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Genome Editing in Agriculture: Between Precaution and Responsibility. An Introduction

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"Europe is going to regulate gene-edited organisms as if they were alien plants from space."[1] Unsurprisingly, the recent Court of Justice of the European Union (CJEU) ruling on July 25th 2018, concerning the regulation of so-called new plant breeding technologies (NBT), was met with bewilderment in the US. Earlier that year, the US Department of Agriculture (USDA) had already decided that plant varieties created with genome editing technology including CRISPR/Cas would not be regulated like GMO plants. In Europe, too, the verdict raised the odd eyebrow, especially among those interested in science. "The fear of genetic engineering has won,"[2] Kathrin Zinkant concluded the same day in the *Süddeutsche Zeitung* and Julia Merlot stated a "Farewell to the facts"[3] in the *Spiegel*. Shortly thereafter, the scientific section of the *Frankfurter Allgemeine Zeitung* (FAZ) ran a guest commentary by the biologists Sarah Schmidt and Wolf B. Frommer on the ruling of the CJEU, stating that "With this judgement, European reason has become obsolete."[4] So, what had happened?

French farming associations had filed a law suit to obtain a judgement that plant varieties produced with the new technologies of genome editing are not to be considered equal to the existing breeding products. The latter have been generated since the 1960s, all along using so-called mutagenesis techniques such as mutagenic chemicals or ionizing radiation to induce undirected and random changes in the genome of plants. These artificially modified plants have formed the basis for new breeding products with improved properties – both in the breeding of conventional and organic plant varieties. Due to this technical intervention, the CJEU generally classifies the organisms created by such methods as "genetically modified organisms (GMO)" in accordance with the applicable Directive 2001/18/EC

1 Clinton 2018.
2 Zinkant 2018. [Quote translated by the authors.].
3 Merlot 2018. [Quote translated by the authors.].
4 Schmidt and Frommer 2018. [Quote translated by the authors.].

on the deliberate release of GMOs.[5] In the same case, however, the court also quoted Recital 17 of Directive 2001/18/EC, which states that "this Directive should not apply to organisms obtained through certain techniques of genetic modification, which have conventionally been used in a number of applications and have a long safety record."[6] The argumentation follows the rationale that the conventional methods of mutagenesis have been used for a long time and can thus be described as safe. Therefore, these methods are exempt from the Directive 2001/18/EC and listed in Annex I B.

According to the CJEU, however, this ruling does not apply to genome editing technologies. The court stated, "the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis."[7] Furthermore, the judges emphasized the fact "that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis."[8] Interestingly, the judges took the very advantages of genome editing, such as breeding speed and precision of the procedure, to classify it as potentially risky. They concluded that approving these new mutagenesis techniques – by simply adding them to the list of exempt techniques in Annex I B – is not justified. Hence, their application was deemed to be potentially dangerous and thus has to be strictly regulated, just like other transgenic techniques.

The CJEU ruling sparked strong protests in the scientific community. For instance, the European Plant Science Organization (EPSO) put out a statement that the verdict "is contrary to scientific evidence and as it stands now it very likely will prevent the use in Europe of such technologies to address food and nutritional security and a more positive impact of agriculture on the environment."[9] The assessment of EPSO is in line with other well-respected scientific organizations. Under the umbrella of the European Academies' Science Advisory Council (EASAC), a position paper was released in March 2017 urging that "it is timely to resolve current legislative uncertainties. We ask that EU regulators confirm that the products of new breeding techniques, when they do not contain foreign DNA, do not

5 CJEU 2018, Paragraph 30.
6 ibid., Paragraph 3,17.
7 ibid., Paragraph 48.
8 ibid., Paragraph 48.
9 EPSO 2018.

fall within the scope of GMO legislation. The aim in the EU should be to regulate the specific agricultural trait and/or product, not the technology by which it was produced."[10]

