms. I will analyse the role which science plays in legitimising barriers to the internal market. EU courts aim at reconciling contraries between purely science-based decision-making and highly politicised precautionary rhetoric involving emotional discourse. Striking a balance between scientific and political legitimacy, ECJ specified that risk to health or environment must be established on new evidence based on reliable scientific data.[13] The doubts have been raised about the Court's capability to demonstrate that certain environmental and health protection measures 'were actually proportionate and justified for simple scientific reasons'[14]. It is indeed difficult to define the criteria under which a restrictive measure can be proved as proportionate and theoretically substantiated. There have been the claims that the ECJ 'has never really taken care to define the necessity/proportionality test it applies'.[15] The case law illustrates a risk philosophy which may favour (or otherwise) scientific evidence as a legitimate factor of restrictive measures. Since science is considered as the prime source of authority in EU decision-making on agricultural biotechnology,[16] the line of case-law concerning GMOs is worthy of close scrutiny. I will examine the judicial approach to measures banning or restricting GMOs. In particular, I will asses such measures on the basis of the following conditions: absence of less restrictive measure; a protection measure must prove to be necessary to reach the goal of protection of health and the environment; a measure must be based on scientific evidence.

In the EU, the problem of environmental and human health risks is primarily addressed through governmental regulations.[17] Scientific assessment of

[13] Joined Cases C-58/10 to C-68/10 *Monsanto SAS and others*.

[14] Laffineur, J. (2010) First ECJ Ruling on REACH: Choosing Registration over Exemption - Case C-558/07, R v Secretary of States for the Environment, Food and Rural Affairs. *Journal of Environmental Law* Vol. 22, 135-146.

[15] Notaro, N. (2000) The New Generation Case Law on Trade and Environment, 25 *European Law Review* 5.

[16] For detailed discussion on this issue see Lee, M. (2008), supra note 4, pp. 85-98.

[17] Covello, V. & Mumpower, J. (1985). Risk Analysis and Risk Management: A Historical Perspective. 5(2) *Risk Analysis* 103.

health and environmental risk lies within the technical paradigm[18], also referred to as the objectivist school[19]. As a positivist concept, objectivism considers risks which are not supported by the technical calculations as clearly erroneous.[20] The issue here is that EU legislation on GMOs is open to opposing explanations, which raises doubts about the adequacy of technical risk assessment paradigm as the main approach to decision-making. Nevertheless, EU environmental policy relies heavily on technical scientific approaches to risk.[21]

It appears that science alone is not a universal guide for dealing with extremely sensitive issues. It has been noted that the stalemates in the regulation of agricultural biotechnologies 'in part are the inevitable result of exclusive reliance on different kinds of specialisation such as scientific risk assessment',[22] and that 'decision making is not the burden that falls upon scientists but is assumed by the public at large'.[23] The procedure of authorization of GMOs shows that errors or contradictions in an opinion issued by expert institution like EFSA can challenge the legitimacy of European institutions.[24] Authorization based on unsubstantiated or deficient risk assessment has implications for the legality of the Commission.

The scientific validity of EU regulation of GMOs has been often questioned and heavily criticized.[25] It appears that the question of scientific credibility

[18] Ortwin, R. (1992) Concepts of Risk: A Classification. In Krimsky, S. & Golding, D. (Eds.) *Social Theories of Risk*. Praeger, Westport, Conn.

[19] Gruszchynski, L. (2010) *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement*. Oxford: Oxford University Press.

[20] Van Asselt, M. (2000) *Perspectives in Uncertainty and Risk. PRIMA Approach to Decision Support*, p. 152.

[21] Risk assessment 'shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner', Article 6(2) Regulation 178/2002 Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety [2002] OJ L 31/1.

[22] Somsen, H. The editor's preface in Lee, M. (2008), *supra note* 4.

[23] Rajan, R. & Letourneau, D. (2012). What Risk Assessments of Genetically Modified Organisms Can Learn from Institutional Analyses of Public Health Risks. *Journal of Biomedicine & Biotechnology*, pp. 1-8, at 1.

[24] Action brought to General Court on 27 May 2010 — *Hungary v Commission* (Case T-240/10). EFSA's opinion granting authorization for cultivation of genetically modified potato was contradicting to the views of WHO and European Medicines Agency.

[25] For an analysis of critical claims, see, e.g., Davison, J. (2010, February). GM plants: Science, politics and EC regulations. *Plant Science.* Vol. 178, issue 2, pp. 94-98; Scott, J.

of environmental policy has often involved complex political and economic choices. The GMOs authorisation involves the Commission as well as the Member States. It is obvious that such a decision-making process is political to a large extent. Therefore, I will examine the legitimate grounds for EU environmental decision-making from the perspective of the role of non-scientific factors in the process of risk assessment and their impact on the objective value of scientific data within the system of EU regulation.

Therefore, the central research question is: *What is the role of scientific evidence in EU regulation of GMOs?* The following sub-questions will help to answer the central research question and to substantiate the research findings: *How EU courts interpret scientific data? To which extent EU courts apply the principles of precautionary and proportionality on the basis of scientific evidence? What are the implications of non-scientific interests in EU courts' jurisprudence?*

1.2. Research problem

The precautionary principle, on which EU policy on environment shall be based, involves due consideration of scientific data. It addresses the cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are the reasonable grounds for concern that potentially dangerous effects on the environment and health may be inconsistent with the high level of protection.[26] Therefore, in case of scientific uncertainty the errors should be skewed towards safety[27], in spite of claims that the precautionary principle "is

(2007). *The WTO Agreement on Sanitary and Phytosanitary Standards*. New York: Oxford University Press.

[26] Communication from the Commission of 2 February 2000 on the precautionary principle [COM(2000) 1 final]. Retrieved from http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

[27] Cameron, J. (1999). The Precautionary Principle. In Sampson, G. and Chambers, B., (Eds.), *Trade, Environment and Millennium*. New York: UN University Press.

hopelessly vague".[28] It follows that environmental decision-making involves a careful consideration of scientific uncertainties. Besides, EU governance regarding biotechnologies allows for a broad input of non-scientific (political, social) factors into decision-making process, which can entail serious consequences. For example, the public policy can be exercised on the basis of values rather than on the basis of empirical evidence (like in *Commission v Poland*,[29] discussed in paragraph 3.3).

The methodology of EU risk regulation comprises three stages: risk assessment, risk management and risk communication. Such a division suggests a differentiation between scientific (assessment) and political (management) aspects of risk regulation, which is compatible with the approach adopted by courts in assessment of the legality of restrictive measures inspired by public health goals[30]. In this form, the risk regulation provides for the legal framework where EU legislators and courts seek for balance between the objectives of environmental protection and the freedoms of internal market[31]. Moreover, the practical meaning of division between risk evaluation and management has increasingly been disputed as artificial, leading to exclusion of other sources of information necessary for decision-making. As a result, EU regulatory institutions face the dilemma of a clash between science and politics, where the courts have to find out how to reconcile these, often contradictory, elements of risk regulation.

Scientific advancement is rapid. It progresses faster than governmental ability to grasp the implications of technological challenges. Technological inventions are produced at a rate which far outpaces the possibilities of legal control.[32] This is especially appropriate for new technologies like agricultural biotechnologies whose progress is 'faster and more difficult to

[28] Sunstein, C. (2005). *Laws of Fear: Beyond the Precautionary Principle*. Cambrigde: Cambridge University Press, p. 26.

[29] Case C-165/08 *Commission v Poland* [2009] ECR I-6843.

[30] Opinion of Advocate General Mischo in Case 192/01 Commission v Denmark [2003] ECR 9693, paragraph 143.

[31] Article 6 (1) of Regulation (EC) No 178/2002 of 28 January 2002 states that "food law shall be based on risk analysis".

[32] Weeramantry, C.G. (1997). *Justice without Frontiers: Protecting Human Rights in the Age of Technology*, (Vol. 1). Kluwer Law International, The Hague, p. 72.

regulate compared to traditional technologies'.[33] The regulatory challenges of modern biotechnologies have significant societal meaning. The proposed research arises from the rapid development of agricultural biotechnology and its social and economic implications. While the central research problem is applicable to agricultural technologies as a whole, the present thesis is specifically about regulation of GMOs. The research area is technically complicated. Therefore, risk assessments in this area 'are made more complex and contentious by both their inherent uncertainty and the inevitability of failure beyond expectation in complex systems'.[34] The proposed research seeks for analysis of the regulatory approaches and judicial interpretation of scientific evidence as it has been developed in the area of EU GMOs regulation. In particular, the analysis aims to bring legally relevant facts established by scientific evidence into focus of the biotechnical decision making balancing between the interests of trade and health protection.

1.3. Research Method

The thesis is based on legal dogmatic method applied through the utilization of quantitative and qualitative analysis of the research texts. The number of questions arisen from the central research problem is inexhaustible. Besides the mentioned ones, the research problem can raise other questions as well (for example, what are the common scientific features of risk assessment techniques applicable within the system of EU regulation of agricultural biotechnology and food safety? What are the possibilities of scientific risk assessment to contribute to political legitimacy of EU? What is the impact of differences in standards of scientific uncertainty on the outcome of

[33] Boisson de Chazournes, L. (2009). New Technologies, the Precautionary Principle, and Public Participation. In Thérèse Murphy (Ed.) *New technologies and human rights*, Oxford: Oxford University Press, p. 162.

[34] Rajan, R. & Letourneau, D. (2012), *supra note* 23, at 1.

decision-making in the field of biotechnologies?). Apparently, the present study can consequently lead to a number of other important questions, which may be answered by means of further research. Thus, the data analysis is a systematic search for the meaning that implies organizing and interrogating data in a way that allows the researchers to see patterns, identify themes, discover relationships, develop explanations, make interpretations, mount cirques, or generate theories.[35]

1.4. The research design, measurement of standards, and data collection

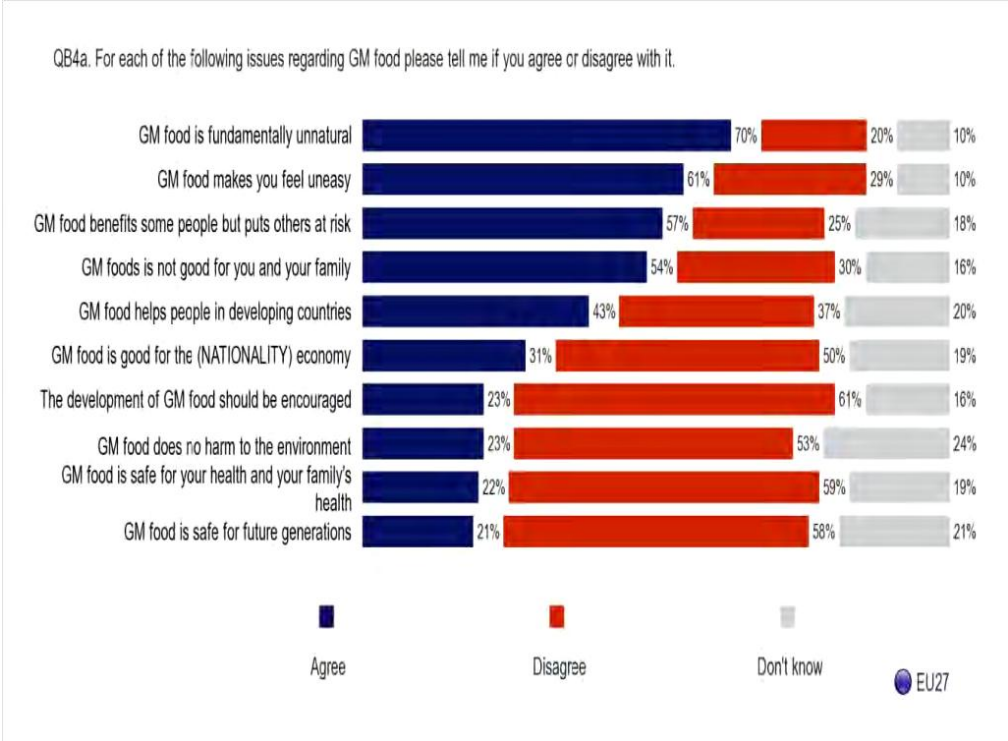
The spectrum of GMO research is broad. The study of biotechnologies operates in a variety of contexts: law, public policy, European studies, sociology etc. The previous works in risk regulation and GMOs have been more focused on the role of public, its involvement in regulatory process, democratisation of authorisation procedures etc (e.g., Wynne, Maasen, Weingart, Levidow, Jasanoff). [36] At the same time, despite a relatively large number of researches in the field of regulation of GMOs, the systematic theoretical studies employing consistent analytical approach towards the

[35] Hutch, A. (2002). *Doing qualitative research in education settings*. New York: State University of New York Press.

[36] See, e.g., Bengtsson, B. & Klintman, M. (2010). Stakeholder participation in the EU governance of GMO in the food chain. In Bäckstrand, K., Khan, J., Kronsell, A. & Lovbrand, E. (Eds.) *Environmental Politics and Deliberative Democracy: Examining the Promise of New Modes of Governance*. Edward Elgar Pub: 105–122; Ferreti, M.P. (2008). Participatory Strategies in the Regulation of GMO Products in the EU. In Steffek, J., Kissling, C. & Nanz, P. (Eds). *Civil Society Participation in European and Global Governance: A Cure for the Democratic Deficit?* (First Ed.). Palgrave Macmillan: 166–184; Fischer, F. (2009). *Democracy and expertise: reorienting policy inquiry*. Oxford University Press; Hagendijk, R. & Irwin, A. (2006). *Public Deliberation and Governance: Engaging with Science and Technology in Contemporary Europe*. Minerva, *44*(2), 167–184; Maasen, S., & Weingart, P. (Eds.). (2005). *Democratization of Expertise?* (Vol. 24). Berlin/Heidelberg: Springer-Verlag; Wynne B. et al. (2001). Public Attitudes towards Agricultural Biotechnologies in Europe (PABE). Final report of project with five partners country teams (Spain, Italy, Germany, France, the UK), funded by DG-Research, Brussels. Centre for the Study of Environmental Change (CSEC), Lancaster University. Retrieved from: http://www.lancs.ac.uk/fss/projects/ieppp/pabe/docs/pabe_finalreport.doc

impact of science on the EU environmental policy is still lacking. I aim to create a specialized and detailed legal account about the role of science in the field of EU regulation of GMOs.

