One-sided attacks and biased reporting of the ECJ judgement regarding new genetic engineering methods reveal an arrogant and unenlightened understanding of science, democracy and law*

European Network of Scientists for Social and Environmental Responsibility (ENSSER), Berlin, Germany

By Dr Eva Gelinsky and Dr Angelika Hilbeck – ENSSER

Introduction

> *"Nothing has been "banned". Interpreting laws that simply recognise the novelty and distinctiveness of different kinds of GM breeding processes, the ECJ is merely offering a consistent framework of interpretation within which continuing healthy reasoned argumentation can be more rigorously played out."*[1]

With the judgement of the European Court of Justice (ECJ) dated 25th July 2018 (in case C-528/16), in which i.a. the question was discussed whether new techniques for "directed mutations" are to be regarded as techniques of genetic engineering and are to be regulated accordingly, the dispute around agricultural genetic engineering in Europe goes into the next round. In essence, it is again a question of how the risks arising from the techniques and from the organisms developed with it are to be assessed and how they are to be dealt with. While those who advocate an *unregulated* application of the techniques and approval of its products, emphasise their precision and safety, and also highlight their potential for "sustainable" agriculture, those in favour of *regulation* refer to the novelty of the techniques, to the speed with which genetic modifications are now possible, to the increasing indications from research that the techniques could have undesired and likely problematic consequences as well as to the many unresolved issues, which therefore suggest *precautions* are taken with them.

Many of the pros and cons presented are known from the debate around conventional genetic engineering. However, it is new that the tone, with which in particular the advocates of the new techniques are speaking out, has once again markedly sharpened. Furthermore, it is their highly polarising position that also almost completely dominates the media reporting of the new techniques and of the ECJ judgement. Our article is a reaction to this one-sided and biased reporting, which is rather spin and lacks in journalistic duty of care.

Some of the central and repeated claims from the genetic engineering sphere, which are picked up by the media, are listed below:

- The ECJ judgement is said to be unscientific because it has already been proven that the new genetic engineering techniques are as safe as conventional cultivation methods. A statement in

[1] https://steps-centre.org/blog/european-court-of-justice-ecj-gene-editing-anti-science/

the judgement that is phrased rather carefully and in the conjunctive mode to the effect that the risks linked to the deployment of the techniques *could* prove to be comparable to the risks occurring with the cultivation and distribution of GMOs by transgenesis (no. 48) is categorically rejected.[2]

- From this unscientific finding it is inferred that the judgement is backward looking and adverse to progress.[3]

- Therefore, it is claimed that the innovation ability of Europe as a centre of research and science is essentially jeopardised,[4] which is why by the same token necessary innovations, such as a more diverse agriculture that manages with fewer pesticides, can also essentially not be developed.[5]

None of these claims can be proven.

The dispute is based on the fact that the object, i.e., the genetically modified organism (usually a plant), is essentially defined differently. The definition is not dependent on which tools of genetic engineering have been applied. Depending on the position held, conflicting requirements concerning regulation are inferred (Hilbeck et al. 2015). While the critics of genetic engineering regulations effectively treat genetically engineered plants as chemicals (sum of parts) and only want to subject individual components to an isolated assessment (reductionistic approach), those in favour of regulations advocate a comprehensive risk evaluation of the whole genetically modified organism, in which interactions between the organism and the environment are also taken into consideration.

Environmental scientists, ecologists and many medical doctors know that it is often not enough to only react when harm has already been documented and certainty of an impending further danger exists. On establishing the precautionary principle in the 70s, it became possible to impose measures even in the case of remaining scientific uncertainty regarding the probability of great harm (e.g., definitive proof of harm). The principle is based on the scientific understanding that the complex and often not fully understood interactions between natural processes and technological interventions do not always allow suitable measures to be taken with certainty and in good time in order to prevent an environmental threat. However, an omission of precautionary measures may lead to irreversible and fatal harm to the environment and human health. In this regard, science has been assigned a key role: that of providing data, discussing unresolved issues, pointing out uncertainties and directing attention above all to surprising, cumulative, synergistic or indirect effects and their consequences. In theory.

