



SCIENTIFIC CRITIQUE OF **LEOPOLDINA AND EASAC** STATEMENTS ON **GENOME EDITED PLANTS** IN THE EU

EXECUTIVE SUMMARY OF A
STUDY BY ENSSER AND CSS

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EXECUTIVE SUMMARY

The EASAC-endorsed Leopoldina Statement on the regulation of 'genome edited' plants is based on a limited number of selected publications. It fails to reflect the findings of at least 200 highly relevant published scientific studies.

These studies document adverse effects of existing genetically modified organisms (GMOs) on the environment and human health, and demonstrate the potential for negative outcomes of more recent genetic engineering tools.

They show that existing GMOs have failed to deliver on their claimed benefits, such as effective control of weeds and pests, resistance against diseases, drought tolerance, enhanced nutritious value and intrinsic yield gains. They also demonstrate the ecological and economic consequences of genetic contamination, as well as detrimental effects on smallholder farmers.

With regard to 'genome editing', the scientific evidence ignored by the authors of the Leopoldina Statement demonstrates that, contrary to their claims, the genetic alterations caused by these methods are fundamentally different from naturally occurring mutations.

The 'genome edited' crops listed in the Statement to illustrate the potential benefits of 'genome editing' are at preliminary exploratory research stages and most even miss functional proof of efficacy. They cannot be taken as evidence that expectations of beneficial traits are justified.

Similarly, the Statement's narrative equating *precision = control = safety* is not supported by the scientific evidence - not for older forms of genetic engineering and not for more recent forms of genetic engineering.

The Statement ignores the growing recognition among experts that the root causes of hunger are related to social and economic issues (conflict, poverty, exclusion, etc.) more than to crop yield. There is no record of GMO interventions increasing crop yields as such, or indeed reducing hunger. In contrast, a series of widely accepted expert reports have called for a rapid shift from input-intensive industrial agriculture to agroecological farming methods.

Based on a selective reading of the scientific evidence, the Leopoldina Statement recommends that the EU should exempt certain 'genome edited' organisms from the scope of its GMO legislation. It also calls for the longer-term loosening of GMO regulations applicable to existing transgenic organisms. Following that advice would move the EU away from the precautionary approach that is enshrined in the EU's founding treaties, and towards the US approach of ignoring potential risks and harm.

The body of evidence ignored by the Leopoldina Statement supports a conclusion contrary to Leopoldina's, namely that EU GMO regulations must be strengthened in order to take account of a new generation of GM organisms created with 'genome editing' tools.

Background and objectives

In July 2018, the European Court of Justice (ECJ) (Case C-528/16) ruled that organisms obtained by directed mutagenesis techniques (the Court's term for 'genome editing') are to be regarded as genetically modified organisms (GMOs) within the meaning of Directive 2001/18.

In response to the ECJ ruling, the German Academy of Sciences Leopoldina published a position statement in December 2019 urging European policy makers "*to exempt genome edited organisms from the scope of genetic engineering legislation if no foreign genetic information is inserted and/or if there is a combination of genetic material that could also result naturally or through traditional breeding methods.*" In March 2020, the European Academies Science Advisory Council (EASAC - formed by the national science academies of the EU Member States) endorsed the content and intention of this Statement with a 'Commentary on the statement by the German National Academy of Sciences Leopoldina'.

Our report (i) deconstructs the claims made in the EASAC-endorsed Leopoldina Statement, (ii) critically assesses the scientific foundations of both publications and (iii) provides some of the information, omitted by the Statements, that is publicly available as scientific evidence and research results. Assessing and fact-checking the claims made by both the Leopoldina Statement and the EASAC endorsement reveals a wealth of more than 200 highly relevant published scientific studies that they have ignored.

The 'collective voice of European science'?

The authors of the Leopoldina and EASAC Statements make it appear like they represent the scientific consensus in Europe. The Leopoldina describes itself as providing '*policymakers and society with independent, science-based guidance on issues of crucial importance for our future*'ⁱ.

EASAC states: "*EASAC – the European Academies' Science Advisory Council – is formed by the national science academies of the EU Member States, Norway and Switzerland to enable them to collaborate with each other in providing independent science advice to European policy-makers. It thus provides a means for **the collective voice of European science** to be heard.*" EASAC also claims to '*provide independent, expert, evidence-based advice about the scientific aspects of public policy*' and deliver views that are '*vigorously independent of commercial or political bias*'ⁱⁱ.

However, the EASAC-endorsed Leopoldina Statement relies on a limited selection of publications rather than the full body of scientific evidence. It ignores the more than 200 published scientific papers and documents cited in our report, which represent but a small part of the rich and diverse scientific literature that is pertinent to an inclusive, science- and evidence-based discussion about the potentials, risks and limitations of all genetic engineering techniques. This means the

i E.g. Leopoldina. 2017. The German Academies of Sciences offer Recommendations for the Reform of Doctoral Practices, <https://www.leopoldina.org/en/press-1/press-releases/press-release/press/2499/>

ii EASAC. About EASAC. Accessed March 2021, <https://easac.eu/about-easac/>

EASAC-endorsed Statement is at best representative of one view among a diversity of scientific opinions. It does not reflect a 'consensus' in science.

