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# The divergent governance of gene editing in agriculture

## A COMPARISON OF INSTITUTIONAL REPORTS FROM SEVEN EU MEMBER STATES

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## ABSTRACT

In 2018, the EU Court of Justice ruled that gene edited organisms "are GMOs and are, in principle, subject to the obligations laid down by the GMO directive [EU Directive 2001/18/EC]". While the EU Court of Justice has established an equivalence between gene edited organisms and GMOs, how have national institutions and committees from EU member states positioned themselves regarding the use of gene editing in agriculture? In order to answer this question, this article examines and compares 11 official reports and position statements from 7 European countries: Germany, France, the Netherlands, Italy, Spain, Denmark, and Sweden. The various kinds of issues that are addressed and arguments that are made in the reports are coded into large categories (innovation, risk, ethics, legislation, etc.) and are analysed. The paper discusses the main similarities and differences in terms of how the governance of gene editing is problematized. For instance, while some reports consider gene editing in terms of technology, risk and regulation, others situate gene editing within larger debates about agriculture, intellectual property, ethics, public participation, and the responsibility of scientists. The paper aims to provide a useful resource to broaden debates on the future regulation of gene editing within and beyond Europe. It also calls for an analysis of the *objectification* of gene editing: how are gene edited organisms rendered tangible, discussable and public via policy processes? How are they tied to national territories, identities, histories or products and how does this (re)nationalizing of gene edited organisms matter within and beyond EU member states?

## KEYWORDS

gene editing, agriculture, governance, European Union, regulation

# Introduction

Recent responses from policy makers concerning the regulation of gene editing in the field of agriculture have shown remarkable divergences. Consider, on the one hand, the position of the US Department of Agriculture (2018): crops modified via gene editing "do not require regulatory oversight." The US Department of Agriculture considers gene edited crops as innovative, safe, and healthy. Consider, on the other hand, the ruling of the EU Court of Justice (2018): gene edited organisms "are GMOs and are, in principle, subject to the obligations laid down by the GMO directive [EU Directive 2001/18/EC]". While establishing an equivalence between gene edited organisms and GMOs, the EU Court of Justice argues that gene edited organisms can potentially be risky, and stresses the need to respect the precautionary principle.

While the position at the EU level is clear-cut, what about positionings within individual European member states? How have national institutions and committees positioned themselves regarding the use of gene editing in agriculture? Do they have similar views on the issue or are there significant differences?

In order to answer these questions this article examines official reports and position statements from seven European countries: Germany, France, the Netherlands, Italy, Spain, Denmark, and Sweden. We have decided to focus on these seven countries for they are the only European countries in which at least one official statement regarding the use and regulation of gene editing in agriculture has been published.[1]

# Context

Today the most prominent gene editing technique is CRISPR/Cas9. CRISPR (for Clustered regularly interspaced short palindromic repeats) sequences have first been described in 1987 and in the 2000s their capacity to "edit" genes has been recognized. The CRISPR/Cas9 technology - often called "gene scissors" - makes it possible to change genetic sequences easier, quicker and cheaper than traditional biotechnology methods and has thus been celebrated as "the iPhone of biotechnology" (Galanopoulo 2016) and the greatest advance in biotechnology since the PCR machine.

2015 is the year that CRISPR/Cas9 made it to the headlines of many academic journals as well as media outlets. The publication in April 2015 of an article on the modification of human embryos in the journal Protein & Cell (Liang et al. 2015) raised international concern

[1] We have searched for reports and statements from all 28 EU member states, with the exception of the UK as its future membership of the EU is uncertain. According to our search, in only 7 countries reports on gene editing have been published. This does not mean, however, that other EU member states have not reflected upon the issue: Eriksson (2018) has provided a detailed list with statements and opinions by EU actors that, beyond the countries we identified, also includes Finland; and Svingen (2019) has analyzed the positions of the Norwegian Biotechnology Advisory Board.

and calls for a moratorium were published in journals such as Nature (Lanphier et al. 2015) and Science (Baltimore et al. 2015). From 2015 onwards, CRISPR/Cas9 became the object of wide and rich debates. Concerns have been raised about ethical issues, about economic issues related to patenting, about environmental and health risks, and about the possibility to produce new kinds of weapons. The issues raised resemble the types of issues that can be observed in debates around GMOs and synthetic biology, which generally revolve around ELSI issues, that is the ethical, legal, and social implications of science (Baumann 2016).

