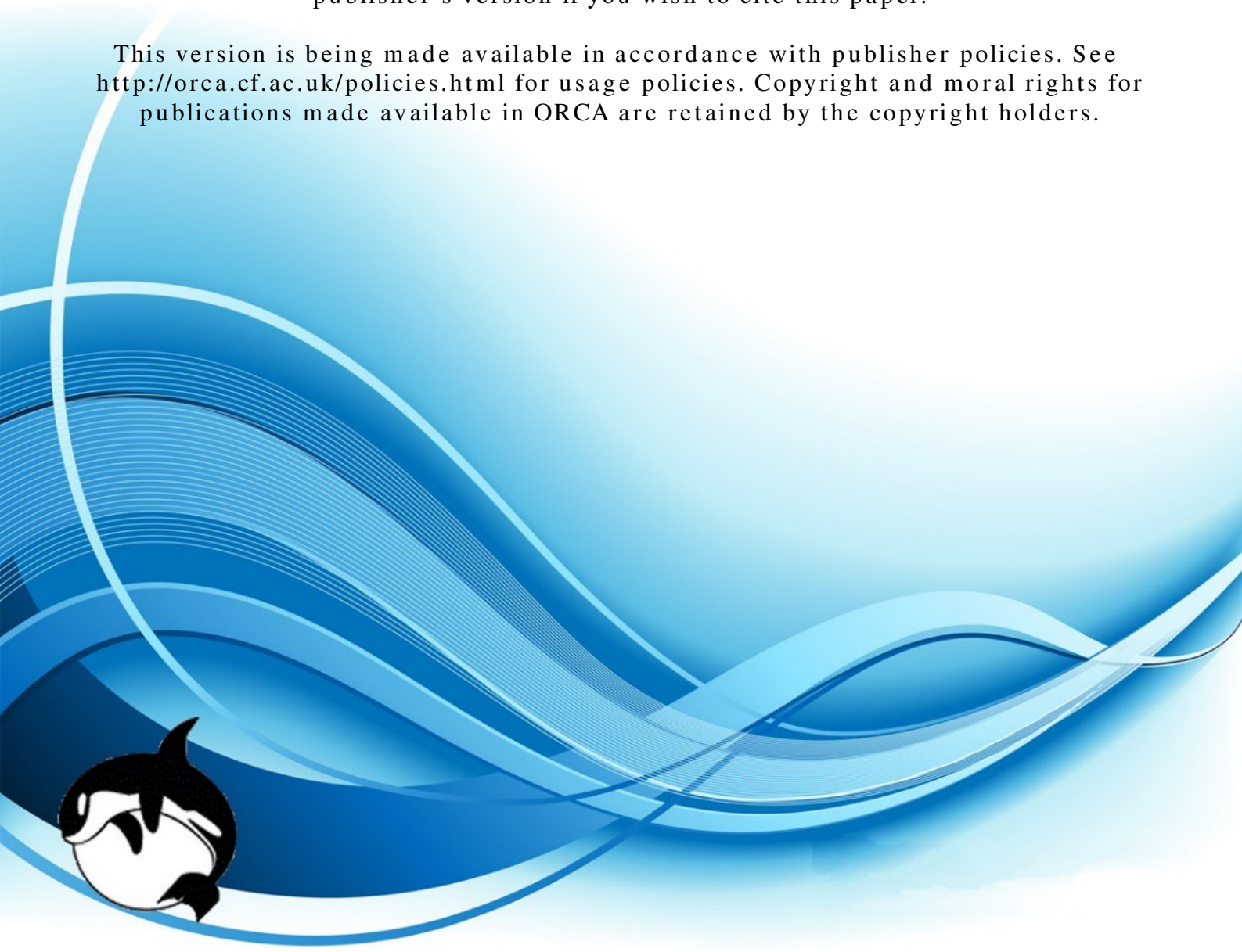

The Precautionary Principle and Non-scientific Factors in the Regulation of Biotech Foods