The CJEU verdict has serious consequences not only for plant research but also for breeders, farmers and companies. As expected, major seed companies such as Bayer/Monsanto, Syngenta, DuPont and KWS had hoped for a competitive advantage due to liberal regulation of genome editing technologies. The Federal Association of German Plant Breeders e.V. (BDP), however, represented the interests of many smaller breeding companies when it criticized the stance of the CJEU for following a purely process-related evaluation and ignoring the traits of the end product. In a statement from July 25th 2018, the BDP assessed the verdict as "a clear departure from innovation and progress in agriculture. This is even more alarming, as other countries bring corresponding products to the market without special regulatory requirements. In line with the long tradition and experience of plant breeding, breeders are convinced that genome-edited plants should not be subject to the regulatory requirements of genetic engineering law, given that respective plant varieties could also be produced naturally or through recognized classical breeding methods."[11] Agreeing with this criticism, the German Farmers' Association (Bauernverband) classified the verdict as a break for innovation that will have serious consequences: "Europe is in danger of missing the boat compared to other regions of the world. This verdict impedes necessary opportunities to use plant breeding as a valuable tool to master the challenges of climate change. For example, the current drought shows us that we need drought-tolerant plant varieties in the future. Thus, the current EU genetic engineering law needs to be reviewed for its future viability in order to take advantage of the opportunities offered by the new breeding technologies."[12]

Even in Germany, then, where GMO criticism has a long and broad tradition,[13] the reactions to the CJEU ruling have turned out to be extremely critical from the science and agricultural sectors. Unsurprisingly, though, the response from the field of environmental policy came at the issue from a very different angle. The Federal Association for the Environment and Nature Conservation Germany (BUND e.V.) welcomed the CJEU ruling because it "placed the protection of citizens and their freedom of choice

10 EASAC 2017, 11.
11 BDP 2018.
12 Bauernverband 2018.
13 Cf. Salem 2013.

above the profit interests of companies, such as Bayer/Monsanto. The verdict eliminates the objectives of those scientists and authorities that wanted to bring the new genetic engineering techniques unchecked and unlabeled on the market."[14] What is more, the Federal Agency for Nature Conservation (BfN), an agency assigned to the Ministry of the Environment, saw its position on NBT confirmed,[15] because the court decision to classify genome editing as genetic engineering followed the same line of argument which the BfN had already developed in the summer of 2017 in a so-called "New Techniques Background Paper".[16]

One may be forgiven for reaching the hasty conclusion, as exemplified by the public reaction to the CJEU ruling, that the statements follow a logic which has been previously lamented – at least in Germany – as a "ritualized discourse"[17] between environmentalists and business associations. This reading of the situation would seem to be supported by a political criterion which has played a critical role in the decision of the CJEU: the Precautionary Principle. In Directive 2001/18/EC, it is the central reference point for the establishment of an environmental impact assessment of GMOs produced by use of biotechnological breeding techniques and developed after the Directive became effective in 2001. Legislators conceived the Precautionary Principle, which has been enshrined in EU law since 1990s, to provide something like a *figure of thought* or a *decision-making aid* for potential situations that endanger the environment or human health, even if the probability of occurrence cannot be adequately assessed by scientific means.[18] Thus, the Precautionary Principle explicitly recognizes the possibility of scientific uncertainty as an additional criterion for risk assessment of new technologies, yet evidently it is not always clear to what extent this uncertainty ought to be redefined after scientific justification. In this respect, Advocate General Michal Bobek hit the mark in his Opinion on Case C-528/16 with the pointed remark: "Beauty is in the eye of the beholder. That also appears to be the case for the content, scope and potential use of the precautionary principle. Over the years, a number of propositions about what the precautionary principle is and how it ought to be used have been made, in particular by the legal scholarship and in the political discourse."[19] In his Opinion of January 18th 2018, Bobek arrived at a

14 BUND 2018.
15 BfN 2018.
16 BfN 2017.
17 Cf. AEU 1999; Hampel and Renn 2001.
18 For detailed information and interpretation rules cf. European Commission 2000.
19 Bobek 2018, Paragraph 47.

conclusion far from that of the CJEU when he assessed the differences between conventional and new mutagenesis methods as irrelevant with regard to the application of the Precautionary Principle, provided that the definitions of Annex I B to the Directive 2001/18/EG apply. With regard to the scope of the Precautionary Principle, Bobek took the view that "the bottom line in all those cases is that there must be at least some discernible risks based on science. In contrast to permanent measures, the threshold for triggering the application of the precautionary principle with regard to provisional measures is lower. But there must still be some clear data on the alleged risk(s), which must be buttressed by a minimum set of scientific data, coming from a minimum number of different reliable national or international independent sources. A mere fear of a risk induced by something new, or a vaguely and generally asserted risk of a risk where it cannot be conclusively stated that the new thing is safe, is an insufficient trigger for the precautionary principle."[20]

These different readings of the Precautionary Principle make one thing clear: In the EU, the understanding of precaution and the question of how to balance remaining scientific uncertainty with regard to potential innovations by NBT remains controversial and, above all, open. The recent verdict only addressed whether current law – as stated in Directive 2001/18/EG – can be interpreted in such a way that novel mutagenesis methods, such as CRISPR/Cas, fall under the requirements of exempt methods listed in Annex I B. As the court clarified, this is not the case. Nevertheless, the question whether the existing legal regulations adequately capture the dynamics of biotechnological research is in no way answered by the ruling of the CJEU. And how could it be? After all, this is not the task of a court but that of the legislature. Whether reformed definitions and regulations on the release of organisms produced by genome editing are appropriate for state-of-the-art breeding techniques is, ultimately, a political issue.