At the end of 2015, the first international summit on human gene editing was held in Washington (Jasanoff et al. 2015). After this summit, numerous countries have issued reports or statements about human gene editing, including the UK, the US, Germany, France, the Netherlands, India, Denmark, Canada, and Australia. Various other conferences such as CRISPRcon have been organised (since 2017) in order to address scientific, ethical, legal and policy issues. Gene editing then broke again the headlines in November 2018 when scientist He Jiankui announced that he had modified the embryos of twins via gene editing; an announcement made just a few days before the second international summit on human genome editing in Hong Kong (Meyer 2018). As in 2015, the organizing committee released a statement about the use of gene editing in human embryos and many countries and scientific institutions issued position statements thereafter.

While human gene editing has been much discussed and written about, much less has been written on the use of gene editing in agriculture and its implications in terms of governance, regulation, economics, social and ethical issues. There have been, on the one hand, several reports on the topic - for example the report New Techniques in Agricultural Biotechnology published by the European Commission in 2017 - as well as international conferences on the topic, such as Genome Editing: Applications in Agriculture - Implications for Health, Environment and Regulation held at the OECD in 2018. On the other hand, only a few academic articles have discussed and examined the wider implications of gene editing. Gutzmann et al. (2017) discuss the need for interdisciplinarity and public engagement when reflecting upon the ethics and governance of CRISPR-based gene drives in agriculture. They conclude: "Scientists, social scientists, regulators, advocacy groups, and public audiences have been and must continue to engage clearly and candidly with one another to shape the future of this technology". Helliwell et al. (2019) analyse how non-governmental organisations contest and challenge the wider politics, framings, and power issues in the debate. Holman (2019) has compared regulatory frameworks, in particular between the US, who are moving towards less regulation, and the EU, who intents to regulate gene editing via the "same burdensome regime" than for GMOs. A wide scope is provided by Erikkson et al. (2019), who look into regulations in Argentina, Brazil, Chile, Colombia, Canada, the United States and Australia in comparison to the EU approach. They also discuss some of the concerns raised in the aftermath of the ruling of the EU Court of Justice: concerns with trade disruptions, agricultural innovation, and the difficulty to detect and label gene edited products. The present article aims to contribute to this recent and emerging academic literature on the social, ethical, legal and political aspects of the use of gene editing in agriculture. Its originality consists in examining and comparing how different councils, commissions and/or institutions within the EU have addressed gene editing. Such an approach is useful, we hope, because governance and public debates on gene editing occur both on national and transnational levels and since comparisons can reveal the specificities

of a given position, and point to commonalities and potential divergences between countries and institutions.

# Methods and results

We have selected and analysed altogether 11 texts published in 7 countries (see table 1). The reports have all been published from 2015 onwards, which doesn't come as a surprise since gene editing rose to prominence in 2015 both within and beyond academic circles. There is a notable heterogeneity regarding the institutions that have published them: independent councils (i.e. the French Haut Conseil des Biotechnologies, the Danish Council on Ethics); ministerial commissions (i.e. the Spanish Comisión Nacional de Bioseguridad) and intra-ministerial commissions (i.e. the Italian Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita); as well as scientific institutions (i.e. the common ethics committee of INRA, CIRAD, and IFREMER, the Max Planck Society). While the provenances and forms of these texts are heterogeneous, they were all written in response to regulatory concerns associated with the future governance of - and debates on - gene editing and all include recommendations.

In order to examine the content of these texts in more detail, we have used what social scientists call a "grounded method": we have scrutinized the texts to seek for the various kinds of issues that are addressed and arguments that are mobilised, and we then coded these into eight large groups (innovation, risk, ethics, etc.). To these eight categories we added a ninth rubric: the reports' recommendations (see table 2).

In a second round of analysis, we have examined if and how, in each of these 11 reports, the eight themes have been addressed and what kinds of recommendations they draw. Table 2 provides a summary of the results of our analysis.