In the current climate of rising food insecurity, new technologies such as modern agricultural biotechnologies, i.e. the genetic modification of plants and animals, and the cloning of animals, are identified as one of the main solutions to achieve sustainable intensification.[1] The development of modern agricultural biotechnologies and their derived products have been controversial. Biotech foods are allegedly underpinned by scientific uncertainty. To regulate such technologies and to ensure information and safety, the European Union has adopted a precautionary approach relying on premarket authorisation and mandatory labelling. Despite these provisions, biotech foods continue to attract close scrutiny, in particular from the EU public. Against this background, this opinion explains why I came to research biotech foods, how these foods are currently regulated in the EU and why the existing regimes could be improved to allow for the consideration of consumer preferences and more generally non-scientific factors.

I. Why biotech foods?

Coming from a family of dairy farmers and horticulturists, I have particular attachments to the biodiversity, food, and the social relationships that can be created through such mediums. Further, I have always been interested in science and technological innovations. I have translated this passion into my research since finishing my undergraduate Law degree. Through the combination of my personal background and education, I decided to focus my PhD research on the transatlantic policy and regulation of products resulting from modern agricultural biotechnology. As a PhD student undertaking this type of research I stumbled across the fact that biotech foods were received very differently in the EU and the US: the EU restricts their use and requires premarket authorisation and labelling, while the US allows their development and expansion by adopting a more laissez-faire approach. The risk assessments of these modern agricultural biotechnologies rely on similar scientific data and came to similar conclusions: such technologies are safe. Therefore, why are the US and EU approaches so different?

Multiple aspects can be mentioned when explaining these regulatory differences but two are of particular interest when writing about risk regulation and biotech foods: the roles of scientific uncertainty, especially the precautionary principle, and non-scientific factors.[2]

II. The precautionary principle as the basis to EU regulation of biotech foods

Risk plays a crucial role in the regulation of biotech foods and is particularly significant since scientific evidence is inconclusive. To handle the risks and scientific uncertainty underpinning biotech foods, the EU has created distinctive and separate frameworks for biotech foods. The regulatory intervention of the European legislature in the domain of GMOs and their derived foods is "not founded on scientific certainty, but is on the contrary motivated by the uncertainty

[1] See e.g., Commission Communication, 'The CAP towards 2020: Meeting the Food, Natural Resources and Territorial Challenges of the Future', COM(2010)672 final; European Commission, 'Sustainable Agriculture for the Future We Want' (2012); and The UK Government Office for Science, 'Foresight Report on The Future of Food and Farming: Challenges and Choices for Global Sustainability' (2011).

[2] Due to word constraints, the US regulation of biotech foods will not be mentioned here.

of the existence and scope of the potential risk of these organisms".[3] The EU adopts a "better safe than sorry" or precautionary approach to manage the uncertainty created by biotech foods. GM foods from plants and animals are regulated under the Food and Feed Regulation and Regulation 1830/2003 whilst cloned foods presently fall under the scope of the 1997 Novel Foods Regulation and from 1 January 2018, the 2015 Novel Foods Regulation.[4] As noted, these regulations require the premarket authorisation and labelling of such products. The established mechanisms create a safe and precautionary commercialisation of such foods following thorough risk assessment and risk management decisions.[5]

To minimise risks, precaution is the linchpin of the regulation of EU biotech foods. Under EU law, the 2002 General Food Law Regulation (GFL)[6] enshrines the precautionary principle[7] as a fundamental element of the EU food safety system and establishes the first legally binding definition of the principle within EU Law.[8] The precautionary principle is central, applicable in all food safety legislation. Commonly, the precautionary principle provides that regulatory action is not precluded and should not be postponed in the face of scientific uncertainty. For de Sadeleer, the precautionary principle is significant within the "broader context of risk analysis, which comprises a two-step process: risk assessment and risk management".[9] As it is an encompassing principle within a risk analysis, the precautionary principle can further advance relationships between science (risk assessment) and politics (risk management) and the various actors involved.[10] Both phases are strongly intertwined.

