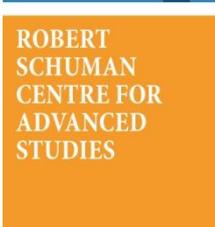




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EU Courts, Global Risks, and the Health and
Environmental Safety Revisited:
On Nuances of a Less Deferential Standard of Review

Patrycja Dąbrowska-Kłosińska

European University Institute
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EUI Working Paper **RSCAS** 2013/63

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Abstract

This paper examines judicial reasoning in risk regulation cases from the perspective of the standard of review. It takes a doctrinal-positivist approach and uses the decisions of the Court of Justice of the European Union, where it is asked to decide on powers of national (and EU) authorities to adopt measures restricting the functioning of the internal market on the grounds of human health and the safety of the environment, as a case-study. In these cases EU Courts have to face and decide on difficult questions of risk, scientific risk assessment, and uncertainty. The paper argues that in these factually, scientifically, and politically complex cases the traditionally limited scope of judicial review has moved towards a more broader evaluation by European judges of scientific and risk issues. Thus, the formally deferential standard of review in reality appears to have become a much more restrictive one, through paradoxically, the extensive review of procedural guarantees and of the plausibility of (scientific) evidence. It has the implications of the CJEU engaging in structuring decision-making processes on risk, but at the same time possibly lacking a clear vision on how to deal with the knowledge paradoxes and scientific uncertainty. This in turn provokes a broader question what should be the place for EU courts in transnational risk regulation.

Keywords

Transnational risk regulation, EU Courts, standard of review, scientific uncertainty, precautionary principle.

Introduction*

The phenomenon of globalisation, the development of the Internet and social media, and the intensity of international trade and travel have reached unprecedented levels lately reinforcing the probability of manifestation of well-known threats world-wide. Global risks have also taken on new forms and assumed ever greater significance.¹ The types of risk are innumerable, both natural and man-made, as they correspond to the countless things nowadays that have the potential to do harm, cause damage or bring about economic loss. Potential dangers range from threats to human health and the environment (e.g. climate change effects, natural disasters, the use of biotechnology in agro-food sector or ethically controversial technological developments) through spectacular financial crises and transport catastrophes to criminal offences as international terrorism, bio-terrorism, the use of weapons of mass destruction, Internet paedophilia or human trafficking to name a few.²

Some of the risks have been controlled through domestic, regional and international governance regimes including products safety, public health and environmental regulations, security laws or, especially recently, banking and financial regimes. Yet, the core difficulty faced by legislators and implementers rests with a concept of risk itself which is inherently impossible to ‘regulate’ in its entirety. First, ‘risk’ is the estimation of the likelihood of the occurrence of an undesirable state of reality (adverse effect, danger, hazard) which takes account of external causes that may be imputed to nature or human activity.³ In order to become ‘regulated’, risk requires specific provisions, both procedural and substantive, to capture its nature of actually being a measure of that potential’s likelihood and extent (specified in terms of time, intensity, or amount). Second, regulatory instruments of risk calculation/ measurement must rely either on technological achievements or expertise what implies regulation of scientific evidence, conditions of knowledge and uncertainty, scientific uncertainty and the constantly changing technical environment. Under these complex circumstances, public administration is required to ensure the well-being of their citizens through the performance of diverse approaches and strategies based on regulatory impact assessment, cost-benefit analyses, risk assessment, and risk management decisions.⁴ Moreover, the extent of regulation vary across the fields, the executive power is acknowledged a different degree of discretion to protect from risks, and boundaries of regulation are often prescribed by diverging analyses and perceptions of risks worldwide, e.g. in case of security or biotechnology laws.⁵

Adjudicating on cases underpinned by risk and potential dangers to human and animal health and the environment is an equally demanding task as issuing risk-based regulations or taking risk

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¹ See U. Beck, *World at Risk* (Cambridge, Cambridge University Press 2009) and N. Luhmann, *Risk: a Sociological Theory* (Berlin, W. de Gruyter, 1993).

² Cf. e.g. C.R. Sunstein, *Risk ad Reason: Safety, Law, and the Environment* (Cambridge, Cambridge University Press, 2002).

³ D. Garland, *Risk and Morality* (Toronto, University of Toronto Press, 2003), pp. 50-53. See also J. Steele, *Risks and Legal Theory* (Oxford, Hart Publishing, 2004).

⁴ See e.g. N. de Sadeleer, ‘The Precautionary Principle in European Community Health and Environmental Law: Sword or Shield for the Nordic Countries?’, in *Implementing the Precautionary Principle*, N. de Sadeleer (ed.) (2008), pp. 10-58.

⁵ Cf. e.g. H. Rothstein, O. Borraz, M. Huber, ‘Risk and the limits of governance: Exploring varied patterns of risk-based governance across Europe’; *Regulation & Governance*, Vol. 7(2)/2013, pp. 215-235; J. Black and R. Baldwin, ‘Really Responsive Risk-Based Regulation’, *Law and Policy*, Vol. 32(2)/2010, pp. 181-213.

management decisions. This is so because resolving disputes which require the assessment of scientific evidence and risk analysis put courts at particular risk of making inadequate decisions with consequences for the health and environmental interests. The need to deal with global risks has already become reflected in the outcomes of case-law and in judicial reasoning in different jurisdictions at both national and international governance level. These decisions have been extensively analysed in the literature.⁶ The authors have been increasingly exploring roles, behaviours and ‘thinking’ of courts under the conditions of risk, new governance, regulatory reforms and globalisation more generally.⁷

Taking into account this considerable amount of the scholarship, this paper examines judicial reasoning in risk regulation cases from the perspective of the standard of review.⁸ It takes a doctrinal-positivist approach and uses the decisions of the Court of Justice of the European Union (later ‘CJEU’) rendered in the face of some of risks to health and the environmental safety as a case-study. The standard of review applied by EU Courts in these complex cases has important effects on the Member States powers, the functioning of the internal market and the construction of the EU policies in the area of human and animal health and the protection of the environment, but also globally, because some protective measures within the EU can be claimed as incompatible with the WTO framework.⁹

There have been several trends which can be identified in the case-law of the CJEU in this field from the standard of review perspective. That is, there was an established tradition of a deferential standard of review applied by EU Courts in risk cases involving scientific complexity (although somewhat less deferential towards the Member States than to the EU bodies).¹⁰ This approach has been changing gradually over time, and especially after 2002 when the famous judgments in the Pfizer and Alpharma cases were decided.¹¹ It is argued that since those decisions EU Courts have increasingly shown willingness to involve themselves in process of weighing the merits of scientific opinions and assessing their quality and validity.¹²

⁶ See e.g. I. Cram, ‘Failing Justice Brennan’s quest? Anticipating terrorism risks and the US Supreme Court’, *Public Law* 2013, pp. 30-51; V. Paskalev, ‘Taking Reasoning Seriously: The Role of Courts in Enforcing Argumentative Rationality’, *EUI Working Paper LAW*, No. 16/2012; C. Foster, *Science and the precautionary principle in international courts and tribunals: expert evidence, burden of proof and finality* (Cambridge, Cambridge University Press, 2011); A. Alemanno, ‘The Shaping of European Risk Regulation by Community Courts’, *Jean Monnet Working Papers*, No. 18/2008; J. Corkin, ‘Science, legitimacy and the law: Regulating risk regulation judiciously in the European Community’, *European Law Review*, Vol. 33(2)/2008, pp. 359-384; J. Scott and E. Vos, ‘The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle Within the EU and the WTO’ in: C. Joerges and R. Dehousse (eds.), *Good Governance in Europe’s Integrated Market* (Oxford, Oxford University Press 2002).

⁷ See e.g. A. Vauchez, ‘The Fabric of International Jurisprudence An Interdisciplinary Encounter’, *EUI Working Paper RSCAS*, No. 51/2012; G. de Búrca, ‘The European Court of Justice and the International Legal Order after Kadi’, *Harvard International Law Journal*, Vol. 51(2)/2010, pp. 1-50; and J. Scott and S. Sturm, ‘Courts as Catalysts: Rethinking the Judicial Role in New Governance’ *Columbia Journal of European Law*, Vol. 13(3)/2007, pp. 565-594.