In the argumentation of those who advocate an unregulated application of the old and new genetic engineering techniques, this concept of precaution is nevertheless essentially rejected. They plead for a so-called “evidence-based approach” (also called ‘sound science’) that only justifies state interventions when harm to the environment and health caused by a GMO is

[2] https://www.tagesspiegel.de/wissen/reaktionen-auf-den-eugh-zur-gen-schere-crispr-ein-richtig-schlechtes-urteil/22851838.html

[3] https://www.vci.de/presse/pressemitteilungen/rueckwaertsgewandt-und-fortschrittsfeindlich-vci-zu-eugh-urteil-genome-editing.jsp

[4] https://www.tagesspiegel.de/wissen/reaktionen-auf-den-eugh-zur-gen-schere-crispr-ein-richtig-schlechtes-urteil/22851838.html

[5] https://www.zeit.de/wissen/umwelt/2018-07/crispr-gentechnik-europaeischer-gerichtshof-urteil-kommentar

conclusively proven (e.g., EASAC 2013). Therefore, it is not a question of a *pre*cautionary principle, but rather of the old familiar principle of *post*caution or rather the proof-of-harm, which is common in the USA and which is to be furnished as a rule by the victim, in as far as it still can. Europe counters this with the precautionary principle; a collective civilizational achievement, resulting from the bitter lessons from past 'innovations'. The case studies collected in the two volumes "Late lessons from early warnings" (EEA 2001, 2013) about new technologies and chemical substances, whose application have in retrospect proven to be fatal, show that too often warnings were ignored or pushed aside until harm to health or the environment was inevitable. In many cases, companies put short-term profit ahead of public safety and hid or ignored evidence of harm. In other cases, scientists downplayed the risks, sometimes under pressure from interest groups.

Once again, the same points known from the debate about the old genetic engineering techniques are being raised. Voices, who point out risks, reject the principle of '*post*caution' and therefore want to perform further investigations *before* any commercial use, are being dismissed, defamed and attacked. Now, this is also happening to the judges at the ECJ, whose task it is to interpret the applicable European law; the law that is based on the precautionary principle. This behaviour does not only reveal a dubious understanding of science and democracy but also a questionable notion of what the law can and should do in a civil society.

Precision is not the same as safety – also the new genetic engineering techniques must be subjected to a comprehensive risk assessment

To start with, it is worth looking back to the beginnings of the genetic engineering discussion. It is noticeable that the old genetic engineering techniques were already promoted with postulations of the 'natural' and 'precision'. "*Genetic engineering is (…) a complementary research tool to identify desirable genes from remotely related taxonomic groups and* ***transfer these genes more quickly and precisely*** *into high-yield, high-quality crop varieties*." (Borlaugh 2000)

"*Molecular techniques now permit the direct and* ***precise introduction of genes*** *from wild relatives, and cellular methods allow screening for the desired phenotype to proceed more efficiently.*" (Tiedje et al. 1989)

Back then, it was also inferred that genetic engineering was essentially safe, safer than all forms of conventional cultivation, in particular mutation cultivation, and for that reason should not be regulated beyond the usual extent used for variety approval.

"*On the one hand so-called GM techniques which in the precise and targeted way bring in a couple of genes that you know what they do and you know where they are is* ***vastly safer, vast, vastly more controlled than this so-called conventional breeding*** *that reshuffles about a tenth of the genome*." (Sir Robert May, BBC Interview, 9 March 2000)[6]

However, interestingly, meanwhile even the biotechnologists agree with the assessment of the earlier critics, which at the time was vilified. This assessment stated that actually conventional genetic engineering is not precise and for that reason safety-relevant aspects may be important. Admittedly, this is only stated today in order to advertise the new genetic engineering

[6] http://www.bbc.co.uk/science/horizon/1999/gmfood_script.shtml

techniques as being definitively safer or much safer than conventional genetic engineering, which in any case is already safe.

