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AGRICULTURE  
ACADEMY

Brussels, March 30th, 2021

## Open letter:

### Regulation of new genomic techniques

Dear Vice President of the European Commission Timmermans,

As civil society and business organisations we are deeply alarmed about attempts to deregulate an emerging new generation of genetically modified (GM) crops and animals that are engineered with new genomic techniques<sup>1</sup>, such as CRISPR/Cas.

The European Court of Justice (ECJ) has ruled that a new generation of genetically modified organisms must be regulated under the EU's existing GMO laws.<sup>2</sup> Their exclusion from the EU GMO directive “*would compromise the objective of protection pursued by the directive and would fail to respect the precautionary principle which it seeks to implement,*” according to the Court (para 53 of the ruling).

The agricultural biotech industry claims these GM organisms carry only small DNA changes,

which could also arise naturally, and therefore do not pose any risks. However, scientific publications show that new techniques of genetic modification allow developers to make significant genetic changes, and that these changes can be very different from those that happen in nature.<sup>3</sup> Products obtained by genomic techniques are novel and the technical process fundamentally different to traditional breeding techniques, which is why products from genomic techniques are covered by patents. Moreover, new techniques of genetic modification can cause a range of unwanted genetic modifications that can result in the production of novel toxins or allergens, or in the transfer of antibiotic resistance genes.<sup>4</sup> But also intended modifications can result in traits which could raise food safety, environmental or animal welfare concerns.<sup>5</sup>

The application of new genomic techniques for breeding farm animals also raises serious animal welfare and ethical concerns. This, amongst other reasons, is due to the high number of animals required in the test phase to produce viable offspring and the lack of predictability or stability of the edits to the animals.<sup>6</sup> To genetically modify animals, plants or microorganisms with new genomic techniques could therefore pose a danger to consumers, animal welfare and the environment.

**As Vice President of the European Commission, you will be involved in three upcoming decisions that are relevant to the matter. We urge you to ensure that all organisms derived from genomic techniques continue to be regulated in accordance with existing EU GMO standards, that their products do not enter our food supply illegally and that the EU takes a clear stance against the release of gene drive organisms into the environment.**

#### **(1) European Commission decision on the regulation of new genomic techniques**

The European Commission is expected to set out its views on the future regulation of new genomic techniques at the end of April, based on an in-house study mandated by the Council of Ministers.<sup>7</sup> The responsible European Commissioner, Stella Kyriakides, appears to view GM technology as a way to enhance the sustainability of farming. We are concerned that she may want to propose an exclusion of certain genomic techniques from the EU's GMO laws, as proposed by the agricultural biotech industry.

It is not realistic to expect new genomic techniques to contribute to reducing the negative impacts of farming on the environment and climate. Promises to create drought-resistant GM crops and to reduce the need for pesticides are as old as GM technology itself.<sup>8</sup> These promises have failed, not least because stable yields in an unstable climate are a matter of sound farming practices and locally adapted seeds, of which there are already many successful examples.<sup>9</sup> In addition, products from genomic techniques are covered by patents. Patents on seeds have negative economic consequences for the agricultural sector, including monopolisation and concentration of the seed market.

- **We urge you to oppose any weakening of EU GMO regulations**, and to ensure the full application of the ECJ ruling of 25 July 2018 in line with the precautionary principle. To achieve this, the European Commission should support member states' efforts to prevent the illegal contamination of EU imports with unauthorised GM crops created with new genomic techniques.<sup>10</sup>

#### **(2) Announced UK regression on EU GMO standards**

The UK government is conducting a public consultation on whether to include or exclude new breeding techniques including genetic engineering in its definition of Genetically Modified Organisms (GMOs). If they change their current definition, this would clearly weaken their national health and environmental standards vis-à-vis those of the EU.<sup>11</sup>

- **We ask you to support a strong European Commission response to the UK's consultation regarding a possible change in regulations**, which would represent a clear breach of the TCA's principle of non-regression. **Please ask the UK government to drop its plans** or face the consequences with regards to future trade in agricultural goods between the EU and the UK.

