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Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council

Fields marked with * are mandatory.

Questionnaire on new genomic techniques to contribute to the study requested by the Council

Discussed and finalised in the Ad-hoc Stakeholder meeting on 10 February 2020

Background

The Council has requested [1] the Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law" (*i.e.* Directive 2001/18/EC, Regulation (EC) 1829/2003, Regulation (EC) 1830/2003 and Directive 2009/41/EC).

To respond to this Council's request, the Commission is collecting contributions from the stakeholders through the questionnaire below. The study covers all new genomic techniques that have been developed after 2001.

Instructions

For the purpose of the study, the following definition for new genomic techniques (NGTs) is used: techniques that are capable of altering the genetic material of an organism and which have emerged or have been developed since 2001 [2].

Unless specified otherwise, the term "NGT-products" used in the questionnaire covers plants, animals, micro-organisms and derived food and feed products obtained by NGTs for agri-food, medicinal and industrial applications and for research.

Please substantiate your replies with explanations, data and source of information as well as with practical examples, whenever possible. If a reply to a specific question only applies to specific NGTs/organisms, please indicate this in the reply.

Please indicate which information should be treated as confidential in order to protect the commercial

interests of a natural or legal person. Personal data, if any, will be protected pursuant to Regulation (EU) 2018/1725 [3].

[1] Council Decision (EU) 2019/1904, OJ L 293 14.11.2019, p. 103-104, https://eur-lex.europa.eu/eli/dec/2019/1904/oj
[2] Examples of techniques include: 1) Genome editing techniques such as CRISPR, TALEN, Zinc-finger nucleases, mega nucleases techniques, prime editing etc. These techniques can lead to mutagenesis and some of them also to cisgenesis, intragenesis or transgenesis. 2) Mutagenesis techniques such as oligonucleotide directed mutagenesis (ODM). 3) Epigenetic techniques such RdDM. Conversely, techniques already in use prior to 2001, such as Agrobacterium mediated techniques or gene gun, are not considered NGTs.
[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

Guidelines

Please note that the survey accepts a maximum of 5000 characters (with spaces) per reply field. You might be able to type more than 5000 characters, but then the text will not be accepted when you submit the questionnaire. You will also receive a warning message in red colour below the affected field.

You have the option to upload supporting documentation in the end of each section. You can upload multiple files, up to the size of 1 MB. However, note that any uploaded document cannot substitute your replies, which must still be given in a complete manner within the reply fields allocated for each question.

You can share the link from the invitation email with another colleague if you want to split the filling-out process or contribute from different locations; however, remember that all contributions feed into the same single questionnaire.

You can save the draft questionnaire and edit it before the final submission.

You can find additional information and help here: https://ec.europa.eu/eusurvey/home/helpparticipants

Participants have until 15 May 2020 (close of business) to submit the questionnaire via EUsurvey.

QUESTIONNAIRE

Please provide the full name and acronym of the EU-level association that you are representing, as well as your Transparency Registry number (if you are registered)

If the name of the association is not in English, please provide an English translation in a parenthesis

Greenpeace European Unit, Transparency Registry number 9832909575-41

Please mention the sectors of activity/fields of interest of your association

Greenpeace European Unit is part of the international Greenpeace network, active in over 55 countries worldwide. Greenpeace's goal is to ensure the ability of the earth to nurture life in all its diversity. That means we act to:

- protect biodiversity in all its forms
- prevent pollution and abuse of the earth's ocean, land, air and fresh water
- end all nuclear threats
- promote peace, global disarmament and non-violence

Greenpeace European Unit monitors and analyses the work of the European Union institutions, exposes deficient policies and laws, and challenges decision-makers to implement solutions that work for people and the planet.

If applicable, please indicate which member associations (national or EU-level), or individual companies /other entities have contributed to this questionnaire

If applicable, indicate if all the replies refer to a specific technique or a specific organism

Our submission focusses on genome editing, although we also mention other new GM techniques, such as RNA-based approaches, which we touch upon in our responses to Questions 17 and 25.

Genome editing encompasses so-called Site-Directed Nucleases (SDN), such as ZFN, TALENs and CRISPR-Cas, as well as Oligonucleotide-Directed Mugatenesis (ODM). It is a powerful and relatively easy-to-use GM technology, which can be applied in medicine and in various industries, including agriculture, as much as by hobby scientists (biohackers) and the military.

Whilst most scientists will be cautious about applications in humans (i.e. for gene therapy), there is a genuine “gene rush” to engineer agricultural crops and animals as well as wildlife organisms including algae, bacteria, insects and mammals.