⁸ See J. Bohanes and N. Lockhart, ‘Standard of review in WTO law’ in *The Oxford Handbook of International Trade Law*, D. Bethlehem *et al.* (eds.) (Oxford, Oxford University Press, 2009), p. 379-381.

⁹ See Ł. Gruszczyński, ‘SPS Measures Adopted in Case of Insufficiency of Scientific Evidence: Where Do We Stand after EC-Biotech Products Case’ in: J. Chaisse and T. Balmelli (eds.), *Essays on the Future of the World Trade Organisation* (Geneva, Edis 2008), pp. 91-140.

¹⁰ See E. Vos, ‘The European Court of Justice in the face of scientific uncertainty and complexity’ in: B. de Witte, E. Muir, M. Dawson (eds.), *Judicial Activism at the European Court of Justice* (Cheltenham, Edward Elgar, 2013), pp.143 and 145ff and A. Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO* (Cameron May 2007), p. 325ff.

¹¹ T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305 and T-70/99 *Alpharma v Council* [2002] ECR II-3495. See also E. Vos, ‘The European Court of Justice’, p. 149 where the judgement in case C-269/90 *Technische Universität München v Hauptzollamt München-Mitte* [1991] ECR I-05469 is identified as a ‘turning point’ in the Court’s approach.

¹² A. Alemanno, ‘EU Risk Regulation and Science: The Role of Experts in Decision-making and Judicial Review’, in: E. Vos (ed.), *European Risk Governance – Its Science, its Inclusiveness and its Effectiveness*, Connex Report Series No. 6, Mannheim 2008, pp. 59-63.

The sign of a change in comparison to the earlier judgments has been the Court increasingly extending the scope of judicial review to embrace questions relating to the factual basis of scientific evidence, risks and methodologies for their assessment. The change has been equally visible in cases on national measures and EU decisions. The expanded *scope* of review has necessarily modified the CJEU's *standard* of review which has become less deferential generally.¹³ I have already argued elsewhere that EU Courts appear to be less willing to acknowledge a broad discretion of national authorities when they invoke protective measures based on risk and precaution, than to EU institutions when they perform risk management duties.¹⁴ However, in order to present the new tendency in the applicable standard of review this paper extracts the principles, terms and conditions that EU Courts apply without strictly differentiating between judgments reviewing Member States and EU actions. I also treat the CJEU (the Court of Justice and the General Court) as one functional institution.¹⁵ It is justified by the fact that the broadened scope of judicial review, the applicable judicial reasoning and resulting structural implications are fairly similar in both the EU and the Member States risk regulation cases, and it is the actual *outcome* of judgments which varies depending on whether it is a national regulatory measure or EU-level decision, to the more often advantage of the latter.¹⁶

Accordingly, the scope *ratione personae* of the analysis in this paper will focus mainly on judgments assessing national derogations from the internal market and will also include judgments on EU-level measures relevant for the allocation of national regulatory powers in risk regulation cases. That is, the specificity of the EU constitutional structure and procedural provisions often imply that judicial review of decisions of the EU administration involves deciding either directly or indirectly on national powers.¹⁷ The scope *ratione materiae* of the analysis includes the case-law of the CJEU regarding product safety and environmental regulations adopted to avoid transnational risks on the EU internal market (e.g. the use of food and feed, pharmaceuticals, pesticides, GMOs, effects of radioactive substances, etc.). The study is based on a non-exhaustive list of the case-law and on a rational choice of judgments where EU Courts were faced with complex political, scientific and factual questions.

The paper proceeds in the following parts. First, the theoretical frames which provide for the conceptualisation of *problematique* are presented. Second, I describe the complexities of the normative context. Third, the nuances and implications of CJEU's standard of review towards public authorities is analysed. Finally, determining the relevant standard of review assists in formulating some insights about a role played by EU courts both internally and at the global level in the reality of 'regime complexes' of transnational risk regulation and fragmentation of international law.¹⁸

¹³ See also E. Vos, 'The European Court of Justice', p.144.

¹⁴ P. Dabrowska and P. Quillacq, 'Science goes to court. Some considerations on the Precautionary Principle in the Community Jurisprudence', in: F. Francioni (ed.), *EUI Law Working Paper – The Future of Environmental Law: International and European Perspective*, No. 5/2006, pp. 59-70.

¹⁵ See e.g. exemplary judgments and opinions of Advocates General in cases C-504/04 Agrarproduktion Staebelow GmbH v. Landrat des Landkreises Bad Doberan [2006] ECR I-00679, C-58/10-68/10 Monsanto SAS and others v. Ministry of Agriculture and Fisheries [2011] ECR, nyr, and T-475/07 Dow AgroSciences Ltd. and Others v. Commission [2011] ECR, nyr.

¹⁶ But see e.g. the judgment in case T-182/06 *Netherlands v. Commission* [2007] ECR II-01983 and reversing judgment of the Court annulling the contested Commission's decision to the derogating advantage of the Member State: C-405/07P *Netherlands v. Commission* [2008] ECR I-08301.

¹⁷ For example, under the art. 114 TFEU, see the judgment in case T-69/08 *Poland v. Commission*, [2010] ECR II-05629, or when a Member States is outvoted in the qualified majority voting on risk regulatory measure and files a complaint against the EU institution, see T-257/07 *France v. Commission* [2011] ECR II-05827.

¹⁸ Cf. R.O. Keohane and D.G. Victor, 'The Regime Complex for Climate Change', *Perspectives on Politics* Vol. 9(1)/2011, pp. 7-23; K. Raustiala and D. G. Victor, 'The Regime Complex for Plant Genetic Resources', *International Organisations*, Vol. 58/2004, pp. 277-309.

Conceptual Framework: Knowledge Paradoxes, Uncertainty Intolerance, Precaution and Intricacy of Determinations

Judicial review of measures which aim at protecting human and animal health or the environment must address inevitable questions of risk, probability of various threats, and scientific expertise (evidence). While theorising the terminological context in which adjudicating takes place, two categories of risks should be distinguished, that is 'traditional' and 'uncertain' risks as identified by Marjolein van Asselt and Ellen Vos.¹⁹ In the traditional and established risks (e.g. drinking alcohol and becoming addicted) detrimental effects of a particular activity is certain, and uncertainty relates to the likelihoods of the occurrence which can be calculated by means of statistics on frequencies and impacts (when effect occur, where, by whom, and to what degree). In the second category of 'uncertain risks', uncertainty regards not only likelihoods of the occurrence, but also causal relationships, types of negative consequences, costs and benefits, scales of threats and risk perception. It is usually impossible to calculate these risks with classical risk assessment methods because the society has limited experience with them. Many of the contemporary risks can be classified as 'uncertain' or 'unknown' risks (e.g. the use of GMOs).

The necessity of public policy-making on risks, but also dealing with a nuanced relationship between risk, scientific expertise and uncertainty often leads to intolerance of uncertainty (van Asselt and Vos).²⁰ Both public administration and judicature appear to be vulnerable to this phenomenon.²¹ In addition, regulating risks brings about two types of knowledge paradoxes. First, a 'paradox of expertise'²² when scientific experts, who are 'expected' to offer ready-made policy answers, create a state of scientific uncertainty, either because there is a complete lack or insufficiency of specific knowledge, or diverging interpretations of scientific data (risk assessment) or an abundance of competing scientific standpoints. Second, there is also an 'uncertainty paradox'²³ (linked to 'uncertainty intolerance') when administrative and judicial authorities rely extensively on scientific expertise as a definite source of certainty without admittance and investigation of the inherent uncertainty of some risks and through framing of uncertainties as non-scientific factors.²⁴

In this context, the precautionary principle has become one of the guiding principles of public policy and processes of legal reasoning in risk regulation, especially in the European context.²⁵ The discretion to exercise political risk management (e.g. decision on product withdrawal) can be called 'substantive precaution'²⁶ because public authorities enjoy power to determine the level of acceptable

¹⁹ After M.B.A. van Asselt and E.Vos, 'Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox', *Journal of Risk Research* (2008) Vol. 11, Nos. 1-2, pp. 281-300.