"*In recent years, it has already been possible to introduce new genes into the plants using genetic engineering methods. They could be genes from other species of plants, but also from completely different organisms, such as bacteria. A* ***disadvantage of this technique until now has been that where the gene ends up in the genetic material cannot be controlled***." (Prof. Dr Detlef Weigel, Max Planck Institute for Developmental Biology, Tübingen)[7]

In comparison, he states regarding the new techniques:

"*Therefore, with this method it is also possible to* ***very precisely*** *replace the genes of one species with genes from another variety or a close relative. That is also the aim of conventional cultivation. Therefore, genome editing is a way of achieving the same changes as with conventional cultivation, however* ***much faster***." (Prof. Dr Detlef Weigel, Max Planck Institute for Developmental Biology, Tübingen)[8]

However, no reliable evidence that can prove the postulate of 'speed' or the postulate of safety has been presented for either the conventional or the new genetic engineering techniques. On the other hand, there is a need for clarification regarding which process is being accelerated here anyway. Admittedly CRISPR-Cas makes it possible to produce all kinds of experimental lines within a short period of time, hence, the high number of publications in this field. However, it is questionable if and how quickly marketable varieties can be developed from these lines that can actually perform in the environment and in practice; which will rarely be the case anyway. What they do not document is their high level of precision and safety .

More precise does not mean safer

Although it is true that in comparison to the old genetic engineering techniques, the new genetic engineering techniques, such as CRISPR, can change genetic material more precisely in specific locations; however, even these interventions may have undesired and unpredictable effects, e.g., on the plants' metabolism. In the medical field, all this is completely indisputable. If the activity of one enzyme changes, it could cause unintended biochemical reactions. Also, a genetic engineering intervention can lead to plants unintentionally producing modified proteins. For example, this is worrying with regard to their potential of causing allergies (ENSSER 2017, FGU 2018, Steinbrecher, Paul 2017). In addition, the use of new genetic engineering techniques can also have an impact on the environment, for example, when new properties lead to plants having better survival chances in comparison to other plants (BfN 2017).

Really so precise?

When applying the new genetic engineering techniques such as CRISPR, biotechnologists like to make use of a comparison with editing programs (cf. McLeod, Nerlich 2017, O'Keefe et al. 2015). Accordingly, such interventions are not different to editing a text, in which an individual letter is deleted or replaced.

7 https://www.mpg.de/9943004/gen-editierte-pflanzen
8 https://www.mpg.de/9943004/gen-editierte-pflanzen

"*So what is gene editing? Scientists liken it to the find and replace feature used to correct misspelling in documents written on a computer. Instead of fixing words, gene editing rewrites DNA, the biological code that makes up the instruction manuals of living organisms. With gene editing, researchers can disable target genes, correct harmful mutations, and change the activity of specific gene in plants and animals, including humans*."[9]

Within this comparison, even if it is not factually correct, it is true that we have all tools for exactly cutting individual letters from a text and pasting them somewhere else in the text. However, someone who does not know the language or the grammar well enough will with great precision most likely create great nonsense. Yet, nucleotides are not letters and nucleotide sequences are not sentences but chemical molecules that follow the rules of biochemistry and not those of human languages or the IT sector. Our understanding of these biochemical rules and the resulting gene functions in interaction with the environment and epigenetic regulation factors can to date at best be described as rudimentary. The knowledge in the field of epigenetics is quickly developing and is of huge relevance for genetic engineering, yet it is mostly ignored by bioengineers. Therefore, there is a high possibility that unexpected and unpredictable results will be obtained. These results may be good, bad or trivial but they are not subject to human control. Therefore, the postulate of safety derived from the precision and control narrative is scientifically neither credible nor provable, but in contrast very risky.

