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UNIVERSITY OF AMSTERDAM

EXPERTISE AS JUSTIFICATION
THE CONTESTED LEGITIMATION OF THE EU ‘RISK
ADMINISTRATION’

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Expertise as justification

The contested legitimation of the EU 'risk
administration'

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Abstract:

The legitimate role of scientific expertise in EU public decision-making on risk and technology has been subject to a fierce discussion over the last two decades. The main paradox identified is that despite the acknowledgement that its legitimating resources are limited amidst the politics of risk, EU decision-makers continue to invoke science as the main source of justification for regulatory decisions on risk. This paper contributes to unpacking this paradox by discussing the role of science in EU risk regulation from the perspective of administrative legitimation. It shows that key notions, such as science, risk and uncertainty, are significantly shaped within the legal-administrative discourse on the legitimate role of the EU public administration within the EU legal and political system. The paper analyses decisions of the Commission, a EU agency and the EU general court in the highly controversial field of administrative authorisation of Genetically Modified Organisms. In these decisions it traces back two competing models of administrative legitimation, the control and the deliberative model, each entailing different understandings of the role of science in administration. The paper suggests that these models should be understood as two contrast points the tension between which fosters the search for an adequate concept of administrative legitimation of the EU risk administration.

Introduction

Risk regulation in the European Union (EU) over the last two decades could be seen as a process of relentless soul-searching with regard to the normatively desirable and functionally adequate model of taking collective decisions in the face of technological progress, scientific uncertainty, and societal contestation. In the wake of the BSE crisis at the turn of the century the EU has undergone major legal and constitutional developments in this field¹ including the promotion of the precautionary principle² to a general principle of EU law applicable to all policy fields touching upon environmental, health, animal or plant health protection.³ These developments seem to reflect the recognition that while scientific expertise plays a crucial role in democratic decision-making on risk, its potential to legitimate such decision-making is limited.⁴ In the well-known *Pfizer* ruling the EU general court has expressed this idea by pronouncing that the exercise of public authority by the EU executive is rendered legitimate by way of its political responsibility as well accountability towards democratically established institutions, such as the European Parliament.

¹Ellen Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' 23 *Journal of Consumer Policy* 227.

² Now Article 191 (2) TFEU.

³ Case T-74/00 *Artegodan v Commission* ECLI:EU:T:2002:283; T-13/99 *Pfizer v Commission* ECLI:EU:T:2002:209; see also European Commission, *Communication from the Commission on the Precautionary Principle* (COM 2000/1 final).

⁴ See Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform' (2015) 21 *European Law Journal* 622.

Scientific experts on the other hand, 'although they have scientific legitimacy, have neither democratic legitimacy nor political responsibilities. Scientific legitimacy is not a sufficient basis for the exercise of public authority.'⁵ In this way the general court was careful to preserve a space for the exercise of political discretion bound by law in the face of scientific uncertainty, finding that the Commission was not bound by the scientific opinion of its expert committee when banning the use of a certain antibiotic in animal feed.⁶

So far so good. The considerable policy, legal and scholarly efforts seem to indicate a change of approach in EU risk regulation from a technocratic to inclusive and precautionary governance, and from a naïve positivist understanding of science as infallible authority to a more nuanced view of its contextualized, value-laden and uncertain nature as shown by years of social studies of science, risk and technology.⁷ The politics of EU risk regulation are now well understood. Or are they?

Those following the topic know, of course, that the EU's search for the 'right' model of risk regulation has been accompanied by an inner struggle, and many contradictions both in legal norms and regulatory practices.⁸ Perhaps the biggest paradox is that despite the widespread acknowledgement of the limitations of science as the basis for public decision-making, EU decision-makers continue to justify regulatory decisions on risk and technology almost exclusively in scientific terms.⁹ This paper helps unpacking this paradox by placing the discussion about the role of science in EU risk regulation within the institutional context of the EU public

⁵ Case T-13/99 (n 4) para. 201.

⁶ On the continuing relevance of *Pfizer* see Christopher Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation' (2014) 51 *Common Market Law Review* 425.

⁷ See Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard University Press 1990); Silvio Funtowicz and Jerome Ravetz, 'Science for the Post Normal Age' in Laura Westra and John Lemons (eds), *Perspectives on Ecological Integrity* (Springer Netherlands 1995); Brian Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111. See also European Commission, 'Taking European Knowledge Society Seriously - Report of the Expert Group on Science and Governance' (2007).

⁸ See Marjolein BA van Van Asselt and Ellen Vos, 'Wrestling with Uncertain Risks: EU Regulation of GMOs and the Uncertainty Paradox' (2008) 11 *Journal of Risk Research* 281; Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242; Mihail Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?' [2009] *European Law Review* 405.

⁹ It is undisputed here that scientific expertise is a crucial part of risk regulation. However, the uncertain nature of many late-modern technological risks necessarily changes the role of science in regulation, see *ibid* and above (n 8).

administration and EU administrative law. It is within this context that a vast number of risk decisions in the EU are being made, which in turn shapes the way in which scientific expertise is being used in these decisions.

By doing so, the paper follows the insight that controversies surrounding risk regulation are at their core controversies about the legitimacy of an unelected public administration within modern liberal democracies¹⁰ including about ideas of how law could legitimate the exercise of wide discretionary powers. This concern is particularly pertinent to the EU public administration the institutional complexity of which sets it apart from political-administrative orders both at national and international levels.¹¹ Moreover, the expansion of the EU administrative state intensifies the concern for administrative legitimation¹² in an institutional context strongly reliant on expertise yet relatively remote from national democratic processes. This paper, therefore, explores the legitimacy challenge posed by the emergence of the EU 'risk administration' – a public administration whose main task is to assess, manage and communicate risks on the basis of available, and often limited, scientific evidence. EU law plays a vital role in addressing that challenge. On the one hand, it is a mechanism of constituting, limiting and holding the EU public administration to account thereby ensuring its formal legitimation. On the other hand, EU law itself 'provides both arenas and discourses for disputing the role and nature of public administration.'¹³

This paper explores the co-production of law,¹⁴ administrative legitimation and scientific expertise in a particular field of the EU risk administration, namely in the case of EU market authorizations of genetically modified organisms (GMOs). Based on an in-depth empirical study of two particularly controversial authorization processes, it shows that that the practice of administrative implementation of EU rules on GMOs as well as of judicial review thereof is characterized by competing views on how the EU public administration ought to be legitimated in the face of

¹⁰ Elizabeth Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007); Anderson (n 7).

¹¹ See special issue AseGornitzka and Cathrine Holst (eds), *The role of expert knowledge in EU executive institutions*, (2016) 1 Politics and Governance.

¹² We use the term *legitimation* instead of *legitimacy* to distance ourselves from a sociological understanding of legitimacy as actual social acceptance of the exercise of public authority. Legitimation instead refers to mechanisms of legitimation, which justify the exercise of public authority leading to the assumption that it is acceptable.

¹³ See Fisher (n 11) 23.

¹⁴ See Introduction to this volume.

scientific uncertainty and contestation, which in turn influences ideas about the role of scientific expertise in this process.

1. Shifting sands – administrative legitimation between control and deliberation

EU regulation of GMOs illustrates well the struggle over the appropriate balance between science and politics of EU administrative decision-making as well as the role of EU law in that struggle. Since over a decade the administrative implementation of EU rules on the marketing of GMOs is the arena in which the political battle over this controversial technology has taken place. The resulting problems of regulatory deadlock, failure of deliberation and controversial legal reform have been substantively discussed.¹⁵ In this paper we aim to show that the struggle over GMO authorizations has also been a struggle over ideas of what constitutes a legitimate EU risk administration.

Models of public administration are reflections of constitutional theory.¹⁶ Our understandings of administrative legitimation are thus infused with constitutional theories regarding the legitimacy of public administration within constitutional democracies. These understandings are therefore shaped within, to use Elizabeth Fisher's term, discourses of administrative constitutionalism, which manifest themselves, among others, in legal and administrative decision-making.¹⁷ Naturally, concepts of administrative legitimation will vary from one legal system to another.¹⁸ Yet also within one legal system, the contours of such concepts are essentially contested, in flux, and subject to an on-going constitutional re-settlement.¹⁹ In other words, normative ideals about public administration and how it should be constituted, limited, and held to account so as to ensure its legitimacy are constantly competing with one another within administrative legal practice. In turn, those ideals and discourses shape the process of technological risk evaluation in different ways.

¹⁵ Lee, Maria, *EU Regulation of GMOs* (Edward Elgar 2008); Weimer (n 5).

