Gene Editing for the EU Agrifood: Risks and Promises in Science Regulation

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In today's innovation-driven agrifood domain, the perspective of using so-called New Breeding Techniques (NBTs) on both non-human animals and plants calls into question the regulatory approach (process/product-based) to be used, while asking for a critical reflection on the potential impact of products on the industrial sector and citizens. A possible reconfiguration of European (EU) discipline will have to grapple with not only agrifood market's interests and needs, but mostly and primarily with the growing quest for public and participatory discussion on the current dominant vision on life sciences. Only through restoring visibility to the intertwining of knowledge production will it be possible to obtain EU governance of gene editing that is more authoritatively reliable from a scientific stance, as well as more transparently discussed and democratically shared at legal and policy level.

I. Questioning gene editing techniques

In the European (EU) "knowledge-based bio-economy",[1] where products are derived from biological sources,[2] the concept of "innovation" in the agrifood sector is increasingly shaped by an intricate array of diverse yet intertwined methods and practices. Varied models of "scientificity"[3] interact, co-exist and combine with pioneering technologies[4] – from ICT to synthetic biology, from animal cloning to nanotechnologies – bringing to the attention of the EU legislator a varied set of ethical and legal issues that are difficult to resolve.

In such a composite, data-centric scenario, the use of so-called New Breeding Techniques[5] (NBTs) on both plants and non-human animals (hereafter animals) is

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1 European Commission, *New Perspectives on the Knowledge-based Bio-economy* (Conference Report 2005).

2 OECD (Organisation for Economic Co-operation and Development), *The Bioeconomy to 2030: Designing a Policy Agenda* (Paris, OECD 2005).

3 Such as organics, agroecology and regenerative agriculture. See L Leone, *Organic Regulation – A Legal and Policy Journey between Europe and the United States* (Libellula, Tricase 2019).

4 EGE (European Group on Ethics in Science and New Technologies to the European Commission), *Ethics of Modern Developments in Agricultural Technologies* (Luxembourg, Office for Official Publications of the European Communities 2009).

5 SAM (Scientific Advice Mechanism), *New Techniques in Agricultural Biotechnology, High Level Group of Scientific Advisors Explanatory* (Luxembourg, Publications Office of the European Union 2017).

European Journal of Risk Regulation, 10 (2019), pp. 766–780
doi:10.1017/err.2019.55

increasingly surrounded by great promises and huge expectations, as it allows individual genetic modifications to be obtained more precisely and more quickly than with conventional breeding techniques.[6] At the same time, though, it has re-opened and sharpened the endless debate on which ethical-legal framework is appropriate to accommodate processes and products related to technoscience. Indeed, as an advanced molecular biology technique that can produce precisely targeted modifications in crops and animals,[7] gene editing displays distinguishable characteristics from genetic engineering. The EU legal classification of genetically modified organisms (GMOs) is based on whether the alteration has been made "in a way that does not occur naturally by mating and/or natural recombination".[8] It is elaborated as "at least" requiring the use of a listed technique, which does not explicitly include gene editing techniques.[9] Therefore, although the European Food Safety Authority (EFSA) holds that products developed using SDN-3[10] techniques – which is one of the major categories of the NBTs – would be categorised as GMOs,[11] these new genomic tools call into question, first, the regulatory approach (process/product-based) to be used.[12] Second, they ask for a critical reflection on the potential impact of products on both the industrial sector and citizens.[13] Concerns about the peril of objectifying and controlling humanness by altering and editing the genome are in fact deeply affecting public debate about science regulation.[14]

As a consequence, a possible reconfiguration of the EU discipline will have to grapple with not only agrifood market's interests and needs, but mostly and primarily with growing demand for public and participatory discussion on the currently dominant vision of life sciences.[15] Indeed, not only do life sciences continue to be a crucial locus for both an epistemic[16] and ethical[17] reflection on scientific knowledge, but also

[6] National Academies of Sciences, Engineering and Medicine, Human Genome Editing (Washington, DC, National Academies Press 2017); VT Chu et al, "Increasing the Efficiency of Homology-directed Repair for CRISPR-Cas9-Induced Precise Gene Editing in Mammalian Cells" (2015) 33 Nature Biotechnology 543.

[7] Y Zhang et al, "Applications and Potential of Genome Editing in Crop Improvement" (2018) 19 Genome Biology 210, <doi.org/10.1186/s13059-018-1586-y> accessed 19 September 2019.

[8] Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L 106/1, Art 2(2).

[9] ibid. The techniques are those listed in Annex IA, Part 1; additionally, techniques listed in Annex IA, Part 2 are deemed not to give rise to GMOs.

[10] It stands for "site-Directed Nuclease-3".

[11] EFSA (European Food Safety Authority), "Scientific Opinion Addressing the Safety Assessment of Plants Developed Using Zinc Finger Nucleases 3 and Other Site-Directed Nucleases with Similar Function" (2012) 10 EFSA J 2943 <doi.org/10.2903/j.efsa.2012.2943> accessed 19 September 2019.

[12] J Schiemann and F Hartung, "EU Perspectives on New Plant-Breeding Techniques" in A Eaglesham and RWF Hardy (eds), *DNA-Editing Approaches: Methods, Applications and Policy for Agriculture* (NABC Report 26, 2014) pp 201–210. Summarising the discussions carried out at the institutional level on the legal status of the NBTs, the authors conclude, "There is general agreement amongst experts to define a GMO on the presence of foreign recombinant DNA. When an organism does not contain recombinant DNA, it should not be risk assessed and regulated as a GMO" (p 207).

[13] A Shukla-Jones et al, *Gene Editing in An International Context: Scientific, Economic and Social Issues across Sectors* (Paris, OECD Publishing 2018).

[14] S Jasanoff, *The Ethics of Invention. Technology and the Human Future* (New York, WW Norton & Co 2016).

[15] G Gaskell et al, "Public Views on Gene Editing and Its Uses" (2017) 35(11) Nature Biotechnology 1021.