The role of the precautionary principle in the risk regulation of biotech foods is interestingly restricted to the risk management stage in the GFL.[11] This limitation emanates

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[3] Z.K. Forsman, 'Community Regulation of Genetically Modified Organisms: A Difficult Relationship Between Law and Science' (2004) 10 European Law Journal 580, 583.

[4] See respectively Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, O.J. 2003, L268/1; Regulation (EC) 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, O.J. 2003, L268/24; , Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients, O.J. 1997, L43/1; and Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on Novel Foods, O.J. 2015, L 327/1.

[5] See e.g., M. Lee, *EU Regulation of GMOs: Law, Decision-making and New Technology* (Edward Elgar, 2008).

[6] The GFL replaces the patchwork of rules that existed previously, provides harmonized food safety rules and asserts consumers at the centre of the European food safety system by establishing food safety as the primary objective of food law. See Art. 1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food Law, establishing the European Food Safety Authority and laying down procedures in natters of food safety, O.J. 2002, L31/1.

[7] For more on the precautionary principle, see e.g., J. Cazala, 'Food Safety and the Precautionary Principle: The Legitimate Moderation of Community Courts', (2004) 10 European Law Journal 544; C. Macmaolain, *EU Food Law: Protecting Consumers and Health* (Hart, 2007) 202; and N. de Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law', (2006) 12 European Law Journal 146. For more on the role of the precautionary principle in the EU regulation of foods, see e.g. A. Szajkowska, 'The impact of the definition of the precautionary principle in EU food law' (2010) 47 CML Rev. 173; and A. Szajkowska, *Regulating Food Law: Risk Analysis and the Precautionary Principle as General Principles of EU Food Law* (Wageningen Academic Publishers, 2012).

[8] Art. 7 GFL.

[9] N. de Sadeleer, The Precautionary Principle in European Community Health and Environmental Law: Sword or Shield for the Nordic Countries?, in N. de Sadeleer (eds), *Implementing the Precautionary Principle: Approaches from the Nordic Countries, EU and US* (Earthscan, 2007) 10, 18. See also, Anker and M. Grossman, 'Authorization of genetically modified organisms: Precaution in US and EC law' (2009) 1 European Food and Feed Law Review 3, 5.

[10] De Sadeleer, supra, note 9, 35.

[11] Art. 6(3) GFL.

from the 2000 Commission's Communication on the Precautionary Principle.[12] The precautionary principle offers risk managers some leeway where they can weigh policy alternatives, consult with all interested parties and consider risk assessment and other relevant non-scientific factors, such as the ethics and morals of consumers. Nevertheless, the existing dichotomy between the risk assessment and risk management phases prevents non-scientific factors from playing a role in the risk assessment phase for biotech foods and favours the scientific advice received. Decision-makers cannot be precautionary in the risk assessment stage. Bergkamp argues that by restricting the precautionary principle to risk management, the Commission "denies the precautionary principle special status as an overarching concept".[13] This argument is reinforced by the fact that other legitimate factors, which could include non-scientific factors, are only taken into account in the risk management phase and not during risk assessment under the GFL, the Food and Feed Regulation and the 2015 Novel Foods Regulation.[14]

The precautionary principle and its various interpretations challenges the prevalence of this dominant position of scientific evidence within the decision-making process and privileges a populist model towards biotech foods. For populists, feelings and concerns have normative force and ought to be taken into account. The principle broadens the scope of approaches that can be considered. However, the strict divide between risk assessment and risk management in the regulation of foods, including biotech foods, makes it difficult to take into account the general context and perceptions of such foods and prevents decision-makers from adopting a comprehensive view of the risks and perception of risks at stake. This divide promotes the existence of a technocratic model for biotech foods and favours scientific evidence.[15] It reflects how risk and risk regulation can be utilised as legitimating devices.[16] Risk assessment methods undertaken by experts take little or no account of the social and ethical ramifications of technologies. This is supposedly left to decision-makers under the risk management phase. But, as observed, they are heavily influenced by scientific evidence.