As Greenpeace, we are mostly concerned about the environmental release of genome edited organisms. In this submission, we focus mainly on applications in plants, although we also mention other uses.

We use the term “new GM techniques” and “new GM products”, as well as “new GMOs”, instead of “new genomic techniques” and “NGT-products”.

By “new GM techniques” we mean techniques that are capable of altering the genetic material of an organism in a way that does not occur naturally, and that have been used to develop GM products not yet commercialised, or brought to market only during the last decade.

The Commission’s proposed definition of “new genomic techniques” is not useful, in our view. It excludes techniques such as Oligonucleotide Directed Mutagenesis (ODM), which has clearly “emerged” and “been developed” before 2001.[1]

Also, we do not see why “genomic techniques” should be a better term than “GM techniques”. The term is not defined in law or in science, whereas “genetic modification” has a legal definition in Directive 2001/18, backed by an open list of techniques in Annex IA.

[1] Heinemann, J. A. (2015). Expert Scientific Opinion on the Status of Certain New Techniques of Genetic Modification Under Directive 2001/18/EC. Available at: http://www.canterbury.ac.nz/media/documents/science-research/inbi/new-techniques-of-genetic-modification.pdf

A - Implementation and enforcement of the GMO legislation with regard to new genomic techniques (NGTs)

* **1. Are your members developing, using, or planning to use NGTs/NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Greenpeace members and supporters are unlikely to use or plan to use GMO products. They are more likely to look out for organic or GM-free labelled products when doing their shopping.

As Greenpeace, we were relieved to see the European Court of Justice (ECJ) confirm our understanding that plants and animals derived from genome editing are subject to the same EU safety and labelling requirements as other GM organisms, see our press release on the day. [1]

[1] Greenpeace European Unit, New GMOs cannot escape testing and labelling under EU law, EU court rules 25 July 2018, Available at: https://www.greenpeace.org/eu-unit/issues/climate-energy/1265/new-gmos-cannot-escape-testing-and-labelling-under-eu-law-eu-court-rules/

* **2. Have your members taken or planned to take measures to protect themselves from unintentional use of NGT-products?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

Greenpeace members and supporters, as all other EU citizens, have a legitimate expectation that EU law will protect them from any unintended use of GMOs. After all, EU GMO labelling and traceability requirements are here to ensure people have a choice and are not at risk of “unintentional use” of such products.

Our members adhere to an organisation that publicly opposes GMOs. They are likely to opt for organic or GM-free labelled products and to reject any use of GMOs, whether intentional or unintentional.

Greenpeace opposes GMOs for a variety of reasons. Firstly, the process of genetic modification disrupts the genome and gives rise to safety concerns. Secondly, both process and resulting products are patented, which drives concentration in the seed sector. Finally, market control by a few corporations hampers farming innovation and alternative approaches.

Those GMOs that are on the market today have helped their producers, generally chemical companies, to drive up pesticide use and entrench an unsustainable, chemical-heavy farming model. They have failed to deliver on the promises made by their developers, as outlined in our report Twenty Years of Failure. [1]

It is simply not credible that GMOs derived from genome editing should solve the problems that their producers have created in the first place (such as dependency on chemicals).

Farmers should not rely on these companies' empty promises when trying to better protect nature and the global climate. Ecological farming is the way forward, as outlined in our Food and Farming Vision. [2] It is a path towards an agricultural model that protects the environment and secures farmers’ livelihood.

As Greenpeace, we have always argued that genome edited organisms are GMOs, and that EU GMO law must be fully applied. [3]

We have repeatedly called for the full application of EU GMO law also to new GMOs, so that those who wish to protect themselves from “unintentional use" of such products are in the position to do so. [4]

[1] Greenpeace International (2015). Twenty Years of Failure. Why GM crops have failed to deliver on their promises. Available at: https://www.greenpeace.org/international/publication/6966/twenty-years-of-failure/

[2] Greenpeace International (2015). Ecological Farming: The seven principles of a food system that has people at its heart. Available at: https://www.greenpeace.org/international/publication/7009/ecological-farming-the-seven-principles-of-a-food-system-that-has-people-at-its-heart/

[3] Greenpeace European Unit (2016). New techniques of genetic engineering. Why EU GMO law must be fully applied to the so-called ‘New Plant Breeding Techniques’. Available at: https://www.greenpeace.org/eu-unit/issues/nature-food/1358/new-techniques-of-genetic-engineering/.

[4] IFOAM EU and others (2019) Letter to Vice-President Katainen. Available at: https://www.ifoam-eu.org/sites/default/files/ifoam_eu_policy_kgoo_newgmos_commonletter_20190522.pdf

* 2 bis. Have you encountered any challenges?

