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7 September 2020

Dear Minister Klöckner,
dear Minister Schulze,

we are writing to you regarding the need for the global regulation of a novel genetic engineering technology called Gene Drive. We would like to ask for your timely intervention on this issue regarding present discussions and decisions of the European Union Council's *Working Party of International Environmental Issues* (WPIEI)[1], currently preparing orientation lines for the position of EU Member States and consequent EU position for the upcoming Conference of Parties of the United Nations Convention on Biological Diversity (UN CBD COP 15)[2].

Re-programming or exterminating wild species by means of genetic engineering

In the midst of the planet's sixth mass extinction, with a rate of species extinction unprecedented in human history[i], a new genetic engineering technology called Gene Drive is being developed with the aim of redesigning, replacing and exterminating wild populations and species of animals and plants by means of genetic engineering[ii].

Enabled by new genetic engineering tools such as CRISPR/Cas9, Gene Drives force the inheritance of new traits to *all* offspring over generations of wild populations and species. Once released into the environment, Gene Drive Organisms could spread uncontrollably and irreversibly into all ecosystems that allow for their survival, irrespective of national borders or prior legal approval. Currently, no means of recalling Gene Drive Organisms from nature or reversing their effects are available. Nevertheless, eradication plans exist for invasive mice and rats, agricultural pests like fruit flies and disease carrying mosquitos. First field trials and releases of Gene Drive mosquitos are being scheduled in Burkina Faso for the near future[iii].

Given the lack of specific and comprehensive methodologies for their risk and technology assessment, **any release of Gene Drive Organisms**, particularly at this early stage of development, **poses severe threats of harm to biodiversity and the web of life**[iv]. Therefore, releases of Gene Drive Organisms would be incompatible with the precautionary principle and the aims of the UN Convention of Biological Diversity (CBD) and its Cartagena Protocol on Biosafety, which requires '*an adequate level of protection*' from adverse effects to biological diversity emerging from living modified organisms (LMO)[v].

Gene Drives and the Convention on Biological Diversity (CBD)

Gene Drives have been discussed within the CBD since 2015 as part of the Convention's work addressing synthetic biology and risk assessment of living modified organisms under the Cartagena Protocol on Biosafety.

[1] https://www.consilium.europa.eu/en/council-eu/preparatory-bodies/working-party-international-environment-issues/
[2] https://www.cbd.int/meetings/COP-15

At COP 14 of the UN Convention on Biological Diversity in Sharm-el-Sheik in 2018, over 200 organisations and experts from all over the world called for a global moratorium on the environmental release of Gene Drive Organisms.[vi] However, the precautionary provisions[3] finally agreed at COP 14 may not be sufficient to prevent harm to biodiversity, human health, food security or peace that could emerge from the planned environmental release of Gene Drive Organisms.

Need for a global moratorium on the release of Gene Drive Organisms (GDOs) into nature

COP 15 of the CBD in Kunming, China, which has been postponed to the second quarter of 2021, could be the last moment to enforce precaution by temporarily halting plans to release Gene Drive Organisms into the environment and take the time to:

- develop specific guidance and methodologies for the risk assessment that apply to all types of GDOs
- perform a technology assessment on GDOs, including the assessment of cultural and socio-economic impacts and ethical questions in comparison to consequences from alternative solutions
- develop and implement globally uniform safety standards (including strategies, instruments and safety licencing) for the research and handling of GDOs in contained use laboratories
- install a global notification scheme for research on GDOs
- develop effective risk management measures such as proven methods to recall and control GDOs
- develop and install measures for detection, identification and monitoring of GDOs
- agree and implement specific global rules on liability and redress for damage caused by the intentional or unintentional release of GDOs into the environment
- develop a global procedure for decision making on the release of GDOs
- implement a global ban on the development of GDOs with military application potential

These measures should be in place before any environmental releases of Gene Drive Organisms should be considered and could be used to build on the existing decision 14/19 (paragraph 11) of CBD COP 14.

An informal European expert meeting in preparation of the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-24)[4] of the Convention on Biological Diversity (CBD), convened by the German Federal Agency for Nature Conservation (BfN) recently made the following recommendation on how to include parts of these demands into the current working document on Synthetic Biology[5], which we would recommend to adopt as part of the orientation lines:

> „*Reiterating* decision 14/19 (para 11), furthermore calls upon Parties and other Governments, taking into account the current uncertainties regarding engineered gene drives, to apply the precautionary approach in accordance with the objectives of the convention, and *to refrain from introducing organisms containing engineered gene drives into the environment, including experimental releases for research and development purposes, until the open questions, challenges, as well as the multiple dimensions of lacking knowledge and data requirements and assessment identified by the AHTEG on risk assessment and the AHTEG on synthetic biology have been addressed and solved, and in particular until guidance on risk assessment and risk management has been developed, agreed and implemented by the Parties*."