Table 1: Reports and position statements on gene editing according to their country of origin, the institution(s) that published them, the title and year of publication

| Country | Institution(s) | Title | Year; number of pages |
|---|---|---|---|
| **Germany** | Nationale Akademie der Wissenschaften Leopoldina, Deutsche Forschungsgemeinschaft, Deutsche Akademie der Technikwissenschaften, Union der deutschen Akademien der Wissenschaften | The opportunities and limits of genome editing | 2015; 16 pages |
| **Germany** | Max Planck Gesellschaft | Statement on the scientific and translational impact of genome editing and arising ethical, legal and societal issues | 2019; 4 pages and discussion paper of 29 pages |
| **France** | Haut Conseil des Biotechnologies (HCB) | Avis sur les nouvelles techniques d'obtention de plantes (New Plant Breeding Techniques - NPBT) | 2017; 1 report of 60 pages + 12 pages of appendix and 1 report of 69 pages + 21 pages of appendix |
| **France** | Comité consultatif commun d'éthique INRA-CIRAD-IFREMER | Avis 11 sur les nouvelles techniques d'amélioration génétique des plantes | 2018; 36 pages |
| **Denmark** | The Danish Council on Ethics | Statement on GMO and ethics in a new era | 2019; 28 pages |
| **Italy** | Società Italiana di Genetica Agraria, Società Italiana di Biologia Vegetale (SIGA/SIBV) | Position document on genome editing techniques applied to agriculture | 2016; 13 pages |
| **Italy** | Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (CNBBSV) | Le New Breeding Techniques (NBT): 1 - La posizione dei principali portatori di interesse Italiani | 2017; 15 pages + 11 pages of appendix |
| **Spain** | Ministerio de Agricultura y Pesca, Alimentación y Medio Ambiente (Comisión Nacional de Bioseguridad) | Comentarios de la Comisión nacional de bioseguridad. Sobre las nuevas técnicas de mejora vegetal (NTMV) | 2015; 5 pages |
| **Spain** | Ministerio para la Transición Ecológica (Comisión Nacional de Bioseguridad) | Informe de la Comisión Nacional de Bioseguridad sobre la mutagénesis dirigida ("edición genética") | 2019; 6 pages |
| **The Netherlands** | Royal Netherlands Academy of Arts and Sciences | Genome Editing - Position Paper of the Royal Netherlands Academy of Arts and Sciences | 2016; 6 pages |
| **Sweden** | Swedish Board of Agriculture | Consequences of the EC-ruling according to Swedish companies and research groups | 2018; 18 pages |

Table 2: Arguments made in official texts

All words are direct quotes unless marked otherwise (italics and brackets)

| | Innovation | Risk | Legislation | Food Quality | Economy | Epistemology | Ethics | Intellectual property | Recommendations |
|---|---|---|---|---|---|---|---|---|---|
| **Denmark (2019)** | simpler; more accurate | gene modification [is not risky] per se; [no] greater risk than conventional plant breeding technologies | [legislation is] paradox[ical] because required risk assessments are too expensive, thus favouring research carried out by large [...]corporations | develop plants that are more resistant to disease, that are healthier to eat, that can keep for longer | *problematic if development and marketing is obstructed*; [only] multinational seed companies can afford risk assessing their GMOs | new genome editing techniques give rise to new research, however, new research is crucially inhibited by current EU legislation | morally, we ought to use the types of GMOs that could be beneficial; genetic modification is wrong because it is unnatural | [Patents on GMO varieties] led to widespread criticism; farmers [...] are forced to buy the seeds from the seed company | not put obstacles in the way of GMOs based on the technology used to produce them |
| **France (2017)** | efficiency; rapid | *different kinds of risks assessed;* uncertainty; the main risk would be related to the presence [...] of the effectors | *different interpretations of EU directive possible*; legal uncertainty; grey zone | nutritional quality can be cited | the nature of the products put on the market, the perceptions and reactions of consumers and actors in the sectors are difficult to anticipate to date | in terms of research needs, [there is a] need to reduce some of the existing uncertainties about NPBTs | *discussed at length* | research on intellectual property in the field of plant biotechnology may be necessary | framework [...] based on both the precautionary principle and a principle of proportionality; in-depth juridical study should be done; *case by case* |
| **France (2018)** | precious tool; possibilities; limits; perceived as more precise, more rapid, easier, [...] and less expensive | environmental, sanitary, agricultural, economic, social and political [risks need consideration]; uncertainties | be active in discussions [...] on regulatory questions; two types of regulatory systems envisaged; legal uncertainty | improve [...] nutriments | render explicit contradiction between [...] competition and [...] the agroecological transition | interdisciplinary; transdisciplinary; common good; public research; co-construction [*need consideration*]; *pertinent tool for knowing life/genes* | defence of the ethical values associated to the COV system [which guarantees just intellectual recognition and availability of genetic resources] | be active in discussions [...] on intellectual property; patentability of CRISPR-Cas9 system [...] is not subject to litigation; *benefits of open source* | *10 recommendations* |
| **Germany (2015)** | simple; time-saving; cost-effective; more efficient; more controllable | risk is primarily associated with gene drive technologies | legally acceptable in many areas; regulatory consequences for the classification, assessment and approval of the plant varieties obtained by new molecular breeding methods [should be taken] | *indistinguishability between GEOs and animals or plants bred by natural processes require new processes for the product-based assessment and regulation of GMOs* | *only indirectly mentioned in statements about the potentials of possible applications* | [detailed discussion regarding] new dimensions for all molecular biological basic research and for potential applications in plant breeding, industrial biotechnology and biomedicine | ethically [...] acceptable in many areas | / | *applications and ethical or legal problems should not be mixed up or condemned*; there should be public debate on the scientific, ethical and legal possibilities of genome editing and on its limits |
| **Germany (2019)** | much simpler; versatile platform for precise alterations | research drawing on new gene editing techniques should be carried out, in order to understand the risks | Directive 2001/18 requires revision and updating | interest to the consumer, such as reduced gluten content | / | enormous potential both for understanding biological principles and for improving human, animal and plant health | it is necessary to develop universal ethical [...] standards with regard to gene drives | ensure license practices coherent with freedom of research and equal access to resulting applications | pursue new and amended legislation |