[16] C Dürnberger et al (eds), *Genome Editing in Agriculture: Between Precaution and Responsibility* (Baden-Baden, Nomos Verlagsgesellschaft 2019).

[17] Federal Ethics Committee on Non-Human Biotechnology ECNH, *New Plant Breeding Techniques – Ethical Considerations* (Berne, Ariane Willemsen, ECNH Secretariat 2016).

they remain the emblem of a peculiar perspective where science, law and society legitimately evolve as places for co-production of knowledge and values.[18] Science cannot settle normative questions or determine policy judgements and decisions about regulating genetic engineering merely on its own assumptions, as both values and interests jointly contribute to framing social choices about the data to be acquired, analysed and interpreted. [19]

In the light of this portrait, this contribution will proceed beyond the dilemma about the extent to which current EU regulations on GMOs should apply to genome edited organisms to be used in agriculture and the food industry. In a time in which GM legislation has come under criticism for being inconsistent, disproportionate, scientifically obsolete and vague in terms of its scope,[20] the right question to be asked should focus on whether one technology is responsibly designed and assessed,[21] by questioning which rules should guide precautionary and responsible research and development of technoscience.

This is the crucial point which this paper is structured on and around. After a brief overview looking back at the ethical and legal framework that the EU established to cope with biotechnology, the third section will explore the dilemma on the legal status of the NBTs as it arose after the 2018 Court of Justice of the EU (CJEU) ruling[22] on the matter. This analysis will help to focus on current risk assessment procedures, for a reflection on the modalities needed to re-think of and re-frame them to establish peace with the risk management phase. Taking this broad approach will finally allow experts to advance plausible perspectives on law-science interactions when grappling with the advent of novel yet disruptive technologies, such as gene editing, within the agrifood marketplace. Our main conclusion posits that only through restoring visibility to the intertwining of knowledge production will it be possible to obtain EU governance of gene editing that is more authoritatively reliable from a scientific stance, as well as more transparently discussed and democratically shared at both legal and policy level.

II. Biosciences at issue: a look back at the past

Alluding to a set of novel techniques for manipulating the genome, the term "gene editing" is grounded on promises of innovating several fields (from biomedicine[23] to

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

[19] E Millstone et al, "Regulating Genetic Engineering: the Limits and Politics of Knowledge" (2015) Issues in Science and Technology 23 at p 24.

[20] C Zetterberg and KE Bjornberg, "Time for a New EU Regulatory Framework for GM Crops?" (2017) 30(3) J Agric Environ Ethics 325 <doi.org/10.1007/s10806-017-9664-9> accessed 19 September 2019.

[21] JB Biddle, "Genetically Engineered Crops and Responsible Innovation" (2017) 4(1) Journal of Responsible Innovation 24 <doi.org/10.1080/23299460.2017.1287522> accessed 19 September 2019.

[22] Case C-528/16, *Confédération paysanne, Réseau Semences Paysannes, Les Amis de la Terre Frane, Collectif Vigilance OGM et pesticides 16, Vigilance OG2M, CSFV49, OGM dangers, Vigilance OGM 33, Fédération Nature et Progrès t. Premier ministre, Ministre de l'Agriculture, Agroalimentaire et de la Forêt*, ECLI:EU:C:2018:583.

[23] H Garden and D Winickoff, *Gene Editing for Advanced Therapies: Governance, Policy and Society* (Paris, OECD Publishing 2018).

agriculture[24]) through much greater precision than pre-existing forms of genetic engineering. Both precision and speed of using site-specific nucleases, such as CRISPR/Cas9,[25] TALEN[26] or ZFNs,[27] to insert, delete, or alter either one or more DNA nucleotides have been heralded as valuable and flexible tools through which to enable a wide spectrum of applications, while addressing industrial challenges. In the agrifood domain, applications unleash solutions spanning from yields similar to natural genetic variation, to increased crop diversity;[28] from the development of perennial cereal crops,[29] to more efficient variations in domestic breeds (for instance, hornless cattle and miniature pigs);[30] from bacterial blight-resistant rice,[31] to nutritionally enhanced staple foods.[32]

As with the advent of any new technology, though, innovation brings risks and uncertainty that cannot be taken for granted.[33] Research has shown that a DNA-cutting enzymes used for genetic modification can create large deletions and shuffle genes.[34] Unintended changes to agricultural methods, problematic consequences on biodiversity, and effects on the management of pest resistance in crops are examples of some implications for the agrifood field.[35] Ethical issues address the application of genomics to animal production in the human food chain,[36] raising concerns on animal welfare and dignity.[37] Further alarms deal with potential trade disruptions and public acceptance, as well as with changes in regulatory conditions between trading partners.[38]

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[24] The Center for Food Integrity, *Gene Editing Engage in Conversation* (2018) <geneediting.foodintegrity.org/wp-content/uploads/sites/2/2018/11/CFI_GeneEditingCommunicationResource_2018.pdf> accessed 19 September 2019.

[25] CRISPR/Cas9 stands for "Clustered Regularly Interspaced Short Palindromic Repeats" associated to a Cas9 protein.

[26] TALEN stands for "Transcription Activator-Like Effector Nucleases".

[27] ZNF stands for "Zinc-Finger Nucleases".

[28] Zhang et al, supra, note 7.

[29] K Khandagale and A Nadaf, "Genome Editing for Targeted Improvement of Plants" (2016) 10(6) Plant Biotechnology Reports 327 <doi.org/10.1007/s11816-016-0417-4> accessed 19 September 2019.

[30] W Tan et al, "Gene Targeting, Genome Editing: From Dolly to Editors" (2016) 25 Transgenic Res 273; G Laible et al, "Improving Livestock for Agriculture – Technological Progress from Random Transgenesis to Precision Genome Editing Heralds a New Era" (2015) 10 Biotechnol J 109; A Bruce et al, "Novel GM Animal Technologies and their Governance" (2013) 22 Transgenic Res 681.