Making unfounded claims of GMOs' safety and efficacy

Both Statements claim that existing GMOs are safe and their intended traits are effectively achieved. They ignore the documented adverse effects of existing GMOs on the environment and human health, including the chemical pollution connected to the vast majority of current GMOs. They also ignore the fact that no intrinsic gains in yield have been proven, and fail to acknowledge the widespread evolution of resistance in plants and insects that the GMOs were meant to control, which has led to the loss of efficacy of the GM traits. The ecological and economic consequences of genetic contamination are also ignored. Also omitted are failures in India and Burkina Faso that illustrate the detrimental effects that these technologies have had on smallholder farmers' livelihoods. None of the documented cases of harm are mentioned by the EASAC- and Leopoldina authors.

The Statements' narrative equating *precision = control = safety* has been shown by empirical evidence to be false in relation to existing GMOs. It is increasingly shown to be untrue also for more recent forms of genetic engineering. A necessary prerequisite for exercising 'control' is precise knowledge not only about the targeted gene sequence to be altered or replaced, but also about the context within which the intervention is carried out. The lack of understanding of these complex networks of interactions, including networks of genes and their epigenetic regulation, is the reason why the 'precision' narrative has lost credibility as an indication of safety.

Unproven link between GMOs, crop yields and hunger

Another (old) narrative promoted by the Leopoldina Statement is the idea that reductions in hunger over the last century have been achieved due to 'science-based breeding'. While the yield increases of the Green Revolution are documented, no comparable recording has followed GMO interventions. More importantly, there is growing recognition among experts, ignored by the Statement, that the root causes of hunger are related to social and economic issues (conflict, poverty, exclusion, etc.) more than to crop yield.

Little evidence of efficacy of 'genome edited' crop plants

The Leopoldina Statement claims that 'genome editing' has already proved successful in generating a large number of 'market relevant' crops. However, only two 'new generation' GM crops are commercialised in the US, despite generous subsidies and a permissive regulatory environment. One of them is (yet another) herbicide-tolerant plant. Although 'genome editing' technologies have been deployed since the 1990s, the majority of 'genome edited' crops mentioned by the Statement are at exploratory stages without functional proof of efficacy.

False premise that ‘genome editing’ resembles traditional breeding

A growing body of evidence challenges the Leopoldina Statement’s premise that ‘genome editing’ is akin to traditional breeding methods and therefore safe. It shows that the effects of ‘genome editing’ differ from those resulting from random mutagenesis. ‘Genome editing’ methods can result in the modification of many genes simultaneously, the alteration of all copies of a single gene, or the transformation of regions of the genome ordinarily protected from novel mutations. Further, repair mechanisms deployed by the cell following editing-induced mutations appear to differ from repair mechanisms used following random mutagenesis or naturally arising mutations. The error-prone repair mechanisms deployed to repair ‘edited’ DNA breaks lead to distinct changes in the genome.

There is nothing ‘natural’ in genetic engineering. All ‘genome editing’ methods aim to circumvent natural processes and turn them from ‘repair’ mechanisms into ‘delete’, ‘insert’ or ‘replace’ mechanisms. These natural repair processes are part of fine-tuned networks protecting some regions of the genome from mutations more than others. By contrast, so-called ‘genome editing’ procedures can indiscriminately access all genomic regions equally. Neither the epigenetic and genetic regulation of these cellular processes nor the consequences of these ‘genome editing’ interventions are well understood. Unintended effects have been documented in human and plant cells.

Promoting outdated models of ‘regulation’

What the Statement proposes as an innovative and science-based model for European regulation actually predates any European or international GMO regulation. The model is founded in the US’ decades-old policy that simply declares what is *not* being regulated, i.e. not evaluated at all. Such backward-looking policy releases developers from any responsibility to prove the efficacy and safety of their products. It cannot be called ‘innovative’.

Overlooking recognised solutions

The Statement disregards a series of high-level expert reports that have called for a rapid shift away from input-intensive industrial agriculture, towards agroecological farming methodsⁱⁱⁱ. These reports suggest that funding should be shifted towards solutions that work to address nutritional needs, food security, and environmental sustainability, as well as existing farmer knowledge and practices, leaving very little room for the patented interventions from genetic engineering with its questionable safety and success track record.

Conclusion

Our report provides some of the large body of information that the Statements have omitted, and that is publicly available as scientific evidence and research results. Had these publications, although not comprehensive, been included and evaluated in a balanced and transparent way,

the Statements would have been unable to recommend the exclusion of certain forms of 'genome editing', or the wider relaxation of EU GMO regulations. In fact, the totality of the evidence available supports the contrary conclusion, namely that EU GMO regulations must be strengthened in response to the new generation of genetic engineering tools. ⁱⁱⁱ



Read the full report

iii IPES-Food. 2016. From uniformity to diversity: a paradigm shift from industrial agriculture to diversified agro-ecological systems. International Panel of Experts on Sustainable Food systems, http://www.ipes-food.org/_img/upload/files/UniformityToDiversity_FULLL.pdf; International assessment of agricultural knowledge, science and technology for development IAASTD 2009, <https://www.weltagrarbericht.de/fileadmin/files/weltagrarbericht/IAASTDBerichte/GlobalReport.pdf> and Transformation of our food system. The making of a paradigm shift. 2020, <https://www.arc2020.eu/wp-content/uploads/2020/09/FullTextOfTransformationFoodSystems.pdf>; Food and Agriculture Organisation FAO 2020. The state of food security and nutrition in the world, http://www.fao.org/3/ca9692en/online/ca9692en.html#chapter-executive_summary



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