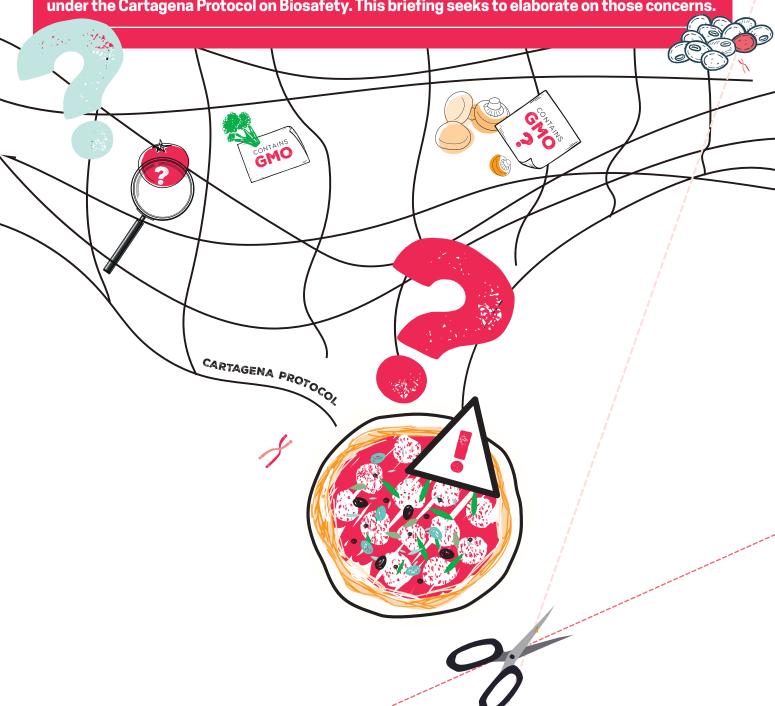




The European Union is in the process of introducing new legislation that would exclude most of the "new generation" of genetically modified organisms (GMOs) - seeds, plants and foods developed through new genomic techniques (NGTs) such as gene editing - from its existing GMO regulations. The draft law significantly weakens the approval process for these new GMOs, removing safety checks, transparency and labelling requirements. These changes have sparked widespread concerns about the environmental impacts, and in particular raises the question whether the new legislation is compatible with the European Union's obligations under the Cartagena Protocol on Biosafety. This briefing seeks to elaborate on those concerns.



The EU's proposal to deregulate new GMOs



Under current legislation, all GMOs are covered by EU-wide laws for genetically modified (GM) food, feed and seeds, including the new generation of GMOs. Any GM product can be marketed and grown, if it has been authorised under relevant EU laws (directive 2001/18, regulations 1829/2003 and 1830/2003).

To get an authorisation, a GMO must be assessed for any potential risk to the environment, animal and human health. The company that is seeking authorisation must provide a testing method, to ensure that authorities or the private sector can test to check whether a product contains GMOs.

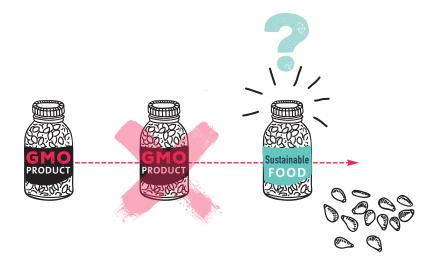
Once authorised, a GM product can be marketed or grown in the EU, but all GM food and feed must be labelled as a GMO. Where GM ingredients are processed like GM rapeseed oil in the dough of a frozen pizza, this must also be labelled. Furthermore, the EU introduced a traceability system (regulation 1830/2003) for all GMO products.

In the summer of 2023, following a long lobby campaign by agribusiness,1 the EU Commission published proposals to deregulate new GMOs (2023/0226 (COD)). Under the new law, the majority of new GMOs could be sold and grown in the EU without any safety checks. Companies would no longer be required to provide a method to test for the

presence of the new GMOs and all traceability requirements would be removed within the EU as well as for exports. No food and feed labelling would be required for most new GMOs and traceability abolished, so it would be impossible to find out whether a product had been grown or produced with new GMO techniques.

In cases where a risk was detected (i.e. harm to health or environmental damage), companies would be able to continue to sell the new GM food, feed and seeds. This means there would be no protection for conventional or organic farmers whose crops could be contaminated with new GMOs. Consumers would not know anymore whether food is containing new GMOs. And there would be no protection for contamination of the environment.

The consequences of this law would be that a handful of agribusiness corporations² would be able to market their new GMO food and seeds without any relevant regulatory costs and without any liability for contamination or potential harm caused by them. The conventional and organic sector would have to bear the costs of testing and taking measures to minimisze contamination of the food chain.



Obligations under the Cartagena Protocol



The Cartagena Protocol on Biosafety³ is an international treaty governing the movement of living genetically modified organisms between countries. It entered into force in September 2003 and seeks to protect biodiversity against potential risks resulting from modern biotechnology.

One of the key measures established under the Protocol is a procedure for informing countries of any risks related to the conservation and sustainable use of biological diversity from imports of living modified organisms. The information shared must be based on a risk assessment, carried out in a scientifically sound and transparent manner,⁴ with risks assessed on a case-by-case basis. This allows countries to decide whether the modified organism in question should be allowed into their territory.

Risk assessments should consider the risk of potential adverse effects on biodiversity, an evaluation of the likelihood of these effects being realised, an evaluation of the consequences and an estimation of the overall risk based on these evaluations, as well as a recommendation as to whether the risks are acceptable.

This information must also be provided for processed material originating from living modified organisms and containing detectable novel combinations of replicable genetic material.