### **(3) EU position on the global regulation of gene drive organisms**

- 1) A particularly worrying application of new genomic techniques are gene drives. This technology can genetically engineer, decimate or eradicate entire populations of wild organisms, of which most prominently insects.<sup>12</sup> In times of ecological crisis, when one million species are under threat, we simply cannot experiment with a technology that has aptly been termed "extinction on demand".<sup>13</sup> A first representative poll among citizens from eight EU countries shows high levels of opposition to and very low levels of support for the use of gene drive technology in the environment.<sup>14</sup>

The European Commission has declared it wants the EU to be a leader in the defence of nature. It will represent the EU in the upcoming negotiations under the UN Convention on Biological Diversity and the Cartagena Protocol.

- **We ask you to support a global moratorium on the environmental release of gene drive organisms for precautionary reasons at international level**, as called for by the European Parliament.<sup>15</sup>

**Vice President of the European Commission, the outcomes of these three policy processes will determine the safety of our food supply, and the future health of our environment and climate. We urge you to make sure the ECJ ruling will be fully implemented. We count on you to uphold the precautionary principle, safeguard a high level of protection and the right of farmers and consumers alike, to choose what they plant and eat. This requires that all new genomic techniques are regulated, thoroughly risk assessed and labelled.**

## **Signatories**

### **International**

Biodynamic Federation Demeter International  
FIAN International  
Navdanya International

### **Europe**

Corporate Europe Observatory  
European Coordination Via Campesina (ECVC)  
Forum Civique Européen  
Four paws  
Friends of the Earth Europe  
Greenpeace  
IFOAM Organics Europe  
Pesticide Action Network Europe  
Slow Food Europe  
WeMove Europe

### **Austria**

Arche Noah  
GLOBAL 2000 - Friends of the Earth Austria  
ÖBV-Via Campesina Austria

### **Belgium**

Agroecology In Action  
Amis de la Terre Belgique  
BioForum  
Boerenforum  
CNCD-11.11.11.  
FIAN Belgium  
FUGEA (Fédération Unie de Groupements d'éleveurs et d'agriculteurs)  
Inter Environnement Wallonie (IEW)  
Libère Terre, association citoyenne et paysanne  
Mouvement d'action paysanne (MAP)  
Natagora  
Nature & Progrès Belgique  
Quinoa  
Réseau Meuse Rhin Moselle pour les semences paysannes et citoyennes  
Terre-en-vue  
UNAB Union des Agrobiologistes belges  
Velt  
Vereniging voor Ecologisch Leven en Tuinieren  
Vitale Rassen  
vzw Climaxi  
Wervel

### **Croatia**

Croatian Organic Farmers Associations Alliance - HSEP  
Zelena akcija / Friends of the Earth Croatia  
ZMAG

### **Cyprus**

FoE Cyprus

## **Czech Republic**

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STUŽ - Spoločnosť pro trvale udržateľný život

## **Denmark**

Dansk Vegetarisk Forening

Demeterforbundet i Danmark

Foreningen for Biodynamisk Jordbrug

Frie Bønder Levende Land

Grøn Hverdag

Landsforeningen Praktisk Økologi

NOAH - Friends of the Earth Denmark

Slow Food København

## **Finland**

Biodynaaminen yhdistys - Biodynamiska föreningen

Esvy

## **France**

Confédération paysanne

Demeter France

MABD Mouvement de l'Agriculture Biodynamique

Objectif Zéro OGM

OGM Dangers

Pollinis

Sciences Citoyennes

Terres d'abeilles

## **Germany**

BUND - Bund für Umwelt und Naturschutz Deutschland e.V.

Kulturpflanzen- und Nutztiervielfalt e.V.

Apfel Gut e.V.

Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) e.V.

Bioland

BOLW

Bundesverband Grüne Liga

Demeter e.V.

Förderungsgemeinschaft Ökologischer Obstbau (FÖKO e.V.)

Fruchtwechsel e.V.

