Legal Issues of Genome Editing in Plants and Animals

Subproject 4 in the cooperative BMBF-project *Ethical, Legal and Socio-economic Aspects of Genome Editing in Agriculture* (ELSA-GEA, www.elsa-gea.de, www.genomeditierung.de)

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Objectives

The project evaluates the current national, European and comparative international legal situation regarding new genome editing technologies. The objective is to analyse the legal questions of biosecurity, biosafety, relevant fundamental rights and consumer protection against the background of the question whether genome editing technologies should be considered as instances of the category of genetic modification technologies, of the category of traditional breeding techniques, or of a *sui generis* category of new genome technologies.

Summary

Genome editing (GE) techniques may not fall squarely within the scope of the presumed legal framework (e.g., European Directives 2001/18/EC, 2009/41/EC, or the German GenTG), which is delimited by means of the basic concept of genetic modification. While the relevant legal framework applies to generic modification (GM) techniques and their products, genetically modified organisms (GMOs), it remains unclear whether GE techniques and their products, genetically engineered organisms (GEOs), should be considered to constitute subcategories of the categories of GM techniques and GMOs, respectively. Hence there is a need for legislative action which ought to be carried out on an evidence basis as well as a basis of analysis of the core categories of GM/GMO and GE/GEO. This subproject will generate the required basis for legislative action by a systematic comprehensive and comparative analysis of existing and planned regulation regarding GMO and gene editing in selected countries in Europe, South America, and the United States. It is expected that future legislative action will have to shift from a process-based regulation, to an outcome-based regulation.

State of the Art

Genome editing (GE) – first published in 2012 – is a novel technology to “modify” the genes of an organism without necessarily inserting new DNA into the genome. Ever since its inception, a highly charged debate on the ethical, legal and economical questions raised by this

technology is ongoing. The focus of this debate is centered on biosafety aspects, and whether an organism modified by gene editing technology falls within the scope of the legal framework for genetically modified organisms (GMOs), such as European Directive 2001/18/EC. There are also, however, additional issues with respect to fundamental rights, international agreements and biosecurity, as well as consumer protection rights aspects making this a field which urgently requires clarification.

Additionally, there is an ongoing controversial debate on a European and global level on the regulatory status of new breeding technologies like genome editing. Many states are currently in the process of reviewing their frameworks (Schuttelaar 2015). Argentina recently passed a resolution which determines that “all crops derived through the use of NBTs, and thus modern biotechnology, are to be reviewed on a case-by-case basis” (Schuttelaar 2015). Due to the process-based approach the same process of case-by-case review takes place in the United States (Schuttelaar 2015). In Germany, the Central Commission for Biological Safety (ZKBS 2012) and the German Scientific Academies (Leopoldina et. al. 2015) expressed the view that organisms of which the genes were altered by genome editing (i.e., GEOs) are not genetically modified organisms (GMOs) because no transgenes have been inserted into their genomes, and therefore do not fall within the scope of the European Directives on GMOs or the German Genetic Engineering Act (GenTG) (Jones 2014).

At the same time, some commentators have drafted legal opinions, commissioned by opponents of genetic engineering, which contradict this view. They argue that genome editing technologies would certainly fall under this regime. An opinion of the European Commission was expected by the end of 2016. It is in doubt whether an opinion will be forthcoming, however, since the European Parliament rejected the Commission's proposal for a regulation, which would allow EU member states to limit or ban the use of genetically modified food and animal feed within their territories on the basis that such a ban would have a negative impact on agriculture and would be incompatible with the internal market (which without border control would be unenforceable). A ban on genome editing and other comparable new breeding techniques could have the very same effect, and such a ban also may threaten research and academic freedom, the protection of property and the general freedom of action (Leopoldina 2015).

On the other hand, consumer protection and consumer rights of free choice may be at risk because of genome editing. Many consumers in Europe, and especially Germany, have concerns about GM food and call for a “GM-free”-labelling regime (Lucht 2015), and it would be important to gain more clarity about the question whether similar concerns would also arise with respect to GE food. GM- or GE-free labelling is a difficult undertaking, however, given that there is currently no way to clearly identify crop varieties generated through genome editing. Paper trails seem to be the only way of control but have inherent frailties and are liable to

misuse. In this context, it is paramount that the conflicting rights be analysed and described fully.