Table 1. Public opinion about GM food.[37]



There are wide choices of empirical sources for research in relation to EU regulation of biotechnologies. In fact, the thesis is based on legal desk research through utilization of an instrumental perspective, which is used, for example, in order to find out the means to secure the EU law's "effectiveness". It looks at the tools and techniques which the specific relevant actors have. This perspective also brings in a normative discussion on how the EU goals, rules, procedures and institutional structure can be

[37] Eurobarometer, October 2010, retrieved from http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

brought into better agreement with each other.[38] The cases selected for study are developed around applications for GMO authorization. The case law analysis is especially relevant since it involves the complex regulatory procedures and societal controversies across scientific uncertainties and risks.

The specific relevant actors are:[39]

- risk producers – those pursuing potentially hazardous activities or technologies;
- risk assessors – scientific experts, EFSA in particular;
- risk managers – the European Council and Commission and the Member States;
- risk protesters – those objecting new technologies or activities through lobbying, protesting and critical reports;
- risk reviewers – EU courts.

In order to come up with the challenges of application of the precautionary principle and to understand how scientific uncertainty is assessed and interpreted in the area of EU regulation of GMOs, I will use a variety of sources. I will research information from academic literature, journal articles, documents of European institutions. I will analyze relevant EU law, with a special focus on the courts' case law. I will examine the role of science in shaping judicial decisions and influencing legislation. The thorough examination of EU courts' case law will help to define the characteristics of the European model of scientific risk regulation. I will address the effects of EU courts' judgments on the development of EU environmental law through the analysis of jurisdictional interpretation of science in justification of restrictive measures to free trade.

The present analysis involves "working with data, organizing them, breaking them into manageable units, synthesizing them, searching for patterns, discovering what is important and what is to be learned, and

[38] Snyder, F. (1993). The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques, 56 *Modern Law Review*, p. 19-54.

[39] Ravetz, J.R. (2001). Models of risk: An exploration. In Hisschemöller, M., Hoppe, R., Dunn, W.N. & Ravetz, J.R. (Eds). *Knowledge, power and participation in environmental policy analysis*. London: Transaction Books.

deciding what you will tell others".[40] In other words, the current research represents the investigation of conditions facilitating analysis of impact of scientific evidence on EU regulation of GMOs within the theoretical framework of risk regulation.

1.5. Restrictions of the research

The primary methodological challenge to the outcome of the research is the issue of integration of the natural science perspectives in the legal field as a social science study. The core methodological problem of the research is how to connect biotechnology and GMOs in particular as natural phenomena with social and economic phenomena, like health and food safety, economic development, internal market freedoms etc. In other words, the main methodological concern is the question of integration and unification of natural and social sciences perspectives in the study. The legal concept of knowledge is not identical to the scientific concept. In the field of environmental law, the legal facts are closely linked to the principle of precautionary and based therefore on the scientific information. A possible way of correlation of terms is 'problem-feeding', which 'is a common and apparently fruitful way of connecting disparate disciplines'.[41] It is possible to apply this concept to the research in order to analyse how problems are defined by natural sciences and exported to the law. The feeding of scientific issue into the field of environmental law is developed by correlation of terms inherent in both science and law. The relevant legal terms are not necessarily the same as scientific facts and they can be

[40] Bogdan, R. & Biklen, S. (1992). *Qualitative Research for Education: An Introduction to Theory and Methods* (2nd ed.). Toronto: Allyn and Bacon, p. 157.

[41] Thorén, H. & Persson, J. (2011). Philosophy of Interdisciplinarity: Problem-Feeding, Conceptual Drift, and Methodological Migration. In *3rd Biennial Conference of the Society for Philosophy of Science in Practice* (June 22-24, 2011; Exeter, UK), retrieved from http://philsci-archive.pitt.edu.ludwig.lub.lu.se/8670/1/Thoren_Persson_Philosophy_of_interdisciplinarity_draft_June2011.pdf?

inconsistent therefore. The 'problem-feeding' method would complement legal desk research by identifying the limitations inherent in science and law and defining the extent of scientific data relevance to legal issues. It would be useful to analyse such discrepancies between science and law by applying an analytical framework based on epistemology and ontology[42]. According to Lena Walberg, problem-feeding from law to science is difficult because the understanding of causation in the two fields differ. The correlation of terms (or the ontological differences corresponding to legally relevant facts and scientifically relevant facts) is only superficially in place. The attempts to establish causal relations in both fields are liable to give rise to misconceptions about the opportunities for problem-feeding.

Ontologically, scientific versus legal facts are disposed to a different set of entities relevant to scientific versus legal theory. Science and law are also, correspondingly, disposed to different epistemologies, where legal dogmatic method makes 'knowledge (or part of it) a phenomenon that is bestowed on men and vouchsafed by higher powers and authorities'[43], while scientific method gives greater emphasis to the empirical self-groundedness of knowledge, involving experiment and experience: *cogito ergo sum*. In other words, legal knowledge as a rule is derived by logic from the general principles of law, rights, and freedoms, whereas scientific knowledge is derived from experience and experiment.

Apparently, the field of environmental law offers unique opportunities for integration and unification of natural and social sciences perspectives. Such a methodological approach is very advanced and time-consuming and it goes far beyond the empirical limits of the present thesis. This issue will be possible to elaborate on during further research.

Besides, the data collection is limited to gathering information from the official sources. Moreover, the research easily becomes outdated since the concerned developments are rapid.

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[42] See, to that extent, Wahlberg, L. (2010). *Legal Questions and Scientific Answers: Ontological Differences and Epistemic Gaps in the Assessment of Causal Relations*. Diss. Lund University.

[43] Gouldner, A. (1976). *The Dialectic of Ideology and Technology*. London: The Macmillan Press LTD, p. 26.

A significant challenge to the research is that it is difficult to define beforehand what level of risk generally justifies the application of measures in accordance with the precautionary principle. As AG Mengozzi mentioned, '[c]ase-law couched in abstract terms would be of little or no use for the decisions which must be taken in practice',[44] since the risk assessment has been carried out on a case-by-case basis.

In spite of different pitfalls inherent in any research, there are no stringent algorithms or demands on data processing in a research since analysis is "as much art as science".[45] The present research, utilizing mainly information from official sources, aims at optimizing the procedure of data collection in order to reduce the research errors within available time. For this purpose, the optimal data collection method is a combination of two or more methods of data collection in order to address the problem of data reliability.[46]

1.6. Structure of the thesis

The issue of GMOs involves a broad range of concerns. In order to arrange the arguments and findings in a substantial and coherent way, this thesis is structured as follows. Chapter I provides for the introductory description of the central research issue, explains the purpose and object of the research. Besides, Chapter I elaborates on the research strategy, develops the methodology of current study and discusses the research design. It explains the research strategy and methodology of the present study in order to connect the research questions to methods and to discover what tools and procedures will be used in answering these questions. It explains the chosen methodology of data analysis through amalgam of such methods as legislation analysis and accessory informational data analysis. The chapter also examines the

[44] Opinion of Advocate General Mengozzi in Joined cases C-58/10 to C-68/10 *Monsanto SAS and others*, paragraph 67.

[45] Babbie, E. (2007). *The practice of social research*. Thomson Learning, Inc, p. 384.

[46] Leeuw, D. (2005). To Mix or Not to Mix Data Collection Modes in Surveys. *Journal of Official Statistics*, Vol. 21, No. 2.

advantageous and disadvantageous points of represented methodology. This chapter presents a way to answer the main research question, describing what kinds of information are necessary to collect for the analytical part of research, and which consecutive steps are needed to be done in order to answer the main research question. Chapter II outlines the theoretical framework of investigation. It explains the risk regulation doctrine as a theoretical concept relevant to EU regulation of GMOs. Chapter III describes the framework for GMOs authorization as an important tool of scientific risk assessment since authorisation is required for every GM product. It explains the nature of conflict between science, policy and public in decision making on GMO. The legislation on GMOs authorisation is analysed along these lines of conflict. Besides, Chapter III contains case law analysis. It expounds appropriate cases from EU courts in order to explain how courts interpret scientific uncertainty about possible negative effects of GMO. It also analyses how court assesses the interests of health and environment protection against the freedoms of internal market. Chapter IV concludes this thesis.

CHAPTER TWO

Theoretical Framework

This chapter outlines the theoretical framework for the current research. The background and specifics of EU regulation of GMOs is described. In order to develop the sufficient framework for the further analysis, the present chapter substantiates relevance and applicability of theoretical concepts of risk regulation for the research. The meaning and scope of application of the principle of precautionary and the proportionality principle in relation to environmental risk regulation is explained. Different interpretations of risk related to regulation of GMOs presented in academic literature and documents of EU institutions are discussed. The chapter also explains relevance of the concept of risk regulation and how it is used in the present research. This concept gives the views on what the desired conditions for functioning of the regulation of GMOs are.

2.1. Regulation of risk as relevant theoretical concept of regulatory framework applying to GMOs

The dominant realm of risk regulation is judicial review of decisions of public institutions[47]. Besides, risk regulation has been a central issue of

[47] Rodgers, W. (1987). Guerilla decisionmaking: Judicial review of risk assessments. *Journal of Hazardous Materials*, 15 205-217.

research for many prominent scholars.[48] It is mentioned above that the methodology of EU risk regulation comprises three stages: risk assessment, risk management and risk communication[49]. In fact, the concept of risk regulation is far more nuanced, [50] but it is outside of the scope of the present thesis to analyse the specifics of risk peculiar to different fields of social sciences, since the present study is predominantly concerned with the role of science in the field of EU regulation of GMOs.

Probably, no regulatory framework that addresses only 'risk side' of agricultural biotechnologies can adequately and comprehensively address the complexity of GMOs issues. Nevertheless, as it is previously mentioned, the present research covers only the framework of risk regulation in relation to the role of scientific evidence in the field of regulation of GMOs. The three 'interconnected components of risk analysis – risk assessment, risk management and risk communication – 'provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health'[51].

The breakdown of risk regulation to the mentioned three 'distinct but closely linked' elements was proposed by the Codex Alimentarius Commission, a body established in 1963 by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The Codex's standards are collected in Procedural

[48] For example, Jasanoff, S. (1990). The fifth branch: Science advisers as policy makers. Cambridge, MA: Harvard University Press; Wynne, B. (1995). Technology assessment and reflexive social learning: Observations from the risk field. In Rip, A., Misa, T.J. & Schot, J. (Eds.). *Managing technology in society: The approach of constructive technology assessment*. London: Pinter Publishers; Nowotny, H., Scott, P., & Gibbons, M. (2001). *Re-thinking science: Knowledge and the public in an age of uncertainty*. Cambridge, UK: Polity Press in association with Blackwell Publishers.

[49] For more information with regard to the original ideas about the distinction between risk assessment and risk management see Jasanoff, S. (1986). *Risk Management and political culture*. New York.

[50] To that extent, see Fisher, E. (2010). Risk Regulatory Concepts and the Law. In OECD, *Risk and Regulatory Policy: Improving the Governance of Risk*. See Fisher, E. (2006). Risk and Environmental Law: A Beginner's Guide. In Richardson, B. & Woods, S. (Eds.). *Environmental Law for Sustainability*: *A Critical Reader*. Oxford: Hart Publishing, for discussion on how environmental regulation turned into a question of risk in the end of 20th century.

[51] Regulation EC 178/2002, recital 17, *supra note* 21.

manual[52], comprising international standards, guidelines and recommendations relevant to food production and food safety. Countries are expected to follow these standards and recommendations in devising food safety regulations.[53]

The term 'environmental risk assessment' is understood as the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose.[54]

Table 2: Elements of risk analysis[55]

Risk assessment	A scientifically based process consisting of hazard identification; hazard characterization; exposure assessment; risk characterization.
Risk management	The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.
Risk communication	The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

[52] *Codex Alimentarius Commission – Procedural manual – Twelfth Edition, 2001.* Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome. Retrieved from http://www.fao.org/DOCREP/005/Y2200E/y2200e00.htm

[53] Winickoff, D., Bushey, D. (2010). Science and Power in Global Food Regulation: The Rise of the Codex Alimentarius. *Science Technology Human Values* 2010 35: 356.

[54] Article 2(8) of Directive 2001/18 on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC [2001] OJ L 106/1.

[55] Codex Alimentarius Commission – Procedural manual, *supra note* 52, p.43-44.

The principles of risk analysis in relation to GM food were established by adoption of a new General Food Regulation in 2002.[56] It sets out general principles of food law, establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA). The General Food Regulation defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'.[57] This regulation adheres to strong science in measures relating to food safety and also establishes the three aforementioned components of risk regulation (assessment, management and communication). It was mentioned before that the practical meaning of division between risk evaluation and risk management has been disputed as artificial, in the sense that the Commission generally treats the opinion of the EFSA as a result of both risk assessment and risk management, and not just risk assessment.[58] This may partially be a reason why so far the final decision on authorization has always been in line with EFSA's opinion[59].

According to the General Food Regulation, scientific assessment of risk must be undertaken in an independent, objective and transparent manner based on the best available science. Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the EU. In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and the environmental impact.

[56] Regulation 178/2002, *supra note* 21.
[57] *Ibid*, Article 3(9).
[58] Bengtsson, B. & Klintman, M. (2010), *supra note* 36.
[59] The decisions can be found in EU Register of authorised GMOs, available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

The General Food Regulation states that EFSA is 'an independent scientific point of reference in risk assessment'.[60] Therefore, the Regulation tries to consolidate the EFSA's independent scientific position in attempt to gain legitimate weight from the EFSA's expertise.

The General Food Regulation also establishes the principle that risk management actions are not just based on a scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration. The EFSA plays its role in the separation of scientific excellence from political and business considerations, which can pose a threat to the internal market. The internal market freedoms are particularly sensible to the regulation of risk in the field of application of GMOs, because this area is lacking for harmonized and objective approach.

In the academic field, the discussion of relationships between science and politics seems to have no ending. Scientific expertise develops in a particular cultural and political context that inevitably (and often unconsciously) impacts the scientific expertise of decision making. While expertise is certainly important, public perspective on risk deserves thorough consideration. The dichotomy between expert and public perspectives is theoretically explained by two approaches to risk: the technocratic and the populist[61]. The 'technocrats' clam superiority of science over public opinion, while 'populists' believe that in a democracy government should follow public opinion rather than a will of self-appointed technocratic elite. Both technocrats and populists acknowledge that science is not flawless in terms of public policy deliberation concerning the environmental protection for the reasons of scientific uncertainty. Apparently, science alone is not a universal guide for dealing with extremely sensitive issues of risk regulation in the field of new technologies. That is where 'sacred' expertise clashes with 'profane' public opinion on possible harms of GMOs. This is why the last phase of risk communication is important, being an exchange of information between various stakeholders, shaping that what Jürgen Habermas calls 'communicative

[60] Regulation 178/2002, *supra note* 21, Recital 34.