- (●) Yes
- ( ) No

* Please provide details

The biggest challenge we see is the lack of political will, on the side of the European Commission and some EU governments, to enforce EU GMO rules with regards to all products covered by these rules. This concerns in particular the need to perform effective controls for agricultural goods imported from countries where new GMOs are grown, in order to stop unauthorised GMOs from entering the EU.

So far, we are aware of two genome-edited crops that are cultivated in the US and Canada and could enter the EU market illegally. The first such crop is a herbicide-tolerant oilseed rape obtained using ODM (Cibus' SU Canola), which is sold in tandem with a broad-spectrum herbicide. The second is a soybean with an altered fatty acid composition engineered with TALENs (Calyxt's High Oleic Soybean). It is the responsibility of EU and national competent authorities to ensure effective controls of oilseed rape and soybean imported from these countries.

The Commission has pointed to EU member states' responsibility. In July 2019, when a government official raised the difficulty of identifying two GMOs, the Commission said it was "the responsibility of operators to comply with the European Union legislation, and the responsibility of Member States to enforce the legislation ". [1]

EU member states have said they are not in the position to fulfil their obligations, since they have no technical methods to identify all GMOs. Some government officials stated in April 2019 that "they are not able to fulfil all their obligations to carry out controls and that they therefore cannot in all cases be held responsible for deficiencies in enforcement". [2]

We have called on the Commission and to step in and develop such methods at the EU level - to no avail. [3]

With regards to known products of new GM techniques that are not authorised in the EU, such as Cibus' SU Canola, we have asked the Commission to obtain the specific detection method from Health Canada - without a clear response. [4]

Cibus told the Commission already in 2015 that its SU Canola derived from ODM (or "RTDS" in the company' s jargon) was "likely entering the international commodity chain" and that it could "therefore not be excluded that commodities with RTDS products are imported in the EU". [5]

As a consequence, we cannot be confident that no unauthorised GMOs derived from new GM techniques enter the EU via contaminated imports, leaving Greenpeace members and others potentially exposed to the "unintentional use of NGT-products".

[1] European Commission (2019). SCoPAFF Section Genetically Modified Food and Feed, Summary Report. Available at: https://ec.europa.eu/food/sites/food/files/plant/docs/sc_modif-genet_20190712_sum.pdf

[2] European Commission (2019). Joint Working Group on the implementation of the CJEU ruling on mutagenesis, Summar Report. Available at: https://ec.europa.eu/food/sites/food/files/plant/docs /gmo_modern-biotech_wg_20190425_sum.pdf

[3] IFOAM EU and others (2019) Letter to Vice-President Katainen. Available at: https://www.ifoam-eu.org /sites/default/files/ifoam_eu_policy_kgoo_newgmos_commonletter_20190522.pdf

[4] Meeting with DG SANTE Director General Anne Bucher, 27 November 2019

[5] Cibus Europe B.V. (2015) Letter to DG SANTE. Available at: http://corporateeurope.org/sites/default/files /attachments/12.pdf

* **3. Are you aware of initiatives in your sector to develop, use, or of plans to use NGTs/NGT-products?**

- ○ Yes
- ○ No
- ◉ Not applicable

* **4. Do you know of any initiatives in your sector to guard against unintentional use of NGT-products?**

- ○ Yes
- ○ No
- ◉ Not applicable

* **5. Are your members taking specific measures to comply with the GMO legislation as regards organisms obtained by NGTs?**

Please also see question 8 specifically on labelling

- ○ Yes
- ◉ No
- ○ Not applicable

* Please explain why not

It is not for individual people to comply with EU GMO legislation. Greenpeace members and supporters have a legitimate expectation that EU laws are fully applied, including on GMOs. It is for the Commission and national governments to put in place the measures needed to achieve that.

The rule of law is a cornerstone of EU functioning, and our members rightly expect that public authorities at all levels work to apply the judgments of the European Court of Justice. The fact that the application of EU law as interpreted by the EU's highest court should not be a matter of course, is a cause of concern.

* 5 bis. What challenges have you encountered?

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* **6. Has your organisation/your members been adequately supported by national and European authorities to conform to the legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* What challenges have you encountered?

Whilst it is not for our organisation or our members to conform to the legislation, we would like to restate our concern that national and European authorities have not done enough to ensure compliance with EU GMO law.