²⁰ Ibidem, p. 282, 294-295. See also L. Levidow, S. Carr, and D. Wield, 'European Union regulation of agri-biotechnology: Precautionary links between science, expertise and policy', *Science and Public Policy* (2005), No. 32(4), pp. 261-276.

²¹ See A.-M. Janssen and M.B.A. van Asselt, 'The Precautionary Principle in Court: An Analysis of Pots-Pfizer Case Law', in M.B.A. van Asselt, E. Versluis and E. Vos (eds.), *Balancing between Trade and Risk Integrating Legal and Social Science Perspectives*, Oxon, New York, Routledge 2013, pp. 197-220.

²² U. Beck, *Risk society: towards a new modernity* (London, Sage 1992).

²³ M.B.A. van Asselt and E.Vos, 'Wrestling with uncertain risks', p. 281-284ff. See also A. Stirling, 'Opening Up the Politics of Knowledge and Power in Bioscience', *PLoS Biology*, Vol. 10(1)/2012.

²⁴ Cf. in this context a study by G.-E. Seralini proving that NK603 GM maize poses risk to health, *Food and Chemical Technology*, 2012 and the response by EFSA, *Review of the Seralini et al. (2012) publication on a 2-year rodent feeding study with glyphosate formulations and GM maize NK603 as published online on 19 September 2012 in Food and Chemical Toxicology*, in *EFSA Journal*, Vol.10(10), 2012, p.2910.

²⁵ See J. Zander, *The application of the precautionary principle in practice: comparative dimensions* (Cambridge, New York, Cambridge University Press 2010) and E. Fisher, *Risk Regulation and Administrative Constitutionalism* (Oxford, Hart Publishing 2007).

²⁶ O. Segnana, 'The Precautionary Principle: New Developments in the Case Law of the Court of First Instance', (2002) *German Law Journal*, Vol. 3 No. 10, 5.

risk for society and the possibility of adopting protective measures. And the procedural constraints imposed on this discretion, usually through judicial decisions, can be referred to as ‘formal precaution’ or the proceduralising role of the precautionary principle because powers and duties of public administrations in taking protective measures under conditions of scientific uncertainty are constrained by important procedural guarantees.²⁷ That is, public authorities are required to take into account the principle of proportionality, are obliged to perform *ex ante* scientific risk assessment, give reasons for their action (burden of proof), and perform cost-benefit analysis.²⁸

The conditions of knowledge paradoxes resulting from risk and uncertainty as well as the precautionary principle which provides a normative expression of the phenomena affect the applicable standard of review. It is understood as ‘the role of court or tribunal in reviewing decisions taken by another authority’, especially by other branches of government (legislative and executive) and a way of ‘describing the degree of deference or discretion that the court accords to legislators and regulators’.²⁹ The challenge here results mainly from a necessity to decide on the enormous intricacy of determinations. That is the factual density of regulatory situations is usually combined with the application of complex normative conditions relating to the competing interest and values (e.g. trade in goods vs. human, consumer, animal and environmental safety). Consequently, courts need to determine the discretion of public authorities and assess their political choices.³⁰ As a result, deciding on factual determinations must face the knowledge paradoxes, while formulating legal determinations often involve interpretation of open terms and discretionary provisions what altogether implies adjudicating on political determinations.³¹

Normative Context: Member States’ Powers to Derogate from the Internal Market Rules in view of Risk and Scientific Uncertainty

Member States have several legal opportunities to derogate from the EU internal market principles while invoking the reasons of the protection of human and animal health or the environment and often applying the precautionary principle. These are described below together with some examples of their application in the case law.

Article 36 TFEU

In the absence of EU harmonisation, Member States can invoke the protection of health and life of humans, animals or plants to justify the rules which constitute a restriction of trade within the internal market on the basis of Article 36 TFEU. EU Courts accept generally that Member States can legitimately differ in the degree of protection accorded to public health subject to the principle of proportionality which is carefully scrutinised by the CJEU against the factual basis of the national defence.³² That is why, ‘*it is for the Member States in the absence of harmonisation and in so far as*

²⁷ J. Scott, ‘The Precautionary Principle before the European Courts’, in *Principles of European Environmental Law*, R. Macrory (ed.) (Europe Law Publishing 2004), pp. 63-65.

²⁸ See T-13/99, *Pfizer*, par. 162 and C-41/02, *Commission v Netherlands*, par. 48-56. See also H. van den Belt, B. Gremmen, ‘Between Precautionary principle and “Sound Science”: Distributing the Burdens of Proof’, *Journal of Agricultural and Environmental Ethics*, Vol. 15(1)/2002, 103.

²⁹ J. Bohanes and N. Lockhart, ‘Standard of review in WTO law’, p. 379.

³⁰ Cf. M. Maduro, *We the Court* (Oxford, Hart publishing 1998).

³¹ See e.g. the recent judgments in cases T-257/07 *France v. Commission* [2011] ECR II-05827, its appeal, C-601/11P, judgment of the Court of 11 July 2013, nyr, and C-36/11 *Pioneer Hi Bred Italia Srl v. Ministry of Food, Agriculture and Forestry Policy* [2012] ECR, nyr.

³² See generally, P. Craig, G. de Búrca, *EU Law Text Cases Materials* (Oxford, Oxford University Press, 2011), p. 672-674 and C. Barnard, *Substantive Law of the EU: The Four Freedoms* (Oxford, Oxford University Press, 2010), pp. 70-192.

doubts subsist in the current state of scientific research, to decide at which level they intend to ensure the protection of the health and life of persons' while taking into account the requirements of the free movement of goods within the EU.³³ That discretion '*relating to the protection of public health is particularly wide where it is shown that there is still uncertainty in the current state of scientific research*' as to certain products.³⁴ But again, in order to effectively justify the derogation Member States must also comply with the principle of proportionality.³⁵

For example, in the well-known *Nutrients*-saga, the Commission brought Denmark, Holland and France to the Court of Justice for failing to fulfil their Treaty obligations under Article 34 TFEU (free movement of goods) because they introduced special conditions and/or administrative practices for marketing of foods fortified with vitamins and minerals (nutrients) in their national territories, what impeded the free trade of the products.³⁶ The dispute regarded the alleged differences in risk assessment exercised at national and EU level (scientific uncertainty) regarding the nutritional value of vitamins added to foodstuffs (and the respective amount of these vitamins) and the possible risk arising from their consumption to human health. National authorities invoked the precautionary principle to justify their measures. The Court agreed in this context that '*Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures*'³⁷. However, it did not uphold Member States actions in these cases. In the Danish case, it was done on the basis of the breach of the principle of proportionality with regard to the risk assessment process. That is, the administrative practice was found disproportionate because the systemic prohibition of fortified foodstuffs did not allow for the complex evaluation of individual products and '*the identification and assessment of a real risk to public health, which requires a detailed assessment, case-by-case, of the effects which the addition of the minerals and vitamins in question could entail*'.³⁸ In the Dutch case, the Court found the insufficiency of the scientific evidence in support of risk assessment provided by national authorities ('*the Netherlands Government has not produced any scientific studies showing that any intake over the recommended daily allowance of any of the six nutrients in question, regardless of by how much, entails a real risk for public health*') and inadequacy of the risk assessment processes itself ('*the Court finds that the Netherlands authorities have not complied with the requirements of Community law, particularly the requirement of an in-depth assessment, case by case, of the possible effects on public health of marketing foodstuffs fortified with any of the six nutrients in question*').³⁹

³³ C-333/08 *Commission v. France*, [2010] ECR I-00757, par. 85. See also judgments in cases C-67/97 *Criminal proceedings against Ditlev Bluhme* [1998] ECR I-8033 and C-154/04 *Nutri-Link* [2005] ECR I-06451.