The papers in this anthology address the scientific, legal and social aspects involved in finding a political compromise on genome editing in agriculture. All contributions were presented and discussed at an international summer school: "Beyond the Precautionary Principle? Ethical, legal and societal aspects of genome editing in agriculture".[21] The summer

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20 ibid., Paragraph 53.

21 A detailed report and video statements by participants (both in German) can be found online: https://www.pflanzen-forschung-ethik.de/aktuelles/1680.genome-editing-landwirtschaft-rolle-vorsorgeprinzips.html.

school took place from October 2nd to 6th 2017 in the study house Gut Schönwag near Wessobrunn in Oberbayern, Germany, and was organized by the Institute of Technology, Theology and Natural Sciences at the LMU Munich, which for many years has been working on the scientific, ethical and political issues around the use of green biotechnology in agriculture.[22] This anthology contains revised and partially updated versions of the individual lectures. As recent reactions to the CJEU ruling indicate, modern biotechnology in agriculture remains a controversial subject, which is to say that the papers presented here are highly relevant to the ongoing debate. What is more, these papers draw much-needed attention to the fact that the relationship between scientifically based precaution, innovation and responsibility has political and ethical dimensions which challenge the current self-positioning of European knowledge societies in an exemplary way. After all, in spite of their contradictory nature, the reactions to the CJEU's verdict also reflect a societal condition that is rather typical of the ambivalent attitudes held by political institutions and individual citizens alike when it comes to the potential of science and technology to change nature and everyday life.

The first chapter of this volume contains three articles which address **scientific aspects concerning the benefits of modern breeding techniques**. The article by JARST VAN BELLE, JAN SCHAART and ROBERT VAN LOO describe the use of novel genome editing technologies (e.g. CRISPR/Cas) for breeding plant varieties with novel traits. The authors take the crop plant camelina, which could be engineered to contain an improved oil composition, as an example of the potential of CRISPR/Cas. Camelina with improved oil composition could be grown in Europe and used as a substitute for palm oil imports. This novel camelina variety could therefore have economic as well as environmental advantages. Furthermore, the authors compare regulatory frameworks from different countries (European Union and Canada) and classify them according to distinct regulatory approaches: process- and product-based evaluation of new plant varieties. The authors argue that the current EU framework needs to be revised as it does not account for new genome editing technologies. They use the Canadian framework as an example of an alternative regulatory system. In addition to revising the EU regulatory framework, BELLE and co-authors support the idea of the 'innovation principle' as complementation to

22 Cf. Grimm and Schleissing 2012, Meyer and Schleissing 2014, Brandl and Schleissing 2016 and the website www.pflanzen-forschung-ethik.de.

the 'precautionary principle' because it would balance precautionary measures with potential benefits for society.

KATHARINA UNKEL and THORBEN SPRINK discuss the use of new plant breeding techniques (NPBT) in agriculture by using an example of a new carrot variety. The authors explain the biological processes behind different NPBT and highlight their advantages compared to conventional breeding methods. On the strength of this analysis, the authors argue that the current EU regulatory regime for NPBT plants is inadequate and needs to be adapted. Not only would a classification of NPBT as genetically modified organisms (GMO) be scientifically unjustified. It would also lead to a negative public perception of NPBT plants. In addition, the authors stress that this classification would have a negative economic impact, and it would do so for two compelling reasons. One, breeders would have to meet costly regulatory requirements. And two, it would render NPBT plants economically unfeasible due to fierce public rejection of GMOs.