[3] https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-19-en.pdf
[4] https://www.cbd.int/meetings/SBSTTA-24

[5] https://www.cbd.int/doc/c/5992/a98b/e60a7d8dde36888c553b92d4/sbstta-24-04-en.pdf

We hope that you will consider taking action on this pressing matter of Gene Drive regulation by instructing your representatives at the WPIEI to insist on including language in the SBSTTA 24 orientation lines that will halt any environmental release of Gene Drive Organisms, including for experimental reasons, in order to collect more data, agree on globally specific rules and procedures and implement precautionary measures that prevent adverse effects to biodiversity from possible future Gene Drive releases.

By enforcing such a strict application of the precautionary principle on the research and use of GDOs at national and international level you would respond to:

- **the European Parliament's** resolution of 16 January 2020 on CBD COP 15, calling on the EU Member States to support a global moratorium on the release of Gene Drive Organisms (GDOs) into the wild at the forthcoming Conference of the Parties to the UN Convention on Biological Diversity in China.[vii]
- Warnings by **the** agencies for **environmental protection and nature conservation of Austria, Germany, Italy, Finland, Lithuania, Malta and Switzerland** highlighting possible negative effects of GDOs on the environment, including irreversible changes of food chains and ecosystems, and losses of biodiversity, therefore suggesting a technology assessment prior to any environmental releases.[viii]
- **Independent scientists such as the European Network of Scientist for Social and Environmental Responsability (ENSSER)** who, based on their comprehensive scientific report on Gene Drives[ix], recommend that, in light of the unpredictability, the lack of knowledge and the potentially severe negative impacts on biodiversity and ecosystems, any releases (including experimental) of GDOs into the environment should be placed on hold to allow proper investigation until there is sufficient knowledge and understanding.
- **more than 200 organisations and experts worldwide**[x] including **78 Civil Society Organisations from all over Europe**[xi] calling for a global moratorium on the release of GDOs
- More than **160.000 European citizens** in an ongoing petition[xii] who call on EU Member States to implement a global moratorium on the release of GDOs[xiii]

In case you would like some more information on the topic we would be happy to provide you with the contact to relevant experts.

Yours sincerely

Martin Häusling
Tilly Metz
Ville Niinistö
Maria Noichl
Michal Wiezik

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[v] Cartagena Protocol on Biosafety: https://bch.cbd.int/protocol/text/

[vi] A Call to Protect Food Systems from Genetic Extinction Technology: The Global Food and Agriculture Movement Says NO to Release of Gene Drives: https://www.etcgroup.org/sites/www.etcgroup.org/files/files/forcing_the_farm_sign_on_letter_english_web.pdf

[vii] European Parliament resolution of 16 January 2020 on the 15th meeting of the Conference of Parties (COP15) to the Convention on Biological Diversity (2019/2824(RSP)), paragraph 13: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0015_EN.html

[viii] Dolezel, M. et al. (2019): Gene Drive Organisms. Implications for the Environment and Nature Conservation. Umweltbundesamt, Vienna: https://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0705.pdf

[ix] CSS, ENSSER, VDW (2019). Gene Drives. A report on their science, applications, social aspects, ethics and regulations. Online: https://genedrives.ch/wp-content/uploads/2019/10/Gene-Drives-Book-WEB.pdf

[x] A Call to Protect Food Systems from Genetic Extinction Technology: The Global Food and Agriculture Movement Says NO to Release of Gene Drives: https://www.etcgroup.org/sites/www.etcgroup.org/files/files/forcing_the_farm_sign_on_letter_english_web.pdf

[xi] Joint letter by 78 European civil society organisations calling on the EU Commission to advocate for a global moratorium on the environmental release of Gene Drive Organisms at CBD COP 15: https://update.zs-intern.de/fileadmin/files/SOS/gene_drive/Open_Letter_to_the_EU_Commission_Please_support_a_global_moratorium_on_the_release_of_Gene_Drive_Organisms_30.06.2020.pdf

[xiii] European petition calling for a global moratorium on the environmental release of Gene Drive Organisms: https://act.wemove.eu/campaigns/gene-drive-moratorium-INT-EN