³⁴ C-333/08 *Commission v. France*, par. 86. Cf. also judgments in cases C-319/05 *Commission v. Germany* [2007] ECR I-9811 and C-270/02 *Commission v. Italy* [2004] ECR I-01559.

³⁵ C-333/08 *Commission v. France*, par. 90.

³⁶ See judgments in the following cases: C-192/01 *Commission v. Denmark*, [2003] ECR I-9693; C-24/00 *Commission v. French Republic*, [2004] I-1277; and C-41/02 *Commission v. the Netherlands*, [2003] ECR I-11375.

³⁷ C-192/01 *Commission v. Denmark*, par. 52; and C-41/02 *Commission v. the Netherlands*, par. 54.

³⁸ C-192/01 *Commission v. Denmark*, par. 52, par. 56.

³⁹ C-41/02 *Commission v. the Netherlands*, par. 59, 67

Article 114 TFEU

On the basis of Article 114 TFEU Member States can derogate from the EU measure approximating national laws (regulation, directive).⁴⁰ In particular, according to Article 114(4) Member States may *maintain* divergent national legislation *after* the adoption of a harmonisation measure, when they deem it necessary on grounds of the major needs referred to in Article 36 TFEU, or relating to the protection of the environment or the working environment. Pursuant to Article 114(5) Member States are empowered to *introduce* divergent national provisions, but the conditions are more detailed. The justification for national legislation must be 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 and arising after the adoption of a harmonisation measure.

The CJEU explains: *‘The difference between the two situations envisaged in Article 95 [now 114] is that, in the first, the national provisions predate the harmonisation measure. They are thus known to the EU legislature, but the legislature cannot or does not seek to be guided by them for the purpose of harmonisation. It is therefore considered acceptable for the Member State to request that its own rules remain in force. (...) By contrast, in the second situation, the adoption of new national legislation is more likely to jeopardise harmonisation. The EU institutions could not, by definition, have taken account of the national text when drawing up the harmonisation measure. In that case, the requirements referred to in Article 30 EC [now 36 TFEU] are not taken into account, and only grounds relating to protection of the environment or the working environment are accepted, (...)’*⁴¹

Both provisions provide the Commission with the authority to approve or reject national provisions through the process of weighing the protection of environment and public health against the proper functioning of the internal market. It attaches high importance to the scientific evidence presented by the national authorities and its innovation (it must be a new evidence under art. 114 par. 5 when Member States wish to introduce derogating measures after harmonisation was adopted).⁴² A decision is later subject to judicial review by the CJEU. Approval of national measures is conditioned on the regulatory instruments not constituting means of arbitrary discrimination or erecting disproportionate (as interpreted by the Court) obstacles to free movement within the internal market.

In one of the cases decided under art. 114 par. 4, the Court agreed on Member States’ discretion to maintain provisions which were based on the divergent assessment of risks than that exercised at the EU level. The derogation from EU harmonisation of Danish provisions concerning the limitation of use of nitrites and nitrates as additives in foodstuffs were accepted by the Court, which annulled the Commission’s decision in this respect. With regard to the justification Court observed that *‘the applicant Member State may, in order to justify maintaining such derogating national provisions, put forward the fact that its assessment of the risk to public health is different from that made by the Community legislature in the harmonisation measure. In the light of the uncertainty inherent in assessing the public health risks posed by, inter alia, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence’*.⁴³

⁴⁰ See e.g. the following judgments: C-512/99 *Germany v. Commission* [2003] ECR I-845; joined cases T-366/03 and T-235/04 *Land Oberösterreich and Austria v. Commission* [2005] ECR II-4005; T-234/04 *Netherlands v. Commission* [2007] ECR II-04589, and the footnotes 16 and 17 supra.

⁴¹ See C-3/00 *Denmark v. Commission* [2003] ECR I-2643, par. 58. See also P. Wenneras, ‘Fog and Acid Rain Drifting from Luxembourg over Art 95(4) EC: Case 3/00 Kingdom of Denmark v. the Commission of European Communities (Danish Food Case)’, *European Environmental Law Review*, Vol. 12/2003, p. 169 and J. Zander, “‘Green Guarantee’ and the EC Treaty, Case Law Analysis”, *Journal of Environmental Law*, No. 16/2004, p. 72.

⁴² See generally I. Maletic, *The Law And Policy Of Harmonisation In Europe’s Internal Market* (Edward Elgar Publishing, Cheltenham, 2013); N. de Sadeleer, ‘Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC’, *Common Market Law Review*, Vol. 40/2003, p. 911.

⁴³ Case C-3/00 *Denmark v. Commission*, par. 67.

Safeguard clauses in secondary law

In the third place, Member States can adopt derogating measures on the basis of the safeguard clauses contained in the European regulations or directives approximating national laws.⁴⁴ That is, EU legislation on GMOs, seeds, pesticides, cosmetics, pharmaceuticals, foodstuffs, food additives or other products, usually contains safeguard clauses in order to provide for emergency measures when there is a need of withdrawal from the market of a dangerous product. The specific content of clauses vary, but their central feature rests on the premise that national authorities must have the possibility to differentiate from the EU provisions when they realise that a product concerned poses risk to safety. National measures are usually subject to the Member States' and/or the Commission's acceptance via the national committees (old comitology) structure, and can be later reviewed by the CJEU.

For example, in the *Monsanto* case Italian competent authority invoked a safeguard clause from the Novel Food Regulation with the aim of blocking genetically modified novel foodstuffs on the Italian market because of the alleged potential risks of genetically modified products.⁴⁵ Interestingly, it was the first case in which the Court invoked directly the precautionary principle regarding Member States' powers to adopt a provisional prohibition on the marketing of GMO-derived novel foods.⁴⁶ The Court held that the safeguard clause gives specific expression to the principle which must, where relevant, constitute an '*integral part of the decision-making processes leading to the adoption of any measure for the protection of human health*'.⁴⁷ As Joanne Scott rightly observes, the Court by this statement declared, albeit implicitly, that the principle can be seen as imposing positive obligations on Member States to integrate precaution into their decision-making processes while invoking safeguard clauses.⁴⁸

The precautionary principle

In this context, it is important to recollect briefly, that most of the cases where Member States adopt measures restricting the functioning of the internal market on the grounds of human health and the safety of the environment concern the application and interpretation of the precautionary principle. Although some complain that the content of the precautionary principle is not entirely settled in the EU legal order,⁴⁹ it nevertheless constitutes one of the EU law principles.⁵⁰ In view of the General Court, it '*is a general principle of European Union law (...) requiring the authorities in question, in the particular context of the exercise of the powers conferred on them by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic*

⁴⁴ See e.g. C-165/08 *Commission v. Poland* [2009] ECR I-06843.

⁴⁵ Judgment in case C-236/01 *Monsanto Agricoltura Italiana SpA and Others v. Presidenza del Consiglio dei Ministri and Others* [2003] ECR II-8105. See also C-6/99 *Association Greenpeace France and Others v. Ministère de l'Agriculture et de la Pêche and Others* [2000] ECR I-1651; C-58/10-68/10 *Monsanto SAS and others v. Ministry of Agriculture and Fisheries*; and C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679.

⁴⁶ See P. Dąbrowska, 'GM Foods, Risk, Precaution and the Internal Market: Did Both Sides Win the Day in the recent Judgment of the European Court of Justice?' for the extensive analysis of the case.

⁴⁷ C-236/01, *Monsanto*, par. 110 and 133.

⁴⁸ J. Scott, 'The Precautionary Principle before the European Courts', p. 51.

⁴⁹ See e.g. N. Salmon, 'A European Perspective on the Precautionary Principle, Food Safety and the Free Trade Imperative of the WTO', *European Law Review*, Vol. 27/2002, p.138; J.L. da Cruz Vilaça, 'The Precautionary Principle in EC Law', *European Public Law*, Vol. 10/2004p.369; and V. Heyvaert, 'Facing the consequences of the precautionary principle in European Community Law', *European Law Review* Vol. 31/2006, p.185.