| .../... | Innovation | Risk | Legislation | Food Quality | Economy | Epistemology | Ethics | Intellectual property | Recommendations |
|---|---|---|---|---|---|---|---|---|---|
| **Italy (2016)** | promising; precise; predetermined; innovation; successfully | predictable risk; avoids the risk | regulatory limbo; [regulate as GMOs is a] serious mistake | nutritious; safe | compete globally; inexpensive food | / | / | / | should be excluded from Directive 2001/18/EC |
| **Italy (2017)** | innovative; promising; precise; excellent instrument; low cost | minor risk; similar risks [as conventional technologies] | legislative void; uncertain about their regulation; outdated | / | competitiveness; import; strategic sectors | / | / | important question of patentability | *legislation should be product oriented*; revise directive |
| **Netherlands (2016)** | cheaper, more efficient, more precise | need to be vigilant and to address social and ethical dilemmas | EU must clarify and, where required, amend legislation | higher yields, and disease- and pest-resistance | negative consequences [...] for commercial applications in agriculture and horticulture | significant advances in our knowledge | genome editing [...] gives rise to critical ethical questions | / | simplification of the regulations |
| **Spain (2015)** | rapid; useful | security analysis [is needed] | / | quality of the fruit | commercial value | / | / | / | case by case evaluation; product and not the process |
| **Spain (2019)** | rapid; precision; specific; efficiency | minimal risk; safety for health and the environment [needs consideration]; security | for a revision of the actual norms regarding GMOs | these techniques are used [...] to improve crop quality | international commerce | advancement of European science | / | / | clarifications are needed on some implementation issues; revise the current regulation on GMOs |
| **Sweden (2018)** | great potential; efficient; rapid; precision | risk of losing collaborators, companies and researchers from academic institutions | legal uncertainties; ruling [...] means a ban on genome edited crops | plant varieties with higher quality; increased food safety | expensive authorisation procedures; less [...] funding for research; products [...] will not reach the market; loss of competitiveness; obstruct commercialisation | collaboration [...] will decrease; loss of competitiveness; *research projects have been changed or paused* | / | made investments in patent [...] will be lost; [dependence] on licenses from biotechnology companies | / |

# Discussion

Some texts take a strong stance in favour of the exclusion of gene editing from current regulation making claims about the negative consequences for science and economy should the EU regulation (i.e. EU Directive 2001/18/EC) not be renewed. This is the case, for instance, in the two reports from Italy. The 2016 SIGA/SIBV report says that it would be a "serious mistake" to qualify as GMOs gene edited organisms with mutations that are indistinguishable from spontaneous ones, and that the "remake of European GMO history" will lead to "a nonsense of logic, a scientific absurdity, a legal mess and an economic damage altogether". The 2017 CNBBSV report, albeit a bit softer in tone, is also clearly in favour of not regulating gene editing, arguing that there are only "minor risks", and that the 2001 EU directive is "inadequate" and that regulation should be "purely product-oriented" (and not process-oriented). In a section devoted to market issues, concerns are raised about "grave repercussions on strategic sectors [...] with an inevitable loss of international market".