III. Towards a risk assessment encompassing non-scientific factors

Regulating technological innovation is critical to reduce and mitigate risks but is also problematic for states, particularly "when different stakeholders have differing views over the existence of risks and how they should be regulated, as well as which factors should be relevant to regulation-making".[17] The EU public has had mixed approaches concerning modern agricultural biotechnology and is concerned such technology. This is due to the scientific uncertainty raised by the technology, in particular about the environment and public health, and due to the animal health and welfare concerns relating to the cloning and genetic modification of animals.[18] Gaining consumer confidence and acceptance of these foods has

[12] European Commission, 'Communication from the Commission on the Precautionary Principle', COM(2000) 12. For more on the Communication, see J.D. Graham and S. Hsia, 'Europe's Precautionary Principle: Promise and Pitfalls' (2002) 5 Journal of Risk Research 371.
[13] L. Bergkamp, 'Understanding the Precautionary Principle' (2002) 10 Environmental Liability, Part II, 67, 72.
[14] Art. 7(1) Food and Feed Regulation; Art. 3(12) GFL; and Art. 10(6) 2015 Novel Foods Regulation.
[15] See e.g. M. Dani, 'Assembling the Fractured European Consumer' (2011) 36 European Law Review 362.
[16] J. Black, 'The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom' (2005) Public Law 512, 519.
[17] L. Petetin, 'Frankenburgers, Risks and Approval' (2014) 5(2) European Journal of Risk Regulation 168, 172.
[18] See e.g. Gaskell et al., "Europeans and biotechnology in 2010: Winds of change?", (Special Eurobarometer 341, 2010); and The Gallup Organization, "Europeans' attitudes towards animal cloning", (Flash Eurobarometer 238, October 2008).

proved problematic as EU citizens feel that the regulatory frameworks do not reflect their preferences for mandatory labelling and potential bans.

Public perception of risk is multi-faceted, embedded in values, morals and ethics, and depends on social influences. Two schools oppose each other when scrutinising the "risk regulation and public" relationship. For Sunstein, risk regulation ought to be kept away from the irrational public.[19] Public concerns are a "source of risk, and so risk management is partly an exercise in governing 'unruly perceptions'".[20] In contrast, Jasanoff argues for the consideration of other factors in risk assessment rather than a blindness to technology's disruption posed to patterns of living.[21] Ordinary people are not mistaken and their perceptions about risks involve evaluative judgments that are worthy of respect.[22] The development of technological innovations "no longer rests with governments alone but must be shared with increasingly knowledgeable publics".[23]

In the EU, the scientific approach to assessing risk results in a fragmented and compartmentalised approach towards measures relating to biotech foods to the detriment of other factors and values which dominate the decision-making process. A characteristic of new challenges, such as modern biotechnology, is that "paradigms such as safe science or rigid distinctions between risk assessment and risk management are highly traditionalist, and are unable to accommodate the full texture and range of either the politics of risk or the politics of anxiety".[24] Risk is not just a matter for the experts, various factors, such as the institutional, social, and economic contexts, play an important role in the determination of the threshold above which the risk is judged unacceptable.[25] Risk is more than a calculation of probabilities by experts and generally goes beyond conventional tools of prediction, such as cost-benefit analysis.[26] The divide should be removed to unable non-scientific factors to play a role. This means that the European way to perceive and assess risk relating to (biotech) foods must be adapted as society evolves.