⁵⁰ Art. 191 TFUE. See K. Lenaerts, "'In the Union We Trust": Trust-enhancing Principles of Community Law', *Common Market Law Review*, Vol. 41/2004, p. 317 and Majone, 'What Price Safety? The Precautionary Principle and its Policy Implications', *Journal of Common Market Studies* No. 40/2002, 89, pp. 106–07.

interests.⁵¹ In addition, '(...) where there is scientific uncertainty as to the existence or extent of risks to human health, the precautionary principle allows the institutions to take protective measures without having to wait until the reality and seriousness of those risks become fully apparent (...) or until the adverse health effects materialise.'⁵² Consequently, the scientific uncertainty regarding risk affects the scope of Member States' discretion to take protective measures.⁵³

Standard of Review: Limited Power of EU Courts or *de facto* Less Deference Accorded to Authorities?

Let us now turn to the analysis of the intensity of EU Courts' review in risk regulation cases while bearing in mind that the applicable judicial reasoning is fairly similar for both the EU and the Member States measures, but the actual outcomes of judgments are more often affirmative to EU-level decisions. Still, it appears from the reading of the case-law that it is possible and justified to frame common conditions regarding the scope and standard of applicable judicial review in these type of cases. Their common feature is the need to protect human health or the environment often in the light of inconclusive scientific evidence and on the basis of the precautionary principle.

Review of Powers Exercised by Administrative Authorities

It follows from the construction of the EU legal framework and its interpretation by EU Courts, that in cases of the human and animal health or environmental policy, it is the public institutions (national administrative authorities or the EU Commission) who 'must carry out complex assessments' and 'complex technical evaluations' of knotty scientific and factual problems. Consequently, they enjoy a 'broad discretion' in defining policy objectives and making political choices about the required level of protection and the 'appropriate means of action' necessary to fulfil these objectives (decision on the level of risk and the level of protection that is deemed appropriate).⁵⁴ When it comes to judicial review, the below logic of reasoning can be extracted from the judgments.

First, according to the Court, complexity of technical and scientific determinations and of the acceptable level of risk imply that the judicial review limited.⁵⁵ In the EU context it is observed: '*That broad discretion and those complex assessments imply a limited power of review on the part of the Courts of the European Union. That discretion and those assessments have the effect that review by the Courts as to the substance is limited to verifying whether the exercise by the institutions of their powers is vitiated by a manifest error of appraisal, whether there has been a misuse of powers, or whether the institutions have manifestly exceeded the limits of their discretion.*'⁵⁶

Second, the CJEU does not substitute institutions in their assessing of the complexity of facts. It is explained that *in order to establish that that institution committed a manifest error in assessing complex facts (...), the evidence adduced by the applicant must be sufficient to make the factual*

⁵¹ See e.g. joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others v Commission* [2002] ECR II-4945, par.183 and 184; and T-392/02 *Solvay Pharmaceuticals v Council* [2003] ECR II-4555, par. 121.

⁵² T-257/07 *France v. Commission*, par. 66-68; C-236/01 *Monsanto Agricoltura Italiana*, par. 111; C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, par. 39.

⁵³ C-41/02 *Commission v. Netherlands* [2004] ECR I-11375, par. 51.

⁵⁴ C-333/08 *Commission v. France*, par. 85-86; C-192/01 *Commission v. Denmark*, par. 42-43. See also T-257/07, *France v. Commission*, par. 84 and C-405/07 P *Netherlands v. Commission*, par. 54.

⁵⁵ Cf. C-333/08 *Commission v. France*, par. 87; C-192/01 *Commission v. Denmark*, par. 46 for the national context. See also joined cases C-211/03, C-299/03, C-316-318/03, *HLH Warenvertriebs GmbH and Orthica BV v. Germany* [2005] ECR I-05141, par. 74-79 for some analogies between the EU and national judicial review.

⁵⁶ T-257/07, *France v. Commission*, par. 85. See also e.g. C-236/01 *Monsanto*, par. 135.

assessments used in the act implausible.(...) Subject to that review of plausibility, it is not the Court's role to substitute its assessment of complex facts for that made by the institution which adopted the decision(...).⁵⁷

Third, the CJEU exercises the review of plausibility of evidence and emphasises that the above limits do not affect its duty to *'establish whether the evidence relied on is factually accurate, reliable and consistent but also whether that evidence contains all the information which must be taken into account in order to assess a complex situation and whether it is capable of substantiating the conclusions drawn from it'*.⁵⁸

In addition, it is of *'fundamental importance'* that the EU Courts also examine *"the observance of guarantees conferred by the European Union legal order in administrative procedures"* and *'The Court of Justice has had occasion to specify that those guarantees include, in particular for the competent institution, the obligations to examine carefully and impartially all the relevant elements of the individual case and to give an adequate statement of the reasons for its decision'*.⁵⁹ What is more, *"a scientific risk assessment carried out as thoroughly as possible (...) is an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures."*⁶⁰

The cited passages tell us an interesting story about the steps and content of the Court's reasoning. Formally, in cases where authorities enjoy broad discretion (powers) with regard to the realisation of a given policy and must make complex assessments, EU Courts pursue a limited review of the exercise of these powers. It is limited to the verification by the judicature if the exercise of powers was not affected by a manifest error of assessment (appraisal), if there was no misuse of powers and/ or if the institutional discretion was not manifestly exceeded (i).⁶¹ The establishment of manifest error in assessment of complex facts in a given case means that the Court does not substitute its assessment for the institutional assessment of complex facts, either technical or scientific facts, but it does review the plausibility of factual evidence submitted regarding the factual assessments (ii). The plausibility review of evidence is pursued in view of assessing whether it substantiates conclusions drawn from it, whether it *'contains all the information which must be taken into account in order to assess a complex situation'* and whether it is *'factually accurate, reliable and consistent'*.⁶² In consequence, the formally limited scope of judicial review does not preclude, and moreover, it requires, a *de facto* substantive, and detailed evaluation of the submitted evidence (*'their duty to establish'*). Next, the EU Courts ensure and review the observance of procedural guarantees by public authorities (iii) in view of their claimed wide discretion in risk regulation cases, where they exercise risk management and apply the precautionary principle.⁶³ The guarantees include the obligation to examine *'carefully and impartially'* of each individual case, to perform *ex ante* scientific risk assessment, give reasons for their action (burden of proof), and perform cost-benefit analysis as well as the application of the

⁵⁷ T-257/07, *France v. Commission*, par. 86. Cf. also C-333/08 *Commission v. France*, par. 94-98.

⁵⁸ C-405/07 P *Netherlands v. Commission*, par. 55. Cf. T-257/07, *France v. Commission*, for the judicial discussion on national versus EU-level scientific evidence.

⁵⁹ C-405/07 P *Netherlands v. Commission*, par. 56-57; see also C-192/01 *Commission v. Denmark*, par. 56.

⁶⁰ C-236/01 *Monsanto*, par. 107; and T-257/07, *France v. Commission*, par. 89. Cf. also C-333/08 *Commission v. France*, par. 88-90 for the national context.

⁶¹ See e.g. the conclusion of the judgement in case T-257/07, *France v. Commission*, par. 265.

⁶² C-405/07 P *Netherlands v. Commission*, par. 55; T-257/07, *France v. Commission*, par. 87. See also C-41/02 *Commission v. the Netherlands*, par. 59.

⁶³ Cf. T-257/07, *France v. Commission*, par. 89.

principle of proportionality.⁶⁴ Finally, the review of the exercise of national discretion inevitably includes the evaluation that the measures do not constitute means of arbitrary discrimination (iv).