[61] For more information of these two approaches see Sunstein, C., The Laws of Fear (2001 June). *U Chicago Law & Economics, Olin Working Paper* No. 128.

rationality'. The risk communication concerning decision-making on GMOs therefore pursues the goal to achieve full transparency and authentic mutual understanding, to realize a public interest in a context of multi-governance approach to EU regulation of GMOs. Lack of communicative rationality in form of transparent communication, according to Habermas, can disguise ideology in science clothing.[62] Ideology substitutes science by reducing practical questions about the implications of new technologies for people's life to technical problems for experts. This leads to diminishing the importance of transparent public policy deliberation. As a result, technocratic elites can eliminate the need for public, democratic discussion of values in favour of ideology that masks the value-loaded nature of EU decision making in the field of GMOs. Therefore, the legitimate public interest in technical control plays a significant role in mitigating EU's 'democratic deficit',[63] since the EU capacity of effective and democratic governance has often been challenged as lacking of representativeness, accountability and transparency.[64]

2.3. The proportionality principle

The restrictive measures imposed by Member States can be justified on the basis of Article 36 TFEU (ex Article 30 EC Treaty), if they were proved to be necessary and proportionate.[65] The proportionality test implies that a national measure should not be prohibited as a restriction on trade if it is proportionate to the objective pursued and if there is no less restrictive

[62] Habermas, J. (1970). *Toward a Rational Society*, J. J. Shapiro (trans.). Boston: Beacon.

[63] 'The democratic deficit is a concept invoked principally in the argument that the European Union and its various bodies suffer from a lack of democracy and seem inaccessible to the ordinary citizen because their method of operating is so complex', retrieved April 17th 2013 from EU glossary at http://europa.eu/legislation_summaries/glossary/democratic_deficit_en.htm

[64] Eriksen, E., Fossum, J. (2000). Democracy in the European Union: Integration through Deliberation? (1st ed.). Routledge.

[65] Krämer, L. (2000) *EC Environmental Law* (4th ed.). London: Sweet and Maxwell.

measure.[66]According to paragraph 2 Article 7 General Food Regulation, measures adopted in relation to the precautionary principle shall be *proportionate* and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

Proportionality acts as a control tool over measures and actions falling within the sphere of application of EU law.[67] The first legislative manifestation of proportionality can be considered Article 5 of EC Treaty where it was attributed to as part of subsidiarity.[68] Nevertheless, the leading role in establishing and developing proportionality as one of the general principles of EU law has been played by EU courts. The principle of proportionality requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.[69] Therefore, the application of proportionality presupposes suitability and necessity of adopted measures in order to verify the legality of a national or EU measure. A particular expression of the principle of proportionality is the cost-benefit analysis[70]. Though the role of EU courts in applying the proportionality test is rather limited because EU ‘judicature may not substitute its assessment of the facts for the assessment

[66] Dillon, S. (2002) *International Trade and Economic Law and the European Union.* Oxford: Hart.

[67] Craig, P. (2012) *EU Administrative Law* (2nd ed.). Oxford University Press.

[68] Paragraph 3 Article 5 EC Treaty: “Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty”.

[69] Case C-331/88 *Fedesa and Others* [1990] ECR I-4023, paragraph 13; Case T-13/99 *Pfizer Animal Health v Council*, [2002] ECR II-3305, paragraph 411.

[70] Pfizer, *supra note* 69, paragraph 410.

made by the authority concerned',[71] the courts verify whether the measure entailed disadvantages that were disproportionate to the objectives pursued.

The proportionality test plays important role in the EU courts' approach to national measures. In cases like Danish Bottles, Shmidberger, and Aher-Waggon[72] the proportionality test has been applied with a great deal of detail. Sometimes, like in PreussenElektra, Swedish Match, Arnold Andre, REACH cases[73], the test application is rather superficial if not completely lacking. To a certain extent, it might have happened because the Court can extensively expand its own jurisdiction and employ a "generous" approach to interpretation of the EU law in order to enhance health and the environment protection. On the other hand, such approach makes it difficult to define the criteria under which a restrictive measure can be proved as necessary and proportionate. For example, in the so-called "snuss cases"[74] concerning a prohibition of tobacco for oral use in the EU, the Court found that ban justifiable on the basis of long-term objective of a tobacco-free world since "no other measure would have the same preventive effect in terms of the protection of health[75]".

Apparently, the Court aspires to retain the opportunity to keep a balance between trade and environment on a case-to-case basis, since adoption of decisions in the field of environmental law have often involved complex political and economic choices. The common trend of the Court's case law in the field of environment is that "the Court has displayed willingness to accept trade restrictive, and even discriminatory trade restrictive, measures where this complied with a positive environmental protection principle"[76]. Recognizing that environmental protection can be considered as a

[71] Case C-120/97 *Upjohn Ltd* [1999] ECR 223, paragraph 34; Case C-405/92 *Mondiet* [1993] ECR 6133.

[72] Case C-302/86 *Commission v Denmark* [1988] ECR 4607; Case C-122/00 *Schmidberger* [2003] ECR I-5659; Case C-389/96 *Aher-Waggon* [1998] ECR I-4473.

[73] Case C-379/98 PreussenElektra [2001] ECR I-2099; Case C-210/03 Swedish Match [2004] ECR I-11893; Case C-434/02 Arnold Andre [2004] ECR I-11825; Case C-558/07 The Queen, on the application of: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs [2009] ECR I-5783.

[74] *Swedish Match*; *Arnold Andre*, supra note 73.

[75] *Ibid*, paragraph 57.

[76] Heyvaert, V. (2001). Balancing Trade and Environment in the European Union: Proportionality Substituted? 13 *Journal of Environmental Law* 3.

mandatory requirement,[77] which may be accepted as necessary for trade restriction through application of the proportionality test, the Court can also create a new justification, like in Walloon Waste case[78] where an export ban on non-hazardous waste considered as non-discriminatory regarding the nature of goods, or in Toolex Alpha case where the Court invented a novel substitution principle ,[79] under condition that no safer replacement product is available and provided that the applicant continues to seek alternative solutions which are less harmful to public health and the environment.

The readiness to accept restrictive approach to free trade was recognized by EU courts insofar as the protection of public health 'must take precedence over economic considerations'.[80] At the same time, such prohibitive or restrictive measures should not 'constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States'.[81] Besides, a Member State has to provide evidence that a measure 'is restricted to what is actually necessary to secure the protection of public health'.[82]

Therefore, application of the proportionality principle implies that the objective of the adopted measure cannot be attained in a less restrictive manner. The proportionality principle allows policymakers and courts to assess scientific uncertainty than the need to protect health and environment must be balanced against the freedom of trade. In its essence, the proportionality principle is an effective legal tool of risk regulation.

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[77] Case C-302/86 Commission v Denmark, *supra note* 72. The mandatory requirements arose out of Case C-120/78 Rewe-Zentral (also known as Cassis de Dijon): the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions, and the defense of the consumer.

[78] Case C-2/90 Commission v Belgium [1992] ECR I-4431.

[79] Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-5681, paragraph 47. In fact, the Court mentions that the substitution principle emerges, *inter alia,* from Council Directive 89/391/EEC and Council Directive 90/394/EEC.

[80] Case T-13/99 Pfizer, *supra note* 69, paragraph 456, besides that, see Case C-183/95 *Affish* [1997] ECR 4315, paragraph 43, and Case 160/88 *Fedesa v Council* [1988] ECR 6399.

[81] Article 36 TFEU.

[82] Case 178/84 *Commission v Germany* [1987] ECR 1227.

2.3. Nature of the precautionary principle within the framework of risk regulation

The precautionary principle is a central concept of the EU regulatory framework and is a basis for the environment policy. In the field of health and environmental decision-making, 'the precautionary principle is perhaps one of the most significant principles of the contemporary era'.[83] This principle addresses the cases where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are the reasonable grounds for concern that potentially dangerous effects on the environment and health may be inconsistent with the high level of protection chosen by the EU.[84] Risk regulation is designed to protect health and the environment from negative consequences of human action even when the expected negative effects are not yet proven by scientific results. Based on scientific risk assessment, decision makers define political objectives to determine the level of risk acceptable for the society, taking into account not only the results of risk assessment, but also the precautionary principle and other factors legitimate to the matter under consideration.[85]

The precautionary principle is intended to improve rational design of public policy. The difference between risk assessment and risk management is framed within the theory of *bounded rationality* developed by Herbert

[83] Fisher, E., Jones, J. & Von Schomberg, R. (2006). Implementing the Precautionary Principle: Perspectives and Prospects. In Fisher, E., Jones, J. & von Schomberg, R. (Eds.). *Implementing the Precautionary Principle.* Edward Elgar, p. 11.

[84] Regulation 178/2002, *supra note* 21, paragraph 1 Article 7: "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". For more information see Communication from the Commission on the precautionary principle, available at http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

[85] Fisher, E., Jones, J. & Von Schomberg, R. (2006), *supra note* 83.

Simon[86], where scientific expertise is *substantive rationality* prioritizing *knowledge* and answering the questions *what is rational? Is the substance of this decision 'rational'?* Simultaneously, political decision-making is *procedural-interactive rationality*, concentrating on the questions *how to deliberate? Who (how, and/or when) has to participate in the deliberation and decision-making process?*

The use of the precautionary principle in public policy deliberation involves balancing between value judgments and factual scientific statements in the public policy context.[87] Risk regulation and precautionary principle are interconnected concepts of public policy. The links between these two concepts are described in Table 3.

Table 3. Deliberation level of application and implementation of the precautionary principle

Stage of risk regulation	Type of deliberation	Operational framework	Factors of risk regulation	Decision model
Assessment	Scientific	Risk assessment prior to authorization	Preliminary scientific evaluation	Allocation of burden of proof etc
Assessment	Scientific	Scientific evidence identification, qualification of uncertainties	Lack of knowledge, scientific controversy	Scientific qualification of available information, quality of available data
Management	Societal	Choice of level of protection	Goal of high level of protection, consistency, non-discrimination	Defining adverse effects
Management	Societal	Cost-benefit	Balance	Priority setting

[86] Bounded rationality is displayed as neurophysiological limits on rationality, e.g., limited brain capacity to memorize, see Simon, H. (1957). A Behavioral Model of Rational Choice. In Models of Man, Social and Rational: Mathematical Essays on Rational Human Behavior in a Social Setting. New York: Wiley; Simon, H. (1991). Bounded Rationality and Organizational Learning. *Organization Science* 2 (1): 125–134.

[87] Schomberg, R. (2006). The precautionary principle and its normative challenges. In Fisher, E., Jones, J. & von Schomberg, R. (Eds.). *Implementing the Precautionary Principle: Perspectives and Prospects*. Cheltenham, UK and Northampton, MA, US: Edward Elgar, chapter 2, pp. 19-42.

		analysis	between health/ environment protection and freedoms of internal market	
Management	Political/ societal	Application of precautionary practice	Necessity and proportionality requirement, least restrictive measure	Monitoring, limited licensing, labelling
Communication	Political/ societal	Consensus over political debate, NGOs involvement	Public concern, threat of adverse effects	To act or not to act

For the sake of precaution, different Member States disputed adequacy of legislation[88] and opposed GMOs. Heavy reliance on expert authority rather than on deliberation policy led to the situation where little attention 'has been paid to the interaction between civil society and the EU institutions from a deliberative perspective'.[89] In 1990s, the protest against GMOs was intensive but hardly surprising and unreasonable. The tensions about agricultural biotechnologies 'could hardly occur without wrenching political upheavals'.[90] The consumer backlash against the technology was so intense that 'the adequacy of the legislation was suspect even to a techno-enthusiastic Europhile'[91] A number of Member States blocked the authorization of any GM products for import and cultivation through the introduction of measures preventing access of GMOs to the national markets. This regulatory deadlock was de facto moratorium on the authorization of GMOs. Twelve out of the then fifteen Member States issued declarations that they were against the authorization in the 2194th Council Meeting during 24-25 June 1999. The declaration stated the Member States' intention to block the authorization in Council. Ireland, Portugal and the UK did not join the declarations. From 1998 to 2004, no

[88] In particular, Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.

[89] Tanasescu, I. (2009). The European Commission and interest groups: towards a deliberative interpretation of stakeholder involvement in EU policy-making. Asp/Vubpress/Upa, p. 34.

[90] Jasanoff, S. (2005). Designs on Nature: Science and Democracy in Europe and the United States. Princeton University Press, p. 4.

[91] Lee, M. (2008), *supra note* 4, p. 8.

applications for authorization of GMO were approved. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms repealed Council Directive 90/220/EEC.

In the field of judiciary, EU courts developed the application of the precautionary principle. EU courts recognized that the 'zero risk' degree is practically unattainable and rejected a 'purely hypothetical approach to the risk'[92] therefore. The CFI in particular stated that 'a "zero risk" does not exist, since it is not possible to prove scientifically that there is no current or future risk'[93] associated with activity. The application of cost-benefits analysis is required as a part of the precautionary principle.[94]

The Pfizer approach to interpretation of risk and scientific uncertainty set the tone for the subsequent judgments of EU courts. This approach proved to be rather restrictive, emphasizing the role of scientific evidence in legal analysis of risk. It acknowledges a possibility for scientific evidence to be a legitimate ground for justification of restriction on the freedom of trade for the sake of health protection: 'To the extent to which the Community institution opts to disregard the [scientific] opinion, it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter'.[95] There is a judicial preference for the evident objectivity and certainty of scientific information, over the politically stimulated value judgements concerning GMOs.

[92] Pfizer, *supra note* 69, paragraph 143; Case T-392/02 *Solvay Pharmaceuticals BV v Council* [2003] ECR II-4555, paragraph 129.
[93] Pfizer, *supra note* 69, paragraph 145.
[94] *Ibid*, paragraph 469.
[95] *Ibid*, paragraph 199.

CHAPTER THREE

Decision Making within EU Regulation of GMOs

This Chapter deals with the decision making process in the field of regulation of GMOs. I will scrutinize the regulatory concerns of GMOs outlined in the EU authorisation system. I will examine external challenges to EU regulation of GMOs exacerbated by trade conflicts with the US and other countries concerning the complaints that the EU does not comply with the WTO agreements. Besides, I will study the approach of EU courts to the environment and health protection measures banning or restricting GMOs, as well as the role of EU courts in risk assessment and interpretation of scientific evidence.