Living modified organisms must also be clearly identified as such, according to the Protocol (article 18), including details of relevant traits, any criteria for safe handling, storage, transport and use, with a contact point provided for further information. This should ensure that countries are provided with the necessary information necessary to make decisions before agreeing to the import of such organisms into their territory.

The Cartagena Protocol was ratified by the European Union in 2002 and it was transposed into European law via Regulation (EC) No. 1946/2003 which came into force in 2003. The Cartagena Protocol is therefore binding on the European Union and its member states and prevails over EU internal legislation.⁵



Conflicting requirements



The EU's legal requirements set out under the Cartagena Protocol raise questions about the legality of the EU's proposal to deregulate new GMOs.6

The European Court of Justice has already made it clear that new genomic techniques result in GMOs,7 meaning that the requirements of the Cartagena Protocol are relevant to the movement of new genetically modified organisms, or products derived from genetically modified organisms.

The EU's proposed legislation allows for some genetically modified organisms to be easily grown and sold in the EU. This means that these GMOs would not be subject to any safety checks. The absence of any safety checks for these new GMOs would mean that other countries would not have access to adequate information what is imported in their territories nor on the risks presented by the modified organism, resulting in a lower level of protection for the environment.

This lack of an adequate risk assessment would also mean that exporting countries would not be able to comply with the requirement under the Cartagena Protocol to provide a formal notification to the importing country that the product contained genetically modified material. Under the protocol, exporting countries are required to provide certain key information to the importing country, including the existing risk assessment.

Whilst seeds would remain labelled, other transparency for the safe handling, storage, transport and use set out in the Cartagena Protocol are not met anymore.8 This would again result in a lower level of protection for importing countries and would appear to be in breach of the Cartagena Protocol.

While signatories under the Protocol can make regional agreements regarding cross-border movement of modified organisms, such agreements must not result in lower levels of protection than provided by the Protocol.

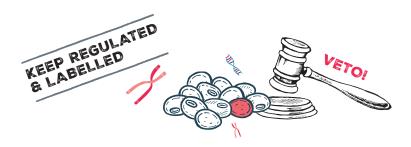
New GMOs can be difficult to detect, with research still on-going to find ways to identify some kinds of modification through genetic sequencing. This means that if the modification is not transparently disclosed, it may remain undetected.

With the ongoing decision making on the new legislation to deregulate most of new GMOs. the impacts of these planned abolishment of labelling, traceability and risk assessment on the international duties defined by the Cartagena Protocol haven't been assessed by EU decision makers.

Endnotes:

- 1 https://corporateeurope.org/en/2021/03/derailing-eu-rules-new-gmos
- https://friendsoftheearth.eu/wp $content/uploads/2022/10/G2_BIOTECH_GIANTS_EXPOSED_MEDIA_BRIEFING.pdf$
- https://bch.cbd.int/protocol/background
- 4 https://bch.cbd.int/protocol/cpb_art15.shtml
- 5 Article 216(2) TFEU
- Article 18 of the Cartagena Protocol provides for mandatory labelling of living modified organisms: "Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of $the \ Protocol, \ clearly \ identifies \ them \ as \ living \ modified \ organisms; \ specifies \ the \ identity \ and$ relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the export
- 7 Judgement of the Court of 25 July 2018, Case C-528/16, Confederation Paysanne
- Article 18 of the Cartagena Protocol states "The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article] 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I."





The EU's proposal to amend the regulations concerning new GMOs raises serious conflicts with the EU's obligations under the Cartagena Protocol to protect biodiversity. The proposal to exempt some new GMOs from the current requirements for safety checks and labelling will mean essential information cannot be shared with third countries, as required by the Cartagena Protocol.

If new GMOs will be allowed onto the market unlabelled and untested, they can be exported to a third country without any notification or warning. Importing countries would not be able to make an informed decision about the safety of the import as they would not even know it was entering their territory. This not only undermines the protection envisaged by the Cartagena Protocol but also raises questions about the credibility of the EU's support for such protection.

Friends of the Earth Europe believes that to protect biodiversity the EU must retain the current requirements for safety tests and mandatory labelling for all generations of GMOs. This ensures EU member states comply with the international requirements of the Cartagena Protocol and provide the information needed to protect global biodiversity.

WE URGE

EU decision makers:

- to ensure that third parties will remain fully informed whether EU exports contains living GMOs;
- to ensure that GMOs underwent an environmental safety checks prior to its exports.

Friends of the Earth Europe is the largest grassroots environmental network in Europe, uniting more than 30 national organisations with thousands of local groups. We are the European arm of Friends of the Earth International which unites 74 national member organisations, some 5,000 local activist groups, and over two million supporters around the world. We campaign on today's most urgent environmental and social issues, challenging the current model of economic and corporate globalization, and promoting solutions that will help to create environmentally sustainable and socially just societies. We seek to increase public participation and democratic decision-making. We work towards environmental, social, economic and political justice and equal access to resources and opportunities on the local, national, regional and international levels.

Author: Helen Burley. Editors: Mute Schimpf, Laura Hieber. October 2024. Design: contact@onehemisphere.se Images: © Shutterstock.





Friends of the Earth Europe gratefully acknowledges financial assistance from the European Commission (LIFE Programme). The sole responsibility for the content of this document lies with Friends of the Earth Europe. It does not necessarily reflect the opinion of the funder mentioned above. The funder cannot be held responsible for any use that may be made of the information contained therein.

www.friendsoftheearth.eu

for the **people** | for the **planet** | for the **future**



tel: +32 2 893 1000 info@foeeurope.org twitter.com/foeeurope linkedin.com/company/friends-of-the-earth-europe