To sum up, the EU Courts apply a logic of reasoning which aims to combine formally a broad scope of the institutional discretion with a limited scope of judicial review of administrative powers. Interestingly, however, it appears that this same logic leads to the extension of the applicable scope of review and the resulting less deferential review as originally intended. The *de facto* more restrictive approach to the standard of review is based on two tools: review of procedural guarantees and review of plausibility of evidence submitted. Moreover, the EU Courts combine the two tools (review of procedural guarantees and review of plausibility of evidence) by declaring that scientific risk assessment, which is usually a main content of evidence, is a crucial procedural guarantee and by acknowledging the proceduralising role of the precautionary principle.⁶⁵

Review of Procedural Guarantees

It is now necessary to turn to the content of the procedural guarantees and their requirements as formulated by the CJEU because they constitute a yardstick against which the judicial review is carried on. Within this framework, the conditions for scientific risk assessment, scientific evidence, and the application of the precautionary principle which is directly linked to scientific uncertainty are of paramount significance.

The approach to risk and scientific risk assessment

CJEU defines that ‘*A scientific risk assessment is a scientific process which is commonly accepted as consisting, in so far as possible, in the identification and characterisation of a hazard, the assessment of exposure to the hazard and the characterisation of the risk. In such a situation, ‘risk’ thus constitutes the degree of probability that the acceptance of certain measures or practices will adversely affect the interests safeguarded by the legal order. ‘Hazard’ is commonly used in a broader sense and describes any product or procedure capable of having an adverse effect on human health.*’⁶⁶ It is thus clear that the Court differentiates between a process of risk assessment, for which certain procedural conditions are envisaged in the case-law, and a notion of risk, which is characterised in descriptive terms with references to some substantive criteria to be fulfilled.

The analysis of the relevant judgments reveal the following aspects outlining the approach of EU Courts to risk, risk assessment process and scientific uncertainty in cases where measures to protect public health or the environment are taken.

a) EU Courts approach to risk:

1. there is a demonstration of the existence of ‘real’ or ‘specific’ risk for public health or the environment or a ‘genuine threat’ to public health, and consequently, the identification of the potentially adverse effects arising from a phenomenon;⁶⁷
2. risk assessment and preventive measures ‘*cannot properly be based on a purely hypothetical approach to the risk*’ nor ‘*founded on mere conjecture which has not been scientifically verified*’;⁶⁸

⁶⁴ See C-333/08 *Commission v. France*, par. 90-91; C-41/02, *Commission v. Netherlands*, 48-56. Cf. also N. de Sadeleer, ‘The Precautionary Principle in European Community Health and Environmental Law’, pp. 36-41.

⁶⁵ See also J. Scott, ‘The Precautionary Principle before the European Courts’ and J. Scott and S. Sturm, ‘Courts as Catalysts’.

⁶⁶ C-41/02 *Commission v. the Netherlands*, par. 47. See also T-475/07, *Dow Agrosciences Ltd.*, par. 146-147.

⁶⁷ C-41/02 *Commission v. the Netherlands*; C-236/01 *Monsanto*, par. 109; and C-333/08 *Commission v. France*, par. 87.

3. the reality and the extend of risk need not to be ‘fully demonstrated’ or ‘fully apparent’, but its existence is backed up by the scientific data available when the measure is taken ‘since zero risk does not exist in practice’.⁶⁹

b) Risk assessment process:

According to the CJEU, the risk assessment process should also fulfil several conditions.

1. the object of risk assessment ‘is to appraise the degree of probability of harmful effects on human health (...) and the seriousness of those potential effects’;⁷⁰
2. a risk assessment process should be carried out ‘as thoroughly as possible’ and ‘as complete as possible in the particular circumstances of an individual case’ on the basis of scientific evidence.⁷¹

c) Risk, scientific uncertainty and the precautionary principle:

The Court explains ‘Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures’.⁷²

The above citations explain that the Court differentiates between two ‘extremes’ on a risk continuum: ‘real risk’, the likelihood of which justifies protection (subject to the proportionality test), and ‘hypothetical’ or ‘zero’ risk, that in fact does not exist in practice. The scientific uncertainty lives somewhere in between the two extremes, especially when risk assessment process is not able to provide a definite conclusion because the evidence is insufficient, inconclusive or incomplete. The result, or rather difficulty, is that in such situation the precautionary principle can or even must be applied, but the application of precaution nevertheless requires that the ‘likelihood of real harm persists’.⁷³

Both requirements for the scientifically backed real risk and for the risk assessment process mean a high standard for the burden of proof and scientific evidence for the relevant EU authorities/ Member States. The Court explains that ‘risk’ corresponds to the degree of probability which seems to refer to quantifiable numbers (statistical probability; while the term of plausibility is reserved to the evaluation of evidence). It implies a rather restrictive judicial review with a great reliance on science as a source of all-answers knowledge in risk regulation.

It follows from the reading of the case-law and analysing the CJEU’s approach to risk, that there is some kind of reluctance of the EU Courts to recognise fully the possibility of scientific uncertainty regarding the existence or extent of risk. This conclusion is reinforced by the requirement of the persistence of the ‘likelihood of real harm’ for the application of precaution. It can even be called a certain degree of inconsistency of the Court’s reasoning. Is the Court equating scientific uncertainty with the quantifiable likelihood of real risk or real harm? Is it the Court constructing a judicial

(Contd.) _____

⁶⁸ See C-236/01 *Monsanto*, par. 105–106; C-192/01 *Danish nutrients*, par. 49; C-41/02 *Dutch nutrients*, par. 52; C-333/08 *Commission v. France*, par. 91–96. See also T-229/04 *Sweden v. Commission* [2007] ECR II-2437, par. 161.

⁶⁹ See T-257/07 *France v. Commission*, par. 76. See also J. Scott and E. Vos, ‘The Juridification of Uncertainty’, pp. 264–65.

⁷⁰ C-41/02 *Commission v. the Netherlands*, par. 48–49; C-192/01 *Commission v. Denmark*, par. 47–48; C-24/00 *Commission v. France*, par. 54–55. See also C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute*, [2010] ECR I-13533, par. 75–76.

⁷¹ T-257/07 *France v. Commission*, par. 89 and C-236/01 *Monsanto*, par. 107.

⁷² See e.g. C-192/01 *Commission v. Denmark*, par. 52–53

⁷³ See T-257/07, *France v. Commission*, par. 75.

understanding of scientific uncertainty and risk or is the Court in fact intolerant to uncertainty? Janssen and van Asselt argue in this context that EU Courts lack ‘a clear vision of how to rule on uncertainty and precaution’.⁷⁴ It is too early to provide definite answers to these questions, but it would be desirable if the CJEU addressed the relation of risk, precaution, scientific evidence and uncertainty more uniformly in its rulings to clarify its position.

It is now appropriate to see what requirements the EU Courts foresee for the scientific evidence.

Scientific evidence

According to the CJEU, the assessment of scientific issues and risk assessment should be ‘*entrusted by the institution to scientific experts*’ who are able to give their opinion in an ‘*independent, objective and transparent manner*’ and scientific advice must be ‘*founded on the principles of excellence, transparency and independence*’.⁷⁵ If scientific opinion is procedurally vitiated (e.g. not provided in an independent manner), their (un)lawfulness will also affect the subsequent decision of the authorities.⁷⁶

Further, the scientific evidence that supports protective measures needs to reflect the current state of art and be of the highest available quality at the time of preventive measures. It means that it contains the most recent available information and ‘*the results of international scientific research*’.⁷⁷ To this end, and to establish the state of scientific knowledge, CJEU often refers extensively to the opinions of EU agencies, e.g. European Food Safety Authority, but also to standards external to the EU legal system, that is manuals, guidelines or opinions of international standards bodies and international organizations, for example, UN bodies as FAO, WHO or Codex Alimentarius Commission and OECD, and even U.S. agencies.⁷⁸

In addition, the scientific evidence need not to be conclusive regarding ‘*the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality*’ and the results of conducted studies can be imprecise, incomplete or insufficient.⁷⁹ So, the CJEU accepts that it is impossible to carry out a full scientific risk assessment when available scientific data are of an ‘*inadequate nature*’.⁸⁰ This would suggest the judicial acknowledgment of the scientific uncertainty.