[31] J Zhou et al, "Gene Targeting by the TAL Effector PthXo2 Reveals Cryptic Resistance Gene for Bacterial Blight of Rice" (2015) 82(4) The Plant Journal 632.

[32] W Haun et al, "Improved Soybean Oil Quality by Targeted Mutagenesis of the Fatty Acid Desaturase 2 Gene Family" (2014) 12(7) Plant Biotechnology Journal 934.

[33] For insightful reflections on this matter, see M Weimer and A de Ruijter (eds), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Oxford, Hart Publishing 2017); see also the EJRR's Inaugural Issue: *The Past, Present And Future of Risk Regulation* (2017) <www.cambridge.org/core/journals/european-journal-of-risk-regulation> accessed 19 September 2019.

[34] M Kosicki et al, "Repair of Double-strand Breaks Induced by CRISPR–Cas9 Leads to Large Deletions and Complex Rearrangements" (2018) 36 Nature Biotechnology 765; HY Shin et al, "CRISPR/Cas9 Targeting Events Cause Complex Deletions and Insertions at 17 Sites in the Mouse Genome" (2017) 8 Nature Communications 15464.

[35] M Lusser et al, *New Plant Breeding Techniques: State-of-the-art and Prospects for Commercial Development* (Luxembourg, Publications Office of the European Union 2011).

[36] D Coles et al, "Ethical Issues and Potential Stakeholder Priorities Associated with the Application of Genomic Technologies Applied to Animal Production Systems" (2015) 28 J Agric Environ Ethics 231.

[37] A Bruce, "Genome Edited Animals: Learning from GM Crops?" (2017) 26(3) Transgenic Res 385.

[38] T Zimny et al, "Certain New Plant Breeding Techniques and Their Marketability in the Context of EU GMO Legislation – Recent Developments" (2019) 25(51) New Biotechnology 49.

From a normative stance, this picture of pros and cons incessantly swings between the opposing rhetorics of the "nothing new under the sun" and "the very unfamiliar".[39] The National Academies of Sciences, Engineering, and Medicine, for instance, has argued that emerging processes – such as genome editing and synthetic biology – actually fail to fit current regulatory categories of genetic engineering. In sharp contrast to this opinion, the International Federation of Organic Agriculture Movements (IFOAM) has posited that all new genetic engineering techniques should be considered as techniques of genetic modification leading to GMOs, and as such, they fall within the scope of the existing GM legislation. From here, questions on what exactly to regulate and which kind of normative tools should be used in coping with technology continue to be a matter of heated debate.

As scholarly work has extensively explored,[40] the early years of the development of biotechnology were accompanied by the EU Commission's statement that the then existing legislation was suitable to achieve the objectives set for the new technology.[41] Before the issue of Regulation No 1829/2003,[42] in fact, GMOs fell under the normative framework of Novel Foods,[43] which provided for a simplified procedure for market authorisation based on the concept of substantial equivalence. Only later, after the spread of the bovine spongiform encephalopathy (BSE) crisis, did debates on the safety of biotechnology products lead to a set of binding legal instruments irrespective of the presence of traces of modified DNA in the final product. Those hard law tools – consisting of a set of directives[44] – were clearly inspired by a precautionary approach in order to anticipate possible harmful effects related to the scientific and technological impacts on both the environment and society. At the same time, the reductionist and objectivist vision of science pervaded EU policy- and law-making processes on biotechnological applications, exacerbating the "ideological separation" between "is" and "ought", by relegating social values to technically manageable issues kept away from scientific facts. Several conceptual

[39] D Eriksson, "The Evolving EU Regulatory Framework for Precision Breeding" (2019) 132 Theoretical and Applied Genetics 569.

[40] M Weimer, *Risk Regulation in the Internal Market. Lessons from Agricultural Biotechnology* (Oxford, Oxford University Press 2019).

[41] "From a first review of the situation, it would appear that the application of current Community regulations in the various fields (pharmaceuticals, veterinary medicines, chemical substances, food additives, bioprotein feedstuffs) will meet current regulatory needs, provided that there is close cooperation between the competent authorities in the Member States and the Commission" (Commission of the European Communities, *Biotechnology in the Community [Communication from the Commission to the Council]*, COM(83) 672 final/2, Brussels, 1983, at 11).

[42] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] OJ L 268.

[43] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1997] OJ L 043, Art 3(4). This Regulation has been replaced by Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ L 327/1.

[44] See Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1990] OJ L 117; Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [1990] OJ L 117; Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) [1990] OJ L 374. A fourth directive on the matter was enacted in 1994 (Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road [1994] OJ L 319).

narratives enriched this panorama: the normalisation of risks through their "legal confinement" in controlled environments; the technical governability of risks through the mechanistic language of engineering; the rhetoric of using ethics as a soft and flexible "indicator of normativity" for the civic acceptability of biotech products.[45]

Ethical deliberation in particular – as acutely pinpointed by scholars[46] – was not "an exercise opening up diverse imaginations about issues at stake, but became a boundary-drawing move", namely an abstract normative concept subordinated to narratives of market harmonisation, which closed the door to the creation of legitimate right and genuine public debate.[47] Citizens' role was relegated to that of mere recipients of EU ethics, "adequately informed", albeit without any active involvement in the choice of the values at play. This was also because ethics and cultural values – according to the EU Commission[48] – are predominantly regulated at the national level and follow the principle of subsidiarity, whereby the Union does not take action (except in the areas which fall within its exclusive competence) unless it is more effective than action taken at national, regional or local level. Subsidiarity, therefore, deprived citizens of any possible voice in discussions regarding the principles of EU ethics, binding them, *de facto*, to the bureaucracy of national governments (the only interlocutors of the ethical discourse).[49]

Along this theoretical narrative "creating" EU consumers barely informed of biotech-related issues, a significant number of affluent consumers/citizens committed to such values as freshness and quality, the environment and small-scale farming, taste and food in season, considered genetic modification a long way away from their idea about naturalness of things. Against this backdrop, one relevant question arises: Is the process aimed at legitimising technocracy in the name of the integrity of scientific community newly under way with reference to gene editing techniques?