In addition, the prematurely declared and exaggerated postulates of 'precision' have begun to scientifically unravel in recent months. The ECJ judgement is in line with the most recent scientific findings. For example, it only recently became known that the efficiency of CRISPR appears to be associated with the p53 gene, which influences the suppression of tumours in human cells (Haapaniemi et al. 2018, Ihry et al. 2018). Scientists could now use mutations in the p53 gene to increase the efficiency of CRISPR and in doing so, they accept that unrepaired DNA damage in a totally different location in the genetic material leads to an accumulation of unwanted mutations. In further studies, it could be conclusively proven that the use of CRISPR can lead to consequences ranging from an unintended modification to the removal of large genome sections (Adikusuma et al. 2018, Kosicki et al. 2018). This new evidence shows that the non-target effects of genetic interventions have until now been underestimated. These publications should be understood as an early warning of possible fatal consequences, which have to be thoroughly researched before they become suitable for mass use – in medicine this is undisputed, for plants and the environment it is disputed. Plants also have a gene with a similar function to p53, the SOG1 gene (Yoshiyama et al. 2014, Ogita et al. 2018). It is activated in the case of DNA damage and induces the identification of genes which are responsible for repairing the DNA. It is conceivable that there may be similar correlations between the efficiency of CRISPR and SOG1 but remains to date unknown.

Extensive modification in organisms possible

New genetic engineering techniques hold the potential to fundamentally modify living organisms. Researchers are in the process of developing the CRISPR methods to the extent that it will be possible to use them repeatedly simultaneously or consecutively in the same organism

[9] https://www.theguardian.com/science/2018/jan/15/gene-editing-and-what-it-really-means-to-rewrite-the-code-of-life

(Vogel 2018, BfN 2017, ENSSER 2017, Steinbrecher, Paul 2017). To date, such extensive interventions are not possible with conventional genetic engineering. Therefore, we now have to reckon with a much larger number of organisms that have somehow been genetically modified. Against this backdrop, more releases would be possible and they could be accompanied by a multitude of possible, unresearched, unpredictable and unwanted changes – if the users and applicants are not obligated by a law to document such releases. Therefore, an even stricter statutory regulation may be warranted – in comparison to conventional genetic engineering (ENSSER 2017).

Even if only individual bases of genetic material are introduced or removed (point mutations) by way of the new genetic engineering techniques, they may greatly modify the organisms. In the worst case, point mutations can mean the difference between life and death – in medicine, there are many examples of hereditary diseases that are based on the smallest modifications of the genetic information. Such interventions could lead to proteins being incorrectly produced or not produced at all. Their consequences do not necessarily have to be serious; they may also be completely without consequence. But nobody can predict this in advance. For precisely that reason, the consequences of a supposedly small intervention, albeit an intervention entailing a new patentable modification, must be thoroughly investigated *before* the organisms are irrevocably released into the environment (BfN 2017, Steinbrecher and Paul 2017). The judges of the ECJ followed this scientific assessment. They regulated how organisms that have been developed using the new tools of genetic engineering are to be dealt with. No more, but also no less.

Old and new promises

For at least three decades, astronomical sums of tax payers' money have been invested in the research and funding of biotechnology and genetic engineering. However, this investment is in no way proportionate to the very meager results that have been delivered since then. Both in North America and large parts of South America, the heartlands of the use of green genetic engineering, there is no regulation worth mentioning (if any at all). Despite the prevailing domination of 'deregulation'as biotechnologists' wish for, they also did not even begin to deliver anything close to what has been and continues to be promised. For more than a quarter of a century, the same GM plant types are dominanting: herbicide and insect resistance, integrated into the same industrial crops (soy, corn, cotton and rape). The analysis of the biotechnology chapter in the Agriculture at a Crossroads report (IAASTD 2008) over ten years ago is still applicable today – 99% of all GM plant types have the aforementioned properties. The few other property types and products of green genetic engineering are distributed over the remaining 1%.

Neither has the use of pesticide been reduced nor the yield increased significantly beyond what has also been achieved without GM plants (Quist et al. 2013, Hakim 2016).[10] In contrast, in some cultures the deployment of pesticides has massively increased and farmers have been driven into a dependency, which previously did not exist to this extent (e.g., herbicide resistant weeds, cf., Benbrook 2016).