The Commission appears to have worked with EU member states to bring unauthorised GMO field trials under EU law. However, it has yet to undertake any serious efforts to
- provide a clear mandate and funding for the development of technical methods that allow the detection of unauthorised new GMOs;
- explore options for reliable non-technical solutions to provide traceability;
- set up an international register of GMOs [1];
- obtain the specific detection method for Cibus' SU Canola from Health Canada, which EU member states could use in their controls.

Health Canada has confirmed that: "Cibus Canada Inc. has provided the CFIA with a method for the detection and identification of canola event 5715." [2]

The Commission could use this method to help national authorities to avoid imports of this unauthorised GM crop. It has done so earlier for unauthorised GM flaxseed [3].

[1] Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). Front. Bioeng. Biotechnol. https://doi.org/10.3389/fbioe.2019.00031

[2] Health Canada (2013). Decision Document DD 2013-100. Available at: https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669

[3] Sampling and Testing Protocol for Canadian Flaxseed Exported to the European Union. Available at: https://ec.europa.eu/food/sites/food/files/plant/docs/sc_modif-genet_20180319_sum_ann2.pdf

* **7. Does your sector have experience or knowledge on traceability strategies, which could be used for tracing NGT-products?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe the traceability strategy, including details on the required financial, human resources and technical expertise

Traceability strategies are not a new issue. Already today, public authorities use documentation (“paper trail”) to enforce EU GMO law with regards to processed products such as oil or sugar.

Scientists from German authorities and DowDupont have argued that “the detectability of genome-edited products that might reach the market is not significantly different from that of GMOs and therefore, if necessary, would be covered by the already existing international instruments and technical tools”. [1]

Other research shows that changes triggered by genome editing are significantly different from those triggered by chemical or natural mutagens. These changes pertain to regions in the genome that do not normally undergo mutations, and they occur in several (if not all) gene copies simultaneously, for example. [2]

The latter is also confirmed by Duensing et al who state that “(...) genome editing is adept at knocking out genes present in multiple copies. Thus, whenever a crop is found with multiple copies of the same gene knocked out, it will be almost certain that genome editing was used.”

It should be possible therefore to develop technical methods that identify also those genome-edited products for which no specific detection method is available, based on the “fingerprints” of each technology.

Bertheau 2019 reviews such elements which could allow the identification and detection of new GM techniques. [3]

Finally, it should be remembered that it took time and investment to develop the methods that are currently used to identify unauthorised old-style GMOs. The EU needs to replicate this effort for GMOs derived from new GM techniques such as genome editing.

[1] Duensing, N., Sprink, T., Parrott, W. A., Fedorova, M., Lema, M. A., Wolt, J. D., et al. (2018). Novel features and considerations for ERA and regulation of crops produced by genome editing. Front. Bioeng. Biotechnol. 6:79. doi: 10.3389/fbioe.2018.00079

[2] Kawall K (2019). New possibilities on the horizon: Genome editing makes the whole genome accessible for changes. Frontiers in Plant Science, 10:525. doi: 10.3389/fpls.2019.00525. https://www.frontiersin.org /articles/10.3389/fpls.2019.00525/full

[3] Bertheau, Y. (2019). New breeding techniques: detection and identification of the techniques and derived products. In: Laurence Melton, Fereidoon Shahidi, Peter Varelis, Encyclopedia of food chemistry (p. 320-336). AMSTERDAM, NLD : ELSEVIER SCIENCE BV., DOI : 10.1016/B978-0-08-100596-5.21834-9

* **8. Are your members taking specific measures for NGT-products to ensure the compliance with the labelling requirements of the GMO legislation?**

- ○ Yes
- ◉ No
- ○ Not applicable

* Please describe the measures and their effectiveness including details on the required financial, human resources and technical expertise

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* What best practices can you share?

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* Please explain why not

It is not for individual people to comply with EU GMO legislation. Greenpeace members and supporters have a legitimate expectation that EU laws are fully applied, including the labelling requirements of the EU GMO legislation. However, since no new GM is authorised in the EU, there is also no need to apply a GMO label.

* 8 bis. What challenges have you encountered?

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* **9. Do you have other experience or knowledge that you can share on the application of the GMO legislation, including experimental releases (such as field trials or clinical trials), concerning NGTs/NGT-products ?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please describe for the:

- [x] Agri-food sector
- [ ] Industrial sector
- [ ] Medicinal sector

Agri-food sector

Prior to the ECJ ruling of 25 July 2018, national authorities in Finland, Germany, Ireland, Spain, Sweden and the UK all advised that a GM oilseed rape created with ODM (Cibus' SU Canola) falls outside EU GMO law. In the UK and Sweden, trials were effectively conducted outside GMO law. [1]

Authorities in Belgium, Finland, Sweden and the UK advised that certain GMOs obtained through CRISPR-Cas do not fall under EU GMO law either.[2]

The fact that these authorities failed to enforce EU GMO law is highly concerning since this is an area where EU law, for good reasons, applies the precautionary principle to protect people and the environment.