The contentiousness of these issues is reflected in the tensions between actors involved in the EU decision-making process. A rising number of Member States wish to listen to their citizens and want EU rules to be modified to reflect citizens' concerns towards such foods. Asymmetric relationships between competing European and national policies have led EU Member States to challenge the existing regulatory frameworks. Recent proposals aim at tackling these limitations within the decision-making process for biotech foods. In 2015, the Commission prepared a proposal including an "opt-out" clause that would have allowed Member States to limit trade in GM foods while other Member States could have profited from such trade.[27] Restrictions on the import of GM foods were limited to specific grounds, such as

[19] See e.g., H.F. Chang, 'Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear but Fear Itself?' (2003-2004) 77 Southern California Law Review 743.
[20] M.L. Flear and A.Vakulenko, 'A Human Rights Perspective on Citizen Participation in the EU's Governance of New Technologies' (2010) 10 Human Rights Law Review 661, 682.
[21] S. Jasanoff, 'Biotechnology and Empire: The Global Power of Seeds and Science' (2006) 21 OSIRIS 273, 288.
[22] P. Slovic, *The Perception of Risk* (Earthscan Publications, 2000).
[23] Jasanoff, supra, note 21, 291.
[24] D. Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life' (2005) 30 European Law Review 649, 673.
[25] De Sadeleer, supra, note 9, 160.
[26] S. Jasanoff, 'Technologies of Humility*:* Citizen Participation in Governing Science' (2003) 41 Minerva 223, 224.
[27] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM (2015)177 final.

ethics and moral. Unfortunately, at the end of 2015 the European Parliament rejected the proposal preventing non-scientific factors from playing a role in the decision-making process. The justification for the vote was based on MEPs not willing to see trade barriers rebuilt within the single market by allowing opt-outs from the Europe-wide approval system.[28]

This proposal would have paralleled and supplemented the rights given to Member States to restrict or prohibit the cultivation of GMOs under the Directive (EU) 2015/412.[29] This directive creates an "opt-out" clause which modifies the approval system for GM crop cultivation. The directive establishes a balance between an authorization procedure at EU level based on risk assessments and the option for Member States to express the concerns of their citizens without having to rely on scientific evidence or to take into account other Member States. The directive reinforces the democratic process for GMO approvals by allowing Member States to consider non-scientific factors.[30] There is no reason why this new type of EU approach could not be utilised more generally for food products. The existing competition between national values and policy preferences is not sustainable.

To conclude, the accommodation of non-scientific factors in the authorisation procedure of biotech foods would reinforce the regulatory system. As new modern agricultural biotechnologies develop in changing societies, so should their associated regulatory frameworks.

This opinion would not be complete without mentioning the "B" word. Brexit and its consequences could be detrimental to the regulation of biotech foods and modern agricultural biotechnology in the UK. The UK Conservative led Government that began in 2010 has consistently favoured GM and animal cloning.[31] The consequences of this pro-biotech stance on farming and the food supply chain could be damaging if accompanied by deregulation leading to a spiral to the bottom. Further, the issues of coexistence and trade within the UK as a whole could be affected and negatively impacted as Wales, Scotland and Northern Ireland are against GM and have established moratoria against their cultivation but England appears to be pro-GM.

[28] European Parliament, 'Parliament Rejects National GMO Bans Proposal', 28 October 2015, http://www.europarl.europa.eu/news/en/news-room/20151022IPR98805/Parliament-rejects-national-GMO-bans-proposal.

[29] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of Genetically Modified Organisms (GMOs) in their Territory, [2015] O.J. L68/1.

[30] The amendment is in line with President Juncker's commitment 'to give the democratically elected governments at least the same weight as scientific advice when it comes to important decisions concerning food and environment'. See Euractiv, 'EU Agreement Opens Door for new GMO Cultivation in 2015', 5 December 2014, http://www.euractiv.com/sections/agriculture-food/eu-agrees-bring-back-gmos-2015-310620.

[31] See L. Petetin, 'The Revival of Modern Agricultural Biotechnology by the UK Government: What Role for Animal Cloning?' (2012) 6 European Food and Feed Law Review 296.