GLS Bank

Interessengemeinschaft für gentechnikfreie Saatgutarbeit (IG Saatgut)

Naturland

Save Our Seeds

Slow Food Germany

Umweltinstitut München

Verbraucherzentrale Bundesverband e.V.

Zukunftstiftung Landwirtschaft

**Greece**

Alternative Community Peliti  
Association of Organic Farmers of Northern Greece  
Dimitra"Organic farmers association of Ilia  
Organic Markets of Attica

**Hungary**

Biodinamikus Közhasznú Egyesület  
Fenntarthatóság Felé Egyesület / Towards Sustainability Association  
Hungarian Research Institute of Organic Agriculture – OMKI  
Közép-magyarországi Zöld Kör  
Magyar Természetvédők Szövetsége / Friends of the Earth Hungary

**Ireland**

ISPCA

**Italy**

Demeter Italia  
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Slow Food Italia  
Asociazione Rurale Italiana (ARI)

**Latvia**

Permakultura

**Lithuania**

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**Luxembourg**

Oikopolis Groupe  
SEED Luxembourg asbl  
Vereenigung fir Biolandwirtschaft Lëtzebuerg a.s.b.l.

**Malta**

FoE Malta  
Nadir

**Netherlands**

Slow Food Netherland  
Stichting Demeter  
Vereniging voor Biologisch-Dynamische Landbouw en Voeding

**Norway**

Biologisk-dynamisk Forening

**Poland**

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Ekoland lubelski  
Fundacja Mała Wielka Zmiana  
Fundacja Rolniczej Różnorodności Biologicznej AgriNatura  
Fundacja Strefa Zieleni  
Fundacja Zielone Światło  
Instytut Spraw Obywatelskich/The Civil Affair Institute  
Społeczny Instytut Ekologiczny

Stowarzyszenie Polska Wolna od GMO  
Stowarzyszenie producentów ekologicznych EKOŁAN  
Zielone Wiadomości

### **Portugal**

AEPGA - Associação para o Estudo e Protecção do Gado Asinino  
Circulos de Sementes  
CNA - Confederação Nacional da Agricultura  
Confederação Nacional Da Agricultura  
GAIA-Environmental Action and Intervention Group  
Movimento Cívico Ar Puro  
NDMALO-GE  
Palombar - Associação de Conservação da Natureza e do Património Rural  
Parents for Future Portugal  
Plataforma Transgénicos Fora  
Rede para o Decrescimento  
Térrea - Associação para a Cultura, o Desenvolvimento Sustentável e a Cidadania  
TROCA-Plataforma por um Comércio Internacional Justo  
Wakeseed  
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### **Romania**

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### **Slovakia**

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CEPTA – Centrum pre trvaloudržateľné alternatívy  
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Život Rusyna