It also points to a worrying hands-off approach by the European Commission. Only once, in 2015, did the Commission warn EU member states against the unauthorised approval of field trials with Cibus' oilseed rape. That warning was prompted by a letter from German NGOs [3], and it was not repeated for other new GMOs.

[1] Hartung U. (2020). Inside Lobbying on the Regulation of New Plant Breeding Techniques in the European Union: Determinants of Venue Choices. Review of Policy Research, (2020) 10.1111/ropr.12366 https://doi.org/10.1111/ropr.12366

[2] Greenpeace European Unit, Unauthorised GMO field trial exposed as EU takes hands-off approach, Greenpeace, 24 July 2018. Available at: https://www.greenpeace.org/eu-unit/issues/nature-food/1260/unauthorised-gmo-field-trial-exposed-as-eu-takes-hands-off-approach-greenpeace/

[3] Greenpeace Germany and others (2015) Letter to DG SANTE (attached)

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30e66458-4838-4fbb-b504-d2b97985fc2b/Brief_EU_Comm_Flueh_03_2015_final.pdf

B - Information on research on NGTs/NGT-products

* **10. Are your members carrying out NGT-related research in your sector?**

- ○ Yes
- ○ No
- ◉ Not applicable

* **11. Are you aware of other NGT-related research in your sector?**

- ○ Yes
- ○ No
- ◉ Not applicable

* **12. Has there been any immediate impact on NGT-related research in your sector following the Court of Justice of the EU ruling on mutagenesis?**

Court of Justice ruling: Case C-528/16 http://curia.europa.eu/juris/documents.jsf?num=C-528/16

- ○ Yes
- ○ No
- ◉ Not applicable

*** 13. Could NGT-related research bring benefits/opportunities to your sector/field of interest?**

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

There is a need for independent research into potential safety issues related to new GM techniques, impacts of intellectual property (IP) rights associated with them, and technical methods for the detection of unauthorised new GMOs, which can be applied in standard GMO testing procedures carried out by EU laboratories. (See our answer to Question 15 for further details.)

Beside these three areas, we see no need for publicly-funded research in this area. Programmes to develop new GM techniques or products are a costly distraction from ecological plant breeding efforts that develop locally-adapted plants in a participatory and decentralised manner. Such efforts are urgently needed to maintain plant genetic diversity, and to foster ecological farming as the only way to counter the threats to our food system stemming from the ongoing climate and biodiversity collapse.

*** 14. Is NGT-related research facing challenges in your sector/field of interest?**

- ◉ Yes
- ○ No
- ○ Not applicable

* Please provide concrete examples/data

Independent research in the three areas mentioned under Question 13 appears to be limited due to lack of both interest and funding.

The research that is carried out instead is mainly focussed on the development and application of new GM technology, usually with a view to acquiring IP rights. As a result, most scientists involved are also stakeholders with a marked interest in bringing the technology and related products to market.

Unsurprisinlgy therefore, most scientists active in this field have entered the debate on the regulatory status of new GMOs on the side of the big seed producers, which stand to benefit from the removal of alleged "regulatory hurdles". However, their interests are usually hidden from the public view, as illustrated in a recent German publication. [1]

The focus on development and application of GM technology has also meant that potential risks have received little attention. Whilst full genome sequencing could be done to identify unintended effects, in reality it is hardly done. The reason is simple – the motivation for genome editing is speed, whereas extensive checks for unwanted outcomes would slow down the process. Logically, developers will rather claim precision and control than to effectively pursue these goals. [2]

[1] Testbiotech. Vertrauen in „DIE Wissenschaft"? 17 April 2019. Available at : https://www.testbiotech.org /content/vertrauen-in-die-wissenschaft

[2] Latham, J. Gene-editing unintentionally adds bovine DNA, goat DNA, and bacterial DNA, mouse researchers find. Independent Science News, 24 September 2019. Available at: https://www. independentsciencenews.org/health/gene-editing-unintentionally-adds-bovine-dna-goat-dna-and-bacterial-dna-mouse-researchers-find/

*** 15. Have you identified any NGT-related research needs/gaps?**

- (●) Yes
- ( ) No
- ( ) Not applicable

* Please specify which needs/gaps, explain the reasoning and how these needs/gaps could be addressed

There is a need to investigate the potential implications for public health and the environment, as well as potential implications for farmers and consumers. Most urgently, the EU should fund research into technical methods to identify unauthorised GM products obtained with new GM techniques.