III. Science regulation in dispute

In 2015, the European Academies Science Advisory Council (EASAC) provided general principles on how best to capitalise on genomics research.[50] It argued for evaluating new technologies according to the scientific evidence base, stressing the non-applicability of EU legislation on GMOs in the case of a product of genome editing not containing foreign DNA. More broadly, EASAC requested full transparency in disclosing the process used and a product-based regulation – for plants and animals – being irrespective of the

[45] M Tallacchini, "To Bind or Not Bind? European Ethics as Soft Law" in S Hilgartner et al (eds), *Science and Democracy: Making Knowledge and Making Power in the Biosciences and Beyond* (Florence, KY, Taylor and Francis 2015) p 156.

[46] K Siune et al, *Challenging Futures of Science in Society. Emerging Trends and Cutting-Edge Issue* (Luxembourg, European Commission 2009) at p 32.

[47] B Wynne et al, *Taking European Knowledge Society Seriously* (Luxembourg, Office for Official Publications of the European Communities 2007) at p 52.

[48] Commission, *Research, Science and Society* (cited in Wynne et al, supra, note 47, at p 48).

[49] M Tallacchini, "Governing by Values, EU Ethics: Soft Tool, Hard Effects" (2009) 47(3) Minerva 281.

[50] EASAC (European Academies Science Advisory Council), "New Breeding Techniques" (Statement, 2015), <easac.eu/fileadmin/PDF_s/reports_statements/Easac_14_NBT.pdf> accessed 19 September 2019.

breeding technique employed.[51] Later, in 2016, after continuous controversies and complex discussions on the regulatory status of gene-edited agricultural products between biotech companies, NGOs, and farmers,[52] the case[53] brought by the French Conseil d'Etat to the CJEU ended up representing a turning point for the issue in dispute. It was asked whether organisms obtained by mutagenesis constitute GMOs within the meaning of Article 2 of Directive 2001/18 ("GMO Directive"), although they are exempt under Article 3 of and Annex IB[54] to the directive from the obligations laid down for issuing and placing on the market of GMOs.

Put in other terms, the core question referred to the Court was whether the GMO definition covers the methods used, the result, or both. On 25 July 2018, the CJEU ruled on this request to provide legal certainty for the advancement of life sciences in Europe.[55] Its main conclusion was that "organisms obtained by means of techniques/methods of mutagenesis must be considered to be GMOs within the meaning of Article 2(2) of Directive 2001/18".[56] This statement was grounded on two major considerations. First, that the mutations brought about by techniques/methods of mutagenesis constitute alterations made to the genetic material of an organism.[57] Second, that those techniques/methods alter the genetic material of an organism in a way that does not occur naturally, since they involve the use of chemical or physical mutageneous agents, or the use of genetic engineering.[58] Only "organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record"[59] are excluded from the scope of that directive. Moreover, the Court considered that the risks linked to the use of these new mutagenesis techniques might prove to be similar to those that result from the production and release of a GMO through transgenesis.

This is for two reasons. First, the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into the organism (transgenesis). Second, those new

[51] EASAC confirmed this position in its Report "Genome Editing: Scientific Opportunities, Public Interests and Policy Options in the EU" (EASAC Policy Report 31, 2017) <www.easac.eu/fileadmin/PDF_s/reports_statements/Genome_Editing/EASAC_Report_31_on_Genome_Editing.pdf> accessed 19 September 2019.

[52] For an overview of the different positions and opinions, see European Parliament, *New plant-breeding techniques Applicability of GM Rules* (May 2016) <www.europarl.europa.eu/RegData/etudes/BRIE/2016/582018/EPRS_BRI(2016)582018_EN.pdf> accessed 19 September 2019; T Sprink et al, "Regulatory Hurdles for Genome Editing: Process- vs. Product-based Approaches in Different Regulatory Contexts" (2016) 35 Plant Cell Rep 1493.

[53] See supra, note 23.

[54] Art 3(1) provides as follows: "This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex IB". Annex IB provides as follows: "Techniques referred to in Article 3. Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are: (1) mutagenesis (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods".

[55] On the ambiguous character of this question from a legal viewpoint, see GF Albujar and B van der Meulen, "The EU's GMO Concept: Analysis of the GMO Definition in EU Law in the Light of New Breeding Techniques (NBTs)" (2018) 1 EFFL 14.

[56] Case C-528/16, supra, note 22, at para 30.

[57] ibid, at para 28.

[58] ibid, at para 29.

[59] ibid, at para 54.

techniques make it possible to produce GM varieties at a rate out of all proportion to those resulting from the application of conventional methods of mutagenesis.

In sum, by bringing new mutagenesis techniques within the GMO Directive's scope, the Court teleologically updated legislation that pre-dates technological developments, using the legal instrument of analogy as an ontological and epistemological tool to conceptualise gene editing. In so doing (unproductively, according to some scholars[60]), the ruling went for assuring legal convergence at supranational level, rather than permitting regulatory divergence, as Directive 2015/412/EC[61] did by assigning – as regards the cultivation of GMOs – regulatory responsibility to Member States,[62] in accordance with the precautionary principle.

This situation led the CJEU's judgment to be labelled as "a double-edged sword".[63] On the one hand, the decision – it has been argued – is aimed at precautionarily protecting human health and the environment from potential biotech risks. On the other hand, though, it may hamper research activities due to the lengthy risk assessment and authorisation procedure prescribed for GMOs. Those considerations perfectly mirror the opposing opinions[64] that have emerged among stakeholders. The German chemical industry association VCI[65] and the biotech association EuropaBio[66] have severely criticised the Court's judgment as "backward looking and hostile to progress". The German Bioeconomy Council,[67] moreover, has manifested its disappointment with the "complex, time-consuming and expensive approval procedure" that the future applications of gene editing will have to go through if the GMO Directive is applied. It has thus called for a prompt revision of GM legislation, in order to stipulate which applications of genome editing are essentially allowed (without special provisions relating to genetic engineering), which are prohibited, and which will only be allowed with a special permit. By contrast, the environmental

[60] H Somsen, "Scientists Edit Genes, Courts Edit Directives. Is the Court of Justice Fighting Uncertain Scientific Risk with Certain Constitutional Risk?" (2018) 9(4) EJRR 701.

