



Press Release

A distortion of science and a danger to public and environmental safety

26 April 2021

The EASAC-endorsed Leopoldina Statement, demanding that the EU stops regulating 'genome-edited' plants, represents the narrow interests of 'genome editors' but it does not demonstrate the scientific objectivity or balance required, nor does it represent any consensus in the scientific community at large beyond the self-interested advocates. The EASAC-endorsed Leopoldina Statement is biased and does not withstand scientific scrutiny. ENSER and CSS, in a scientific critique of the Leopoldina Statement, urgently call for stringent regulation of 'genome editing' to protect public and environmental safety. The so-called 'genome editing' techniques, just like the older techniques of genetic modification, give rise to known as well as inadvertently generated risks. Their potential for dual use, abuse and accidental misuse is considerably higher than that of the older techniques and warrants even stricter surveillance. So does their application as gene drives.

The European Network of Scientists for Social and Environmental Responsibility (ENSER) and Critical Scientists Switzerland (CSS) have analysed two publications by the German Academy of Sciences Leopoldina¹ and the European Academies Science Advisory Council (EASAC)² in which both called on the EU Commission to end the regulation of so-called 'genome-edited' organisms and also older transgenic genetically modified organisms (GMOs). ENSER and CSS found both Statements to be seriously lacking in scientific objectivity and rigour. The literature quoted by Leopoldina and EASAC was selected to support their preconceived conclusion. We list more than 200 relevant scientific publications which suggest another conclusion. 'Genome editing', just as much as the older transgenic techniques, demonstrably poses risks to the environment and human health.

Moreover, the relative ease of use and low cost of the ingredients of CRISPR, the best-known and most widely used 'genome editing' tool, give rise to a considerably higher potential for dual use, abuse and accidental misuse. The application of 'genome editing' as gene drives (which are intended to permanently modify, replace or eradicate whole populations or species in the wild) is an additional cause for great concern³.

The Leopoldina and EASAC statements repeat old claims, made since the 1980s for transgenic techniques, for 'genome editing' techniques. In particular, Leopoldina and EASAC claim that 'genome editing' is precise, controllable, predictable, and therefore safe, and that the application of this technology is crucial to help fight hunger by raising food crop yields. In their report, ENSER and CSS demonstrate that these claims are not supported by the available scientific evidence – not for 'genome editing' nor for transgenesis. The term 'genome *editing*' is not even justified in light of its

¹ Leopoldina (2020) Towards a scientifically justified, differentiated regulation of genome edited plants in the EU. https://www.leopoldina.org/uploads/tx_leopublication/2019_Stellungnahme_Genomeditierte_Pflanzen_short_en_web.pdf

² EASAC (2020). The regulation of genome-edited plants in the European Union. https://www.leopoldina.org/uploads/tx_leopublication/2020_EASAC_Genome-Edited_Plants_Web_01.pdf

³ CSS, ENSER, VDW, 2019: "Gene Drives - A report on their science, applications, social aspects, ethics and regulation", <https://genedrives.ch/report>



inaccuracies of action or lacking predictability of consequences. The root causes of hunger are related to social and economic problems (poverty, conflict and exclusion) rather than to crop yields. There is also no record of GMO interventions increasing crop yields as such, or indeed reducing hunger. In contrast, a series of widely recognised expert reports have called for a rapid shift from destructive, input-intensive industrial agriculture to agroecological farming methods, that will not only enhance resilience, food security and human health but also biodiversity and environmental health.

What Leopoldina and EASAC have provided is baseless hype. The majority of 'genome edited' crops mentioned by the Leopoldina statement are at preliminary exploratory research stages and most have not even shown functional efficacy.

The Leopoldina and EASAC statements are all the more disquieting since both organisations portray themselves as representing the collective voice of science in Germany and Europe, respectively. Their documents, however, are a distortion of science and misleadingly imply a scientific consensus. They seem to use the supposed authority of science to cloak partisanship for a particular position, in this case a corporate perspective (also termed "stealth issue advocacy"⁴). This is dangerous, because if gene editing was exempted from regulation it would pose significant risks to public and environmental health.