3.1. Authorisation

The main regulatory concern of GMOs is outlined in the authorisation regime. In fact, the EU authorisation regime is in force since 1990.[96] At that time, GMO subjected itself to greater public scrutiny, leading to unprecedented raise of public awareness and making the GM food one of the greatest social challenges. This enormous social upheaval led to *de facto* moratorium (discussed in the previous chapter). The first regulatory

[96] Directive 1990/220 on the Deliberate Release in to the Environment of Genetically Modified Organisms [1990] OJ L 117/15.

breakthrough was the Deliberate Release Directive[97] of 2001, covering all GMOs for release into the environment or placing on the market. The Food and Feed Regulation[98], and the Traceability and Labelling Regulation[99] were adopted in 2003.

The Deliberate Release Directive applies to the 'placing on the market' of GMOs 'as or in products'.[100] The Food and Feed Regulation applies to 'GMOs for food use' or 'food containing or consisting of GMOs'.[101] The GMOs can be simultaneously covered by both legislative acts.

It is commonly asserted that the so-called moratorium on authorization was ended by the authorization of Bt11 sweetcorn in May 2004.[102] According to the present EU regulatory framework, a GM plant has to undergo proper environmental risk assessment before it can be cultivated in the EU, whereas an initial environmental risk assessment has to be carried out by a Member State. The burden of proof lies on the applicant. The applicant notifies the competent authority of the Member State where the GMO is to be placed on the market for the first time.[103] The notification must contain a range of information, including the environmental risk assessment carried out by the applicant, and a plan for monitoring the GMO following its release into the environment.[104] Environmental risk assessment of a GM plant consists of six steps defined by EFSA[105].

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[97] Directive 2001/18, *supra note* 54.

[98] Regulation 1829/2003 on Genetically Modified Food and Feed [2003] OJ L 268/1.

[99] Regulation 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed products Produced from Genetically Modified Organisms and amending Directive 2001/18/EC [2003] OJ L 268/24.

[100] Directive 2001/18, *supra note* 54, Article 1.

[101] Regulation 1829/2003, *supra note* 98, Article 3(1)(a), (b).

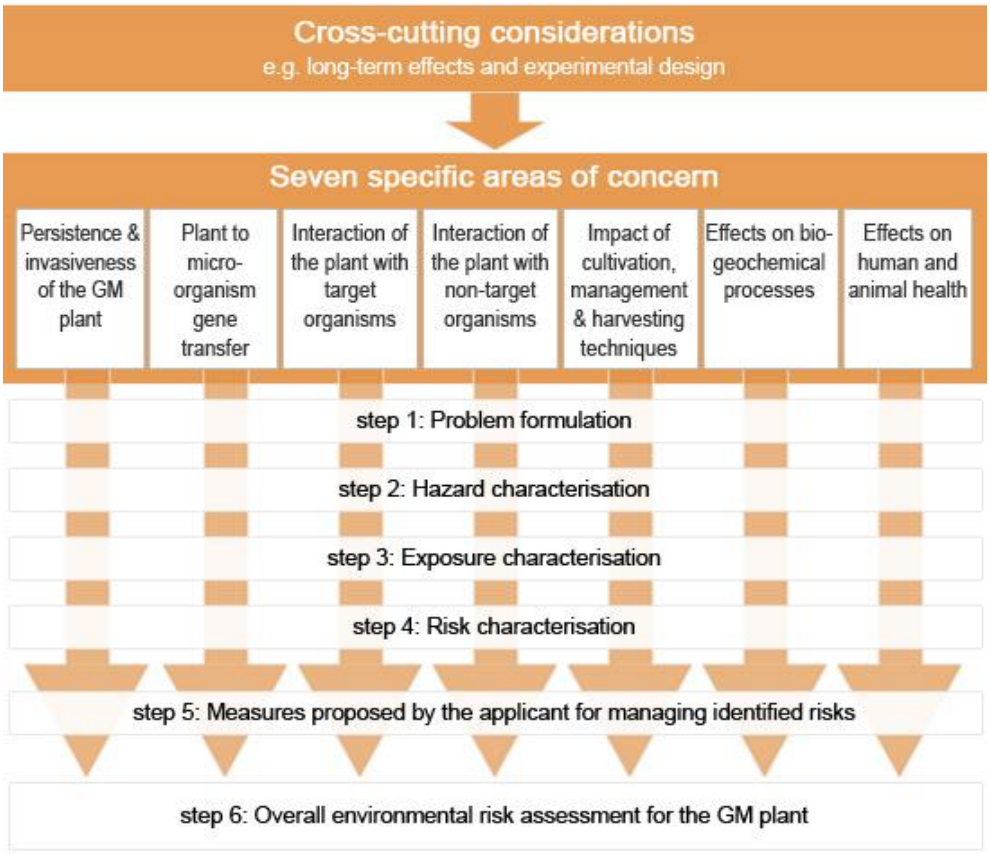
[102] Commission Decision 2004/657/EC authorising the placing on the market of sweetcorn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council. It must be noted that some authors consider that that moratorium ended in 2003 with the adoption of 'the most restrictive regulations in the world', see Tiberghien, Y. (2009). Competitive Governance and the Quest for Legitimacy in the EU: the Battle over the Regulation of GMOs since the mid-1990s. Journal of European Integration, 31(3), 389–407, p. 392.

[103] Directive 2001/18, *supra note* 54, Article 13(1).

[104] *Ibid*.

[105] For more information, see EFSA Panel on Genetically Modified Organisms (GMO). (2010). Guidance on the environmental risk assessment of genetically modified plants. *EFSA Journal* 8(11): 1879, retrieved from http://www.efsa.europa.eu/en/efsajournal/pub/1879.htm

Table 4. Environmental risk assessment approach for a GM plant[106]



The applicants for authorization are required to monitor for possible environmental effects associated with the cultivation of GMOs. Next, they should report their findings to the other Member States and the Commission. EFSA examines the scientific quality of the environmental monitoring plan submitted by the applicants and issues a scientific opinion providing guidance to applicants.

The new legislative framework for authorization of GMOs did not prevent many Member States from opposing to cultivation of GMOs on their

[106] The table retrieved from EFSA's webpage on GMOs: http://www.efsa.europa.eu/en/topics/topic/gmo.htm

territories. The obstruction of GMOs authorizations obtained legal characteristics embodied in the form of safeguard measures. According to Article 23 of the Deliberate Release Directive, a Member States can invoke a safeguard measure if they wish to limit or prohibit the use and/or sale of GMOs for which authorisation has been granted on the basis of this Directive. A safeguard clause is a possibility for a Member State to prohibit provisionally the cultivation or use of GMO on its territory due to safety concerns based on scientific assessment. The Commission in turn may ask EFSA to provide scientific opinion on the information presented by a Member State, whereas EFSA assesses the information in the form of scientific opinion. Such a situation can potentially create a regulatory deadlock challenging the authority of the Commission. EFSA seeks for the way out of this situation by networking and consulting with national authorities and stakeholders. If the application is for the authorization of 'seeds or other plant propagating material', EFSA 'shall ask a national competent authority to carry out' the environmental risk assessment.[107] According to Recital 5 in the preamble to Deliberate Release Directive, the protection of human health requires that due attention be given to controlling risks from the deliberate release of GMOs into the environment. Under Deliberate Release Directive, a specific case-by-case risk assessment has to be conducted for every envisaged GMO product. The precautionary principle must be taken into account in application of this directive.[108] The national safeguard measures can be taken if the product granted the authorization can potentially cause a danger to human health or the environment according to the scientific evidence that has become available after the authorization date. The available evidence must affect 'the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge'.[109]

[107] Regulation 1829/2003, *supra note* 98, Article 6(3)(c).

[108] According to recital 8 in the preamble to Directive 2001/18, *supra note* 54, the precautionary principle has been taken into account in the drafting of that directive and must be taken into account in its implementation.

[109] Directive 2001/18, *supra note* 54, Article 23.

Thus, the problem of Member States' opposition to GMOs still exists. Administrative stalemates create hurdles to free trade and to the functioning of internal market in general. The internal market freedoms constitute a framework for EU legal order. Therefore, the internal market can be perceived as an idea providing for the rationale of functioning of the EU. The barriers to the internal market can raise a threat to the very essence of the EU's existence.

The decision making for GMOs needs to be very sensitive therefore. Risk analysis is a matter of balance between different considerations involved into the issue of authorization of GMO. The decision maker faces a problem of correlation between science and law. Legal decision must be based on science. At the same time, legal decision has to take into consideration economic and political aspects, which are disregarded by natural science as a disciplinary field (presumably) free of value judgements.

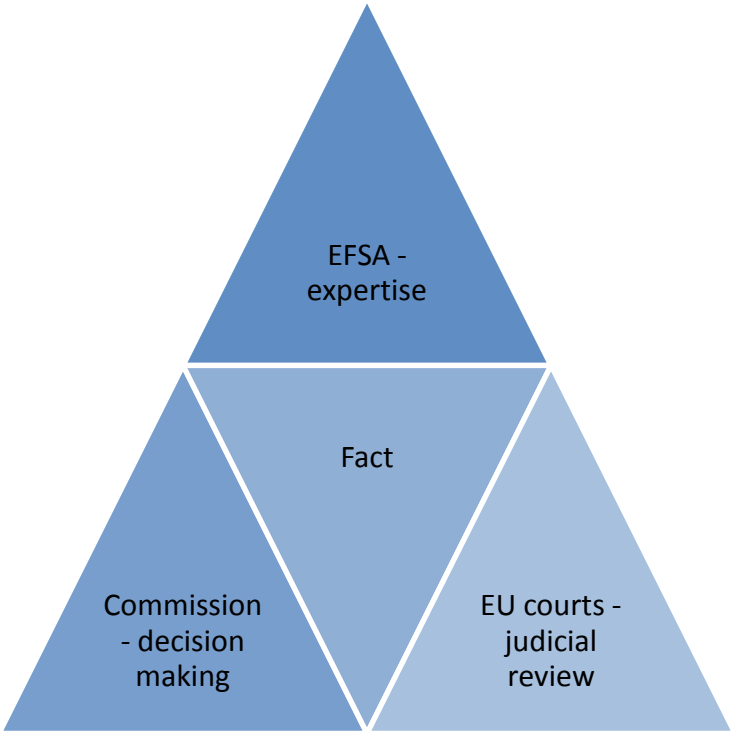
The authorisation process presumes that legal decision is taken on the basis of scientific evidence. The policy maker (the Commission) has to correlate science with law, deciding whether scientific expertise is *prima facie* relevant. Decision makers do not always consider scientific evidence as necessary and relevant. For example, Lena Wahlberg makes an example that during the recent years the courts have always ruled in favour of a patient irrespectively of the expert opinion that the injury was not a consequence of an accident. The reason is that causal links differ in the field of science and law.[110]

The added value of science in decision making is that it allows autonomous stages of risk assessment and risk management to be linked to each other through the causal relations proved by factual evidence.

The scientific evidence operates as the factual information that affects decision making rather than predetermines its outcome. Relevant facts are assessed in two different contexts: scientific and legal, subject to court review (Table 5).

[110] Wahlberg, L. (2010), *supra note* 42.

Table 5. Assessment of facts in different contexts on EU level



Therefore, the decision-making is fulfilled by putting scientific risk assessment through legal assessment. The decisions on GMO authorisation are taken relatively autonomously from scientific risk assessment. On the one hand, such approach favours independence and impartiality of scientific expertise. On the other hand, the division between risk assessment and risk management shifts the responsibility for decision making from those who possess expert knowledge about potential harm of GMOs (EFSA) to those who certainly do not have scientific expertise and are not free from bias and value judgment (the Commission).

In any case, there is no ideal situation in the real word. It is generally asserted that 'law', 'science', and 'politics' are autonomous fields, whereas in the area of regulation of GM food 'the demarcation between these fields

is blurry'.[111] The practice shows that such a division of responsibility proved to be a positive and useful tool for decision making in the field of GMOs. Separation between scientific and managerial aspects of GMOs' authorisation helps the decision making to be backed up by the scientific data without giving the science responsibility for the final decision for lack of legitimacy. It is still a question whether the Commission's democratic legitimacy is solid enough to be able to withstand critical considerations of its activity. Scientific expertise is required for the establishing of legal causal relations where legal facts are based on scientific facts. At the same time, scientific facts and legal facts are not necessarily the same thing. Therefore, legally relevant facts are given priority within decision-making process by reasons that scientifically relevant information may be legally irrelevant. Nevertheless, a legal decision that rejects scientific information must be well-grounded by the reasons which 'must be of a scientific level at least commensurate with that of the opinion in question'.[112]

3.2. The challenges to EU regulation of GMOs beyond European context

The GMOs debate has taken place not only in the context of EU legal order but also in the international context. Since the EU's approach towards risk regulation in the field of GMO comes into conflict with WTO law, it is worthy to examine the extent to which the EU is capable to regulate biotechnology within the EU.

[111] Etty, T., Somsen, H., (2004). Case C-236/01: Monsanto Agricoltura Italia SpA and Others v Presidenza Del Consiglio dei Ministeri and Others. *European Environmental Law Review.* Jan2004, Vol. 13 Issue 1, pp. 3-18.
[112] Pfizer, *supra note* 69, paragraph 199.

Comparison of the EU with the US, as another major representative of Western civilization and main antagonist of the EU in the WTO,[113] shows a different understanding of risks in health and environment policy. In contrast to the EU, the US push forward the cost-benefit analysis.[114] In practice, this may lead to different policy actions. For example, in the EU the consequences of use of GMOs are uncertain and a question of their risks is open, hence the European policy on GMOs is quite restrictive. By contrast, the US estimate the benefits as overweighing the probable harms and the public policy on genetic engineering is therefore supportive. The cost-benefit analysis application in the US' style tends to monetize everything, including human life. It has even been stated that the US Environmental Protection Agency values a human life at about $6.1 million.[115] It seems unlikely that similar calculations could be acceptable in the EU. The difference between regulation policies of the US and the EU are striking.[116] Nearly three-quarters of all genetically modified crops are grown in the US, whereas comparably small quantities are grown in Europe. Unlike the US, in Europe the public opposition to GMOs has been relatively effective[117]. In any case, a conflict between the EU and the US diminishes effectiveness of rules, inducing further expansion of conflict and thereby

[113] For detailed discussion on this issue, see Búrca, G. & Scott, J., (2001). The Impact of the WTO on EU Decision-making. In Búrca, G. & Scott, J. (Eds.). *The EU and the WTO: Legal and Constitutional Issues.* Hurt Publishing.