The article by AURELIE JOUANIN and MARINUS J.M. SMULDERS describes the production of 'gluten safe' wheat by NPBT, such as CRISPR/Cas. The idea behind the construction of this wheat variety is that it would improve the lives of people suffering from celiac disease, while it could also serve as a prime example of the benefits of NPBTs, since it is very difficult to obtain a 'gluten safe' wheat by conventional breeding methods. Furthermore, the authors argue that NPBT plants could even be considered safer than conventionally bred plants due to the accuracy of the molecular scissors as opposed to the random mutations caused by chemicals or irradiation. JOUANIN and SMULDERS emphasize the importance of scientific outreach to the public so as to better understand the public's position on the issue, a position which seems to stretch from negative opinions to categorical rejection. Ultimately, the authors find the current regulatory framework for NPBT plants in the EU to be so unclear that it has led to an innovation break in the European field of modern plant breeding, as regulatory uncertainties prevent companies from investing and applying NPBT in their breeding programs.

Legal considerations on the regulation of genome editing with regard to the Precautionary Principle are at the center of this volume's second chapter. In its judgment of 25 July 2018, the CJEU invoked the Precautionary Principle in order to justify its reasoning that genome edited (GE) organisms obtained through mutagenesis techniques are GMOs within the meaning defined by Directive 2001/18. Consequently, the CJEU ruled that such GE organisms do not qualify for the so-called 'mutagenesis exemption' as listed in Annex I B of the directive. The article of HANS-GEORG DEDERER contributes to the debate sparked by this ruling and it does so

by providing an overview of the current legal framework for GMOs on the EU level, the parameters which frame any GMO or GE organism regulation, and other options for an appropriate regulatory framework for GE organisms. DEDERER points out that the Court's primarily 'process-based' reading of the GMO definition has the unfortunate consequence that any organism developed by GE techniques is a GMO within the legal meaning of GMO definition. However, the present GMO framework does not seem to be fit for the task of adequately regulating GE organisms. It may therefore be necessary to adjust the existing legal framework to the specificities of GE organisms so as to bring it in line with current scientific knowledge. DEDERER discusses simplified procedures and risk assessment along with the possibility of introducing some exemptions which apply either to GE organisms or to certain categories or types of GE organisms. Finally, he emphasizes that genome editing should be perceived as an immense chance to revisit our regulatory approaches, mechanisms and instruments, all of which seem to be outdated with regard to our modern, radically improved GE techniques.

Suppose that the nightmares of scientists and plant breeders were to come true: Many people reject genome editing technologies. This is the starting point of BRIGITTE VOIGT's article written before the CJEU ruling. She envisages the following scenario: Plant variety risk assessment would be based on plant traits, not on their breeding technique, and novel mutagenesis techniques (e.g. CRISPR/Cas) would be considered as risky as conventional breeding techniques. Then how are we to regulate genome editing technologies? In her article, VOIGT explores the legislative possibilities and legal loopholes of legislators to respond to public fears which scientists deem to be irrational. She discusses options within, beyond and independent of the Precautionary Principle, all this by way of raising the final, crucial question: If public opinion is at odds with the overwhelming majority of scientists, as is currently the case with genome editing technologies, whose viewpoint ought to be more important?

Of course, legislative questions about the future regulation of genome editing are not limited to European law. Furthermore, they are not merely concerned with biosafety but also with trade and liability issues. FELIX BECK addresses open questions surrounding the international liability regime for damage caused by the use of genome editing and gene drives in agriculture. He emphasizes that liability for cross-border environmental damage is a highly complex problem, as it not only affects intergovernmental agreements but often requires domestic implementation and enforcement. He identifies critical gaps in all of these areas and discusses approaches to improving liability management in the future. States have al-

ways been reluctant to accept regulations to harmonize civil liability regimes, and they have been reluctant to extend their own responsibility to prevent transboundary damage originating from their territories. Liability for damage from living modified organisms is a prime example of these phenomena. Although it seems unlikely that the regime will be updated in the near future, the scientific debate should not stall at this crucial juncture. After all, as in so many other areas of international law, it is usually the scientific discourse that paves the way for the development of workable solutions.

The paper of JOAO O.B. DEMASI discusses the complicated public policy on the Precautionary Principle and the process of labelling, governed as it is by World Trade Organization (WTO) case law. DEMASI reviews how a labelling legislation based on the Precautionary Principle for gene-edited products could withstand a WTO dispute. He also examines whether a protection claim based on Article XX of the General Agreement on Tariffs and Trade (GATT) satisfies the appeal committee's judicial decision on the 'necessity test'. The latter provides general exceptions to international trade commitments concerning unilateral trade measures which safeguard the need to protect human, animal, or plant life or health. The question is whether the measures were 'necessary' to achieve this public health goal. If there is a health risk and there is no alternative to labelling, does the Appellate Body uphold this? DEMASI discusses precautionary cases under the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and labelling cases under the Agreement on Technical Barriers to Trade (TBT Agreement). The paper concludes with a legal opinion.