ENSSER and CSS stress that 'genome editing' needs to remain stringently regulated, if not more stringently than in the current GMO legislation, in particular as there is no history of safe use for any of these new techniques. The precautionary principle, to which the EU is committed, requires this and it must be applied to new techniques as history shows⁵.

ENSSER, CSS, 2021:

- **"Scientific critique of Leopoldina and EASAC statements on genome edited plants in the EU":** <https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-1.pdf>
- **Executive summary:**
 - **English:** <https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-EN-Executive-Summary.pdf>
 - **French:** <https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-FR-Executive-Summary.pdf>
 - **German:** <https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-DE-Executive-Summary-1.pdf>
 - **Italian:** <https://ensser.org/wp-content/uploads/2021/04/Greens-EFA-GMO-Study-IT-Executive-Summary.pdf>

⁴ Stone, G.D. 2017. Dreading Crispr: GMOs, honest brokers and Mertonian transgressions. *Geographical Review* 107(4):584–591, <https://onlinelibrary.wiley.com/doi/pdf/10.1111/gere.12260>

⁵ Late lessons from early warnings: the precautionary principle 1896-2000. European Environmental Agency, Copenhagen, 2001. Vol I, ISBN 92-9167-323-4 and Late lessons from early warnings: Science, precaution and innovation. European Environmental Agency, Copenhagen, 2013. Vol II, ISSN 1725-9177; https://www.eea.europa.eu/publications/environmental_issue_report_2001_22 and <https://www.eea.europa.eu/publications/late-lessons-2>



- Link to Press Release: https://ensser.org/press_release/press-release-a-distortion-of-science-and-a-danger-to-public-and-environmental-safety

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Quotes and comments from our experts:

Prof. Erik Millstone, Science Policy Research Unit, University of Sussex, UK

"This report shows that the assertion made by Leopoldina and its allies, that the EU should exempt 'genome edited' organisms from regulatory controls, is dangerously over-optimistic. Leopoldina's arguments are not scientifically justified or justifiable. On the contrary, they ignore a growing body of evidence showing that 'genome editing' is not as reliably precise or predictable as claimed. The suggestion that 'genome edited' foods do not need to be regulated is unscientific and anti-scientific. It is unscientific because it ignores a lot of evidence, and it is anti-scientific because it is intended to discourage studies that might show that gene edited foods pose risks to public or environmental health."

Prof. Jack Heinemann, PhD, Centre for Integrated Research in Biosafety, University of Canterbury, New Zealand

"This new report from ENSSER and CSS fatally undermines the case for deregulating gene technology, in whole or in part. Gene technology requires regulatory oversight because it allows human beings to manipulate the genetic properties of organisms at rates and at geographical and biodiversity scales that we alone control; its limits for causing harm are none other than those we impose upon ourselves.

"Technologies are regulated for this reason, no matter what natural analogs may exist in nature. The electricity running through the wires in my home is similar to, although many times weaker than, lightning and far more precisely delivered. Despite this, house fires from electrical faults are twice as common and 42 times as lethal as fires from lightning strikes in the USA.

"Therefore, the use of electricity in my home is regulated by certification requirements placed on my electrician and regulatory standards for the appliances I couple to it. It would be absurd to deregulate the process of installing and using electricity in homes just because atmospheric discharges occur in nature too, or because a shock from an electric eel may be indistinguishable from a shock delivered by a frayed wire.

"ENSSER and CSS describe the drive behind treating gene technology differently from all other technologies. Such efforts are fraying the bonds of trust between society and gene scientists, such



as myself. Gene technology can cause harm. It can cause harm at scales that increase with use of the technology and exposure to it. Improvements in the technology that could reduce harm do not increase safety as quickly as use can increase exposure to potential new hazards.

"Sophistic metaphors do not insulate us from harm. Unregulated gene technology is kindling for the fire of human folly and fanned by our natural overconfidence in our competence."