The position of the Swedish Board of Agriculture - an assessment of the (mostly negative) consequences of the EU Court of Justice ruling - is also in favour of deregulating gene editing. It stresses that for "many researchers, the ruling is perceived as very problematic." According to the report, many things will be "lost" due to the ruling: "Made investments in patent, staff, research, product development and knowledge", "competence", "competitiveness", "control of plant breeding". Both the positive assessment of gene editing, as well as the negative assessment of the ruling are exemplified by the following quote:

> "The ruling will have negative effects on the national economy when it comes to both plant and animal production. It is counter-productive to make it more difficult to use a technique with high precision and with several benefits compared to "older" techniques. Genome editing is a brilliant example of technical development being the most important factor to be able to deal with challenges regarding food supply, resource management, climate adaptation and the environment."

In the same vein, the report of the Danish Council on Ethics holds a position which is largely in favour of a renewal of EU regulations while putting a stronger emphasis on the solution of current planetary crises. A general bottom-line of the Danish Council on Ethics is that CRISPR does not carry more or less risk than traditional gene modification, and that, given this "fact", humanity can no longer "afford" not to use CRISPR. In order to strengthen this utilitarian position, the authors repeatedly refer to the potential role that genome editing could play "in achieving several of the UN's Sustainable Development Goals from 2015". Beyond that, the authors accuse the existing EU regulatory framework of being "paradoxical" while underlining that:

> [this paradoxicality] "raises the question of whether it is ethically problematic if the legislation obstructs the development and marketing of GMOs, e.g. those with positive effects, if they are not deemed more risky than similar conventional varieties."

Despite this vigorous argumentation in favour of CRISPR, the report closes with somewhat fragmented recommendations on how to govern gene editing in the future. In these

recommendations "some members" (the large majority) of the Danish Council on Ethics provide practical suggestions on how to adapt current EU regulation, while "one member" is granted the space to express that he "cannot support measures to ease the authorisation system for GMOs."

At the other end of the spectrum is the 2018 report by the Comité consultatif commun d'éthique INRA-CIRAD-IFREMER. This report is the most critical, reflexive and analytical in our corpus of texts. The report argues, for instance, that "it is important not to be blinded by short-term benefits but to take the time to evaluate long-term risks" and that an "upstream inclusive and collective reflexion" is needed. It situates gene editing within larger debates about the models and politics of agriculture; it discusses controversies and contestations; and it reflects about issues that are not present in any other report, such as recent developments in the field of agroecology as well as matters of public participation, social justice, and open source. The ten recommendations of the report can be roughly summarized as a call for reflexivity, openness and vigilance (for example: consider the forms of agriculture, economy and society in relation to CRISPR/Cas9; foster interdisciplinary research; discuss about regulation and intellectual property issues). The report by the Danish Council on Ethics is somewhat similar to the INRA-CIRAD-IFREMER report in terms of its scope: both reports are interdisciplinary (and their authors include philosophers, ethicists, plant scientists, environmental scientists, etc.) and they provide a much more systemic analysis than the other reports.

To put it bluntly, we can identify three kinds of reports in our corpus: interdisciplinary/systematic ones (France, Denmark); reports that talk in the name of science and offer rather cautions assessments regarding technological advantages (Netherlands, Germany, Spain); and those with a strong normative and affirmative view (Italy, Sweden).

## Similarities and differences within themes

The reports provide a more or less broad view of the use of gene editing in agriculture. They focus not only on the technical aspects of gene editing, but also on risks and legislation. Some issues are, however, present in only a few reports, such as ethics, intellectual property, and what we termed "epistemology" (arguments about the kind, importance and usefulness of knowledge produced). Let us look in more detail at how innovation, legislation, recommendations and the economy have been addressed in the texts.[2:]

- The qualifications of gene editing (the theme "innovation") show remarkable similarity, with terms like "simple", "rapid", "efficient", "precise" being used in most reports.[3]
- The legal implications of gene editing are also treated in a similar fashion: most reports argue for the need of a "revision" and/or "updating" of current legislation, because there are "uncertainties". Most reports also recommend that legislation

[2] We focus on these four themes for they are the ones to which most space is dedicated in the reports.