¹⁶ See Carol Harlow and Richard Rawlings, *Law and Administration* (3 edition, Cambridge University Press 2009) 1-48.

¹⁷ Fisher (n 11).

¹⁸ *ibid.*

¹⁹ See Anderson (n 7).

Contestations with regard to administrative legitimation are also (and perhaps even more so)²⁰ present in the EU legal system, and are particularly visible in the field of EU risk regulation. For the purposes of this paper, we identify two ideal models of EU administrative legitimation, namely the control model and the deliberative model. A key difference between these models is the way they define the role of public administration, including the nature of administrative discretion. Moreover, each model conceptualizes the nature of safety, risk, scientific evidence and uncertainty differently. The control model follows principal-agent or “transmission belt” theories of the administrative state.²¹ Applied to the EU, the control model sees the EU public administration as the agent of the EU legislature as its democratically legitimated principal. Wide discretionary powers are seen as problematic, and need to be limited and controlled in order to maintain the democratic transmission between EU legislative commands and their administrative implementation. EU administrative law then is seen as the main instrument to control administrative power, and to protect individual liberties from arbitrary actions via stringent judicial control.²²

In the field of risk regulation, scientific expertise contributes to that control. By rationalizing administrative decision-making, it becomes an *ex-ante* control mechanism that facilitates *ex-post* judicial review. Therefore, the scientific advice of the European Food Safety Authority (EFSA) into the Commission authorization process on GMOs (see below at 2) is seen as instrumental to delivering the facts, which the Commission can apply to the legislative commands in this field. Because of its control function scientific advice constitutes the main input into the authorization process leaving the Commission with little political discretion. Moreover, in the control model, technological risks in general and GMO risks in

²⁰ Given that EU administrative law is a relatively young field, and its doctrinal developments are lagging behind their national counterparts. See Jurgen Schwarze, *European Administrative Law* (1 Revised, Sweet & Maxwell 2006); Eberhard Schmidt-Assmann and Bettina Schöndorf-Haubold, *Der Europäische Verwaltungsbund: Formen und Verfahren der Verwaltungszusammenarbeit in der EU* (Mohr Siebeck 2005).

²¹ Harlow and Rawlings refer to it as the red-light model, see Harlow and Rawlings (n 17) 22.

²² Harlow and Rawlings associate the red-light model with liberal theories in the spirit of Friedrich Hayek, see *ibid.* In the US context Anderson refers to it as the private law model, see Anderson (n 7).

particular are understood as quantifiable, scientific uncertainty as manageable and knowledge as an objective body of truth claims based on established facts.²³

In contrast, the deliberative model sees public administration as a relatively autonomous institution serving the public good. Instead of emphasising judicial control, it emphasises the value of deliberation in administrative decision-making.²⁴ According to this model the Commission, comitology and the EFSA are all part of a composite EU administration,²⁵ which legitimizes its action on the basis of the cooperative and deliberative nature of its joint decision-making.²⁶ The Commission is granted substantive discretion to achieve broadly formulated legislative goals and objectives in cooperation with other actors, which includes the right to deviate from EFSA opinions as well as to base decisions on so-called other legitimate factors, such as socio-economic and ethical concerns. The exercise of that discretion is legitimated on the basis of the deliberative nature of Commission decision-making, which is supported by reason-giving requirements. The role of EFSA is to inform this process. However, both the limits and value-laden nature of scientific risk assessment are recognized, and the role of EFSA is framed as one of communicating openly about these limits including knowledge gaps and scientific uncertainties. Complexity and uncertainty are recognized as pervasive granting the Commission a wide range of discretion to make policy judgements on the basis of available scientific evidence. In this way EFSA's advice is seen as only one input into the process. In this model, knowledge is seen as an unstable body of contested truth claims.²⁷ Finally, the role of the EU Courts is, while acknowledging substantive discretion on the part of the Commission, to act as catalysts of deliberation. In other words, judicial review

²³ See also Shapiro, Sidney, Fisher, Elizabeth and Wagner, Wendy, 'The Enlightenment of Administrative Law: Looking Inside the Agency for Legitimacy' (2012) 47 Wake Forest Law Review 469.

²⁴ Fisher (n 11). Harlow and Rawlings associate what they call the green-light model with progressive functionalist theories of the administrative state. In the US context Anderson refers to it as the public law model, see Anderson (n 7).

²⁵ See Herwig CH Hofmann and Alexander H Turk, *Legal Challenges in EU Administrative Law: Towards an Integrated Administration* (Edward Elgar Publishing Ltd 2009).

²⁶ Christian Joerges and Jürgen Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 European Law Journal 273; Charles F Sabel and Jonathan Zeitlin, *Experimentalist Governance in the European Union: Towards A New Architecture* (Reprint, Oxford University Press 2012).

²⁷ See European Commission, *The Future of Europe Is Science, A Report of the President's Science and Technology Advisory Council*, October 2014 available at <https://ec.europa.eu/digital-agenda/en/news/report-science-and-technology-advisory-council-stac-future-europe-science> (accessed on 24 February 2016).

should help ensure the functioning of 'process values' in the administrative process such as reason-giving, transparency, consistency, participation, and the quality of the scientific basis of GMO authorizations.²⁸

It should be noted that neither of the above models of administrative legitimation provide for a fully satisfactory answer to the challenges of contemporary risk administration. The control model relies on legal formalism, and tries to preserve the traditional idea of rule of law in the liberal constitutional state including the idea of democratic control and accountability of public administration. Yet it does so at the risk of becoming a fiction, and of not being able to normatively capture the actual complexity of the exercise of administrative power, especially in a multi-level supranational system. Already in 1975 the US scholar Richard Stewart observed the

'disintegration of the traditional model, which has proven unsuccessful in its effort to reconcile the discretionary power enjoyed by agencies with the basic premise of the liberal state that the only legitimate intrusions into private liberty and property interests are those consented to through legislative processes.'²⁹

It can be assumed that this problem intensified over the last decades marked by increased global interdependence, stronger regional integration and the subsequent transfer of executive powers beyond the state. In contrast to the control model, the deliberative model promises a more realistic and pragmatic approach to administrative problem solving guided by the general public interest. However, it could be criticized as problematic for sacrificing legal certainty, overestimating the potential of deliberation in democratic problem-solving, and giving raise to concerns over the arbitrary use of discretionary power.³⁰ Moreover, rather than being a fully fledged model at present it rather serves as a container notion for a series of alternative visions of public administration which are still lacking conceptual sharpness.³¹

²⁸ Scott, Joanne and Sturm, Susan, 'Courts as Catalysts: Rethinking the Judicial Role in New Governance' (2007) 13 *Columbia Journal of European Law*.

²⁹ Stewart, Richard, 'The Reformation of American Administrative Law' (1975) 88 *Harvard Law Review* 1667. For a different type of critique of the US administrative state see Dorf and Sabel, *A Constitution of Democratic Experimentalism*, *Columbia Law Review*, 1998, Vol 98, No 2.

³⁰ For a discussion of advantages and disadvantages of both models see Fisher (n 11) 251.

³¹ See Rodriguez, Frank, 'The Scientification of Participation' in Van Asselt, Marjolein, Versluis, Esther and Vos, Ellen (eds), *Balancing Between Trade and Risk. Integrating Legal and Social Science Perspectives* (Routledge 2013).

The two models therefore should be understood as contrast points the tension between which fosters a productive search for an adequate concept of administrative legitimation, in this case in the EU. Looking through this lens at concrete examples of the EU administrative legal practice helps ascertaining the suitability of one or the other model in a particular context, as well as crystalizing instances of gradual legal and administrative change that is already taking place. What is of interest here is to observe the process whereby the challenges of the techno-scientific progress are transforming ideas and concepts of administrative legitimation including concepts of administrative law. It therefore should be seen as part of the EU's on-going process of soul searching and contestation over the 'right' model of risk regulation.

In the remainder of this paper we use these two models in order to analyze two controversial cases of EU authorization of GMOs. The goal is to trace back discourses about EU administrative legitimation, and to analyse the way in which they shape the practice of GMO decision-making including the role of scientific expertise therein.

2. Administrative legitimation and GMO authorizations: the long tale of *Herculex* and *Amflora*

In the last years, two processes of EU authorization of GMOs have been particularly controversial, and hence emblematic of the regulatory crisis in this field more generally. The first case concerns the GM Maize 1507, branded as *Herculex*; and the second the GM potato EH92-527-1 branded as *Amflora*.³² Both concern applications for cultivation, i.e. for the agricultural use of GMOs, which has been particularly controversial because of its potential environmental and socio-economic implications.³³ Moreover, both cases involved a long and complicated authorization process marked by persistent contestation of both the EFSA's risk assessment and the Commission's risk management; several EFSA opinions as a result of recurrent requests by the Commission; and administrative delay. Moreover, in both cases the EU General Court has (for the first time in the field of GMO regulation) reviewed the legality of the Commission's administrative action.