At the same time, however, there is some ambiguity in the applicable logic of reasoning. While it is possible that the evidence outlines the scientific inconclusiveness (and uncertainty), regarding ‘*the reality of risk and the seriousness of the potential adverse effects were that risk become a reality*’, it is nevertheless necessary in the CJEU’s view that scientific risk assessments provides ‘*sufficiently reliable and cogent information*’ on the scientific questions raised and on the facts.⁸¹ The soundness of scientific evidence will also determine the necessity of protection for the proportionality test. So again, the role of science is framed as providing the eventual certainty, and again, the uncertainty is linked to the reality of risk or potential adverse effects. The latter suggest the inability or unwillingness of the

⁷⁴ A.-M. Janssen and M.B.A. van Asselt, ‘The Precautionary Principle in Court: An Analysis of Post-Pfizer Case Law’, in M.B.A. van Asselt, E. Versluis and E. Vos (eds.), *Balancing between Trade and Risk Integrating Legal and Social Science Perspectives*, Oxon, New York, Routledge 2013, p. 216, but cf. J. Corkin, ‘Science, legitimacy and the law’, p. 360, 374-78.

⁷⁵ See e.g. T-257/07, *France v. Commission*, par. 73 and 89.

⁷⁶ See A. Alemanno, ‘EU Risk Regulation and Science’, p. 55.

⁷⁷ C-41/02 *Commission v. the Netherlands*, par. 47.

⁷⁸ A. Alemanno, ‘EU Risk Regulation and Science’, p. 39 and 52. See also C-504/04 *Agrarproduktion Staebelow*, par. 42; C-236/01 *Monsanto*, par. 79.

⁷⁹ C-192/01 *Commission v. Denmark*, par. 52; and C-41/02 *Commission v. the Netherlands*, par. 54.

⁸⁰ E.g. C-77/09 *Gowan Comércio Internacional*, par. 75-76.

⁸¹ C-236/01 *Monsanto*, par. 112-113; T-257/07, *France v. Commission*, par. 75-77.

CJEU to establish a precise relationship between scientific evidence, uncertainty and risk following a thoughtful concepts of the complex issues in these cases.

Finally, it comes as no surprise in this context that the EU Courts relies mainly on the so-called ‘partisan’ expert evidence brought in by the parties or other sources of secondary scientific evidence. By doing so it refers to the quality of expertise that had already been employed by other bodies, including the expertise of the EU agencies, and the self-commissioning of the experts’ reports remains truly exceptional⁸² (although there are clear provisions regulating experts’ testimony in the rules of procedures).⁸³ It allows the CJEU for the reliance on their own experience while assessing the evidence and the legitimization of the EU institutionalised scientific experts (e.g. agencies).⁸⁴ In addition, it is a safe exercise because references to the already published and known scientific opinions do not pose a ‘danger’ of vesting judicial powers in an external, commissioned expert whose evidence could bring an unexpected outcome that would have to be dealt with in the judgment.⁸⁵

Scientific uncertainty and the scope of authorities’ discretion in the application of the precautionary principle

It follows from the above, that scientific uncertainty regarding the existence and extend of alleged risk affects precisely the scope of EU and Member States’ discretion to take protective measures on the basis of the precautionary principle. On the one hand, while formulating the requirements for scientific risk assessment and scientific evidence the CJEU seems to be aware of the problem of uncertainty in the complex assessments of facts and it explains: “*In a number of cases, the assessment of those factors will demonstrate that there is much uncertainty, in science and in practice, in that regard. Such uncertainty, which is inseparable from the precautionary principle, affects the scope of the Member State’s discretion and thus also the manner in which the precautionary principle is applied.*”⁸⁶ On the other hand, the reasoning of the CJEU on the relation between uncertainty and risk, as explained above, causes further confusion in this context. As a result, it can be truly problematic to determine precisely the discretion of public authorities to apply the precautionary principle. As a consequence, it gives the CJEU the possibility to conduct a more restrictive review of administrative powers, but also to decide in a rather flexible manner when to uphold a given measure or not. Several remarks outlining the difficulties should be added here.

First, the discretion in application of protective measures, in accordance with the precautionary principle as defined by the CJEU, seem to be broader, if it is impossible to carry out a full scientific risk assessment because of inadequacy or incompleteness of available scientific data.⁸⁷

Second, the evaluation of scientific evidence and drawing conclusions from this process by public authorities requires a *de facto* earlier pre-definition of the level of protection which is deemed necessary for the public health and the level of risk (critical probability threshold) which is acceptable for society in a given circumstance of an individual case. Political institutions are to ‘*determine the*

⁸² See E. Barbier de la Serre and A.-L. Sibony, ‘Expert Evidence before the EC Courts’, *Common Market Law Review*, No. 45/ 2008, pp. 948-49ff for the further explanation of the various reasons lying behind this reluctance.

⁸³ Cf. Art. 25 of the Statute, ‘The Court of Justice may at any time entrust any individual, body, authority, committee or other organisation it chooses with the task of giving an expert opinion’, Protocol (No. 3) on the Statute of the Court of Justice of the European Union, annexed to the Treaties, as amended by Regulation No. 741/2012 of 11 August 2012, OJ 2012 L 228/1 and Art. 63-75, in particular Art. 70 Expert’s report, of the Procedural Rules of the Court of Justice, OJ 2012 L 265/1.

⁸⁴ A. Alemanno, ‘EU Risk Regulation and Science’, p. 64.

⁸⁵ E. Barbier de la Serre and A.-L. Sibony, ‘Expert Evidence before the EC Courts’, pp. 958-64.

⁸⁶ C-41/02 *Dutch nutrients*, par. 51. See generally, N. de Sadeleer, ‘The Precautionary Principle in European Community Health and Environmental Law’, pp. 36-41.

⁸⁷ See e.g. C-77/09 *Gowan Comércio Internacional*, par. 75-76.

*critical probability threshold for adverse effects on public health, safety and the environment and for the seriousness of those possible effects which, in their judgement, is no longer acceptable for society and above which it is necessary, in the interests of protecting public health, safety and the environment, to take preventive measures in spite of any existing scientific uncertainty.*⁸⁸ In essence, it means making a decision if or if not the precautionary principle is to be invoked because ‘*where there is uncertainty as to the existence or extent of risks to the health of consumers, the institutions may take protective measures without having to wait until the reality and the seriousness of those risks become fully apparent*’.⁸⁹

Third, when authorities are faced with the level of risk which they found to be unacceptable for the society, in the sense of exceeding their pre-defined critical probability threshold, they are ‘*bound, by reason of the precautionary principle, to adopt provisional risk management measures necessary to ensure a high level of protection.*’⁹⁰ The CJEU also held that a safeguard clause gives specific expression to the principle which must, where relevant, constitute an ‘*integral part of the decision-making processes leading to the adoption of any measure for the protection of human health*’.⁹¹ As Scott rightly observes, the Court by this statement declared, albeit implicitly, that this principle can impose on Member States positive obligations to act in accordance with the principle in decision-making processes.⁹² What is more, Member States and EU institutions are also obliged to review the measures taken in a reasonable period in order to see if new elements change the perception of risk, or new scientific evidence justifies the application of less restrictive measures.⁹³ Then, these aspects can supposedly become a subject of the Court’s review.

Finally, the CJEU points out that ‘*a level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case*’.⁹⁴ Under the obligation to examine ‘*carefully and impartially*’ of each individual case, this statement brings back the requirements of scientific evidence, scientific risk assessment process, and other procedural guarantees which CJEU envisages for making the decisions in risk regulation cases. All these conditions will again be subject to the review performed by the EU Courts.

The Implications of the Less Deferential Review

The literal (formal) reading of the scope of judicial review as explained in the judgments of the CJEU can prompt the conclusion that EU Courts enjoy a limited power in this respect and that the applicable standard of review is narrowed down to a strict interpretation of normative conditions (legal determinations).