(1) Whilst scientists dealing with new GM techniques are not actively hiding unwanted outcomes, there is little dedicated research into such outcomes and their potential implications for consumer and environmental safety. [1]

With regards to genome editing tools such as CRISPR-Cas, we know there will be unintended changes both at the target site and at off-target sites of the genome. But we do not know what this means for consumers and the environment. Robust research into the risks associated with new GM techniques is however needed to inform robust policy decisions in this field that take into account the public interest in health and environmental protection.

It is also required under the EU GMO Directive: "Member States and the Commission should ensure that

systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted." [2]

Independent risk research is all the more important since the companies promoting genome editing as a safe and reliable method of "breeding" have a poor record when it comes to the consumer and environmental safety of their products. Companies like Corteva and Bayer / Monsanto have hidden the nefarious effects of their pesticides for decades and stand by these products even after the EU has banned them for safety reasons. [3]

(2) Research from the US and Canada suggests that strong IP rights, typically granted for new GM techniques and products, lead to higher seed prices, seed industry consolidation and "suspiciously low R&D investment", according to a recent presentation by Mohammad Torshizi, University of Alberta. [4]

We are unaware of such research for the EU, which would be relevant to understand the implications of new GM techniques. What would be the impact on farmers' rights to save and reproduce seeds? What would be the impact on prices, both for farmers and consumers?

(3) EU GMO law requires that no unauthorised GMOs are present on the EU market. To apply the law, authorities cannot only rely on documentation, they also need technical methods to verify the claims made.

We have argued above that it is possible to develop such methods, based on the specific patterns of genetic modification associated with genome editing techniques. The European Commission should urgently mandate and fund such work.

Needless to say, such research should be carried out by scientists without any conflicts of interest. Patent-holding scientists, or scientists from organisations heavily invested in the new GM venture, should be excluded from such projects.

[1] Gelinsky, E., Hilbeck, A. European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling. Environ Sci Eur 30, 52 (2018). https://doi.org/10.1186/s12302-018-0182-9

[2] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0018

[3] The Intercept. The playbook for poisoning the earth, 18 January 2020. Available at: https://theintercept.com/2020/01/18/bees-insecticides-pesticides-neonicotinoids-bayer-monsanto-syngenta/

[4] Mohammad Torshizi, Presentation to ECVC workshop of 20 February on" New GMOs, Patents and the Peasants' Rights to Seeds in Europe". Available at: https://www.eurovia.org/wp-content/uploads/2020/04/M-Torshizi-Presentation-for-ECVC-Feb-20-20.pptx

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C - Information on potential opportunities and benefits of NGTs/NGT-products

*** 16. Could NGTs/NGT-products bring benefits/opportunities to your sector/field of interest?**

- Yes
- No

* Please explain why not

Genome editing is a valuable tool for gene research. However, it should not be used to obtain organisms meant to be released into the environment, for several reasons.

Potential risks are too big, and developers cannot be trusted to do the checks required to identify potential issues (See our response to Question 24). Even if they did try to exclude unwanted side effects of the genetic engineering process, unexpected outcomes could still arise at a later stage, compromising environmental and consumer safety.

At the same time, promised benefits for the environment and global climate are unlikely to materialise. Desired traits such as high and stable yields and tolerance towards various stressors are the result of complex interactions between multiple genes as well as the plant's environment. Genetic engineering approaches are therefore unlikely to deliver such traits. [1]

By contrast, conventional breeding has been successful in producing complex traits, including drought tolerance [2], efficient use of nutrients [3] or disease resistance. [4], [5]

It is important to remember that new GM techniques, including genome editing tools, are controlled and promoted by the same corporations who brought us old-style GMOs – mainly Corteva, Bayer/Monsanto, Syngenta and BASF.

The vast majority of these companies' existing GM crops have been engineered to obtain traits that fit into, and augment, a chemical farming model that has had devastating impacts on nature and the global climate. Today, almost 90 percent of global GM cropland is devoted to herbicide-tolerant crops, according to the International Service for the Acquisition of Agri-biotech Applications (ISAAA). [6]

These companies, which dominate the commercial seed industry, simply have no interest in developing traits that could be valuable to ecological farming. A large part of their business relies on pesticide sales, and GM technology allows them to combine sales of pesticides and seeds.

Under these circumstances, the use of new GM techniques for the development of new plant varieties is likely to exacerbate the negative effects of the dominant farming model on the environment and global climate.