Previous research suggested that EFSA on GMOs 'generally indicate no uncertainty' that might trigger extra risk management measures, and that EFSA has 'framed

³² Our analysis is based on document review and individual semi-structured interviews.

³³ Lee, Maria (n 16); Lee (n 9); Weimer (n 5).

scientific uncertainties in such a way that it can be resolved by extra information, or can be readily managed, or deemed irrelevant to any risk.’³⁴ Therefore, EFSA’s risk assessment has been described as ‘uncertainty intolerant,’ which means that it is reluctant to both acknowledge and communicate scientific uncertainty, instead of genuinely and systematically investigating it.³⁵ The Commission, on the other hand, was found to merely rubberstamp EFSA’s opinions acting ‘as a blind driver taking directions from the passenger in the back seat,’³⁶ thereby inheriting EFSA’s uncertainty intolerance.

Our analysis of decision-making in both cases (see table) offers new findings in this respect. We register a slight yet meaningful gradual change in the way both EFSA and the Commission have acted within the authorization process, notably with regard to how they as EU administrative bodies dealt with scientific advice, risk and uncertainty. The following two sections present our findings in more detail.

Table: Chronology of authorization processes of *Herculex* and *Amflora*

<i>Herculex</i> (maize 1507) ³⁷		<i>Amflora</i> (Potato EH92-527-1) ³⁸	
January 2005	EFSA issues 1 st opinion	April 2004	EFSA issues opinion on the use of antibiotic resistance marker genes in GM plants
November 2006	EFSA issues update with Annex on non-target organisms	February 2005	The World Health Organization (WHO) report classifies kanamycin and neomycin (antibiotics to which <i>Amflora</i> is resistant) as critically important for human medicine
2007 (date unknown)	Commission drafts a decision rejecting authorization (but never submits it to the comitology committee)	December 2005	EFSA issues 1 st opinion on <i>Amflora</i>

³⁴ Les Levidow and Susan Carr, ‘Europeanising Advisory Expertise: The Role of “Independent, Objective, and Transparent” Scientific Advice in Agri-Biotech Regulation’ (2007) 25 Environment and Planning C: Government and Policy 880; Les Levidow, Susan Carr and David Wield, ‘European Union Regulation of Agri-Biotechnology: Precautionary Links Between Science, Expertise and Policy’ (2005) 32 Science and Public Policy 261, 270, 273.

³⁵ Van Asselt and Vos (n 9).

³⁶ Vos, Ellen and Wendler, Frank, *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Intersentia 2007).

³⁷ Application submitted in 2001.

³⁸ Application submitted in 2003.

October 2008	EFSA issues updated opinion reviewing 11 independent studies	December 2006	Commission submits draft authorization to the comitology committee (which later fails to reach a decision)
February 2009	Commission submits proposal to authorize to the comitology committee (which later fails to reach a decision)	February 2007	The European Medicine Agency (EMA) issues opinion concluding that neomycin and kanamycin cannot be classified as of no or minor importance
April 2010	A new (<i>Testbiotech</i>) study criticizes EFSA's assessment	March 2007	EFSA states that the use of <i>nptII</i> gene in GM plants will not compromise the therapeutic effects of kanamycin and neomycin
November 2011	EFSA issues updated opinion acknowledging differences between the <i>Bt</i> toxins Cry1F (contained in <i>Herculex</i>) and Cry1Ab (contained in other GMOs) and acknowledging some potential risks	June 2007	Commission submits draft authorisation to the Council (which later fails to reach a decision)
October 2012	EFSA issues a supplementing opinion acknowledging the need for further studies on the impact of <i>Cry1F</i> on non-target species	June 2009	EFSA issues consolidated opinion acknowledging some uncertainty; A minority opinion of the BIOHAZ panel concludes that a risk assessment is not possible due to scientific uncertainty
November 2012	EFSA issues another supplementing opinion considering new scientific studies	March 2010	Commission authorizes <i>Amflor</i> without a re-submission to the comitology committee
September 2013	The General Court condemns the Commission for failure to act during the authorization process	December 2013	The General Court annuls the authorization on procedural grounds
November 2013	Commission submits draft authorization decision to the Council		
February 2014	Council votes with 19 Member States against authorization (the Commission has so far not taken the final decision)		

2.1. The EFSA as expert agency: from control to deliberation

Our empirical analysis reveals a gradual change in approach in recent years on the part of the EFSA GMO panel³⁹ expressed in its willingness to both acknowledge and communicate knowledge gaps, flaws in methodology, potential risks and remaining scientific uncertainty. We find that this shift has been the result of external pressure from several Member States, other scientific authorities as well as recurrent requests of the Commission.

*Risk assessment of Herculex*⁴⁰

In 2001 Pioneer-DuPont submitted a request for the authorisation for the placing on the market and cultivation of maize 1507 under Directive 2001/18⁴¹ and Regulation 1929/2003.⁴² The latter is an insect-resistant genetically modified maize characterised by the insertion of two genetic constructs: one which produces *Cry1F*, a so-called *Bt*-protein⁴³ that makes the maize resistant to certain *Lepidoptera*,⁴⁴ and another which makes the maize tolerant to *glufosinate ammonium*, a herbicide the use of which shall be phased out in the EU by 2017.⁴⁵ *Herculex* has raised concerns with regard to the risk of resistance development in target organisms, as well as the uncertain impact of the *Bt*-toxin on non-target organisms. In its initial risk assessments the EFSA did not seriously engage with these concerns. Likely being aware of the political pressure to provide authoritative scientific advice as the new EU expert agency, at the time it framed its advice in definite terms following the ‘uncertainty intolerant’ pattern previously identified by Van Asselt and Vos.⁴⁶

³⁹ The GMO panel is the scientific panel responsible for risk assessment of GMOs at EFSA.

⁴⁰ See for more detailed empirical analysis Maria Weimer and Gaia Pisani, ‘Biotechnology: The EU Adventures of *Herculex*’ (2014) 5 European Journal of Risk Regulation 208.

⁴¹ 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/206.

⁴² Regulation (EC) 1929/2003 on genetically modified food and feed, [2003] OJ L 268/1. On the legal framework see Maria Weimer, ‘Applying Precaution in EU Authorisation of Genetically Modified Products – Challenges and Suggestions for Reform’ (2010) 16 European Law Journal 624.

⁴³ *Bt* (*Bacillus thuringiensis*) are bacteria naturally occurring in the soil. Some of them produce a protein crystal which is toxic to insects. *Bt Cry1F* is the result of a modification of the natural occurring *Cry1Fa2* gene.

⁴⁴ Larvae of the European corn borer and of the Mediterranean corn borer.

⁴⁵ Commission Implementing Regulation (EU) No 365/2013 of 22 April 2013 amending Implementing Regulation (EU) No 540/2011, OJ (2013) L111/27.

⁴⁶ Van Asselt and Vos (n 9).

For example, in its first opinion in 2005⁴⁷ EFSA employed a so-called ‘plausibility proof’⁴⁸ by stating that the cultivation of maize 1507 ‘will not have an adverse effect’⁴⁹ (emphasis added) on human health and the environment. It thus framed its advice as conclusive evidence, in which there is no room for uncertainty. Moreover, EFSA employed so-called ‘boundary work’, a process by which the latter draws a boundary between risk assessment and risk management, which in turn allows it to dismiss certain risk claims.⁵⁰ Several Member States pressured EFSA to include monitoring and mitigation issues in its risk assessment followed by a Commission request to cooperate with the national authorities and to update its risk assessment in this respect.⁵¹ EFSA, however, rejected by stating that monitoring arrangements in relation to potential adverse effects on non-target organisms are outside of the scope of risk assessment.⁵²

Finally, EFSA based its initial risk assessment on controversial analogies between different types of the *Bt*-toxin. As mentioned above, *Herculex* contained the *Bt*-toxin Cry1F, which differed from *Bt*-toxins contained in other transgenic plants (e.g. the Monsanto’s Mon810 maize containing Cry1Ab). A controversial issue was to what extent different *Bt*-toxins could be expected to have either similar or different effects on the environment. While no peer-reviewed literature on the effects of the *Herculex* toxin Cry1F existed at that time, some studies highlighted the significantly higher

⁴⁷ EFSA, Opinion of the Scientific Panel on Genetically Modified Organism on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds, Question No EFSA-Q-2004-072, *The EFSA Journal* (2005) 181, 1-33.