[10] Also see: Hakim, D. 2016: Doubts about the promised bounty of genetically modified crops. New York Times, 29th October 2016. https://www.nytimes.com/2016/10/30/business/gmo-promise-falls-short.html

The absences of the promised GMOs with resistance to drought and salt or with specific 'consumer traits' is a problem of genetic engineering, not of regulations, and is certainly not down to the lack of money or state support (see below). If genetic engineering and its techniques worked in the way that has been promised for decades, then by now there ought to be a multitude of custom-tailored GM products. The fact that this is not the case should be the subject of a serious scientific analysis and a (self) critical appraisal, and not be blamed on the bearers of this inconvenient message. For decades, the potentials and the promises have remained the same; now it's about time to deliver results and not constantly blame others for failing to deliver.

The first plant that was modified using the new genetic engineering techniques, and which is already in cultivation, is (again) a herbicide resistant oilseed rape. The new GM plants, currently in the companies' pipelines, include a soybean with a modified fatty acid composition, a potato with improved storage capacity at cool temperatures, a so-called waxy maize with a modified starch composition and a flax, which once again is herbicide resistant. Since knock-out plants are produced in approximately 90% of the current applications of CRISPR, no commercialisation of a yet again promised 'super plant' is to be reckoned with in the near future. Properties, such as resistance to drought or salt, are composed of many different cell components. Plants react to drought, cold or salt stress with the simultaneous modification in the expression of hundreds of genes. These reactions are adjusted in different parts of the plants to the respective levels of the stress condition (e.g., Chen et al. 2002, Deinlein et al. 2014, Ramirez-Gonzalez et al. 2018). Creating stress tolerant plants in a short time using individual, or even several added, point mutations is a complex, risky and maybe even impossible task that is also not easier to achieve using the new genetic engineering technique. Furthermore, the knowledge from various other life science disciplines show us that organisms are not the sum of their parts and not everything is 'coded' in DNA.

Are innovations only possible using the new genetic engineering techniques?

Also over twenty years ago, in the discussions about conventional genetic engineering and establishing the genetic engineering legislation, warnings had been issued concerning the imminent demise of Europe as global centre for research. It did not happen then, and it will also not happen this time round. In the laboratory, biotechnologists can do what their freedom of research allows them to do and the things for which they can acquire funding. And they do so plentiful. Barely any other technology and science sector enjoys such a substantial and comprehensive funding basis as biotechnology, and in particular genetic engineering in all its forms. In fact, for decades the EU and almost all its member states have invested enormous sums of tax payers' money in promoting and researching genetic engineering in all its forms. Over the years, these sums will have gone into the billions.[11] The genetic engineering laboratories do not suffer from lack of money, as long as they satisfy the scientific quality requirements. In addition, this field of research enjoys wide financial and political support from the private sector and large parts of the political sphere. The EU Commission is certainly not suspected of being critical of genetic engineering, quite the contrary. Even EFSA – the European Food Safety Authority – does what it can to approve GMOs and to accommodate needs of the

[11] https://www.nabu.de/imperia/md/content/nabude/gentechnik/bio__konomie_2030_steffi_ober.pdf

users of genetic engineering to the great annoyance of the civil society.[12] Other fields of research can only dream of such comprehensive and substantial funding and support. In comparison, research into alternative, biological or agroecological land use systems and procedures is marginalised and to date has to make do with the proverbial ‘crumbs’, which is also down to the respective structures of research funding (cf. Vanloqueren, Baret 2009). Yet, both agroecological research as well as conventional breeding deliver robust data and products for new approaches to a sustainable agriculture. They delivered indeed those adapted varieties that genetic engineering has been promising us for decades but has yet to produce (Bardgett, Gibson 2017, Gilbert 2014, 2016, Hilbeck, Oehen 2015, ipes Food 2016).