[1] Gelinsky, E., Hilbeck, A. European Court of Justice ruling regarding new genetic engineering methods scientifically justified: a commentary on the biased reporting about the recent ruling. Environ Sci Eur 30, 52 (2018). https://doi.org/10.1186/s12302-018-0182-9

[2] Gilbert N. Cross-bred crops get fit faster. Genetic engineering lags behind conventional breeding in efforts to create drought-resistant maize. Nature. 2014;513:292. doi: 10.1038/513292a

[3] Gilbert N. Frugal farming. Old-fashioned breeding techniques are bearing more fruit than genetic engineering in developing self-sufficient super plants. Nature. 2016;533:308–310. doi: 10.1038/533308a

[4] UC Davis, Field trials find varieties sustainable, high-yielding and disease-resistant, 22 April 2020. Available at: https://www.plantsciences.ucdavis.edu/news/uc-davis-releases-6-new-varieties-organic-beans

[5] The Guardian, Planting hope: the Syrian refugee who developed virus-resistant super-seeds, 31 March 2020. Available at : https://www.theguardian.com/global-development/2020/mar/31/planting-hope-the-syrian-refugee-who-developed-virus-resistant-super-seeds

[6] ISAAA Brief 54-2018, Executive Summary. Available at: http://www.isaaa.org/resources/publications /briefs/54/executivesummary/default.asp

* **17. Could NGTs/NGT-products bring benefits/opportunities to society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic benefits?**

- ○ Yes
- ◉ No

* Please explain why not

As outlined under the previous question, it can be expected that genome editing applied in crop plants will benefit large seed producers. Nobody should expect it to benefit society at large.

Applications in farm animals give rise to similar concerns about environmental and consumer safety, as well as issues related to animal welfare. Under current circumstances, genome editing will likely be used to deal with problems caused by factory farming. Rather than 'editing' the animals to fit the unacceptable conditions they live in, these conditions should be changed to fit the needs of the animals. [1]

With some new GM approaches, the genetic engineering process is effectively moved from a closed laboratory setting into the wild. [2] Again, the negative outcomes of such 'environmental genetic engineering' are likely to outweigh the societal benefits developers may pursue.

[1] Friends of the Earth (2019). Genetically Engineered Animals: From Lab to Factory Farm. Available at: https://foe.org/resources/genetically-engineered-animals-lab-factory-farm/

[2] Sirinathsinghji, E (2019). Transferring the laboratory to the wild: An emerging era of environmental genetic engineering. Available at: https://biosafety-info.net/wp-content/uploads/2019/11/Biosafety-briefing_From-lab-to-wild.pdf

* **18. Do you see particular opportunities for SMEs/small scale operators to access markets with their NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

The likelihood is that, due to IP rights, seed industry consolidation will accelerate, and the role of SMEs will be further diminished.

An SME that successfully develops a new GM product will usually sell it to a large multinational company. This means the real opportunity is for the multinational that will benefit from the outcome of the development process without carrying any risk.

* **19. Do you see benefits/opportunities from patenting or accessing patented NGTs/NGT-products?**

- ○ Yes
- ◉ No

* Please explain why not

Patenting blocks access to genetic material for other breeders and accelerates the concentration of the seed market. This is an ongoing process that is already reducing the diversity of seed supply. It jeopardises the conservation of plant genetic diversity, which is a cornerstone of ecological farming, according to our Food and Farming Vision. [1]

[1] Greenpeace International (2015). Ecological Farming: The seven principles of a food system that has people at its heart. Available at: https://www.greenpeace.org/international/publication/7009/ecological-farming-the-seven-principles-of-a-food-system-that-has-people-at-its-heart/

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D - Information on potential challenges and concerns on NGTs/NGT-products

* **20. Could NGTs/NGT-products raise challenges/concerns for your sector/field of interest?**

- ◉ Yes
- ○ No

* Please describe and provide concrete examples/data

As Greenpeace, we have great concerns about the potential effects of new GMOs on the environment and climate.

On the one hand, we know that the process of genetic engineering invariably results in unintended outcomes that can compromise environmental and consumer safety. Since we are talking about living organisms that, once released into the environment, can no longer be controlled, we fear serious and irreversible repercussions on our ecosystems.

On the other hand, we are also concerned that the development and use of new GM technology, such as genome editing, will entrench a corporate-controlled, obsolete farming system that we urgently need to leave behind us, if we are to stand any chance of overcoming the deepening climate and biodiversity crises that

our planet and ourselves are facing.