[3] The 2018 French report is reflective about these terms, and even critical about the use of military metaphors.

should be based on products, and not the processes of genetic modification anymore.

- There are notable differences regarding the specific recommendations that are given. On the one hand, there are reports that have a moderate view: they recommend to "amend" and "clarify" legislation because it is "unclear" (i.e. the Netherlands, Germany, France). While these reports argue that legislation needs modification and further reflection, they refrain from saying what kinds of modifications should be done. On the other hand, there are reports that take a more normative stance and argue, for example, that gene edited organisms "should be excluded" from legislation (Italy).
- Economic issues are also treated differently in the reports. First, in the German statements economic aspects are virtually absent.[4] Second, in the reports from Spain and the Netherlands, they are mentioned very briefly, usually in a couple of sentences. Quite frequently these brief considerations of the economic issues underline the importance of using gene editing in order to maintain or improve a particular branch of agricultural production that is historically intertwined with the national territory. For example, the position of the Royal Netherlands Academy of Arts and Sciences is that a renewal of the regulation in the EU is needed in the name of horticulture. Third, there are reports, like the Italian, Swedish and French ones, that treat economic issues in great depth on several pages. The French INRA-CIRAD-IFREMER report discusses for instance economic risks and the tensions between the industrial paradigm (concerned with performance and control) and the agro-ecological paradigm (concerned with protection and cooperation), and the HCB report reflects upon commercialisation, competitiveness, traceability, and consumer choices. In the report by the Swedish Board of Agriculture, the negative consequences of the EU Court of Justice ruling on the economy are evaluated and potatoes, rapeseed and barley are discussed as examples of crops that are important for Swedish agriculture. The 2017 CNBBSV report contains discussions of specific sectors in agriculture (rice, grapes, wheat, etc.) and the strategic interest thereof for Italy. It is interesting to note here that the examples given are always plants but very rarely animals.

## Argumentative patterns in relation to GMOs

In addition to the themes that we identified and analysed, we observed that GMOs often serve as a reference frame to make arguments about gene editing. On the one hand, this doesn't come as a surprise since Directive 2001/18/EC is the key legal reference point and since the key question can be summarised as "Should gene edited organisms (GEOs) be considered as GMOs or not?". On the other hand, however, references to GMOs are not limited to legal aspects only. In fact, several argumentative patterns in relation to GMOs can be noted:

[4] In the 2019 German statement terms like economy/economic, market, industry/industrial, commercial do not appear. In the discussion paper from 2015, there is some discussion, but rather abstract, and in relation to GMOs.

1. GEOs are better and different than GMOs: they are safer, more precise, and quicker and cheaper to produce. The argument here is that with regards to the history of GMOs there has been a differentiation and revolution.

2. GEOs are comparable to GMOs: there is no scientific evidence that GMOs pose a risk, they can thus be considered as safe. Therefore GEOs are also safe. This argument relies on the comparability between GMOs and GEOs and - unlike the argument above - upon the historical and technical continuity between them.

3a. GEOs are not GMOs in terms of legislation. GEOs should not be regulated as GMOs. The problem with pace and asynchronicity is put forward here: legislation is seen as "out of date" with regards to new knowledge and new techniques.

3b. GEOs are not GMOs in terms of nature. Since it will not be possible to distinguish most GEOs from natural mutations, GEOs should be excluded from any legal framework. In other words, GEOs' indistinguishability from nature should lead to their unaccountability in law.

An illustrative example for this modular use of references to GMOs is provided by the report of the Danish Council on Ethics. On the one hand, the authors frequently draw comparisons between "20 years of GMO risk assessments" and the "absence of particular risks" of GEOs. On the other hand, they repeatedly refer to the technical difference of "CRISPR-induced mutations" and "traditional mutagenesis", in order to argue that GMOs and GEOs should not be legislated in the same way. In other words, from the Danish Council on Ethics' point of view it seems possible to separate GEOs as objects of risk/non-risk from GEOs as objects of legislation.