[61] Directive 2015/412/EC as regards the possibility for the Member States to restrict or prohibit the cultivation ofngenetically modified organisms (GMOs) in their territory, OJ [2015] L 68/1.

[62] On the role played by the so-called "opt-out" clause, see M Geelhoed, "Divided in Diversity: Reforming The EU's GMO Regime" (2016) 18 Cambridge Yearbook of European Legal Studies 20.

[63] E Rehbinder, "European Court of Justice Ruling on Genome Editing" (*IUCN*, 2018) <www.iucn.org/news/world-commission-environmental-law/201808/european-court-justice-ruling-genome-editing> accessed 19 September 2019.

[64] See "Expert Reaction to Court of Justice of the European Union Ruling that GMO Rules Should Cover Plant Genome Editing Techniques" (Science Media Centre, 2018) <www.sciencemediacentre.org/expert-reaction-to-court-of-justice-of-the-european-union-ruling-that-gmo-rules-should-cover-plant-genome-editing-techniques/> accessed 19 September 2019.

[65] "The decision is not only an obstacle to faster successes in modern agriculture in the breeding of more robust crops with higher yields; it also impairs the production of biopharmaceuticals and bio-based chemicals. The Court takes the wrong standpoint on how to regulate genome editing methods, since researchers obtain with Crispr/CAS the same results as with conventional breeding methods – but much faster" <www.vci.de/vci-online/presse/pressemitteilungen/backward-minded-and-hostile-to-progress-vci-on-ecj-judgment-on-genome-editing.jsp> accessed 19 September 2019.

[66] "We regret that implementation of this ruling could cause European life science innovation effectively to come to a halt. If fast mitigation is not done, the ruling will cause a halt to EU sustainability and competitiveness ambitions by hindering the delivery of innovative bio-based products to the market, sustainable innovative food-solutions and certain healthcare solutions to patients" <www.europabio.org/sites/default/files/EuropaBio_statement_CourtRuling_final_forWEB.pdf> accessed 19 September 2019.

[67] Bioökonomierat, "Genome editing: Europe Needs New Genetic Engineering Legislation" (2018) BÖRMEMO 07 <biooekonomierat.de/fileadmin/Publikationen/berichte/BOER-Memo_Genome-Editing_ENG.pdf> accessed 19 September 2019.

group Friends of the Earth Europe[68] has applauded the Court's attempt to grapple with the current deregulation of recently developed technology. Certainly, this backdrop will continue to trigger renewed quarrels on the role of both the precautionary principle and science regulation in the technology-based agrifood field,[69] all the more so since different yet equally valid ways of reasoning affect the democratic debate on the science-law relationship.

In the meantime, on 23 April 2019, 22 EU business organisations jointly called upon the EU Commission for the adoption of science-based, innovation-friendly rules for plant breeding.[70] With the aim "to achieve important sustainable development goals", while contributing to "a cleaner environment, healthy diets, and the protection of biodiversity", the 22 signatories reiterated their concerns about both the costly and lengthy EU approval process for products resulting from targeted mutagenesis and the difficulty of implementing the CJEU's judgment. This is because – they affirmed – "many gene-edited products may be indistinguishable from products changed by natural processes or with conventional breeding techniques", as shown by a study conducted by the EU Commission's Joint Research Centre.[71]

Appealed on this intricate issue, in 2018 the Scientific Advice Mechanism (SAM) presented its explanatory note[72] to the EU Commission. By stressing that "the safety of a product is determined by its characteristics and not by the way it was generated", it called for an urgent revision of the existing GMO Directive. The novel legal rules – it affirmed – should be "proportionate and flexible" enough to "reflect current knowledge and scientific evidence on gene editing and established techniques of genetic modification", as well as facing future advances in science and technology in the domain.

Both the 22 organisations' and SAM's requests agree, therefore, on a product-based approach to the NBTs that moves away from the process-based argumentation Europe has developed to address GMOs. Indeed, as only rational legal reasoning and evidence-based policy are considered transparent, legitimate and accountable processes through which to regulate intricate social problems, science-based legislations appear reliable tools to make normative statements more objective.

Interestingly, however, in the same proposal for a clear, evidence-based and implementable "legal environment", SAM also focused on the need "to promote a

[68] "These new 'GMO 2.'" genetic engineering techniques must be fully tested before they are let out in the countryside and into our food. We welcome this landmark ruling which defeats the biotech industry's latest attempt to push unwanted genetically-modified products onto our fields and plates" <foeeurope.org/eu-top-court-confirms-safety-checks-needed-new-gmo-250718> accessed 19 September 2019.

[69] E Gelinsky and A Hilbeck, "European Court of Justice Ruling Regarding New Genetic Engineering Methods Scientifically Justified: A Commentary on the Biased Reporting about the Recent Ruling" (2018) 30(1) Environ Sci Eur 52.

[70] "Open Letter to Member States on the EU Court Ruling on Mutagenesis" (2019) <cefs.org/wp-content/uploads/2019/04/Letter-to-Member-States-at-Scopaffs-April-2019.pdf> accessed 19 September 2019.

[71] ENGL (European Network of GMO Laboratories), "Detection of Food and Feed Plant Products Obtained by New Mutagenesis Techniques" (JRC116289, 2019).