Main problem: barely any risk research that is worth the name

There exists only little industry-independent risk research on possible unexpected, unwanted and also long-term effects of the modification of plants with genetic engineering. To particular for the new genetic engineering techniques, only very few studies exist that investigated their risks. There is still an enormous disparity between applied research, whose main interest it is to investigate the possibilities of these techniques and which specific products could be developed, and comprehensive research into the scientific basis and the risks that does not only use the newest molecular analysis tools but also considers the interactions between the plants and the environment as well as long-term data. However, application-orientated biotechnology is barely interested in the functionality and risks of its subjects; instead it is too often satisfied when the plants produce the desired property.

“*There is a mentality that as long as it works, we don’t have to understand how or why it works*.” (quote from Ledford 2015)

However, questions regarding the biological safety begin where the developers’ interests end; but, as a rule, this is also where its funding ends.

Conclusion

> *“As the public debates on GMOs have escalated over the last two decades, the roster of partisan (often militant) proponents has grown to include not only industry executives and public relations operatives, but academic basic bioscientists as well.”* (Stone 2017, 3)

The statements from the genetic engineering circles, which were uncritically adopted by the media, completely lack this type of differentiation. The benefits of the techniques appear to already be clear, furnishing reliable evidence is deemed not necessary. From the very start, risks were considered to be negligible – likewise devoid of any reliable evidence. What’s more, regulation is being portrayed as a ban of research and use, which is factually incorrect, and the ECJ judges, just like the advocates of regulation, are being defamed (“pseudo science”). It is debatable how in this polarised climate a factual and balanced discussion can take place both

[12] https://corporateeurope.org/pressreleases/2017/06/nearly-half-experts-european-food-safety-authority-have-financial-conflicts; https://www.testbiotech.org/aktuelles/efsa-und-industrie-vereinigt-efsi

within the scientific community and in society at large.

Critical voices, who see the institution of science in a serious crisis due to this muddled situation, are on the increase (e.g., Stone 2017). It is not just due to the cases of obvious scientific misconduct by companies and scientists, as was shown, e.g., in the "Monsanto Papers" (McHenry 2018), but also due to the approach of dividing the world into those categorically for or those against genetic engineering. In this construct of irreconcilable opposites, the differentiations, for which science should also be jointly responsible for reasons of precaution, fall by the wayside.

- Precisely in new fields that are developing so dynamically, such as the new genetic engineering techniques, research should consist of more than just superficial proof that the modified organism – allegedly – works as desired.
- Precisely those organisms, which after the intervention do *not* have the desired property modification, ought to be studied.
- The consequences of a genetic engineering intervention on the cell level and on the level of the whole organism and also the effects that the interaction between the organism and the environment should be investigated in more detail.
- Questions, uncertainties and unwanted research results should also be openly communicated, as well as disclosure regarding the funding of research and possible restrictions from the funder(s).
- The starting points of scientific disagreements are often unclear or false positive study results. Furthermore, problems concerning the interpretation of data arise when studies do not meet the statistical requirements for relevance. It is all the more important to create transparency regarding the basic assumptions upon which the scientific interpretations are based.
- If there is disagreement or inconclusiveness, e.g., about the probability of harm occurring, a plausibility check of the available data is to be performed. The plausibility is decided on the basis of the scientific criteria, which are recognised by the scientific community: theories or hypotheses must i.a. explain a specific phenomenon and be testable, fulfil coherence requirements and satisfy the principle of organised scepticism (for instance in the context of a functioning *peer review*). To conduct this check in accordance with scientific criteria, it is necessary to have complete access to the information that has led to the formulation of the scientific theory. The data must be presented in an understandable manner and include such information that does *not* support the scientific theory. In order to ensure that the plausibility check is carried out unbiased to the result and according to scientific criteria, the scientific institutions must also be independent.

All of this should go without saying, not just in theory. However, in practice we are recognising increasing developments in the direction of an authoritarian, arrogant and unenlightened understanding of science, democracy and law. We resolutely oppose such developments.

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