[114] E.g., the arguments in favour of cost-benefit analysis are represented, in various ways, by Sunstein, C. (2004 October). Cost-Benefit Analysis and the Environment. *U Chicago Law & Economics*, Olin Working Paper No. 227; Breyer, S. (1993). Breaking the Vicious Circle*: Towards Effective Risk Regulation.* Harvard University Press; Margolis, H. (1996). *Dealing With Risk*: *Why the Public and the Experts Disagree on Environmental Issues.* University of Chicago Press.

[115] Sunstein, C. (2004 October), *supra note* 114.

[116] It is remarkable that striking differences between the US and the EU policies occur not only in the field of environment, proving a hypothesis that an attitude towards a controversial problem to a great extent depends on a legal culture. For example, the US legal scholars Cass Sunstein and Adrian Vermeule in "Is Capital Punishment Morally Required? The Relevance of Life-Life Tradeoffs" (March 2005), state that capital punishment may have a significant deterrent effect, preventing as many eighteen or more murders for each execution.

[117] Lynch, D. & Vogel, D. (2001). *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*. Council on Foreign Relations Press, April 5, 2001, retrieved from the Council on Foreign Relations website: http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688.

reducing the opportunity to promote an optimal relationship between science and society in the future[118]. A sensible methodological approach is significant because the validity of scientific data is not always able to handle all challenges of the question at issue. The rational policy making, dealing with the question of a clash between trade and environment, rules out the solutions driven by prejudice. Thus, the statement that the environmental protection has a negative impact on international competitiveness of the EU since it places an additional burden on the internal market freedoms is probably erroneous. Such a position can be a hasty conclusion tending to dramatic and dichotomous judgment. Besides, this opinion has been challenged by so-called Porter hypothesis, according to which more stringent environmental policies can stimulate innovations that may compensate for the costs of complying with these policies[119]. The linkage between trade and environment is "a matter of fact... Environmental rules cannot be seen simply as pollution control or natural resource management standards; they also provide the ground rules for international commerce and serve as an essential bulwark against market failure in the international economic system".[120]

The WTO develops its trade liberalization regime through the concept of prohibition of discrimination[121]. Non-discrimination is also provided for in several articles of the TFEU, for example, in Article 36. Nevertheless, both for the WTO and the EU, the most disputable and complicated issue is the removal of non-discriminatory restrictions to trade.

The trade conflict between WTO and EU revolves around the question whether the environmental protective measures constitute possible non-discriminatory restrictions on trade, and if so, how they can be removed. The EU has developed an efficient approach to non-discriminatory restrictions through the harmonisation process with an outstanding

[118] Winham, G. (2003). International regime conflict in trade and environment: the Biosafety Protocol and the WTO. In *World Trade Review* 2: 2, 131–155.

[119] For more information see Porter, M. (1991). America's Green Strategy. *Scientific American*, 264, 4, 168, and Porter, M. & van der Linde, C. (1995). Green and Competitive: Ending the Stalemate. *Harvard Business Review*, 9, 4, 120–34.

[120] Esty, D. (2001). Bridging the Trade-Environment Divide. *Journal of Economic Perspectives*, vol. 15, no. 3: 353-377.

[121] Articles I and III the General Agreement on Tariffs and Trade (GATT).

contribution of the ECJ. It appears that the WTO would have benefitted from the EU experience of harmonization. It was suggested that the WTO could gain much from adopting a proportionality test developed by the Court, according to which a national measure should not be prohibited as a restriction on trade if it is proportionate to the objective pursued and if there is no less restrictive measure[122]. On the other hand, WTO as an international regime is committed uppermost to trade liberalization and the possibilities to interfere with a national legal system do not seem to be strong, while the EU law provides for broad opportunities for close integration of the European legal system with a national legal system.

In 2003, the US, joined by co-complainants Canada and Argentina, filed a suit against the EU before the WTO, challenging the EU's de facto moratorium and its various safeguard measures. In November 2006, the WTO Dispute Settlement Body adopted the WTO panel's ruling in the case, which was largely in favour of the complainants.[123] The main point of criticism regarding EU regulation of GMOs is that the Court does not recognize the direct effect of WTO law. The position of the ECJ opposes resolutely to a possibility to invoke WTO law in order to challenge the lawfulness of the EU measures. In particular, the Court stated that 'the WTO agreements are not, in principle, among the rules in the light of which the Court is to review the legality of measures adopted by the Community institutions.'[124] The Court's approach is criticized as illogical and inconsequent because of its inconsistency with other cases where the Court has given direct effect to provisions of Community trade agreements[125]. On the other hand, the US also refuses to recognize direct effect of WTO law[126].

[122] Dillon, S. (2002), *supra note* 66.

[123] For the analysis of the WTO case and the panel ruling in detail, see Pollack, M. & Shaffer, G. (2009). WTO Dispute Settlement Meets GMOs: Who Decides? In Pollack, M. & Shaffer, G. *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*. Oxford University Press.

[124] Case C-149/96 *Portugal v Council*, [1999] ECR I-8395, paragraph 47; Case C-76/00 P *Petrotub and Republica v Council* [2003] ECR I-79, paragraph 53.

[125] Peers, S. (2001). Fundamental Rights or Political Whim? WTO Law and the ECJ. In de Burca, G. & Scott, J. (Eds.). *The EU and the WTO: Legal and Constitutional Issues*. Hart, Oxford.

[126] See, to that effect, Trachtman, J. (1999). Bananas, Direct Effect and Compliance. *European Journal of International Law,* vol. 10 No. 4: 655–678; Brand, R. (1997). Direct

Thus, there is a risk of subjecting the Court to rules of another conflicting jurisdiction that would compromise the EU legal system.

EU regulation of GMOs tries to learn from the US mistakes. For example, in the US 'StarLink' maize was approved only as an animal feed because of scientific uncertainty about its possible harm on human health. Nevertheless, the traces of this maize were soon revealed in human food chain, causing huge public scandal, product withdrawals, and losses for the producer. The EU provided for a possibility of such risks by demanding all authorized GMOs to meet the requirements for both food and feed. According to Food and Feed Regulation, 'experience has shown that authorisation should not be granted for a single use, when a product is likely to be used for food and feed purposes; therefore such products should only be authorised when fulfilling the criteria for both food and feed'.[127]

It is only where the Community has intended to implement a particular obligation assumed in the context of the WTO (*Nakajima* exception*)*, or where the Community measure refers expressly to the precise provisions of the WTO agreements (*Fediol* exception*)*, that it is for the Court to review the legality of the Community measure in question in the light of the WTO rules[128]. In some instances, the circumstances of a case before the Court do not correspond to either of these two hypotheses, for example, in Biret cases[129]. Biret, a French meat trading company, sought indemnification for alleged damages suffered as a result of the Community import ban on hormone-treated meat and meat products. Biret asked the Court to hold the Community liable for failing to implement the decision within the prescribed period. The Court of First Instance initially rejected the claim on the ground that neither WTO agreements nor rulings could create rights for private individuals. In the appeal, the Court dismissed the action on factual

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Effect of International Economic Law in the United States and the European Union. *Northwestern Journal of International Law & Business*, vol. 17, 556.

[127] Regulation 1829/2003/EC, supra *note* 98.

[128] Case 70/87 *Federation de l'Industrie de l'huilerie de la CEE (Fediol) v Commission* [1989] ECR 1781, paragraphs 19-22; Case C-69/89 *Nakajima All Precision Co Ltd v Council* [1991] ECR I-2069, paragraph 31. To that extent, see, e.g., Bossche, Van den, P., (2008). *The Law and Policy of the World Trade Organization: Text, Cases and Materials.* Cambridge University Press.

[129] Cases C-93/02 P and C-94/02 P *Biret International v Council* [2003] ECR I-10497.

grounds, but did not rule that the plaintiff's claim was unfounded. In this way, the Court left open the possibility to invoke a WTO ruling condemning the Community as a basis for claiming damages before the Court[130]. It is interesting that Advocate General in his opinion recommended the Court to recognize a claim for damages based on infringement of the WTO law, where the Community has failed to implement a binding award of the WTO dispute settlement body within the prescribed period.

Thus, EU risk regulation relates to the WTO legal system through generic characteristics of risks pertaining to biotechnologies in a global context. Both the WTO and the EU mutually influence each other. The EU regime on GMOs crosses over WTO rules on trade liberalization. Therefore, development of the EU regulation of GMOs effects on the US as the EU's main antagonist in WTO, and vice versa.[131]

3.3. Role of EU courts in risk assessment and interpretation of scientific evidence

In this section, I will examine relevant case law in order to explain how EU courts assess scientific uncertainty through interpretation of the principles of precautionary, necessity and proportionality.

In general, EU courts' case law extensively endorses 'risk-analysis theory'[132] as a primary methodological approach to health and environment risks regulation. Science plays a particularly prominent role in this approach. Generally, any activity, brought up before EU courts, requires

[130] Alemanno, A. (2004) Recent Development, Judicial Enforcement of the WTO "Hormones" Ruling Within the European Community: Toward EC Liability for the Non-Implementation of WTO Dispute Settlement Decisions? 45 *Harvard International Law Journal* 547.

[131] For detailed discussion on this issue, see Búrca, G. & Scott, J. (2001), *supra note* 113.

[132] Opinion of Advocate General Mischo in Case 192/01 *Commission v Denmark* [2003] ECR 9693, paragraph 143.

scientific justification.[133] While scientific evidence can considerably facilitate decision making, there are still many science-related questions not fully addressed by EU regulation of GMOs. Since the EU legislation is silent on some questions,[134] the jurisprudence might be a relevant source of information. Some issues have already been interpreted by EU courts, while others are still covered in uncertainty. Undoubtedly all the relevant issues are worthy of thorough examination. Nevertheless, the aim of this section is to elaborate on the way in which EU courts interpret scientific evidence and scientific uncertainty.

The precautionary principle plays a prominent role in the interpretation by EU courts of scientific uncertainty as a legitimate ground for restrictions of freedom of movement of goods. EU courts understand the precautionary principle as meaning that 'where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent'.[135] Pfizer case shows a noteworthy fact: before the establishment of EFSA, the Commission had sometimes assessed scientific uncertainty on its own. For example, the Commission had assessed risks either without consulting with the relevant expert committee[136] or without following its advice. EU courts deem it possible to adopt a preventive measure without consulting with scientists in 'exceptional situations'.[137]

Although EU courts have a broad scope of powers in interpretation of risks in EU law, the ECJ itself states that it observes whether there has been a 'manifest error or a misuse of powers or whether the Community

[133] An example where ECJ did not require scientific evidence are so-called "Snuss cases" (Case C-210/03 *Swedish Match*; Case C-434/02 *Arnold Andre, supra note* 73), where the Court found that a prohibition of tobacco for oral use in the EU was justifiable on the basis of long-term objective of a tobacco-free world since 'no other measure would have the same preventive effect in terms of the protection of health'.

[134] This issue, including the examples of possible questions, has been addressed in more detail in the methodology part of the thesis.

[135] Case C-241/01 *National Farmers' Union v Secretariat General du Gouvernement* [2002] ECR I-907; Case C-180/96 *UK v Commission* [1998] ECR I-3903; Case T 13/99 *Pfizer*, *supra note* 69, paragraph 139.

[136] Case T-70/99 *Alpharma Inc v Council* [2002] ECR II-3495.

[137] *Ibid*, paragraph 213.

institutions clearly exceeded the bounds of their discretion'.[138] In practice, EU courts primarily interpret the implications of scientific uncertainty for national measures seeking higher level of protection. In some cases, the ECJ has condemned a Member State for non-compliance with harmonization measure.[139] Though in such cases the EU courts have successfully precluded derogations of the freedoms of internal market, they did not prevent the Member States from the practice of 'supporting the moratorium on all GM products from using the safeguard clause for purely political reasons'.[140]

A Member State can adopt a prohibition or restriction only if 'the situation is likely to constitute a clear and serious risk to human health, animal health or the environment'.[141] While scientific risk assessment is the core of EU approach to the precautionary principle, the Commission and courts conduct a careful consideration of scientific uncertainties. Decision making in the field of GMOs allows for a broad input of non-scientific factors. The effect of the precautionary principle on decision making on GM products has a specific expression in safeguard clause,[142] which requires scientific uncertainty to be taken into account when assessing the national safeguard measure. With regards to the safeguard clause, paragraph 1 Article 23 of Deliberate Release Directive provides: 'Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of

[138] Pfizer, *supra note* 69, paragraph 166.

[139] See, for example, Case C-419/03 *Commission v France* [2004], where the Court held that France had infringed Community law by failing to transpose Directive 2001/18, and Case C-121/07 *Commission v France* [2008] ECR I-0000, where France were found failing to comply with the previous judgment.

[140] Dabrowska, P. (2004). Risk, Precaution and the Internal Market: Who Won the Day in the Recent Monsanto Judgement of ECJ on GM Foods, 5 *German Law Journal*, p. 151.

[141] Monsanto SAS and others, *supra note* 13.

[142] Case C-236/01 *Monsanto Agricoltura Italio SpA and Others v Presidenza del Consiglio dei Ministri and Others* [2003] ECR I-8105, paragraph 110.

that GMO as or in a product on its territory'. Article 34 of Food and Feed Regulation, entitled 'Emergency measures', contains a similar provision: 'Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, …, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation [No 178/2002].'

In *Monsanto SAS and others*, the Court has declared the distinction between the scope of application of measures adopted under Article 23 of Deliberate Release Directive and Article 34 of Food and Feed Regulation. In case where GMOs were notified as existing products and were subsequently the subject of a pending application for renewal of authorisation, a restrictive or prohibitive measure may be adopted pursuant to Article 34 of Food and Feed Regulation. On the other hand, if GMOs are new products, a Member State may have their use or sale provisionally suspended or prohibited under Article 23 of Deliberate Release Directive. [143]

A protective measure cannot be based on a purely hypothetical approach to the risk, founded on assumptions which have not yet been scientifically verified. The national courts have jurisdiction to assess the existence of such a risk, except where a decision has been adopted at Union level pursuant to Article 53 of General Food Regulation[144]. The factual and legal assessments contained in such a decision are binding on all bodies of the Member State concerned, including its courts. In this way, the assessment and management of serious and evident risk ultimately come under the responsibility of the Commission and the Council, subject to review by EU Courts. The Court is aimed to reconcile contraries of either purely science-based decision making or a highly politicised precautionary rhetoric involving emotion discourse.[145] This tactics insures that the precautionary principle is not used for justification of irrational non-legal reasons.

[143] Monsanto SAS and others, *supra note* 13, paragraphs 43-63.

[144] Article 53 of Regulation No 178/2002, *supra note* 21, concerns emergency measures which may be taken by the Commission, with the adoption of such measures by the Member States coming under Article 54 of that regulation.