[72] SAM (Scientific Advice Mechanism), "statement by the Group of Chief Scientific Advisors A Scientific Perspective on the Regulatory Status of Products Derived from Gene Editing and the Implications for the GMO Directive" (2018) <ec.europa.eu/info/sites/info/files/2018_11_gcsa_statement_gene_editing_1.pdf> accessed 19 September 2019.

broad dialogue with relevant stakeholders, and the public at large", with the aim of clearly and transparently considering the ethical, legal, social and economic considerations that usually inform decision-making processes. Such a problem strictly correlates to the broader debate on the complex mechanisms underpinning risk assessment procedures and their correlation with risk management and communication phases. The actual conundrum, in this respect, not only refers to the process of assessing and communicating science, but mostly regards how to promote more meaningful interactions between policy-decision makers, scientists, producers and the public, so that connections with citizens no longer be viewed as exercises in better communications from a privileged elite.[73] "The starting point" – as has been observed – "is that scientists and the public can learn from each other, that both have access to knowledge as well as having political and normative values that are relevant for scientific choices".[74] The next two sections are devoted to scrutinising these issues. They will be focused, first, on the ongoing EU debate on the need to reframe the role of risk assessment within the wider process of risk analysis; second, on the plausible perspectives the citizens' right to democratically and reflexively participate in the governance of biosciences may elicit for gene editing in the future of EU food and farming.

IV. On re-framing risk assessment

In the EU's employment of a process-based risk assessment framework, EFSA provided two guidance documents for evaluating the impact of GM plants[75] and plant-derived food and feed.[76] In questioning whether those methodologies are adequate to analyse organisms arising from gene editing techniques, though, scholarly work[77] has identified several knowledge gaps that pertain, specifically, to appropriate focus, selection of test organisms, and the use of comparators. Technical discussions on these gaps are beyond this contribution. Here it is worth noticing the modalities through which those hurdles and challenges could be correctly overcome when addressing the value-laden issues associated with gene-edited plants and animals.

In recent years, in the light of the EU Commission's acknowledgement that "risk assessments make little sense unless they are informing risk management",[78] EFSA carried out relevant initiatives to foster communication between risk assessors and

[73] K Ozolina et al, *Global Governance of Science* (Brussels, European Commission, 2009).

[74] Siune et al, supra, note 46, at p 51.

[75] EFSA, "Guidance on the Environmental Risk Assessment of Genetically Modified Plants" (2010) 8 EFSA J 1879, <www.efsa.europa.eu/en/efsajournal/pub/1879> accessed 19 September 2019.

[76] EFSA, "Scientific Opinion on Guidance for Risk Assessment of Food and Feed from Genetically Modified Plants" (2011) 9 EFSA J 2150 <efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2150> accessed 19 September 2019.

[77] SZ Agapito-Tenfen et al, "Revisiting Risk Governance of GM Plants: The Need to Consider New and Emerging Gene-Editing Techniques" (2018) 21 Front Plant Sci <doi.org/10.3389/fpls.2018.01874> accessed 19 September 2019.

[78] <ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_154.pdf> accessed 19 September 2019.

risk managers, such as its 2016 guidance[79] on specific protection goals for environmental risk assessment. Indeed, it is now commonly accepted that issues concerning the identification of significant risks, or the parameters for measuring them, or even the criteria for comparing the implications on the social groups involved, represent implicit assumptions that precede risk assessment procedure. Hence, in spite of the clear distinction between the two phases, "assessment is informed but not influenced by management, at least in terms of how the assessments are carried out and what conclusions are drawn from them".[80] This implies that risk assessment should take into account both social-behavioural factors to better define problems at the formulation stage, and the type of information risk the assessor has to provide to better inform risk managers in addressing different societal needs. If risks related to gene editing constitute "warning signs" requiring prudence, a precautionary decision is expected to pay scientifically rigorous attention to all situations of uncertainty, through a procedure that considers all divergent scientific opinions, including the interests (political, social and institutional) of the stakeholders involved.[81]

At a time of structural challenges to the integrity, validity and reliability of scientific data,[82] making the interpretative aspects of risk assessment policy (namely how are data interpreted?) explicit, and comparing them with each other in open and accountable ways, might give policy-making regimes their scientific and democratic legitimacy. Remarkably, EU public bodies gradually started taking steps in this direction: first, with the "Open EFSA" initiative;[83] second, with the decision to increase the transparency and sustainability of the EU risk assessment model in the food chain, particularly in response to the "EU Citizen Initiative to ban glyphosate".[84]

As for EFSA's activities for wider scrutiny and participation, the plethora of actions aimed at producing more robust, transparent, and open scientific assessments culminated in a Data Warehouse (DWH), which publishes and distributes EFSA's collected data to both improve the overall quality of the data used and comply with normative and societal expectations of openness.[85] In 2018, moreover, practical guidance was released for EFSA communicators on the best way to communicate different expressions of uncertainty in scientific assessments.[86]

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[79] EFSA, "Guidance to Develop Specific Protection Goals Options for Environmental Risk Assessment at EFSA, in Relation to Biodiversity and Ecosystem Services" (2016) 14 EFSA J 4499 <efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4499> accessed 19 September 2019.

[80] See supra, note 78.

[81] A Stirling, "Precaution in the Governance of Technology" in R Brownsword et al (eds), *The Oxford Handbook of Law, Regulation and Technology* (Oxford, Oxford University Press, 2017) p 645.

[82] As well as decreased discretionary funding, perverse incentives and reduced quality of peer review. See, on this matter, MA Edwards and S Roy, "Academic Research in the 21st Century: Maintaining Scientific Integrity in a Climate of Perverse Incentives and Hypercompetition" (2017) 34(1) Environmental Engineering Science 51.

[83] <www.efsa.europa.eu/en/topics/topic/open-efsa> accessed 19 September 2019.

[84] See <=ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002/en?lg=en> accessed 19 September 2019.

[86] EFSA, *Guidance on Communication of Uncertainty in Scientific Assessments* (2018) <efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5520> accessed 19 September 2019.

[86] EFSA, *The EFSA Data Warehouse access rules* (2015) <efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2015.EN-768> accessed 19 September 2019.