⁴⁸ Van Asselt and Vos define those as ‘statements by experts in which their risk judgments are cast as conclusive evidence on the existence or non-existence of an uncertain risk. There is no room for uncertainty in plausibility proofs: risks exist or they do not.’ See Van Asselt and Vos (n 9) 282.

⁴⁹ See above (n 48), 2.

⁵⁰ Following Gyrien boundary work is defined as a strategic and purposeful act in which boundaries are drawn between realms, for example, between science and non-science and between science and politics See Thomas F Gieryn, *Cultural Boundaries of Science: Credibility on the Line* (University of Chicago Press 1999); Van Asselt and Vos (n 9) 288.

⁵¹ EFSA, Clarifications of the Scientific Panel on Genetically Modified Organisms following a request from the Commission related to the opinions on insect resistant genetically modified Bt11 (Reference C/F/96/05.10) and 1507 (Reference C/ES/01/01) maize, 19 November 2006, 2.

⁵² Ibid. 5-7

toxicity of Cry1F *vis-à-vis* Cry1Ab on certain insects.⁵³ In 2008 the Commission asked EFSA to review its previous opinion in the light of eleven independent scientific studies,⁵⁴ which explored the effects and potential toxicity of Cry1Ab on some target and non-target organisms. However, the GMO panel only vaguely engaged with these studies dismissing all of them as not providing *new scientific evidence*.⁵⁵ Most notably, EFSA remained of the opinion that the two proteins (Cry1F and Cry1AB) had high affinities and that their concentration in pollen was relatively low continuing to rely on existing studies of Cry1Ab for the assessment of *Herculex*.⁵⁶

However, in 2010 the Commission yet again asked EFSA for an update on the basis of a new scientific study conducted by a non-profit research institute.⁵⁷ The latter raised a number of objections to EFSA's conclusions, and criticized the inadequacy of founding an environmental impact assessment on analogies with other *Bt* toxins.⁵⁸ It argued that, instead of relying on partial information and overlooking the existent uncertainties, EFSA should have requested further data from the applicant.

This time EFSA delivered a more nuanced response partially acknowledging methodological flaws and the need for further studies.⁵⁹ A new opinion⁶⁰ also

⁵³ A.V. Hanley, Z. Y Huang, W. L.Pett, , (2003) Effects of dietary transgenic Bt corn pollen on larvae of *Apis mellifera* and *Galleria mellonella*. *Journal of Apicultural Research*, Vol. 42 (4) pp. 77 - 81.

⁵⁴ For a comprehensive list, see EFSA, Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507, Question No EFSA-Q-2008-679, *The EFSA Journal* (2008), 851, 1-27 at 6-7.

⁵⁵ *Ibid.*

⁵⁶ In contrast, in 2007 EFSA launched a call for proposal to gather scientific data on *Bt* proteins, in order to better analyse their behaviour in GM plants. See EFSA Call CFP/EFSA/GMO/2007/01, Cry proteins and their expression in micro organisms and genetically modified plants. This call was also mentioned in the proposal for the rejection of the authorisation of *Herculex* as drafted by Commissioner Dimas in 2007 (see n 77 below).

⁵⁷ The study at issue is A. Bauer-Panskus & C. Then, Testbiotech opinion on the application for market approval of genetically modified maize 1507 (DAS-Ø15Ø7-1), April 2010 available at <<http://dx.doi.org/10.1023/A:1007123502914>>. (last accessed 27 February 2016). EFSA makes explicit reference to it in: EFSA, Minutes of the 61st plenary meeting of the scientific panel on genetically modified organisms held on 20 -21 October 2010 in Parma, Italy, adopted on 1 December 2010, 7.

⁵⁸ Notably, they claimed that maize 1507 produced a high concentration of *Bt* toxin in pollen, and that this evidence should have significantly altered the risk assessment outcome as to the development of insect resistance and the impact on soil, air and water.

⁵⁹ See above, EFSA (2010), (n 58), 7. See also two supplementing opinions: EFSA, Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations on the genetically modified insect resistant maize 1507 for cultivation, *EFSA Journal* 2012; 10(11):2934 ; and EFSA, Scientific Opinion updating the risk

acknowledged some potential risks. Firstly, EFSA acknowledged the higher concentration of *Cry1F* in *Herculex* as compared to other *Bt*-toxins in other GMOs.⁶¹ Secondly, it identified potential risks in relation to the evolution of resistance in target pests and the toxicity of the *Bt*-protein to sensitive non-target *lepidoptera*, such as European butterflies. The Panel acknowledged the need for further studies to fill the knowledge gap,⁶² but did not consider this as sufficient to alter the outcome of its risk assessment. Instead, it proposed ‘appropriate management measures,’ notably insect resistance management strategies to *delay* the evolution of resistance in target pests and field studies to *monitor* the effects on non-target *Lepidoptera*. It concluded that *Herculex* is ‘unlikely to raise safety concerns for the environment.’

Risk Assessment of Amflora

BASF Plant Science GmbH requested the authorisation for the placing on the market of the potato *Amflora* under Directive 2001/18/EC and Regulation (EC) 1829/2003 in 2003. *Amflora* is a potato intended for industrial use only, and its modification allows greater production of starch. It is also characterised by the insertion of the marker gene *nptII*. *NptII* is an antibiotic resistance gene, which confers resistance to the antibiotics. The use of *nptII* as marker gene was the main focus of the objections raised by Member States and NGOs to the authorisation of *Amflora*. The major concern regarded the risk that antibiotic resistance could be transferred horizontally (namely from plants to bacteria), with potential implications in the treatment of infections and transmissible diseases such as tuberculosis in humans and animals.

The first EFSA opinion⁶³ on *Amflora* issued in 2005 followed the familiar pattern of framing advice in certain terms, and providing plausibility proofs.⁶⁴ EFSA concluded

assessment conclusions and risk management recommendations on the genetically modified insect resistant maize 1507, *EFSA Journal* 2012; 10(10):2933

⁶⁰ EFSA, Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation, *EFSA Journal* 2011; 9(11):2429.

⁶¹ The concentration of *Cry1F* in pollen of *Herculex* was about 350 times the concentration of *Cry1Ab* in *MON810*.

⁶² See above EFSA (2011), (n 61), which at p. 3 states “The EFSA GMO Panel recommends caution when predicting future responses of the European and Mediterranean corn borer in the EU based on experiences elsewhere, as resistance evolution in target insect pests is dependent upon many factors”.

⁶³ EFSA, Opinion of the Scientific Panel on Genetically Modified Organisms on an application (Reference EFSA-GMO-UK-2005-14) for the placing on the market of genetically modified

that the GM potato was “no more likely to cause adverse effect on human and animal health or the environment than conventional potato” (emphasis added). Most notably, EFSA classified kanamycin and neomycin as antibiotics with “no or only minor therapeutic relevance in human medicine and only restricted use in defined areas of veterinary medicine,”⁶⁵ which is why the use of the *Amflora* marker gene *nptII* was not found to pose any risks.

However, EFSA’s classification contradicted a WHO report published in February 2005 in which kanamycin and neomycin were classified as ‘critically important’ antibacterial agents for human medicine, used in the treatment of *E-coli* and tuberculosis.⁶⁶ This led the Commission to request the advice of another EU agency, the European Medicines Agency (EMA), on the validity of the EFSA assessment of the *nptII*. In line with the WHO report the EMA challenged the EFSA opinion affirming that kanamycin and neomycin belong to a class of antibiotics (*aminoglycosides*) that has become more and more important in the treatment of some serious infectious diseases such as tuberculosis.⁶⁷

This led the Commission to request EFSA to reconsider its previous assessment in the light of both the WHO and the EMA opinions. In a statement adopted in March 2007⁶⁸ the GMO Panel reiterated its findings claiming that the EMA and WHO reports would not change its previous assessment on the safety of using *nptII* in GMOs. It concluded

“The GMO Panel agrees with the EMA that the preservation of the therapeutic potential of the aminoglycoside group of antibiotics is important. The Panel is also of

potato EH92-527-1 with altered starch composition, for production of starch and food/feed uses, under Regulation (EC) No 1829/2003 from BASF Plant Science; Question No EFSA-Q-2005-070; *EFSA Journal* 2006; 324, 1-20.

⁶⁴ On this term see above (n 49).