Dr. Angelika Hilbeck, ENSSER board member:

"This report destroys the oldest claim used to justify genetic modification, old or new (in food): it cannot and will not help to reduce hunger for two reasons. One, the latest basic understanding from molecular genetics tells us that both current transgenics and 'genome editing' simply have not and cannot deliver the complex traits and organisms with whole networked genome functioning in response to the environment at their basis (e.g. higher intrinsic yield, drought tolerance, pathogen / disease resistance). Second, the indisputable fact that GMOs have not had any role in reducing hunger anywhere in the world since a quarter of a century is not due to regulations, but explained by natural, social, economical, cultural, historical and political science. 'Genome editing' will not improve on this record as it ignores the causes of hunger. The hunger claim of GMOs is completely misleading on both counts: concept and reality. Furthermore, the claim that developing countries would be foregoing the supposed benefits of GMOs, regardless by which technique, because they would be blindly following critical European NGOs is simply false, and ignorant of the decisive roles actors from developing countries have had in demanding and inducing as well as shaping international regulations and is patronizing at its core".

Dr Michael Antoniou, Head of the Gene Expression and Therapy Group, Department of Medical and Molecular Genetics, King's College London, UK:

"Using extensive evidence from the scientific literature, the ENSSER/CSS report expertly highlights the conceptual and technical flaws of the Leopoldina and EASAC position statements on the use of 'gene editing' in agriculture to create new varieties of crops and new breeds of livestock. The ENSSER/CSS report clearly shows that the claim that 'genome editing' mimics natural processes is unfounded. Indeed, the ENSSER/CSS critique describes how the 'genome editing' process is a totally artificial laboratory based procedure, which bears no resemblance to natural breeding, and that the assertions that 'genome editing' solely brings genetic changes that are precise, predictable and thus safe are not supported by the science that underpins this technology.

"On the contrary, 'genome editing' can result in unintended, large scale DNA damage, which can lead to alterations in global patterns of gene function. This in turn can result in changes in crop plant biochemistry and composition, including the production of novel toxins and allergens.

"Another scientific failing of the Leopoldina position statement is that it does not acknowledge that the desirable characteristics that it claims can be achieved with 'genome editing' and are needed to 'feed the world', such as higher yields, disease resistance, pest resistance, and tolerance to drought and other environmental stresses, are genetically complex traits. The latest understanding in the field of molecular genetics tells us that complex traits have the functioning of many genes, or even the entire complement of the organism's genes, at their basis. As 'genome editing' can only manipulate one or a few genes, it is beyond the ability of this technology to deliver



these complex traits. Only natural cross breeding can bring together the large complement of gene families needed to impart a new complex trait.

“Thus the Leopoldina and EASAC position statements are not true to the science at the basis of this technology. If their recommendations for the deregulation of 'genome-edited' crops, foods and animals were to be adopted, this would put at risk public health and the environment.”

Critical Scientists Switzerland

Since 2015, Critical Scientists Switzerland (CSS) has promoted independent and unbiased science and research as well as transdisciplinary and participatory research approaches and agendas. Science and research should serve the public interest and help our society during the necessary transition towards a more sustainable way of life. CSS further promotes the consequent application of the precautionary principle where lack of knowledge and scientific uncertainties might critically or irrevocably endanger the environment, biodiversity, social integrity or human health.

More information: <https://www.criticalscientists.ch/en/>

European Network of Scientists for Social and Environmental Responsibility e.V.

The purpose of the European Network of Scientists for Social and Environmental Responsibility e.V. (ENSER) is the advancement of science and research for the protection of the environment, biological diversity and human health against negative impacts of new technologies and their products. This especially includes the support and protection of independent and critical research to advance the scientific assessment of the potentially negative impacts. ENSER promotes the critical European and international discourse on new technologies, their impacts and their regulation. Scientific and technological activities – and their gaps – are increasingly driven by private interests. Consequently, the relationship between science, society and environment has to be restructured in order to better protect the common interest.

More information: <https://ensser.org/>