However, a more functional and careful reading of the case-law, especially regarding the EU Courts approach to risk, scientific risk assessment and uncertainty, reveals that this interpretation does not hold entirely true. Paradoxically, as signalled above, through proceduralisation (declaring the scientific risk assessment as a procedural guarantee, proceduralising role of the precautionary principle, elaborating of procedural conditions for decision-making in view of scientific uncertainty) and review of plausibility of evidence, the CJEU reviews indirectly (or sometimes directly) factual determinations (scientific evidence) and political choices (level of risk) of public authorities. Thus, a

⁸⁸ T-257/07 *France v. Commission*, par. 78.

⁸⁹ See e.g. C-236/01 *Monsanto*, par. 111–112; and also T-13/99 *Pfizer*, par. 139.

⁹⁰ T-257/07 *France v. Commission*, par. 81 (referring to EU institutions).

⁹¹ C-236/01 *Monsanto*, para 110 and 133 (referring to national authorities).

⁹² See J. Scott, ‘The Precautionary Principle before the European Courts’, p. 51.

⁹³ See e.g. C-504/04 *Agrarproduktion Staebelow*, par. 40.

⁹⁴ T-257/07 *France v. Commission*, par. 80.

formally limited standard of judicial review often becomes a *de facto* more restrictive one. At the same time, engaging in questions of risk, risk assessment and scientific evidence seems to have led the CJEU to the intolerance of uncertainty (a strict scientific discipline imposed on decision-making processes), an extensive reliance on partisan expert opinion and external standards. It can have positive effects of upholding the EU Courts authority internally as well as the convergence with international standards (e.g. in the WTO context), but can bring unreliability regarding the actual outcomes of the CJEU judgments. That is, it is difficult to predict firmly when it upholds and when it rejects the risk management choices of the public authorities at the EU and national level, what can have further implications for individual parties.⁹⁵ In addition, the strict scientific discipline which is eagerly followed by the Court makes the involvement of other legitimate factors in the decision-making processes on risk and the enforcement of citizen participation in these processes more difficult.⁹⁶

The less deferential standard of review in risk regulation has also other implications, both EU internally and in the transnational dimension. First, a legal and institutional framework of the EU and Member States regimes becomes affected. Second, the judicial reasoning of the CJEU has also consequences for its approach to international standards.

Structuring EU Decision-making Processes on Risk

One of the key consequences of the CJEU becoming less deferential is structuring of decision-making processes on risk. It means above all the construction of procedural guarantees (see above). Moreover, the necessity of the consultation with scientific bodies and the integration of scientific risk assessment into decision-making processes determines who participates in a decision, what should be taken into account or how regulatory decision-making is structured.

The procedural duty to undertake scientific risk assessment as defined by EU Courts additionally influences the build-up of public authorities since risk assessment must be delegated to experts,⁹⁷ while the determination of the level of risk which is deemed unacceptable for society must be entrusted in 'institutions responsible for the political choice of determining an appropriate level of protection for society'.⁹⁸ As a consequence, CJEU also defines the roles of different actors involved in risk analysis. Finally, EU Courts ensure directly and indirectly the reflexivity and revisability of EU law. It is done through the review of national measures based on Art. 114 or safeguard clauses and the CJEU insisting that competent authorities should review within the time both perception of risk and risk assessment, but also the need for measures in question.

Convergence with International Standards, but Intolerance to Uncertainty?

Furthermore, the declaration of scientific risk assessment to be a procedural guarantee reinforces the role of scientific expertise in decision-making processes. It also allows the Court to review indirectly the issues of risk and uncertainty in relation to scientific evidence, although its approach reveal a certain degree of intolerance to uncertainty.⁹⁹

⁹⁵ See a critical comment by A. Alemanno, 'Case C-77/09, *Gowan Comercio Internacional e Servicos Lda v. Ministero della Salute*, Judgment of the Court of Justice (Second Chamber) of 22 December 2010, nyr', *Common Market Law Review*, Vol. 48(4)/2011, pp. 1329-1348.

⁹⁶ Cf. e.g. M. Kritikos, 'Traditional risk analysis and releases of GMOs into the European Union: Space for non-scientific factors?', in *European Law Review*, Vol. 34, No. 3, 2009, pp. 405-432.

⁹⁷ See J. Scott, 'The Precautionary Principle Before the European Courts', p. 51.

⁹⁸ T-257/07 *France v. Commission*, par. 78.

⁹⁹ See also A.-M. Janssen and M.B.A. van Asselt, 'The Precautionary Principle in Court'.

Following a strict scientific discipline and upholding international standards by the CJEU can also be perceived as a will to ensure some convergence between the results of the research and expertise endorsed by the EU and other international organisations (e.g. WTO) and bodies.¹⁰⁰ For example, in *KYDEP* case regarding the maximum radioactive tolerances in foodstuffs the Court referred to opinions of national experts, the recommendations of the International Commission on radiological Protection and to the instructions of the U.S. Food and Drug Administration.¹⁰¹ The methodology of the Court in the *Monsanto* case on GM food can also be recalled. In that case, the Court's ruling appeared to shift emphasis from the formal reading of the legalised scientific notions toward a more teleological interpretation in order to uphold the controversial concept of substantial equivalence, which was recognised at the international level.¹⁰²

Concluding Remarks: What Place for the EU Courts in Transnational Risk Regulation?

To conclude, the analysis of the relevant CJEU case-law in the area of risk regulation reveals that there has been a tendency of the standard of review moving from a deferential to a more restrictive one. While EU Courts still formally declare exercising a 'limited' judicial review, they have *de facto* developed a less deferential standard of reviewing regulatory measures through, paradoxically, the extensive proceduralisation and review of the plausibility of evidence. It seems that in reality the standard of review as applied here offers more possibilities for the EU Courts to construct the functioning of the internal market, influence national competence, institutional and normative structures as well as play a role in the convergence of international standards through a strong reliance on scientific expertise. At the same time, it is done at the cost of the disparity between a declared and a *de facto* intensity of review and the certain intolerance of (scientific) uncertainty which both affect the degree of foreseeability of the possible outcomes of individual cases. Where does this trend place EU Courts in the complex field of transnational risk regulation?

On the one hand, EU Courts often refer to the results of international research and scientific evidence, their reasoning is science-based and highly resonates with the wording of the WTO Panel reports.¹⁰³ It amplifies the significance of international regulation for the EU system and opens the possibility of convergence of the applicable standards. It indicates not only an appreciation of international developments, but also a will to maintain consistency between the EU rules and transnational standards of review.

On the other hand, the implications of the less deferential standard of review (and the engagement in the evaluation of the intricacy of determinations) pushes the CJEU to a rather defensive position where it can become vulnerable to criticism of its lacking a clear vision of how to deal with the relationship between normative analysis, risk, scientific risk assessment, and knowledge paradoxes. In order to avoid the critical appraisal, EU Courts will soon need to take a clearer stance on the 'non-normative' aspects of decisions on risk regulation. The clarification of the approach to risk and scientific uncertainty would also help the CJEU to better perform its role as a 'catalyst actor'¹⁰⁴ and to contribute to the improvement in functioning of EU law under the conditions of globalised risks.

¹⁰⁰ See also A. Alemanno, 'EU Risk Regulation and Science', p. 39 and 45.

¹⁰¹ See C-146/91, *KYDEP v. Council and Commission* [1994] I-04199, par. 40-43, quoted in A. Alemanno, *ibid.*

¹⁰² See P. Dąbrowska, 'GM Foods, Risk, Precaution and the Internal Market'.

¹⁰³ See J. Scott, 'European Regulation of GMOs: thinking about "judicial review" in the WTO', in E. Vos and M. Everson (eds.), *Uncertain Risks Regulated* (London, Routledge Cavendish 2009), pp. 295-321.

¹⁰⁴ J. Scott and S. Sturm, 'Courts as Catalysts'.

Author contacts:

Patrycja Dąbrowska-Kłosińska

Centre for Europe

University of Warsaw

Al. Niepodległości 22

02-653 Warszawa

Poland

Email: p.dabrowska@uw.edu.pl; Patrycja.Dabrowska@eui.eu