[145] Emotional discourse in regard to GMOs plays, indeed, an important role. E.g., in attempt to redeem its public image and that of genetically-engineered food, Monsanto began an expensive advertising campaign in the UK and France in 1998. Both in the UK

Scientific credibility of risk evaluation and risk management in relation to protective measures has been often challenged by non-legal reasons. In *Commission v Poland*[146], the question at issue was a Polish law prohibiting marketing of GMO. This case is of particular interest because the Polish government grounded the prohibition on the ethical and religious considerations. Polish government stated that the most members of Polish Parliament who passed the contested law were guided by Roman Catholic values, which are prevalent in society and shared by the electorate, rather than by considerations related to the environment or public health, which are scientifically complex and more difficult to understand[147]. This prohibition barred from marketing the GMO varieties authorized by the EU authorities, which was in breach of Deliberate Release Directive and Directive 2002/53[148]. In this case, public morality was not invoked as a separate justification, but as an aspect of the justification relating to protection of human health and the environment, which is precisely the concern of Deliberate Release Directive [149]. According to the case law, a Member State cannot rely on the views of public opinion in order to challenge unilaterally a harmonising measure adopted by the Community institutions[150]. As the Court previously observed, a Member State may not plead difficulties of implementation that emerge at the stage when a Community measure is put into effect, such as difficulties relating to opposition on the part of certain individuals, to justify a failure to comply with obligations and time-limits laid down by Community law[151].

Ultimately, the Court declared that the general prohibition laid down in the contested national law infringes the obligations of Poland under the aforementioned Directives. Nonetheless, the Court has not explicitly stated

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and in France the campaign backfired, leading to more public protests against GMO, see Margaronis, M. (1999 December 27). As Biotech 'Frankenfoods' are Stuffed down Their Throats, Consumers Rebel. *The Nation*.

[146] Case C-165/08 *Commission v Poland* [2009] ECR I-6843.

[147] *Ibid*, paragraph 41.

[148] Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species.

[149] See, to that effect, Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251, paragraph 66.

[150] *Ibid*, paragraph 67.

[151] Case C-121/07 *Commission v France* [2008] ECR I-0000, paragraph 72.

whether a Member State could impose a trade restriction based on ethical and/or religious grounds. Nor it analysed a range of extension of public morality to environmental concerns. Thus, the question is open for 'public deliberation at a local level where, if a state or locality comes to a view that an EU law poses insurmountable ethical or religious difficulties for it, and it wishes to protect a domestic provision on this ground, it might be not incompatible with EU law'.[152] It is noteworthy that both public morality and environmental protection fall under a broad definition of public policy. Apparently, interrelation between environmental interests and political as well as ethical (moral, religious) aspects of free trade deserve a separate thorough investigation. So far, the grounds of public morality, public policy or public security might be used to maintain national provisions after the adoption of a harmonisation measure. At the same time, such situations are not expressly provided for in EU law, so it is doubtful that they might be the legal grounds for a prohibition or restriction on the cultivation of GMOs. Besides political reasons unrelated to considerations of protection of human health or the environment, some Member States tried to impede free movement of GMOs by bureaucratic procedures. In *Pioneer*[153] case, Italian Ministry of Agricultural, Food and Forestry Policies adopted national measures prohibiting cultivation of GMOs accepted for inclusion in the common catalogue and authorised as existing products pending the adoption by the regions of rules to ensure the coexistence of conventional, organic and genetically modified crops. The ECJ considered that such a measure would run counter to the system implemented by Food and Feed Regulation and Deliberate Release Directive. Authorisation of GMOs at EU level and acceptance for inclusion in the common catalogue ensure the immediate free movement of products, once the requirements of protection of health and the environment have been taken into consideration during the authorisation and acceptance procedures. Therefore, the Court ruled that the cultivation of GMOs cannot be made subject to a national authorisation procedure when

[152] Chalmers, D., Davies, G. & Monti, G. (2010). *European Union Law: Cases and Materials*. (2nd ed.). Cambridge University Press, pp. 326-327.

[153] Case C-36/11 *Pioneer Hi Bred Italia Srl v Ministero delle Politiche agricole alimentari e forestali* [2012] ECR 00000.

the use and marketing of those varieties are authorised pursuant to Regulation No 1829/2003 and those varieties have been accepted for inclusion in the common catalogue provided for in Directive 2002/53. Besides, the ECJ stated that Directive 2001/18 does not entitle a Member State to prohibit in a general manner the cultivation on its territory of GMOs pending the adoption of coexistence measures to avoid the unintended presence of GMOs in other crops.[154]

Errors or contradictions of risk management can challenge the legitimacy of European institutions. For example, an expert opinion of European Food Safety Agency sometimes contradicts to the views of WHO and European Medicines Agency. Therefore, the credibility of EU regulation of GMOs has been often questioned and heavily criticized. Authorization based on unsubstantiated or deficient risk assessment can question the legitimacy of the Commission. The GMOs authorisation has often involved complex political and economic choices capable to undermine scientific credibility of environmental policy. It is obvious that decision-making process is largely political. In case T-240/10,[155] concerning authorization of a genetically modified potato for cultivation in Europe, the question was whether the potato may confer resistance to certain antibiotics to consumers through the food chain and whether these antibiotics are actually or potentially used in human medicine. According to EFSA's opinion, it was very unlikely that the potato cultivation may confer antibiotic resistance to humans and that the concerned antibiotics were not important for human and veterinary medicine. This opinion served as a basis for the Commission's decision granting authorization to the product. The EFSA's conclusion was contradictory to the views held in this matter by the World Health Organization, the World Organization for Animal Health and the European Medicines Agency, which published a report identifying concerned antibiotics as very important. As a consequence, many Hungarian politicians, NGOs, and individuals raised objections to the effect that the authorization, regarding the objectives to guarantee a high level of

[154] *Ibid*, paragraphs 63-76.
[155] Hungary v Commission, *supra note* 24.

protection of the environment and health, could cause damage to the health of humans and animals and to the environment. Nevertheless, EFSA did not reverse its opinion. Therefore, the EFSA's credibility was questioned and heavily criticized as to the point that the authorization based on unsubstantiated or deficient risk assessment has implications for the legality of the Commission. In this regard, new available evidence challenges the credibility of previous empirical grounds for scientific decision. Ultimately, it is up to the General Court to resolve the problem and the decision on the question at issue is likely to be a stepping stone in the way of evolution of EU environmental law. Besides, this decision promises to be a challenge to the obligation to ensure a high level of protection for health and the environment. It is difficult to predict the verdict of judges issued on a case to case basis, but if we look for the cases where different scientific opinions exists, it is evident that the rulings of EU courts are not consistent on the different levels of judicial review. For example, in *Commission v CEVA* the ECJ stated that 'the Court of First Instance is none the less obligated to provide reasons which will allow the Court to exercise its judicial review. Those reasons must make it possible for the Court to review any distortion of the evidence submitted to the Court of First Instance'.[156] In this case, the Commission stressed before the CFI the differences between the opinions of the CVMP, the SCVPH, the JECFA and the IARC. These differences were in fact 'divergent and in some respects conflicting scientific information.'[157] As a result, the ECJ set aside the CFI judgment based on an opinion of 'the CVMP without explaining why the Commission was obliged to follow that opinion, and disregarded the differing opinions from other sources'.[158]

By analogy to the case law like *Phizer* and *Alpharma*, it is possible to surmise that in *Hungary v Commission* the General Court could interpret scientific uncertainty in favour of the precautionary principle and could rule out for the claimant taking into account the available scientific contradictions.

[156] Case C-198 P *Commission v CEVA Santé Animale SA* [2005] ECR I-6357, paragraph 50.
[157] *Ibid*, paragraph 53.
[158] *Ibid*.

Any restrictive activity usually requires scientific evidence. In case of a safeguard measure, new scientific evidence is required. A Member State applying stricter national measure must refer to such evidence. According to paragraph 5 Article 114 TFEU (ex Article 95 TEU), if a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

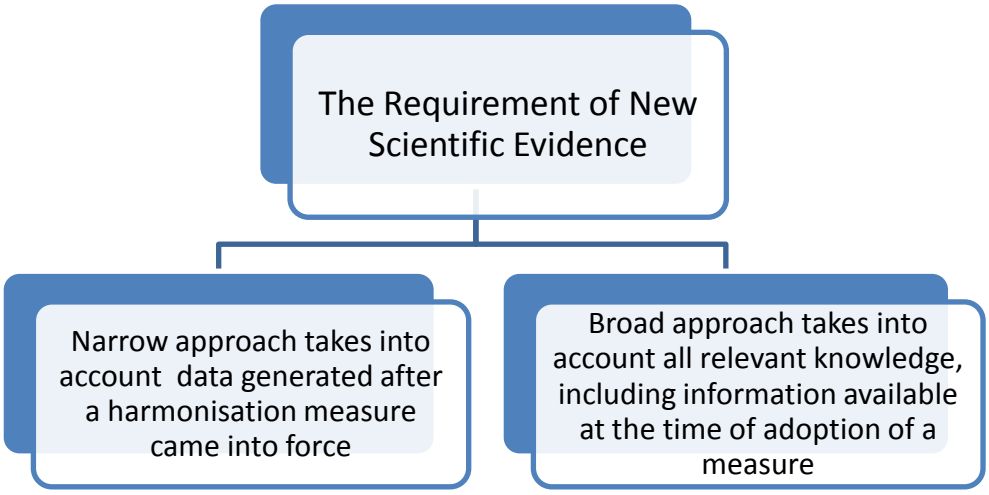
Table 6. Conditions for application of Article 114(5) TFEU.

1	New evidence must be presented.
2	The evidence must be scientific.
3	It must relate to protection of the environment or the working environment.
4	There must be a problem specific to the Member State.
5	The problem must have been arisen after the adoption of the harmonising measure.

There are two possible interpretations of new scientific evidence requirement: broad and narrow[159]. The narrow approach takes into account data generated after a harmonisation measure came into force, whereas the broad approach takes into account all relevant knowledge, including information available at the time of adoption of a measure (Table 7).

[159] Fleurke, F. (2008). Analysis. What Use forArticle 95(5) EC? *Journal of Environmental Law 20:2.*

Table 7. Interpretations of new scientific evidence requirement.



The EU courts interpret new scientific evidence requirement in the narrow sense. The courts therefore have to define whether the relevant information occurred before or after the moment of time when a harmonisation measure came into force.

In Land Oberösterreich, the ECJ rejected the scientific report dated before the harmonization measure since it 'did not provide any new information capable of calling into question the provisions'[160] of Deliberate Release Directive. In order to substantiate the national prohibition on GMOs, Austria invoked the precautionary principle before the CFI and ECJ. The ECJ rejected the application of the precautionary principle as the national measure did not comply with the requirements that the measure must be substantiated by a new scientific evidence specific to that Member State.

The ECJ did not elaborate on what the characteristics of 'new scientific evidence' are. The Court stated that 'the introduction of new national provisions must be based on new scientific evidence relating to the

[160] Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission* [2007] ECR I-7185, paragraph 63.

protection of the environment or the working environment by reason of a problem specific to that Member State arising *after* the adoption of the harmonisation measure'.[161] AG Sharpston mentioned that 'evidence' normally designates the raw material from which conclusions may be drawn[162]. She concluded that those new conclusions drawn from existing data *may* constitute new scientific evidence within the meaning of Article 95(5) EC.[163] The requirement of 'specific to the Member State' criterion is also left unresolved. The ECJ did not assess this issue because the conditions for application of Article 95(5) are cumulative. Therefore, this criterion was not assessed by the Court since Austria failed to fulfil the previous criterion of new scientific data.

Land Oberösterreich is not the first case where Austria failed to provide new scientific evidence as possibly justifiable reason for national measure. In Greenpeace,[164] Austria provided a scientific report in support of its safeguard measure on maize. The court rejected that report as not presenting new scientific evidence. Besides, Austria had also provided an opinion poll signed by one fifth of population, also rejected by the ECJ.

In *Land Oberösterreich,* Austria unsuccessfully claimed that the issue of coexistence of GMOs and natural crops is a problem specific to Austria. The court rejected this argument because this problem is general for the present public debates about GMOs rather than unique for Austria only. This issue was emphasized in Bablok,[165] where German beekeepers sued the Bavarian government after their honey was unintentionally contaminated by pollen from a MON8io GM maize.

Therefore, it is impossible to invoke higher level of protection relying on the precautionary principle if a measure is not supported by new scientific data. The ECJ considers safeguard provisions as closely related to application of the precautionary principle. The Court states that 'Article 34 of Regulation

[161] *Ibid*, paragraph 31. Besides, see to that effect Case C-3/00 *Denmark* v *Commission* [2003] ECR I-2643, paragraph 57.

[162] Opinion of Advocate General Sharpston in Cases C-439/05 P and C-454/05 P *Land Oberösterreich*, paragraph 124.

[163] *Ibid*.

[164] Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others* [2000] ECR I-1651.

[165] Case C-442/09 *Karl Heinz Bablok and Others v Freistaat Bayern* [2011].

No 1829/2003 on genetically modified food and feed requires Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data. Protective measures adopted under Article 34 of Regulation No 1829/2003 cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified. On the contrary, such protective measures, notwithstanding their temporary character and even if they are preventive in nature, may be adopted only if they are based on a risk assessment as complete as possible in the particular circumstances of an individual case, which indicate that those measures are necessary'.[166]

In conclusion, the analysis of relevant case law shows that when EU courts assess whether EU law precludes application of restrictive measure, they examine the legality of measure by the principles of precautionary and proportionality, if the causal relation between GMOs and possible risks is proved to be true. If such a causal relation is not established, courts reject a measure as not proved by facts and precluded by EU law.

The Court has interpreted the existence of a situation which is 'likely' to constitute a 'serious risk' as referring to a significant risk which clearly jeopardises human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data. Ethical or socioeconomic considerations are generally not permitted by EU courts as a justification. The precautionary principle demands risk assessment to be based on scientific evidence. The principle of precautionary designates low tolerance for any potential adverse effects of GMOs, although seeking 'zero risk' is not generally allowed by EU law as based on 'purely hypothetical approach to risk'. Besides, scholars have generally accepted the inevitability of uncertain risks in the debates on GMOs, suggesting that it is not uncertainty but rather the experts' inability

[166] Monsanto SAS and Others, *supra note* 13, paragraphs 76-77. See also to that extent *Monsanto Agricoltura Italia and Others*, supra note 142, paragraphs 106-107.

to acknowledge uncertainty that causes problems.[167] At the same time, attempts seeking to reduce identified risk to zero are highly desirable.