As for the EU Commission's action addressing risk assessment, a Regulation for a rethinking of risk assessment in the food chain was released in September 2019.[87] The novel rules, which find their legal basis in Articles 43, 114 and 168(4) lett. b) of TFEU, provide EFSA with a toolkit of transparency rules regarding several areas – like GMOs, additives and plant protection products. Their major focus spans from the appointment of the members of the Management Board of EFSA, to consultation of third parties to identify the availability of other relevant scientific data or studies. Further novelties range from compliance of studies submitted by business operators with applicable standards to public access – as early as possible in the risk assessment process – to all scientific data and information supporting requests for authorisations. The proposed rules, however, are not free from concerns,[88] especially as regards the exception to public access to a general horizontal list of confidential items, such as, with respect to GMOs, "DNA sequence information (except for sequences used for the purpose of detection, identification and quantification of the transformation event) and breeding patterns and strategies" (Article 25(2)). Such a kind of information is considered central to providing the breeding sector with sufficient information, for example to identify varieties covered by patents.[89] Further initiatives are therefore expected to solve these limits. Meanwhile, implementing the EFSA's and the EU Commission's commitments would support revolutionary rethinking of decision-making practices in a participatory sense, democratising the cognitive structure within which public policies are formed, and including lay people in the notion of expert and expertise. In this way, the widest range of relevant knowledge dispersed in society may reach the table of political decision-makers, for the achievement of a more democratic vision of the EU society under uncertainties.

V. Democratic tools for the future of EU food and farming

In which "terrain" is the EU agrifood domain predisposed to accommodate gene editing processes and products? One of the main lessons from the GM experience is that

[87] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231/1.

[88] See, for instance, the European Consumer Organisation's (BEUC) clarifications/changes to strengthen the proposal: "It must better ensure that public health prevails over commercial considerations when examining industry confidentiality requests. No important piece of safety-related information should be hidden away from the public. It must allow independent scientists to quote or re-use the data disclosed by EFSA without having to ask for industry's permission. It must foresee meaningful sanctions for industry applicants failing to notify EFSA of studies commissioned to support a regulatory dossier. If pre-submission meetings between EFSA staff and industry applicants are introduced, the proposal must guarantee that they are held in full transparency and that they do not lead to any shift in the allocation of EFSA internal resources, at the expense of other activities of public interest" (BEUC, *Closing the Trust Gap between Consumers and the EU Food Regulatory System* (2018) at 1 <www.beuc.eu/publications/beuc-x-2018-059_beuc_position_paper_general_food_law_revision.pdf> accessed 19 September 2019).

[89] See <www.ifoam-eu.org/en/news/2018/06/18/general-food-law-unsuccessful-attempt-european-commission-bring-more-transparency> accessed 19 September 2019.

science-based forms of appraisal need to be embedded within a much broader reflection on public values, especially in the entrenched technoscientific fields where scientific uncertainty is steadily in the driver's seat. The inability of mathematical language to correctly translate across the borders of converging technologies requires that the actors involved in decision-making be expanded to include new decision-makers for pluralistic reflections and opinions.

Over the years, the EU institutions seem to have learned from GMO events. While EFSA is gradually changing its approach towards the handling of scientific uncertainty, by opening up its working activities, the traditional risk regulation process is moving towards a more open dialogue among stakeholders and a diversified collection of scientific expertise within the ongoing and still unfinished process of rethinking science governance.[90] However, many obstacles tend to slow this democratic impetus. Contextualising science governance in a broader context of new "social geographies" requires to reshape the boundaries between policy institutions and society and rethink the role of EU citizens in the deliberative process.

Over the years, the EU "Smart or Better Regulation programme"[91] has continued to promote a still mechanistic vision of reason. The EU legislator is expected to act as a sort of "body-machine": the smarter it is, the more capable it is of rationally predicting citizens' choices and behaviours; the more efficient it is the more capable it is of leveraging on the "scientifisation" of regulatory procedures to legitimise them.[92]

It is true, however, that against the regulatory responses of "command and control" in GM food,[93] the CJEU's ruling left room for future interpretations and reasoned argumentations on the systemic interactions between science and society. In this regard, the scholar Sheila Jasanoff has drawn attention to the unavoidable need to make use of "technologies of humility"[94] to lead the public debate on the role of science in society towards new democratic horizons. This fascinating expression alludes to the desire to institutionalise those habits of thought that are fragmented in society to create more than mere formal mechanisms of engagement. Those new social technologies – which focus on public assessments of framing, vulnerability, distribution, and learning – would permit experts to recognise uncertainty, as well as multiplying knowledge production and making the normative dimension of science explicit.

Although these exploratory forms of sharing ideas, values and knowledge are to be further explored and discussed, they could represent valid and influential tools for spreading transparency and dialogue between heterogeneous knowledge sources. To this end, two proposals appear worthy of being highlighted for the subject we are discussing.

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[90] A Liberatore and S Funtowicz, "'Democratising' Expertise, 'Expertising' Democracy: What Does This Mean, and Why Bother?" (2003) 30(3) Science and Public Policy 146.

[91] European Commission, "Future of Europe: President Juncker Creates Task Force on 'Doing Less More Efficiently'" (Press Release, Brussels 2017).

[92] L Leone and M Tallacchini, "Nudging Citizens' Knowledge in Knowledge-based EU: The Case of Breast Cancer Screening Programmes and Participatory Rights in Choice Architectures" in H Straßheim and S Beck, *Handbook of Behavioural Change and Public Policy* (Edward Elgar 2019) pp 148–162.

[93] T Ehnert and E Vos, "Innovating Regulatory Approaches to New Technologies in Food: The EU Approach to Bio and Nanofoods" in F Leonini et al, *Innovating Food, Innovating the Law. An Interdisciplinary Approach to the Challenges in the Agro-food Sector* (Tricase, Libellula 2014) p 175.

[94] S Jasanoff, "Technologies of Humility: Citizen Participation in Governing Science" (2003) 41 Minerva 223.