⁶⁵ The classification used by EFSA was developed in a previous opinion evaluating the use of antibiotic resistance genes as marker genes in GM plants more generally, see EFSA, Opinion of the Scientific Panel on Genetically Modified Organisms on the use of antibiotic resistance genes as marker genes in genetically modified plants; Question No EFSA-Q-2003-109; *EFSA Journal* 2004; 48, 1-18, at 11.

⁶⁶ World Health Organization, *Critically important antibacterial agents for human medicine for risk management strategies of non-human use*, report of a WHO working group consultation, 15-18 February 2005, Canberra, Australia. Available at http://apps.who.int/iris/bitstream/10665/43330/1/9241593601_eng.pdf (last accessed 28 February 2016).

⁶⁷ European Medicine Agency, Presence of the antibiotic resistance marker gene *nptII* in GM plants for food and feed uses, EMA/CVMP/56937/2007 – Final, 22 February 2007.

⁶⁸ EFSA, *Statement of the Scientific Panel on Genetically Modified Organisms on the safe use of the *nptII* antibiotic resistance marker gene in genetically modified plant*, adopted on 22-23 March 2007.

the opinion that the therapeutic effect of these antibiotics *will not* be compromised by the presence of the *nptII* gene in GM plants, given the *extremely low probability* of gene transfer from plants to bacteria and its subsequent expression. Furthermore, the GMO Panel considers it *very unlikely* that the presence of the *nptII* gene in GM plants will change the existing widespread prevalence of this antibiotic resistance gene in bacterial sources in the environment. The GMO Panel also points to evidence which indicates that integration of the *nptII* gene would only be one of many mechanisms by which bacteria could become resistant to aminoglycosides such as kanamycin. Therefore, the GMO Panel reiterates its earlier conclusions (EFSA, 2004)". (emphasis added)

Hence, EFSA barely engaged with the contesting scientific views expressed by the WHO and EMEA. It defined its response in a decisive and clear-cut way ('will not be compromised'), and evaded the uncertainty surrounding the use of *nptII* by employing terms, which create the appearance of certainty and low risk ('extremely low probability' and 'very unlikely').

However, given the continuing criticism of EFSA's work including pressure from the Member States and some NGOs the Commission asked the GMO Panel to work together with another EFSA scientific panel, the Biological Hazard (BIOHAZ) Panel, to deliver a joint scientific opinion on the use of antibiotic resistance marker genes in GM plants. In June 2009 EFSA issued a consolidated opinion (hereafter EFSA consolidated opinion) acknowledging some uncertainties, knowledge gaps,⁶⁹ and admitting a number of limitations.⁷⁰ Similar to the *Herculex* case, EFSA gradually shifted towards more uncertainty tolerance while at the same time concluding that the identified risks were not significant enough to justify a modification of its assessment of the safety of the *nptII* gene. The Panel concluded that

"Notwithstanding these uncertainties, the current state of knowledge indicates that adverse effects on human health and the environment resulting from the transfer of

⁶⁹ EFSA, Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of antibiotic resistance genes as marker genes in genetically modified plants" and the Scientific Opinion of the GMO Panel on "Consequences of the opinion on the use of antibiotic resistance genes as marker genes in genetically modified plants on previous EFSA assessments of individual GM plants"; EFSA-Q-2009-00589 and EFSA-Q-2009-00593; *EFSA Journal* 2009; 1108, 1-82.

⁷⁰ *Ibid.*, at 3, "There are limitations related among others to sampling, detection, challenges in estimating exposure levels and the inability to assign transferable resistance genes to a defined source"; see also at 67-82.

these two antibiotic resistance genes from GM plants to bacteria, associated with the use of GM plants, *are unlikely*".

Importantly, for the first time since the establishment of EFSA, two scientists (of the BIOHAZ Panel) disagreed with the majority opinion and raised objections to the assessment of the likelihood of horizontal gene transfer and its potential implications for the medical use of kanamycin and neomycin. The minority opinion found that "it would be imprudent to regard resistance to *any* antibiotic as being of little or no relevance to human health"⁷¹ (emphasis added); and that the level of risk for human health and the environment could not be assessed, as the probabilities of horizontal gene transfer were below the detection limits. Hence, the minority opinion openly acknowledged that a risk assessment was not possible under the given circumstances. The EFSA consolidated opinion, however, dismissed these arguments without further explanation by simply stating that it had taken into due account the minority opinion and that 'from a scientific point of view, the joint opinion of 2009 did not require further clarification or additional work of a scientific nature.'⁷²

We observe, therefore, that the pressure exerted on EFSA by national authorities, independent scientific studies and other agencies, as well as the Commission's recurrent requests had forced the agency to engage more seriously with competing views and scientific uncertainty. This resulted in a more nuanced risk assessment combined with more explicit communication of uncertainty information. However, this opening up in EFSA's opinions ultimately did not result in a modification of the overall conclusions regarding the risks of both GMOs. This reveals that EFSA understood uncertainty as something negligible for the overall risk assessment, because it was assumed that uncertainty is not pervasive, but can be reduced through risk management. Moreover, EFSA's tendency to conclude the risk assessment with a definitive and certain response indicates an understanding of its role as risk assessor in line with the control model. EFSA sees itself as instrumental for the provision of facts, to which the Commission can apply legislative commands.

⁷¹ See above (n 70) at p. 81.

⁷²As explained in Case T-240/10, *Hungary v European Commission*, see below (n 94) at para 39: "On 28 April 2009, the Director of EFSA asked the chairmen of the GMO and BIOHAZ panels and the chairman of the joint working group whether the two dissenting opinions required further work of a scientific nature. On 25 May 2009, those chairmen replied that, during the preparation of the joint opinion of 2009, the content of the two dissenting opinions had largely been taken into account, so that, from a scientific point of view, the joint opinion of 2009 did not require further clarification or additional work of a scientific nature".

The role of EFSA therefore is not merely to facilitate the exercise of administrative discretion by the Commission, but to be a decisive basis for it thereby controlling discretion.

2.2. The Commission as risk manager: from deliberation to control

The conduct of the Commission in both the *Herculex* and *Amflorac* cases follows a similar pattern. The cross-analysis of both cases demonstrates the ambiguous role of the Commission in its attempt to overcome the exacerbation of scientific, regulatory and political conflicts in this area, and to maintain its own legitimacy as the EU public administration. While EFSA gradually shifted from an uncertainty intolerant to a more uncertainty tolerant approach in both authorizations, the opposite holds true for the Commission.

Initially, in both cases the Commission had operated in a rather cautious and politically sensible way arguably at the expense of an efficient and timely administrative process. It engaged with different scientific authorities encouraging their collaboration with the EFSA. It repeatedly put pressure on EFSA to respond to competing scientific views expressed either by national authorities or independent studies. Therefore, the Commission could be seen as having acted as an administrative body with substantive discretion whose task it is to foster a deliberative process, which should inform the final authorization decision on a scientifically complex and politically sensitive application. Likely aware of the resistance on the part of the Member States that it might encounter in comitology, the Commission tried to accommodate different concerns in a pre-emptive manner. It thereby acted in a manner indicative of the deliberative model.

In the *Herculex* case, its self-understanding as a body with wide discretion is evidenced by the fact that for the first time in the field of GMOs (as far as we know) the Commission attempted to depart from EFSA's advice, and to refuse authorisation for *Herculex*. In 2007, former Commissioner Stavros Dimas presented a draft decision proposing not to approve the maize for cultivation on the basis of the high degree of scientific uncertainty and the lack of scientific knowledge over significant traits of this GMO. The draft proposal stressed the need for an approach based on the precautionary principle, and indicated that the degree of uncertainty was so high

that it was 'not possible to establish appropriate management measures which would effectively mitigate the potential damage on the environment'.⁷³

However, instead of pursuing this proposal in comitology, the Commission again returned to EFSA. After the agency re-affirmed its previous findings about the safety of *Herculex* (see above), the Commission made a U-turn in its position. It drafted a new proposal, this time in favour of authorisation. The Commission now relied on EFSA's statement that there is no evidence of the adverse effects of *Herculex* on human health and the environment. It is striking that the previous concerns about existent knowledge gaps no longer appeared in the new draft.