[167] For example, Wynne, B. (2001). Creating Public Alienation: Expert Cultures of Risk and Ethics. *Science as Culture* 10, No. 4: 445–81. (2001), states that the demands for zero risk are 'naïve' and 'grotesque'. See also Guehlstorf, N. & Hallstrom, L. (2005). The Role of Culture in Risk Regulations: A Comparative Case Study of Genetically Modified Corn in the United Stated of America and European Union. *Environmental Science & Policy* 8: 327–42.

CHAPTER FOUR

Conclusions

The present research analyses the amount and weight of the evidence that have to be adduced in EU decision making on GMOs. Risk regulation is the prevailing theoretical concept for EU environmental decision making. Scientific evidence is the core aspect of EU regulation of GMOs. EU environmental law assigns a particular role to science. Any restrictive measure on basis of health and environment protection usually requires justification substantiated by scientific evidence.

To sum up, the approach of EU courts to the environment and health protection measures banning GMOs looks as follows. A protection measure can be acknowledged as justified by evident risk to health and environment. The necessary conditions for such measure are:

- absence of less restrictive measure;
- a protection measure must prove to be necessary to reach the goal of protection of health and the environment;
- a measure must be based on scientific evidence.

In the field of environmental law, the doctrine of risk regulation is concerned with the governance of risks to health and safety, weighed up against economic interests such as the cost of regulatory measures and their potential negative impact on trade. In other words, a health protection measure can affect trade negatively, as well as trade liberalisation can affect health protection interests.

Errors or contradictions of risk management can challenge the legitimacy of European institutions. For example, an expert opinion of European Food Safety Agency sometimes contradicts to the views of WHO and European

Medicines Agency.[168] Therefore, the credibility of EU regulation of GMOs has been often questioned and heavily criticized. Authorization based on unsubstantiated or deficient risk assessment questions the legitimacy of the Commission. The GMOs authorisation has often involved complex political and economic choices capable to undermine scientific credibility of the environment and health policy.

Science is considered as the prime source of authority in EU decision-making on agricultural biotechnology. Policymakers and courts are aimed to reconcile inconsistencies between purely science-based decision-making and highly politicised rhetoric. In other words, they aim at striking a balance between scientific and political legitimacy. The precautionary principle plays a prominent role in keeping this balance. Risk to health or environment must be established on the basis of new evidence based on reliable scientific data. Case law illustrates how the courts interpret the role of scientific evidence and uncertainty in legitimising barriers to free trade.

A possibility of Member States to invoke safeguard measures in order to block GMOs in their territory depends on their ability to base higher level of protection on relevant scientific evidence.

As Advocate General Mengozzi noted, the safeguard clauses, such as Article 23 of Deliberate Release Directive and Article 34 of Food and Feed Regulation, are expressions of the precautionary principle.[169] The precautionary principle which is enshrined in Article 191(2) TFEU, means, according to settled case-law, that '[w]here there is uncertainty as to the existence or extent of risks …, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'.[170]

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[168] Hungary v Commission, *supra note* 24. EFSA's opinion granting authorization for cultivation of genetically modified potato was contradicting to the views of WHO and European Medicines Agency.

[169] Opinion of Advocate General Mengozzi in Joined cases C-58/10 to C-68/10 *Monsanto SAS and others*, paragraph 64.

[170] Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63. See also, more recently, Case C-95/01 *Greenham and Abel* [2004] ECR I-1333, paragraph 43, and Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, paragraph 39.

The scientific evidence acts as a tool substantiating alternatives for decision making, and impacts the distribution of cost and benefits of a taken decision between politicians, public officials, producers, consumers. Risks inherent in EU regulation of GMOs are distributed between different actors during the decision making process. The burden of proof is shifted between different stakeholders. On the other hand, one may note that the responsibility for authorization of GMO can also be shared, which can challenge the legitimacy of the EU.

The scientific risk assessment of GMOs is a matter of weighing evidence, a principle inherent in every empirical science. The rejection of purely hypothetical approach to the risk by EU courts has a practical meaning. Any interested party that wishes to bring science into the GMOs dispute must refer to established facts supported by scientific evidence. EU courts avoid interpretation of ethical grounds for restrictive measures, assessing the collective weight of the quantitative data (i.e., that most evidence points away from health risk), and living no room for a hypothetical qualitative conclusion (i.e., that health risk has not been absolutely proven to be reduced to 'zero').

The role of science in environmental decision making is that it allows autonomous stages of risk assessment and risk management to be linked to each other through the causal relations proved by factual evidence. At the same time, science and law view uncertainty and risks to health and the environment differently, and this issue is far from resolved[171]. EU courts avoid providing definitions of scientific evidence and uncertainty. Besides the reason of lack of natural science expertise, such *laissez-faire* policy in relation to scientific risk assessment can also be driven by considerations of risk management. There is no doubt that the Commission bears a primary responsibility for management of potential risks of goods and services for health and environment. EU courts, however, play an important corrective role, assessing and mitigating potential negative effects of business operations on health and environment. Both the system of GMOs' authorization and the judicial decision making on GMOs have implication

[171] The methodological issues of such differences are discussed in Chapter I of this thesis.

for health and the environment, quite often causing serious consequences to manufacturers and importers, including a prohibition of import and sales. It is understandable that, once the state of the art in EU regulation of GMOs has been achieved 'upon at the expense of a great amount of time, energy, and negotiation process, the Commission will display little enthusiasm for initiatives that have the potential to destabilise these hard-fought'[172] *status quo*, even if the system is not perfect, until it functions.

Contradictions regarding decision making in the field of GMOs is an unavoidable fact since scientific uncertainty potentially is a characteristic feature of all the varieties of biotechnologies. Such uncertainty is exacerbated by a possibility of decision to be based on non-objective criteria. It is still unclear, and the analysed case law remains silent on this question, how EU regulation of GMOs should respond to possible changes of scientific information that serves as empirical grounds for risk management and decision making in the field of EU policy on health and the environment.

It is apparent that the EU courts' approach to prohibitive and/or restrictive measures can employ, among others, a reasoning based on administrative feasibility and the EU policy objectives, especially with regard to such politically sensitive issue as GMOs. The Court refrains from interfering in purely scientific debates in order to maintain a subtle balance between trade and environment. It is up to an interested party to bear a burden of proof concerning legal relevance of scientific evidence and acceptability of risks. For example, an application for market placement of GMO for food use must show that food does not have adverse effects on health and environment. Regarding the nationa measurea, a Member State can adopt a prohibition or restriction only if the situation is likely to constitute a clear and serious risk to human health or the environment.

Scientific evidence operates as factual information which affects decision making rather than predetermines its outcome. Relevant facts are assessed in two different contexts: scientific and legal, subject by court review. Hence EFSA has a competence to establish scientific validity of facts by its

[172] Heyvaert, V. Ibid, p.3.

expertise, the Commission establishes legal facts by decision making process, EU courts conduct judicial review of causal relations between scientific and legal facts by application of the principles of precautionary and proportionality. In view of the case law concerning EU regulation of GMOs, EU courts tend to frame the risks pertinent to GMOs with priority to the legal context of assessment of the relevant facts without deep engagement with the content of science. Meanwhile, scientific context is instrumental in establishing causal relation between factual information and decision making. For example, when EU courts assess whether application of restrictive measure is precluded by EU law, they examine the legality of measure against the principles of precautionary and proportionality, if the causal relation between GMOs and possible risks is proved to be true. If such a causal relation is not established, courts reject a measure as not proved by facts and precluded by EU law. Nevertheless, the application to national derogations of the 'other legitimate factors' criterion suggest a possibility for decision to go beyond scientific evidence in risk assessment.

The conflict between the freedom of movement of goods and the protection of health and the environments needs to be reconciled. At present, the European institutions try to address public opposition to GMOs by proposing relevant legislative changes. The adjustments to the existing legislation would favour more national autonomy. For example, on 13 July 2010 the Commission issued a proposal to amend Directive 2001/18[173]. The proposal emphasizes the need for more flexibility on GMO cultivation. This proposal expands the available justifications for restrictive measures. Member States would carry out their own assessments to justify their decisions about cultivation of GMOs in their territories at national or regional levels. The amendment of the legislation would support the legitimacy of EU system of authorisations based on the scientific assessment of health and environmental risks. Besides, Member States would be granted freedom to address specific local issues raised by the

[173] Proposal of 13 July 2010 for a Regulation of the European Parliament And of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, retrieved from http://ec.europa.eu/food/food/biotechnology/docs/proposal_en.pdf

cultivation of GMOs. Therefore, this approach could push the boundaries acceptable for the internal market, while preserving EU authorisation system of GMOs as well as the free circulation and import of GMOs.

Ongoing policy debates suggest that progress of biotechnologies is an inevitable fact in witness of socio-economic development. New technologies can be affected by experience from previous technologies. Industrial and medical biotechnologies can be addressed by the tools that proved effective for agricultural biotechnology. For example, the agricultural biotechnology experience can secure constructive scientific discussion of nanotechnology. Therefore, the understanding of legally relevant facts established by scientific evidence provides decision makers with the tools for balancing the interests of trade and health protection.

Bibliography

Alemanno, A. (2009, January 1). The Shaping of European Risk Regulation by Community Courts. *The Jean Monnet Working Papers*, n. 18/2008.

Babbie, E. (2007). *The practice of social research*. Thomson Learning, Inc.

Bengtsson, B. & Klintman, M. (2010). Stakeholder participation in the EU governance of GMO in the food chain. In Bäckstrand, K., Khan, J., Kronsell, A. & Lovbrand, E. (Eds.). *Environmental Politics and Deliberative Democracy: Examining the Promise of New Modes of Governance*. Edward Elgar Pub: 105–122.

Bogdan, R. & Biklen, S. (1992). *Qualitative Research for Education: An Introduction to Theory and Methods* (2nd ed.). Toronto: Allyn and Bacon.

Boisson de Chazournes, L. (2009). New Technologies, the Precautionary Principle, and Public Participation. In Thérèse Murphy (Ed.) *New technologies and human rights*, Oxford: Oxford University Press.

Bossche, Van den, P., (2008). *The Law and Policy of the World Trade Organization: Text, Cases and Materials.* Cambridge University Press.

Brand, R. (1997). Direct Effect of International Economic Law in the United States and the European Union. *Northwestern Journal of International Law & Business*, vol. 17, 556.

Breyer, S. (1993). *Breaking the Vicious Circle: Towards Effective Risk Regulation.* Harvard University Press.

Brosnan, D. (Fall 2007). Science, Law, and the Environment: the Making of a Modern Discipline. *Environmental Law* (00462276), Vol. 37 Issue 4, 987-1006.

Búrca, G. & Scott, J., (2001). The Impact of the WTO on EU Decision-making. In Búrca, G. & Scott, J. (Eds.). *The EU and the WTO: Legal and Constitutional Issues.* Hurt Publishing.

Cameron, J. (1999). The Precautionary Principle. In Sampson, G. and Chambers, B., (Eds.), *Trade, Environment and Millennium*. New York: UN University Press.

Chalmers, D., Davies, G. & Monti, G. (2010). *European Union Law: Cases and Materials*. (2nd ed.). Cambridge University Press.

Covello, V. & Mumpower, J. (1985). Risk Analysis and Risk Management: A Historical Perspective. 5(2) *Risk Analysis* 103.

Craig, P. (2012). *EU Administrative Law* (2nd ed.). Oxford University Press.

Dabrowska, P. (2004). Risk, Precaution and the Internal Market: Who Won the Day in the Recent Monsanto Judgement of ECJ on GM Foods, 5 *German Law Journal*, p. 151.

Davison, J. (2010, February). GM plants: Science, politics and EC regulations. *Plant Science*. Vol. 178, issue 2, pp. 94-98.

Dillon, S. (2002). *International Trade and Economic Law and the European Union*. Oxford: Hart.

Dobbins, S. et al. (2001). Asking the Gatekeepers: A National Survey Of Judges On Judging Expert Evidence In A Post- Daubert World. 25 *Law & Human Behaviour*, 433.

Dobbins, S. et al. (2002). Applying Daubert: How Well Do Judges Understand Science and Scientific Method? 85 *Judicature* 244, 247.

Eriksen, E., Fossum, J. (2000). *Democracy in the European Union: Integration Through Deliberation?* (1st ed.). Routledge.

Esty, D. (2001). Bridging the Trade-Environment Divide. *Journal of Economic Perspectives*, vol. 15, no. 3: 353-377.

Etty, T., Somsen, H., (2004). Case C-236/01**:** Monsanto Agricoltura Italia SpA and Others v Presidenza Del Consiglio dei Ministeri and Others. *European Environmental Law Review.* Jan2004, Vol. 13 Issue 1, pp. 3-18.

Falkner, R., & Jaspers, N. (2012, February). Regulating Nanotechnologies: Risk, Uncertainty and the Global Governance Gap. *Global Environmental Politics*, Vol. 12 Issue 1, pp. 30-55.

Ferreti, M.P. (2008). Participatory Strategies in the Regulation of GMO Products in the EU. In Steffek, J., Kissling, C. & Nanz, P. (Eds). *Civil Society Participation in European and Global Governance: A Cure for the Democratic Deficit?* (First Ed.). Palgrave Macmillan: 166–184.

Fisher, E. (2006). Risk and Environmental Law: A Beginner's Guide. In Richardson, B. & Woods, S. (Eds.). *Environmental Law for Sustainability: A Critical Reader*. Oxford: Hart Publishing.

Fisher, E., Jones, J. & Von Schomberg, R. (2006). Implementing the Precautionary Principle: Perspectives and Prospects. In Fisher, E., Jones, J. & von Schomberg, R. (Eds.). *Implementing the Precautionary Principle.* Edward Elgar.

Fischer, F. (2009). *Democracy and expertise: reorienting policy inquiry*. Oxford University Press.

Fisher, E. (2010). Risk Regulatory Concepts and the Law. In OECD, *Risk and Regulatory Policy: Improving the Governance of Risk.*

Fleurke, F. (2008). Analysis. What Use forArticle 95(5) EC? *Journal of Environmental Law 20:2.*

Gouldner, A. (1976). *The Dialectic of Ideology and Technology*. London: The Macmillan Press LTD.

Gruszchynski, L. (2010). *Regulating Health and Environmental Risks under WTO Law. A Critical Analysis of the SPS Agreement.* Oxford: Oxford University Press.

Guehlstorf, N. & Hallstrom, L. (2005). The Role of Culture in Risk Regulations: A Comparative Case Study of Genetically Modified Corn in the United Stated of America and European Union. *Environmental Science & Policy* 8: 327–42.