The third part of this book "**Genome Editing and the Precautionary Principle – Theory and Democratic Practice**" addresses democratic options for governing Genome Editing in respect of precaution and responsibility. BARTOSZ BARTKOWSKI describes to what extent novel genome editing techniques render existing regulatory regimes for GM crops inadequate. Their fast-changing nature is likely to increase the pressure to find adequate and flexible governance solutions. BARTKOWSKI discusses the relevant challenges and argues that, given the ambiguity and irreversibility of new technologies, a thorough and open public debate is indispensable if we are to design a CRISPR/Cas-sensitive governance regime. Until such a debate is underway, BARTKOWSKI argues, a temporary moratorium on the cultivation of CRISPR/Cas-generated crops would appear to be recommendable; technocratic, 'evidence-based' regulations are *not* an option simply because they would not be regarded as legitimate in most countries, where opposition towards GM food is still strong.

CHAD M. BAUM examines the potential for a 'constructive' Precautionary Principle for genome-editing technologies: BAUM first explores the debate on the existing Precautionary Principle to tease out, at least in part, the arguments for why precaution and innovation are supposed to be mutually exclusive. By focusing on this antagonism, there is a tendency to neglect the more constructive function of precaution. We should therefore reframe the issue, not asking whether precaution or innovation should be prioritized, but rather how innovation is to be applied or why certain applications cause greater public anxiety. According to BAUM, the crucial question is not how fast a technology should be allowed to develop but how we can use the opportunities to improve human life and perhaps even make it more meaningful.

ALEXANDER BOGNER and HELGE TORGERSEN address the regulatory demand for responsible innovation. They provide a brief overview of different ways to govern (bio)technological change and the principles behind it, arguing that the main problem would seem to be how we are to identify benefits and risks, fairly organize their balancing and responsibly reconcile interests as well as values. Using the example of genome editing, the article explains the concept of Responsible Research and Innovation (RRI) as a governance approach on the EU level, which involves a variety of stakeholders and non-scientific actors in the research and innovation process. Against this background, BOGNER and TORGERSEN discuss benefits and pitfalls of public engagement with science and technology.

SEBASTIAN SCHUBERT focuses on the regulation of biotechnology in the age of digitization, more specifically on the role which the Open Access paradigm could play in this context. According to SCHUBERT, the Open Access approach could help decision-makers formulate ideas for a new policy framework and, in the future, draft legislation on genome editing in plants and livestock that would provide a normative framework for determining the use of new breeding methods for the public good. It may also help to provide a new, more appropriate picture of the methods used in molecular genetics.

ANNE F. HOFFMANN addresses the most important philosophical tenet of the Precautionary Principle in the German tradition, namely the work of Hans Jonas. In his "The Imperative of Responsibility", Jonas describes how ethics must be transformed in the modern technological era in order to meet the emerging challenges posed by technological and scientific developments. In facing these challenges, Jonas proposes the so-called 'Heuristics of Fear': If in doubt, one should listen to the worse prognosis, rather than the better one. Yet HOFFMANN goes beyond a restating of

Jonas's main arguments. She also discusses their effects on current (Protestant) ethical reflections.

KSENIA GERASIMOVA compares GMO discourses in the UK and Germany to understand similarities and differences, in particular when it comes to the role of public confidence (or lack thereof) in scientific research and its impact on policy-making. The comparison of the two national contexts shows that Germany has a stronger version of the Precautionary Principle in its environmental law, while the United Kingdom takes a more 'optimistic' approach, allowing science to give more direction to public policy. Since the main opposition to GM crops in both countries is shaped by groups of laypeople who, according to GERASIMOVA, have better understood the public's fears about transgenic organisms than politicians and scientists, the article also provides an analysis of anti-GMO NGOs and their work in the UK and Germany.

Finally, KAROLINA RUCINSKA proposes a concrete method to promote scientific-public dialogue on biotechnology in the context of farm animals. The main aim of the so-called Eating Information Together method is to generate a fruitful exchange between scientists and the public in an environment which promotes mutual and common understanding of the issue, democratizing the decision-making process and fostering open communication. The article provides a detailed overview and discussion of the proposed method.

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