This clearly shows that different ideas about the nature of the Commission's discretion including its ability to deviate from EFSA's advice have been competing with one another internally within the Commission. Interestingly, both decision proposals on *Herculex* have been drafted under Commissioner Dimas, so that the change of approach cannot be seen as a result of change in the Commission's leadership. There are indications that external rather than internal factors were decisive in this change of heart. Following the WTO *EC-Biotech* panel report⁷⁴ in 2005, which was unfavourable to the EU, the Commission found itself under strong external pressure to adopt an interpretation of the Commission's discretion along the lines of the control model. The latter implied that the Commission's discretion to reject authorization was considerably reduced in light of EFSA's findings. In the words of a Commission official, 'The Commission felt that it should apply the legislation.'⁷⁵

⁷³ The document reported a number of objections raised by MSs concerning the impact on soil organisms and anthropods, the long-term effects of the Bt toxin on the environment, and it also pointed out that, *ex lege*, environmental risk assessments need to consider potential effects on non-target organisms and cumulative long-term effects which, at that time, were not adequately evaluated. Importantly, the Commission seemed to question the reliability of a meta-review of the applicant's assessment, marking the lack of crucial data such as the concentration of Bt toxin, and contesting the methodology used by EFSA in its assessment. See EU Commission (2007), Draft Commission Decision of [...] concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinateammonium. ENV/07/.

⁷⁴ WTO Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291 from 29 September 2006.

⁷⁵ Interview with a member of the Commission Legal Service on 21 February 2014.

Both processes of authorisation were marked by delay, inaction, and, ultimately, rulings of the EU general court.⁷⁶ As usual for GMO authorisations,⁷⁷ the comitology process failed to produce the necessary majority, which meant that, under the rules applicable at that time, the Commission had to forward the draft authorization proposals to the Council. However, in the *Herculex* case, it was not until November 2013, twelve years since the filing of the Pioneer application, that the Commission submitted its authorization proposal to the Council. The Commission justified the proposal on the basis that the EFSA had not identified new scientific publications that would have invalidated its previous opinions on the safety of *Herculex*.⁷⁸ What is most striking about this proposal is the absence of any references⁷⁹ to the potential risks and uncertainties identified by the EFSA in its latest more nuanced opinions (see above).

In February 2014 the Council voted on the authorisation of *Herculex*. Nineteen Member States opposed the proposal, five were in favour, and four abstained.⁸⁰ Despite the high number of opposing Member States, no qualified majority was reached against the Commission proposal, paving the way for the Commission to approve *Herculex*. Following the vote, twelve ministers⁸¹ addressed a letter to former Commissioner Tonio Borg asking the Commission to withdraw its proposal in the light of the broad opposition of the majority of stakeholders. The Commission has

⁷⁶ See below at 3.. Overall, in the *Herculex* case it took two court actions by Pioneer to move the procedure along. The first one was brought in 2007 (Case T-139/07) forcing the Commission to submit a draft proposal to the comitology committee, after which the EU Court filed the case because there was no need to adjudicate anymore.

⁷⁷ See Weimer (n 5).

⁷⁸ European Commission, Proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests, COM(2013) 758 Final, 6 November 2013.

⁷⁹ With the exception of the potential Bt toxin resistance in corn borers, for which the Commission refers to an EFSA opinion from 2005. See *ibid.*, European Commission Proposal (2013), para 17.

⁸⁰ Spain, the UK, Finland, Estonia and Sweden voted in favour, Portugal, Czech Republic, Belgium and, quite surprisingly, Germany abstained. France, Italy, Hungary, the Netherlands, Slovenia, Slovakia, Austria, Poland, Greece, Romania, Bulgaria, Croatia, Cyprus, Latvia, Ireland, Denmark, Malta, Luxembourg and Lithuania voted against the Commission's proposal for approval.

⁸¹ Letter dated 12 February 2014, signed by the Ministers of Austria, Bulgaria, Cyprus, France, Hungary, Italy, Latvia, Lithuania, Luxembourg, Poland, Slovenia and Malta. The text of the letter is available at http://m.greenpeace.org/greece/Global/greece/image/2014/gmos/gmo_general_petition/2379_001.pdf (last accessed 28 February 2016).

until present not proceeded with the authorization, nor taken a formal position in this case.⁸²

In the *Amflora* case, the Commission presented a proposal to the Council in June 2007. After the Council failed to gather the necessary majority to vote on the proposal, the Commission went on to authorize *Amflora* in March 2010.⁸³ In the preamble of the authorization decision, the Commission included a general reference to the debate between EFSA, WHO and EMEA over the risks of using *nptII* as marker gene. However, it did not engage with the minority opinion included in the 2009 EFSA consolidated opinion. Moreover, it did not consider it necessary to again consult the comitology committee in the light of the new consolidated opinion. Later on, this resulted in the general court annulling the authorisation for breach of procedural rules (see below).

We conclude that EFSA's shift towards a more uncertainty-tolerant deliberative approach was ultimately not followed by the Commission, but was, instead, met with a strikingly uncertainty intolerant response along the lines of the control model. We argue that an important factor influencing the Commission has been that it interpreted its mandate to implement GMO legislation along the lines of the control model: as being restraint by the EFSA majority opinion. For example, in its press release on the authorization of *Herculex*, the Commission has explained its proposal with the obligation to comply with the ruling of the EU general court and thereby with the rule of law.⁸⁴ This is astonishing at least in the sense that the Court found the Commission guilty of failure to act, but did not impose on the Commission *how* to act in this case. Therefore, it seems that the Court's ruling did not prevent the Commission from adopting a different proposal, for example, rejecting the authorization. It shows, however, that when it comes to taking the final decision the Commission does not see itself as a body with substantive discretion able to make a

⁸² At the time of writing no decision on Maize 1507 was yet adopted.

⁸³ Commission Decision of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (*Solanum tuberosum* L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch, C (2010) 1193, OJ (2010) L 53/11.

⁸⁴ European Commission MEMO/13/960, Statement by EU Health Commissioner Tonio Borg, on Commission's decision on GM Pioneer 1507, 6 November 2013, available at [http://europa.eu/rapid/press-release MEMO-13-960_en.htm](http://europa.eu/rapid/press-release_MEMO-13-960_en.htm) (last accessed 28 February 2016).

policy judgment on the basis of scientific information, if it means deviating from its expert agency.

3. Judicial responses

In both (the *Herculex* and the *Amflora*) cases, the EU general court (hereinafter the Court) had for the first time the opportunity to scrutinize the administrative process of GMO authorisations, thereby acting in its function as an administrative court. In doing so, it revealed an understanding of administrative legitimation of the Commission along the lines of the deliberative model. While granting the Commission a wide discretion to make factual assessments on the basis of the EFSA opinions, the Court stressed the importance of the requirement to act consistently and to provide reasons on the part of the Commission. However, the legal nature and significance of both judgments are rather different.

In the *Herculex* case, the Court ruled on an action for the Commission's failure to act brought by Pioneer.⁸⁵ Under the comitology rules applicable at the time, the Commission was obliged to submit its draft decision on *Herculex* to the Council 'without delay.'⁸⁶ However, the Commission did not proceed with this step. It was not disputed among the parties that the Commission exceeded the time period for forwarding its draft decision to the Council as laid down in the relevant rules. The question was whether this delay could be justified.

What is interesting about this case is the Commission's defence strategy before the Court. It framed its role in the authorization procedure heavily in terms of the deliberative model asserting that when deciding on when, and if at all, to proceed with the Council stage of the comitology procedure it must be granted a wide discretion to consider a variety of factors. Making a reference to the *Pharos* judgment⁸⁷ of the Court of Justice the Commission argued that 'it must have sufficient time to consider the possible courses of action in the light of the complexity of the problem and the need to ensure that its proposal was not rejected by the

⁸⁵ Case T-164/10 *Pioneer Hi-Bred International v European Commission* ECLI:EU:T:2013:503.

⁸⁶ Article 18 (1) of Directive 2001/18 together with Article 5 (2) of Council Decision laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/468/EC).

⁸⁷ C-151/98 P *Pharos v Commission* ECLI:EU:C:1999:563, where the Court ruled that when confronted with highly sensitive and complex matters the Commission had the right to request a new scientific opinion.

Council.’ Moreover, the Commission invoked the need at the time to consider the political circumstances of the on-going legislative reform on GMO cultivation.

The Court, however, rejected these arguments. It ruled against the Commission rebuking both the inconsistency⁸⁸ and insufficiency of reason-giving by the Commission as follows

‘the Commission had not raised *any issue of scientific uncertainty* that has been reported to it concerning the placing on the market of maize 1507. It *merely stated* that the period (...) was necessary in order to examine the various possible courses of action, but *without explaining* what the various available options were” (emphasis added).⁸⁹

The Court’s language reflects an understanding of administrative legitimation along the lines of the deliberative model. Firstly, the phrase ‘*any issues of scientific uncertainty reported to it*’ (see above) could be read as a sign of recognition of the scientific complexity of risk assessment entailing that not only EFSA opinions, but also uncertainty information coming from other sources could have been accepted as justification for delaying the procedure. Secondly, the Court seems to reject the Commission’s arguments also on the ground that they were not sufficiently explained. The Commission ‘*merely*’ asserted that it needed to exercise its discretion ‘*without explaining*’ better to the Court what are the relevant considerations in this regard.