The first one suggests inclusion and application of the so-called "Open Access Paradigm"[95] as a guiding principle for research and development in the biotech field. Given the inadequacy of current treaties, such as the Nagoya Protocol, to deal with the digitalisation and privatisation of genetic resources, such an approach could push for the structuring and standardisation of information, together with reframing molecular genetics as a participatory and democratising toolbox. Going beyond those metaphors and analogies that courts used in the coproduction of biotech intellectual property,[96] the free transfer, use, and reuse of knowledge may facilitate the promotion and spread of creative common licensing and plant breeders' rights under the umbrella of genetic resources and digitalisation. This sharing of knowledge would also contribute to guaranteeing the emerging citizens' rights to access to open and raw food-related data,[97] for more active and trustworthy interactions with authorities.

This vision is perfectly in line with the recent (2019) CJEU decision[98] that requests EFSA to disclose details of studies on toxicity and carcinogenic properties of glyphosate. Interestingly, this judgment is grounded on interpreting "the concept of information which 'relates to emissions into the environment' [. . .] as covering not only information on emission as such [. . .], but also data concerning the medium to long-term consequences of those emissions on the environment". In so ruling, the Court has *de facto* re-affirmed the importance and necessity of increasing public transparency in food and health safety.

In parallel with these quests for public access to scientific data, an international network of scholars and organisations has advocated a wide consortium on the norms that should guide research.[99] It aims to determine how the potential of gene editing can be better steered by the values and priorities of society, promoting information exchange across cultural divides.[100]

With gene editing technology potentially altering plant and animal farming practices, government support and impetus from interlinked networks – such as farmers' unions and activist organisations, agricultural companies and institutions focused on development – are considered powerful instruments in this respect. They would allow for connecting people to debates on the social, political, moral and economic implications of gene editing,[101] bringing different sets of evidence and entirely different values to democratic discussion.[102] Such a creative and intellectual environment would also permit individuals to question those "master narratives" – from the myth of progress

[95] S Schubert, "Regulating Biotechnology in the Age of Digitalization: The Open Access Paradigm" in Dürnberger et al, supra, note 16.

[96] E Gambini, "The Seeds of Dispute. The Doctrine of Patent Exhaustion in the *Bowman Case*" in Leonini et al, supra, note 93, p 345.

[97] S Cappè et al, "Editorial: The Future of Data in EFSA" (2019) 17(1) EFSA Journal e17011; A Alemanno, "Big Data for Good: Unlocking Privately-Held Data to the Benefit of the Many" (2018) 9(2) EJRR 183; L Leone, "Towards New 'Digital Insights'". The Value of Open Data for Food Information in Europe" (2017) 2 Rivista di diritto alimentare 4.

[98] Case T-329/17, *Heidi Hautala and Others v European Food Safety Authority*, ECLI:EU:T:2019:142.

[99] National Academies of Sciences, Engineering, and Medicine, *On Human Gene Editing: International Summit Statement* (2015) at Section 5.

[100] S Jasanoff and JB Hurlbut, "A Global Observatory for Gene Editing" (2018) 555 Nature 435.

[101] S Burall, "Rethink Public Engagement for Gene Editing" (2018) 555 Nature 438.

[102] D Sarewitz, "CRISPR: Science Can't Solve It" (2015) 522 Nature 413.

to the identification of modern rational science as a valuable and privileged type of knowledge – that in policy practices continue to shape the collective imagination, outlining the possible and acceptable actions on the basis of factual data.[103] Certainly, framing science governance in these terms would not diminish the value of scientific knowledge. Rather, the redistribution of decision-making powers within the innumerable sites of knowledge production would give concrete form to a renewed EU citizenship, while favouring the multi-functionality of EU agricultural and food systems in the near future.[104]

VI. Final remarks

Since the political debut of biotechnology in the 1970s, food law has approached scientific reality by displaying control and flexibility in balancing the strength of rules with the endemic uncertainty of science. Yet history shows how the complexity of emerging technologies, and the levels and contours of uncertainty running with them, are such that, when addressing the "seemingly unfamiliar", acceptance and tolerability of risks depend on the convergence of factors inextricably merged with each other. Consequently, the dichotomy of "regulation versus deregulation" recursively re-emerges to trigger adaptive capacity in dealing with the technology at issue.

Exploring the moral questions raised by the use of genome editing in food production, the Nuffield Council on Bioethics has supported the vision of enlarging critical reflection and discussion on new techniques. It has suggested challenging the debates' parameters (introducing new future visions) and the assumptions (such as the significance of the GMO/non-GMO disjunction) underpinning them, together with addressing normative and ethical questions from the standpoint of the societal challenges that run with genomic tools.[105] These considerations clearly fit into the open and democratic infrastructure which scholars are promoting for accountable and transparent research on gene editing techniques. Meanwhile, Europe is strongly committed to supporting knowledge, innovation and technology for a smarter and more resilient agriculture of tomorrow, by providing farmers, through the Common Agricultural Policy (CAP), with a diverse set of tools to prevent and manage risks in food production chains.[106] With such a landscape in mind, the growing and essential need to preserve the "human dimensions" of biosciences[107] is hoped to guide the future regulation and governance of EU agricultural biotechnology.

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[103] A Benessia et al, *The Rightful Place of Science: Science on the Verge* (Tempe 2016).

[104] S Hartley et al, "Essential Features of Responsible Governance of Agricultural Biotechnology" (2016) 14(5) PLoS Biol e1002453 <doi.org/10.1371/journal.pbio.1002453>.

[105] Nuffield Council on Bioethics, *Genome Editing: An Ethical Review* (London, Nuffield Council on Bioethics 2016).

[106] European Commission, *Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. The Future of Food and Farming*, COM(2017) 713 final, Brussels, 2017.

[107] M Bertolaso and F Sterpetti (eds), *Will Science Remain Human? A Critical Reflection on Automated Science* (Cham, Springer forthcoming).