# Concluding remarks

Gene edited organisms have become, over the past four years, the topic of a wide array of texts: reports, statements, rulings, etc. While some of these texts have been published by scientific institutions, others have been published by ministerial commissions and advisory councils that are involved in concrete acts of doing politics. It is thus fruitful to ask a wider question here: What kind of objects are gene edited organisms and how can we grasp their political dimensions? In order to answer this question, let us consider the following quote by Vytenis Andriukaitis, the current EU commissioner for Health and Food Safety:

> "new breeding techniques can help us tackle some profound challenges such as food security, food intolerances, or climate change. Examples include low-gluten, non-transgenic wheat [...] Or potatoes with a non-browning trait and producing less asparagine have been developed through gene editing. These potatoes provide the potential for the formation of acrylamide to be reduced by 60-70% when potatoes are baked, fried or roasted at high temperatures. (This could completely 'save' Belgium fries)" (Andriukaitis 2019).

Gene edited organisms are very specific objects. They bring together not only technological and scientific considerations but also issues to do with consumers and health. They are

socio-technical objects. The pun regarding the "saving" of Belgian fries reveals another important facet of gene edited organisms: they are also geopolitical objects. In the reports we have analysed, Dutch horticulture, Italian grapes, and Swedish potatoes have been put forward as relevant issues. Even the call for the "advancement of European science" made in the 2019 report by the Comisión Nacional de Bioseguridad is not only an argument about knowledge, but also about politics. In a similar way, the report by the Danish Council on Ethics interweaves its specific argument for a renewal of the EU legislation regarding GEOs with more general references to UN Sustainable Development Goals that might be attained by means of new gene editing tools. In other words, the report translates complex and planetary problems such as climate change and hunger into the less complex (and easier-to-imagine) problems of finding the right tools and indicators.

These kinds of entanglements between the technical, the social and the political are particularly interesting to examine and compare. While we have analysed these entanglements across national and institutional positions, there is scope for further analysing national policies in more detail. This could be done, for instance, by looking more specifically at the history and the making of policies in a given country/institution and how different kinds of expertise and scientific disciplines are mobilised in this process. If one moves beyond the neatly crafted world of policy reports and position statements, the picture gets more complex (and would require further analyses).[5] This could also entail an analysis of the objectification of gene editing: how are gene edited organisms rendered tangible, discussable and public via policy processes? How are they tied to national territories, identities, histories or products and how, if at all, does this "(re)nationalizing" of gene edited organisms matter within and beyond EU member states?

Given that gene edited organisms raise technical, social, ethical, legal and political issues, how are they to be governed? Our paper has shown that there are a number of similarities, but also a great number of differences in terms of how their governance is problematized. Some reports are the result of a framing that mainly focused on technology, risk and regulation, whereas other reports considered ethics, intellectual property, and societal issues as well. And while some reports considered gene editing in itself, others chose to situate gene editing within larger debates about agriculture, gene drives, medicine, public participation, and the responsibility of scientists. Given that the governance of gene editing can hardly be confined to national boundaries, expertise and policy about gene editing is also very likely to cross national borders. However, this is not necessarily an easy and smooth process: the divergences across positions within EU member states make a synthesis and common view difficult to achieve. Can diverse European policy options for GEOs co-exist and what consequences would this coexistence have? Asked differently: could gene editing become a "European object" (Laurent 2019), and if so, how? The ruling of the EU Court of

[5] If one takes a look, for example, at Germany's agricultural policy arena, one can observe a proliferation of positions that are far from convergent: the Federal Agency for Nature Conservation "welcomes" the European Court of Justice ruling with reference to the precautionary principle, whereas the Federal Office of Consumer Protection and Food Safety takes the opposite view; at the level of farmers' associations, the conventionally oriented "Deutscher Bauernverband" argues that "CRISPR/CAS-9 cannot be meaningfully regulated with the existing genetic engineering law", whereas an umbrella organization of the German organic sector (BÖLW) supports the ruling.

Justice is a key site which addresses this question. The ruling not only assesses the technical aspects of GEOs, it also defines and constitutes them as a very specific kind of object: an object that, in Europe, requires regulatory oversight. Whether one agrees with this ruling or not, further debates about the entanglement - and disentanglement - between the law and technology are to be expected. We hope that our paper will provide a useful resource to broaden debates on the future regulation of gene editing within and beyond Europe.

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