### **Slovenia**

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Združenje Demeter Slovenija

### **Spain**

Amigos de la Tierra

**Sweden**

Nordbruk

Svenska Demeterförbundet

**United Kingdom**

Biodynamic Association Certification UK

Econexus

GM Watch

Land Workers' Alliance



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## **1References**

- <sup>1</sup> According to the European Council (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1904&from=EN>) new mutagenesis techniques (i.e. new genomic techniques) must be defined in the light of the ECJ ruling in case C-528/16. They therefore include all genetic modification techniques “which appeared or were mostly developed since Directive 2001/18 was adopted” (para 51 of the Ruling of the European Court of Justice, 25 July 2018, Case C 528/16, <http://curia.europa.eu/juris/document/document.jsf?text=&docid=204387&pageIndex=0&doclang=EN& mode=req&dir=&occ=first&part=1&cid=709582>)
- <sup>2</sup> Arguing that “the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis. It thus follows from the material before the Court, first, that the direct modification of the genetic material of an organism through mutagenesis makes it possible to obtain the same effects as the introduction of a foreign gene into that organism and, secondly, that the development of those new techniques/methods makes it possible to produce genetically modified varieties at a rate and in quantities quite unlike those resulting from the application of conventional methods of random mutagenesis.” (para. 48 of ECJ ruling quoted in note [1])
- <sup>3</sup> Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). <https://doi.org/10.3389/fbioe.2019.00031>  
Kawall, K., Cotter, J. & Then, C. Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. *Environ Sci Eur* 32, 106 (2020). <https://doi.org/10.1186/s12302-020-00361-2>
- <sup>4</sup> Sansbury, B.M., Hewes, A.M. & Kmiec, E.B. Understanding the diversity of genetic outcomes from CRISPR-Cas generated homology-directed repair. *Commun Biol* 2, 458 (2019) <https://doi.org/10.1038/s42003-019-0705-y>  
Norris, A.L., Lee, S.S., Greenlees, K.J. et al. Template plasmid integration in germline genome-edited cattle. *Nat Biotechnol* 38, 163–164 (2020). <https://doi.org/10.1038/s41587-019-0394-6>  
Rezza, A., Jacquet, C., Le Pillouer, A. et al. Unexpected genomic rearrangements at targeted loci associated with CRISPR/Cas9-mediated knock-in. *Sci Rep* 9, 3486 (2019) <https://doi.org/10.1038/s41598-019-40181-w> ,  
Robinson, Cl. Antoniou, M. & Fagan J. GMO myths and truths. Updated with new information on ‘new GM’ techniques, Earth Open Source, Fairfield, (2018) (4th ed)  
Adikusuma, F., Piltz, S., Corbett, M.A. et al. Large deletions induced by Cas9 cleavage. *Nature* 560, E8–E9 (2018). <https://doi.org/10.1038/s41586-018-0380-z>  
Rayner, E. et al. CRISPR-Cas9 Causes Chromosomal Instability and Rearrangements in Cancer Cell Lines, Detectable by Cytogenetic Methods, *The CRISPR Journal*. Dec 2019. pp. 406-416. <http://doi.org/10.1089/crispr.2019.0006>
- <sup>5</sup> Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs) <https://doi.org/10.3389/fbioe.2019.00031>
- <sup>6</sup> Ormandy EH, Dale J, Griffin G. Genetic engineering of animals: ethical issues, including welfare concerns. *Can Vet J*. 2011;52(5):544-550. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/>
- <sup>7</sup> Council Decision (EU) 2019/1904 on the study on new genomic techniques, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D1904&from=EN>. Scope of the European Commission’s study: [https://ec.europa.eu/food/plant/gmo/modern\\_biotech/new-genomic-](https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-)

- <sup>8</sup> Greenpeace International (2015). Twenty Years of Failure. Why GM crops have failed to deliver on their promises: <https://www.greenpeace.org/static/planet4-international-stateless/2015/11/7cc5259f-twenty-years-of-failure.pdf>
- <sup>9</sup> Chable, V. et al. A. Embedding Cultivated Diversity in Society for Agro-Ecological Transition. *Sustainability* 2020, 12, 784. <https://doi.org/10.3390/su12030784>
- <sup>10</sup> Ribarits, A. et al. Detection Methods Fit-for-Purpose in Enforcement Control of Genetically Modified Plants Produced with Novel Genomic Techniques (NGTs). *Agronomy* 2021, 11, 61. <https://doi.org/10.3390/agronomy11010061>  
<https://www.detect-gmo.org/>
- <sup>11</sup> <https://www.gov.uk/government/news/gene-editing-creates-potential-to-protect-the-nations-environment-pollinators-and-wildlife> <https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/>
- <sup>12</sup> Simon, S., Otto, M. and Engelhard, M. Synthetic gene drive: between continuity and novelty *EMBO Rep* (2018) 19:e45760 <https://doi.org/10.15252/embr.201845760>
- <sup>13</sup> <https://www.economist.com/briefing/2018/11/08/the-promise-and-peril-of-gene-drives>
- <sup>14</sup> <https://www.stop-genedrives.eu/en/survey-eu-citizens-reject-genetic-engineering-of-wild-species-with-gene-drives/>
- <sup>15</sup> 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)) [https://www.europarl.europa.eu/doceo/document/TA-9-2020-0015\\_EN.html](https://www.europarl.europa.eu/doceo/document/TA-9-2020-0015_EN.html) para 13)