Case T-240/10 Hungary v Commission (Amflora)

The *Amflora* judgment of the Court, in contrast, contains a more far-reaching engagement with the Commission’s role as risk manager acting under the conditions of scientific uncertainty. Following the Commission authorization of *Amflora* Hungary has brought an action before the EU General Court seeking the annulment of this decision.⁹⁰ Hungary’s pleas focused mainly on the quality of EFSA’s risk assessment, and the precautionary principle.⁹¹ It claimed that the Commission erred manifestly in its assessment, and infringed the precautionary principle; and that the

⁸⁸ The Court pointed out that on 2 March 2010 the Commission authorized another controversial GMO, namely the *Amflora* potato (see above at 2.2).

⁸⁹ See above (n 86) at para 53.

⁹⁰ Case T-240/10 *Hungary vs Commission* ECLI:EU:T:2013:645.

⁹¹ *Ibid* at para 67-68.

authorization was based on a risk assessment that was 'deficient, inconsistent, and incomplete,' which amounted to a breach of the Commission's obligations under Directive 2001/18,⁹² namely to follow the principles of environmental risk assessment laid down therein, and to take into particular consideration GMOs, such as *Amflora*, which contain antibiotic resistant marker genes. The plaintiff therefore asked the Court for a substantive review of the Commission decision including of the quality of its factual basis.⁹³

The Court, however, did not rule on these claims, but chose a procedural detour around them instead. It raised, of its own motion, a new potential ground for annulment, namely the infringement of essential procedural requirements.⁹⁴ The Court ruled that the Commission breached a procedural rule governing the adoption of the authorization decision, namely the obligation to re-submit its draft decision on *Amflora* to the competent comitology committee following the 2009 consolidated EFSA opinion.

As explained above, the Commission, before adopting the final decision, did not re-submit to the comitology committee the amended draft of this decision, together with the consolidated EFSA opinion and the dissenting opinion, which would have effectively restarted the comitology process. Instead, the Commission following the Council's failure to adopt a decision on the initial draft went on to authorize the product. In its defense, the Commission argued that it was not necessary to resubmit the proposal, because its enacting terms were identical to the initial draft, which had already been discussed in the committee. Moreover, the new proposal contained no changes in substance.⁹⁵

⁹² Article 4 (2) of Directive 2001/18 states that "Any person shall, before submitting a notification under part B or part C, carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B."

⁹³ Thereby following a recent trend in EU case law to intensify the standard of review of science-based decisions, see Vos, Ellen, 'The European Court of Justice in the Face of Scientific Uncertainty and Complexity' in Dawson, Mark, De Witte, Bruno and Muir, Elise (eds), *Judicial Activism at the European Court of Justice* (Cheltenham: Edward Elgar).

⁹⁴ See above (n 91) at para 70.

⁹⁵ See above (n 91) at para 74.

The Court disagreed. It found the new proposal not to be identical with the one initially submitted to the committee, because the scientific basis on which the Commission relied when adopting the former had changed. The Court considered the updated scientific basis of the proposal as part of the reasoning on which it was based, therefore concluding

‘It must therefore be noted that the Commission, in deciding to seek a consolidated opinion from EFSA as result of the observations of an NGO and of the Danish Government, and in using that opinion in particular as a basis for the contested decisions without allowing the competent committees to take a position either on the opinion or on the statement of reasons on which the amended draft decisions were based, disregarded the regulatory procedure laid down in Article 5 of Decision 1999/468’.⁹⁶

From the point of view of administrative legitimation, two aspects of this judgment deserve further attention. Firstly, the Court avoided reviewing the EFSA opinion as the basis of the Commission authorization decision.⁹⁷ It did not examine the quality of the scientific risk assessment nor did it scrutinize Hungary’s claim that the Commission had breached the principles of environmental risk assessment and the precautionary principle. Here the Court could arguably be criticized for being too pragmatic, and for understanding in too narrow terms the role of judicial review in risk regulation. It has been argued that a more proactive and less differential role of the Courts is desirable when reviewing the informational basis of science-based measures. The principle of the public administrator’s duty of care (i.e. the duty to examine carefully and impartially all the relevant aspects of the case) is particularly important in this regard. EU Courts have used the latter in a line of case law aiming at scrutinizing the Commission’s interpretation of information of complex economic or technical nature.⁹⁸ More importantly, the duty of care is inherently linked to the Commission’s duty to pursue public interests enshrined in EU legislation when exercising its administrative discretion. In the words of Mendes,

⁹⁶ See above (n 91) at para. 83.

⁹⁷ Which it could have done, as in other similar cases, by reviewing the Commission discretion in ascertaining the factual basis of the decision.

⁹⁸ For an overview of the case law see Joana Mendes (2016), *Discretion, Duty of Care and Public Interests in the EU Administration: the Limits of Law* (unpublished manuscript at file with the authors).

‘It is this assessment of the circumstances in relation to the interpretation – and construction – of the public interests envisaged by law that ought to guide the substantive choices of the administrative decision-maker.’⁹⁹

Judicial review of the Commission’s compliance with its duty of care, then, becomes an important mechanism in ensuring the public interest orientation of administrative decisions. In the field of risk regulation, the Courts could contribute to unveiling the value-laden choices behind scientific risk assessment including the uncertainties surrounding it by scrutinizing more closely both the process and informational basis of scientific opinions (including e.g. consistency, independence, and transparency of methodological choices).¹⁰⁰ It seems that the Court in this case has missed an opportunity to fulfil its function as an ‘informational catalyst’.¹⁰¹

Secondly, the reasoning of the Court in this case reveals an understanding of administrative legitimation along the lines of the deliberative model. This is evident in its understanding of the nature of the EU comitology procedure as fulfilling an important function in securing the composite or cooperative nature of the EU public administration.¹⁰² Comitology has been described as providing a network structure, which transforms top-down supranationalism into a process of deliberative cooperation between national representatives and supranational institutions, and which marries techno-scientific and political rationalities in this process.¹⁰³ Therefore, the Court’s procedural approach can be read as aiming to preserve the shared political responsibility of the participating institutions for administering GMOs, and to prevent the Commission from acting unilaterally.¹⁰⁴ It is obvious from this judgment that given the complexity of the risk assessment of *Amflora*, expressed among other in the existence of conflicting scientific opinions, the Court refused to accept the Commission’s unilateral move to proceed to authorization without seeking the opinion of national representatives in the comitology committee. This shines especially through the following pronouncement: the ‘great political

⁹⁹ Ibid.

¹⁰⁰ See Shapiro, Sidney, Fisher, Elizabeth and Wagner, Wendy (n 24); Scott, Joanne and Sturm, Susan (n 29).

¹⁰¹ Scott, Joanne and Sturm, Susan (n 29). Note however that there is a fine line between a more intense procedural review of the scientific basis of administrative decisions and a more intrusive substantive review, in which the Court would substitute the scientific judgment by its own judgment, see for the latter Case T-229/04 *Sweden v Commission* ECLI:EU:T:2007:217.

¹⁰² Schmidt-Assmann and Schöndorf-Haubold (n 21); Hofmann and Turk (n 26).

¹⁰³ Joerges and Neyer (n 27); Sabel and Zeitlin (n 27).

¹⁰⁴ See Weimer (n 42); Weimer (n 5).

sensitivity' and the 'complexity of the subject-matter' of GMO authorizations 'argue exactly in favour of the Commission's obligation to submit the amended drafts of the authorization decisions in relation to the *Amflora* potato to the competent regulatory committees, and where applicable, to the Council.'¹⁰⁵

Furthermore, despite of its restraint in reviewing the Commission decision including its informational basis, the Court nevertheless managed to act as an accountability forum for the Commission's actions in this case. It has done so by weaving process values such as reason-giving and consistency on the part of the Commission into its review of procedural compliance. The Commission claimed that the scientific basis of its last amended draft (namely the 2009 EFSA consolidated opinion) did not change in comparison to the previous drafts, and that therefore there was no 'substantive amendment' that would have required going back to the committee. In response the Court dedicated a significant part¹⁰⁶ of the judgment to examining the consistency of the Commission's actions throughout the authorization process effectively holding the latter to account for the exercise of its administrative discretion. In doing so it revealed an understanding of the role of the Commission in this process according to the deliberative model.