Gene editing is also described as a technology which is so easy to deploy that it may be used by “biohackers”, “DIY-biologists”, and even terrorists. It seems possible that gene editing may be used, inter alia, to induce or increase the resistance of listed agents against therapeutic or prophylactic antimicrobial or antiviral substances, to increase the transmissibility and infectious potential, to enable the weaponisation of listed agents, to generate new, especially dangerous biological agents or to reconstitute highly dangerous biological agents that have already been eliminated (through eradication, control or extinction) (Newson & Wrigley 2015). Hence it is necessary to examine the existing regulation and measures concerning dual use in the light of this new technology.

When analyzing the respective legal positions, a fundamental issue is raised: how is the law able to contribute to an equitable resolution of conflicts? Are existing laws efficient enough to adequately define the conflicting fields, and to solve these conflicts, or is it necessary that parliament intervenes with new regulation? And if the answer is that new regulation is needed, it is prima facie not clear whether this would be at domestic, supranational or international level; this, in turn, requires a very close look at a conflict between regulatory hierarchies (i.e. where domestic law is at odds with European law). At this stage, only a small number of publications in Germany explicitly address legal questions of gene editing (e.g., Spranger 2015, Krämer 2015). One point of discussion is that these legal questions are not fundamentally new. It is this supposition which needs to be investigated and clarified, and it is rather assumed that the technologies resulting from the capability to edit the genome will raise novel legal and ethical issues which need to be separately addressed. A prerequisite for a further examination of this supposition is the ontological analysis of the relevant categories of techniques (GM and GE) and products (GMOs and GEOs) as well as how these categories are related to one another. If a good argument can be made that GEOs do not constitute a proper subcategory of the category of GMOs, this would be an argument for separate legislation and separate ethics debate for GMOs and GEOs. If, on the contrary, it is found that GEOs are nothing more than a subcategory of GMOs, the need for separate legal and ethical treatment seems to vanish.

Project Structure

The intended legal analysis and comparison will carried out step by step on the basis of the available law texts, commentaries and further existing legal literature.

Work Package 1: Ontological Foundations

In parallel to the legal analysis that will be carried out, conceptual ontological work will be done on the categories of GM, GMO, GE and GEO. At this time the principal categorical distinction in legislative contexts is between GMOs and traditional organisms: GMOs are considered to constitute a special category of organisms and consequently are subject to separate regulation from traditional organisms. The first question is whether the dichotomy is still adequate in the light of GE technologies such as CRISPR/cas9. GEOs might have to be treated as a separate third category besides GMOs and traditional organisms. In this context a number of questions arise, such as what exactly are the targets of regulation (i.e., the technologies and entities to be regulated), how do we delimit the entities that can be regulated in practice, and how much genetic alteration (i.e., engineering or modification) would be required to support a need for separate regulation? In case the need for a third category besides those of traditional organisms and GMOs arises, the question is how this category is to be defined so as to be adequate to the current state of affairs in biological research as well as the requirements regulatory practice, and to be sufficiently flexible to accommodate future technologies.

Work Package 2: Legal Analysis, Opinion and Comparison

In a first step after a legal analysis of the current legal situation with a focus on Germany, a legal opinion shall be delivered, addressing the question of whether organisms modified by gene editing fall within the scope of the legal framework for GMOs. After a systematic review and analysis of existing regulations in food importing countries, the advantages and disadvantages of different regulatory approaches (eg. case-by-case-review, product- versus procedural rules) will be analyzed using a comparative legal methodology especially in relation to the question of biosecurity, biosafety, consumer protection and fundamental rights. Recommendations for regulation (de lege ferenda) will be developed.

Work Package 3: Legal Monitoring and Support

The German, European and international legal debate concerning genome editing will be monitored, particularly in those countries which are the main countries of food import to Germany. The legal subproject will also give up-to-date legal advice and support to the other subprojects if needed or requested.

Work Package 4: Stakeholder Involvement (Questionnaire and National Reports)

Based on a questionnaire that will be developed by this subproject in coordination with the other subprojects, legal experts in different selected countries (e. g. USA, Canada, Argentina, China, Russia) will be asked to compile respective national reports on legal questions of gene editing that will be evaluated and summarized.