Habermas, J. (1970). *Toward a Rational Society*, J. J. Shapiro (trans.). Boston: Beacon.

Hagendijk, R. & Irwin, A. (2006). Public Deliberation and Governance: Engaging with Science and Technology in Contemporary Europe. *Minerva, 44*(2), 167–184.

Heyvaert, V. (2001). Balancing Trade and Environment in the European Union: Proportionality Substituted? 13 *Journal of Environmental Law* 3.

Hutch, A. (2002). *Doing qualitative research in education settings*. New York: State University of New York Press.

Jasanoff, S. (1986). *Risk Management and political culture*. New York.

Jasanoff, S. (1990). *The fifth branch: Science advisers as policy makers*. Cambridge, MA: Harvard University Press.

Jasanoff, S. (2005). *Designs on Nature: Science and Democracy in Europe and the United States*. Princeton University Press.

Krämer, L. (2000). *EC Environmental Law* (4th ed.). London: Sweet and Maxwell.

Laffineur, J. (2010). First ECJ Ruling on REACH: Choosing Registration over Exemption - Case C-558/07, R v Secretary of States for the Environment, Food and Rural Affairs. *Journal of Environmental Law* Vol. 22, 135-146.

Lee, M. (2008). EU Regulation of GMOs. Law and Decision Making for a New Technology. Edward Elgar Publishing.

Leeuw, D. (2005). To Mix or Not to Mix Data Collection Modes in Surveys. *Journal of Official Statistics,* Vol. 21, No. 2.

Levidow, L., Carr, S. & Wield, D. (2000). Genetically modified crops in the European Union: Regulatory conflicts as precautionary opportunities. *Journal of Risk Research* 3, no. 3: 189–208.

Levidow, L., Carr, S. & Wield, D. (2005). European Union regulation of agri-biotechnology: Precautionary links between science, expertise and policy. *Science and Public Policy* 32, no. 4: 261–76.

Lynch, D. & Vogel, D. (2001). *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory*

Politics. Council on Foreign Relations Press, April 5, 2001, retrieved from the Council on Foreign Relations website: http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688.

Maasen, S., & Weingart, P. (Eds.) (2005). *Democratization of Expertise?* (Vol. 24). Berlin/Heidelberg: Springer-Verlag.

Margaronis, M. (1999 December 27). As Biotech 'Frankenfoods' are Stuffed down Their Throats, Consumers Rebel. *The Nation*.

Margolis, H. (1996). *Dealing With Risk*: *Why the Public and the Experts Disagree on Environmental Issues.* University of Chicago Press.

Notaro, N. (2000). The New Generation Case Law on Trade and Environment, 25 *European Law Review* 5.

Nowotny, H., Scott, P., & Gibbons, M. (2001). *Re-thinking science: Knowledge and the public in an age of uncertainty*. Cambridge, UK: Polity Press in association with Blackwell Publishers.

Ortwin, R. (1992). Concepts of Risk: A Classification. In Krimsky, S. & Golding, D. (Eds.) *Social Theories of Risk*. Praeger, Westport, Conn.

Peers, S. (2001). Fundamental Rights or Political Whim? WTO Law and the ECJ. In de Burca, G. & Scott, J. (Eds.). *The EU and the WTO: Legal and Constitutional Issues*. Hart, Oxford.

Pollack, M. & Shaffer, G. (2009). WTO Dispute Settlement Meets GMOs: Who Decides? In Pollack, M. & Shaffer, G. *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods*. Oxford University Press.

Porter, M. (1991). America's Green Strategy. *Scientific American*, 264, 4, 168.

Porter, M. & van der Linde, C. (1995). Green and Competitive: Ending the Stalemate. *Harvard Business Review*, 9, 4, 120–34.

Rajan, R. & Letourneau, D. (2012). What Risk Assessments of Genetically Modified Organisms Can Learn from Institutional Analyses of Public Health Risks. *Journal of Biomedicine & Biotechnology*, pp. 1-8.

Ravetz, J.R. (2001). Models of risk: An exploration. In Hisschemöller, M., Hoppe, R., Dunn, W.N. & Ravetz, J.R. (Eds). *Knowledge, power and participation in environmental policy analysis*. London: Transaction Books.

Rodgers, W. (1987). Guerilla decisionmaking: Judicial review of risk assessments. *Journal of Hazardous Materials*, 15 205-217.

Schomberg, R. (2006). The precautionary principle and its normative challenges. In Fisher, E., Jones, J. & von Schomberg, R. (Eds.). *Implementing the Precautionary Principle: Perspectives and Prospects*. Cheltenham, UK and Northampton, MA, US: Edward Elgar, chapter 2, pp. 19-42.

Scott, J. (2007). *The WTO Agreement on Sanitary and Phytosanitary Standards*. New York: Oxford University Press.

Simon, H. (1957). A Behavioral Model of Rational Choice. In *Models of Man, Social and Rational: Mathematical Essays on Rational Human Behavior in a Social Setting*. New York: Wiley.

Simon, H. (1991). Bounded Rationality and Organizational Learning. *Organization Science* 2 (1): 125–134.

Snyder, F. (1993). The Effectiveness of European Community Law: Institutions, Processes, Tools and Techniques, 56 *Modern Law Review*, p. 19-54.

Sunstein, C. (2001 June). The Laws of Fear. *U Chicago Law & Economics, Olin Working Paper* No. 128.

Sunstein, C. (2004 October). Cost-Benefit Analysis and the Environment. *U Chicago Law & Economics*, *Olin Working Paper* No. 227.

Sunstein, C. (2005). Laws of Fear: Beyond the Precautionary Principle. Cambridge: Cambridge University Press.

Sunstein, C. & Vermeule, A. (2005 March). Is Capital Punishment Morally Required? The Relevance of Life-Life Tradeoffs. Working Paper No. 05-06, AEI—Brookings Joint Center for Regulatory Studies.

Tait, J. (2001). More faust than Frankenstein: The European debate about the precautionary principle and risk regulation for genetically modified crops. *Journal of Risk Research* 4, no. 2: 175–89.

Tanasescu, I. (2009). *The European Commission and interest groups: towards a deliberative interpretation of stakeholder involvement in EU policy-making*. Asp/Vubpress/Upa.

Tanford, J.A. (1990). The Limits of a Scientific Jurisprudence: The Supreme Court and Psychology. 66 *Indiana Law Jornal* 137, 144-145.

Tiberghien, Y. (2009). Competitive Governance and the Quest for Legitimacy in the EU: the Battle over the Regulation of GMOs since the mid-1990s. *Journal of European Integration*, *31*(3), 389–407.

Thorén, H. & Persson, J. (2011). Philosophy of Interdisciplinarity: Problem-Feeding, Conceptual Drift, and Methodological Migration. In *3rd Biennial Conference of the Society for Philosophy of Science in Practice* (June 22-24, 2011; Exeter, UK), retrieved from http://philsci-archive.pitt.edu.ludwig.lub.lu.se/8670/1/Thoren_Persson_Philosophy_of_interdisciplinarity_draft_June2011.pdf?

Trachtman, J. (1999). Bananas, Direct Effect and Compliance. *European Journal of International Law*, vol. 10 No. 4: 655–678.

Van Asselt, M. (2000). *Perspectives in Uncertainty and Risk. PRIMA Approach to Decision Support*.

Wahlberg, L. (2010). *Legal Questions and Scientific Answers: Ontological Differences and Epistemic Gaps in the Assessment of Causal Relations*. Diss. Lund University.

Weeramantry, C.G. (1997). *Justice without Frontiers: Protecting Human Rights in the Age of Technology* (Vol. 1). Kluwer Law International, The Hague.

Winham, G. (2003). International regime conflict in trade and environment: the Biosafety Protocol and the WTO. In *World Trade Review* 2: 2, 131–155.

Winickoff, D., Bushey, D. (2010). Science and Power in Global Food Regulation: The Rise of the Codex Alimentarius. *Science Technology Human Values* 2010 35: 356.

Wynne, B. (1995). Technology assessment and reflexive social learning: Observations from the risk field. In Rip, A., Misa, T.J. & Schot, J. (Eds.). *Managing technology in society: The approach of constructive technology assessment*. London: Pinter Publishers.

Wynne, B. (2001). Creating Public Alienation: Expert Cultures of Risk and Ethics. *Science as Culture* 10, No. 4: 445–81. (2001).

Wynne B. et al. (2001). Public Attitudes towards Agricultural Biotechnologies in Europe (PABE). Final report of project with five partners country teams (Spain, Italy, Germany, France, the UK), funded by DG-Research, Brussels. Centre for the Study of Environmental Change (CSEC), Lancaster University. Retrieved from: http://www.lancs.ac.uk/fss/projects/ieppp/pabe/docs/pabe_finalreport.doc

Zika, E. et al. (2007). *Consequences, Opportunities and Challenges of Modern Biotechnology for Europe*. JRC, European Commission.

Table of Cases

Case C-180/96 *UK v Commission* [1998] ECR I-3903.

Case C-389/96 *Aher-Waggon* [1998] ECR I-4473.

Case C-120/97 *Upjohn Ltd* [1999] ECR I-223.

Case C-379/98 *PreussenElektra* [2001] ECR I-2099.

Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-5681.

Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others* [2000] ECR I-1651.

Case T-13/99 *Pfizer Animal Health v. Council*, [2002] ECR II-3305.

Case T-70/99 *Alpharma Inc v Council* [2002] ECR II-3495.

Case C-3/00 *Denmark* v *Commission* [2003] ECR I-2643.

Case C-76/00 *P Petrotub and Republica v Council* [2003] ECR I-79.

Case C-122/00 *Schmidberger* [2003] ECR I-5659.

Case C-95/01 *Greenham and Abel* [2004] ECR I-1333.

Case C-236/01 *Monsanto Agricoltura Italio SpA and Others v Presidenza del Consiglio dei Ministri and Others* [2003] ECR I-8105.

C-241/01 National *Farmers' Union v Secretariat General du Gouvernement* [2002] ECR I-907.

Case 192/01 *Commission v Denmark* [2003] ECR I-9693.

Case C-93/02 P *Biret International v Council* [2003] ECR I-10497.

Case C-94/02 P *Biret v Council* [2003] ECR I-10565.

Case T-392/02 *Solvay Pharmaceuticals BV v Council* [2003] ECR II-4555.
Case C-434/02 *Arnold Andre* [2004] ECR I-11825.

Case C-198/03 P *Commission v CEVA Santé Animale SA* [2005] ECR I-6357.

Case C-210/03 *Swedish Match* [2004] ECR I-11893.

Case C-419/03 *Commission v France* [2004].

Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679.

Joint cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission* [2007] ECR I-7185.

Case C-121/07 *Commission v France* [2008] ECR I-0000.

Case C-558/07 *The Queen, on the application of: S.P.C.M. SA and Others v Secretary of State for the Environment, Food and Rural Affairs* [2009] ECR I-5783.

Case C-165/08 *Commission v Poland* [2009] ECR I-6843.

Case C-442/09 *Karl Heinz Bablok and Others v Freistaat Bayern* [2011].

Joined cases C-58/10 to C-68/10 *Monsanto SAS and others*.

Case T-240/10, action brought to General Court on 27 May 2010 — Hungary v Commission.

Case C-36/11 *Pioneer Hi Bred Italia Srl v Ministero delle Politiche agricole alimentari e forestali* [2012] ECR 00000.

Opinion of Advocate General Mengozzi in Joined cases C-58/10 to C-68/10 *Monsanto SAS and others*.

Opinion of Advocate General Mischo in Case 192/01 *Commission v Denmark* [2003] ECR 9693.

Opinion of Advocate General Sharpston in Cases C-439/05 P and C-454/05 P *Land Oberösterreich and Republic of Austria v Commission* [2007] ECR I-7185.

List of Legislation

Authority and Laying Down Procedures in Matters of Food Safety [2002] *Official Journal L* 31/1.

Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, *Official Journal L 183, 29/06/1989 P. 0001 – 0008.*

Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), *OJ L 196, 26.7.1990, p. 1–7.*

Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species, *OJ L 193, 20.7.2002, p. 1–11.*

Commission Decision 2004/657/EC authorising the placing on the market of sweetcorn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council.

Commission Decision 2010/419/EU renewing the authorisation for continued marketing of products containing, consisting of, or produced from genetically modified maize Bt11 (SYN-BTØ11-1), authorising foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and repealing Decision 2004/657/EC. OJ L 197/11.

Consolidated Version of the Treaty Establishing the European Community, 2006 OJ C 321 E/37.

Consolidated Version of the Treaty on the Functioning of the European Union, 2008 OJ C 115/47.

Consolidated Version of the Treaty on European Union, 2010 OJ C 83/01.

Directive 1990/220 on the Deliberate Release in to the Environment of Genetically Modified Organisms [1990] OJ L 117/15.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Repealing Council Directive 90/220/EEC [2001] OJ L 106/1.

General Agreement on Tariffs and Trade (GATT), retrieved from http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. *Official Journal L 043, 14/02/1997 P. 0001 – 0006.*

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. *OJ L 31, 1.2.2002.*

Regulation No 1829/2003 on genetically modified food and feed [2003] OJ L 268/1.

Regulation 1830/2003 concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed

products Produced from Genetically Modified Organisms and amending Directive 2001/18/EC [2003] OJ L 268/24.

Regulation No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

Regulation No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

UN Convention on Biological Diversity, retrieved from http://www.cbd.int/convention/text/

Other documents

Codex Alimentarius Commission – Procedural manual – Twelfth Edition, 2001. Secretariat of the Joint FAO/WHO Food Standards Programme, FAO, Rome. Retrieved from http://www.fao.org/DOCREP/005/Y2200E/y2200e00.htm

Communication from the Commission of 2 February 2000 on the precautionary principle [COM(2000) 1 final]. Retrieved from http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

EFSA Panel on Genetically Modified Organisms (GMO). (2010). Guidance on the environmental risk assessment of genetically modified plants. *EFSA Journal* 8(11): 1879, retrieved from http://www.efsa.europa.eu/en/efsajournal/pub/1879.htm

EFSA's webpage on GMOs http://www.efsa.europa.eu/en/topics/topic/gmo.htm

EU glossary, available at: http://europa.eu/legislation_summaries/glossary/

EU Register of authorised GMOs, available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Eurobarometer, October 2010, retrieved from http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

European Commission: Europe 2020, available at http://ec.europa.eu/europe2020/index_en.htm

International Service for the Acquisition of Agri-biotech Applications (ISAAA) Executive Summary on Global Status of Commercialized Biotech/GM Crops: 2012, retrieved from http://www.isaaa.org/resources/publications/briefs/44/executivesummary/