The Court found three major differences between EFSA's consolidated opinion of 2009 and EFSA's earlier opinions, which also confirm our previous findings of the EFSA's gradual shift towards more uncertainty tolerant risk assessments. The Court walked a tight rope between comparing the different EFSA opinions without actually evaluating their quality, explicitly insisting that it was 'not necessary to rule on whether the risk assessments carried out in each of those opinions were well-founded.' The first difference, according to the Court, was that the 2009 opinion was authored not only by the GMO panel, but also by the BIOHAZ panel, and was drafted in collaboration with the EMA. The other two differences were identified as follows:

'Secondly, the findings of EFSA's consolidated opinion of 2009, on which the amended proposals are based, place *greater emphasis on scientific uncertainty* ('not fully understood', 'limitations', 'uncertainties', 'unlikely') and *dangers* ('cause for global concern') than the findings of EFSA's 2005 opinion ('no reason to assume', 'would not pose any additional risk', 'no significant risk', 'no adverse environmental effects were observed or

¹⁰⁵ See above (n 91) at para 110.

¹⁰⁶ See above (n 91) at paras 93-104.

would be likely') and the EFSA declaration of 2007 ('will not be compromised', 'extremely low probability', 'very unlikely', 'does not pose a risk'), on which the earlier drafts are based. Thirdly, EFSA's consolidated opinion of 2009 contains dissenting opinions from two members of the BIOHAZ panel emphasising scientific uncertainty, whereas EFSA's 2005 opinion and the EFSA declaration of 2007 did not include any dissenting opinion.'¹⁰⁷ (emphasis added)

Moreover, the Court referred to the Commission's written submissions made in the course of another judicial action against the Commission, namely the action for failure to act filed by the applicant BASF back in 2008 before the Commission adopted the *Amflora* authorization.¹⁰⁸ In that procedure the Commission defended the delay in the authorization procedure as being caused by unclear, ambiguous and contradictory EFSA opinions, which justified the need to ask EFSA for a new consolidated opinion. It argued that given the scientific uncertainty underlying *Amflora*'s risk assessment it had exercised its discretion appropriately, and according to the precautionary principle decided to ask EFSA for another opinion. The Court summarized the Commission's approach as follows:

'It is apparent from those assertions that the Commission, at the very least after receiving the letters from an NGO and the Danish Government, considered that the EFSA declaration of 2007, which was inconsistent with EFSA's 2004 opinion read in conjunction with the EMA declaration of 2007, constituted *a scientific basis too uncertain* for the adoption of the proposed decisions already submitted to the regulatory committees and to the Council and that, having regard to the *pervading scientific uncertainty*, it was incumbent upon the Commission, *pursuant to the precautionary principle*, to consult EFSA once more in order to obtain clarification on the scientific assessment of the risks linked to the *Amflora* potato, in particular to the *nptII* gene.' (emphasis added)¹⁰⁹

The Court took the Commission by the word. It was rigorous in showing that it was contradictory of the Commission to argue that the EFSA consolidated opinion was merely a confirmation of previous EFSA opinions, and not significant enough to alter substantively the scientific basis on which the final *Amflora* authorization was based.

¹⁰⁷ See above (n 91) at para 98.

¹⁰⁸ Case T-293/08 *BASF vs Commission* closed by order of the Court of 9 June 2010 due to lack of the need to adjudicate.

¹⁰⁹ See above (n 91) at para 103.

And, *en passant*, the Court also proved to be quite sensitive to the pervasive scientific complexity of the authorization process.

Read along the lines of the deliberative model of administrative legitimation the Court's reasoning indicates that the EU public administration, understood as a composite and cooperative institution, has a relatively wide substantive discretion in deciding on GMO authorizations. In exercising this discretion it must get the procedure right, cooperate, avoid contradictions, and provide for a sound and consistent reasoning of its actions. In contrast, nothing in this judgment points to an understanding of the role of the Commission along the line of the control model as being obliged to follow the EFSA's final recommendation, to disregard the uncertainties communicated by EFSA as irrelevant, and as not having the discretion to take into account dissenting opinions.

4. Conclusions

This paper has argued that key notions of EU risk regulation, such as science, risk, uncertainty, risk assessment and risk management are significantly shaped in the legal administrative discourse through which EU risk regulation takes place. It has analyzed EU administrative and judicial decision making in the case of two highly controversial GMO authorizations tracing how notions of administrative legitimation (i.e. ideas of how the EU public administration is constituted, controlled and held to account) have co-produced notions of GMO risks as well as understandings of the role of scientific experts in administrative decision-making on risk.

The findings indicate that different models of administrative legitimation, namely the control model and the deliberative model, are competing with each other in EU legal administrative practice (see above at 1.) Moreover, different actors (EU agency, Commission, courts) can embrace different notions depending on the stage of the administrative process (risk assessment or risk management) and the level of contestation and pressure from other actors (e.g. national scientific authorities, NGOs, or courts).

In the GMO cases analyzed the EU expert agency EFSA has initially understood its role mainly in terms of the control model, namely as being instrumental in enabling

decision-making by the Commission by providing the latter with ascertained facts about quantifiable risks. It therefore framed its risk assessments in an uncertainty intolerant way, and tried to establish scientific authority vis-à-vis other scientific sources. However, over time EFSA has responded to pressure and contestation coming from national authorities and NGOs by gradually moving towards the deliberative model. This resulted in more nuanced risk assessment communicating scientific uncertainty more openly, and in one case including a dissenting opinion.

The Commission, in contrast, has shifted in the opposite direction. During the phase of risk assessment (which took many years in both cases investigated) the Commission assumed the role of facilitating deliberation among different actors and using its discretion to delay the process in order to enable all actors to voice their concerns. Interestingly, it interpreted the precautionary principle as justifying delay. In contrast, the closer the Commission approached the final decision, the more it followed the control model. The Commission attributed a major role to EFSA in determining the outcome of the authorization procedure. EFSA's majority opinion was seen as a constraint on the Commission's exercise of discretion not leaving space to consider instances of scientific uncertainty or dissenting opinion. Moreover, when adopting the final decision the Commission did not see itself as entitled to invoke the precautionary principle. Thus, the final decision was justified mainly in (majority) scientific terms leaving barely any space for the exercise of policy judgment on the part of the Commission. And for that purpose, scientific expertise was construed as being able to provide sufficient facts and certainty about GMO risks. This shows that the Commission regarded scientific expertise as a surrogate for legislative control in the control model. Given the wide framework character of EU legislative provisions, the fiction of an objective and prescriptive law in the control model has been replaced with the fiction of an objective expert that is able to tame administrative discretion.

Interestingly, the Commission's preference for the control model cannot be explained by judicial approaches to administrative legitimation. The rulings of the EU General Court analysed in this paper reveal the continuing relevance of *Pfizer* and the deliberative model expressed therein. In other words, the Court grants the Commission a wide discretion in ascertaining the factual basis for risk decisions while imposing procedural requirements of reason giving, consistency, and compliance with all legally prescribed procedures. While shying away from directly

reviewing the quality of EFSA's risk assessments, in the *Amflora* case the Court was nonetheless able, along the lines of the deliberative model, to hold the Commission to account by emphasizing the cooperative nature of the EU public administration as well as process values such as reason-giving and consistency.

This paper, therefore, revealed an interesting discrepancy between the Commission's and the Courts' approach to administrative legitimation, which should be subject to further research. From the perspective of the EU courts, the Commission's exercise of discretion is legitimated in terms of the deliberative model: as risk manager the latter has the responsibility, in a scientifically informed way, to exercise a *political judgment*. The Commission, however, according to the control model, sees its discretionary space radically reduced to following the lead of its expert agency. In a highly politicized and contested field of EU risk regulation the Commission sees scientific expertise as the main, if not the only way of justifying its decisions. It does, in other words, *not* exercise political judgment when it comes to GMO authorizations other than to delay the process, and *not* to decide. It follows that the *Pfizer* Court's emphasis of political legitimacy together with the recognition of the limits of scientific legitimacy is not meaningful in practice. To put provocatively, the Court constructs political legitimacy of the EU administration without questioning the reality of that legitimacy.¹¹⁰ This raises questions with regard to the viability of the deliberative model indicating that the search for the adequate model of administrative legitimation of the EU public administration is far from being over.

¹¹⁰ See also Anderson (n 7).