Concerns linked to the genetic engineering process

The genome editing process is prone to unintended genetic alterations that can pose serious risks to the environment and public health. Some of these are identical to old-style GM, others are new. (See also our response to Question 24)

However, even the intended changes in the genome can be problematic. Since genes do not work in isolation, but interact with each another, they will normally have knock-on effects affecting the functioning of the genome as a whole. For example, genome editing in rabbits to enhance muscularity has been found to result in enlarged tongues. [1] Genome editing in cattle has produced double eyelashes, in addition to the intended hornlessness trait.[2]

Given the problems linked to both unintended and intended genetic changes, genome edited organisms will never be “safe by design”. This is why scientists have called for a case-by-case risk assessment, taking into account not only the intended outcome but also the specifics of the genetic engineering process. [3]

Concerns linked to the foreseeable use of new GM techniques

Intended applications of genome editing are also a cause of concern. For example, a likely application of genome editing in plants is herbicide tolerance (HT). [4] In fact, the first genome edited crop brought to market is a herbicide-tolerant oilseed rape, Cibus’ SU Canola. [5]

Herbicide tolerance has been shown to lead to higher herbicide use and build-up of resistances in the targeted plants. Companies selling HT systems actually benefit from these effects, as they replace HT systems whose patent protection has run out with new packages. [6]

Another example are so-called ‘gene drives’. Gene drives are a technology that can wipe out whole populations or species, or replace them with genetically engineered ones. [7]

In practice, it is impossible to predict how a gene drive would work (or not) outside the laboratory. This is why NGOs [8] as well as the European Parliament [9] have called for a global moratorium on gene drives.

Both herbicide tolerance and population extinction are entirely realistic applications of genome editing. They are also applications that show how today’s market opportunities run counter to the needs of the environment and climate.

[1] Guo, R., Wan, Y., Xu, D. et al. (2016) Generation and evaluation of Myostatin knock-out rabbits and goats using CRISPR/Cas9 system. Scientific Reports 6: 29855. Retrieved from https://doi.org/10.1038/srep29855

[2] ABC. Mutants or miracles? Australia's GM cows, 15 March 2020, Available at: https://www.abc.net.au/radionational/programs/backgroundbriefing/mutants-or-miracles-australias-gm-cows/12050786

[3] Eckerstorfer MF et al (2019). An EU perspective on biosafety considerations for plants developed by genome editing and other new genetic modification techniques (nGMs). Front. Bioeng. Biotechnol. https://doi.org/10.3389/fbioe.2019.00031

[4] Sedeek, K. E., Mahas, A., Mahfouz, M. (2019). Plant genome engineering for targeted improvement of crop traits. Front. Plant Sci. 10, 114. doi: 10.3389/fpls.2019.00114

[5] Cibus, Cibus And Rotam Announce Launch Of Their First Non-Transgenic Commercial Product, 19 November 2014. Available at: https://www.cibus.com/press-release.php?date=111914

[6] WSJ, New Weed Killer Arrives Amid Fears of Crop Damage, 13 November 2016. Available at: https://www.wsj.com/articles/new-weed-killer-arrives-amid-fears-of-crop-damage-1479038407?mod=article_inline

[7] ENSSER, 2019, Gene Drives. A report on their science, applications, social aspects, ethics and regulations. Available at: https://ensser.org/publications/2019-publications/gene-drives-a-report-on-their-science-applications-social-aspects-ethics-and-regulations/

[8] Save our Seeds and others, NGO letter to all MEPs. Available at: https://www.gmo-free-regions.org/news/meldung/33914.html

[9] European Parliament resolution 'COP15 to the Convention on Biological Diversity', 16 January 2020. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0015_EN.html

* Are these challenges/concerns specific to NGTs/NGT-products?

- (●) Yes
- ( ) No

* Please explain

Whilst some of these concerns are similar to those related to old-style GMOs, many are specific to the powerful new GM techniques that have been developed more recently, such as genome editing.

* **21. Could NGTs/NGT-products raise challenges/concerns for society in general such as for the environment, human, animal and plant health, consumers, animal welfare, as well as social and economic challenges?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

As explained earlier, these new GM techniques are, just as the older ones, largely in the hands a few multinational corporations that already dominate the global commercial seed market. The applications they pursue will likely exacerbate the negative effects of the dominant farming system.

The fact that new GM technology comes with strong IP rights means that their application will lead to further consolidation in the industry, creating a few too-big-to-fail seed companies with enormous economic and political power. These companies are likely to use this power to obstruct the profound changes needed at all levels to enable an ecological farming system that is in harmony with nature, not working against it.

On a more practical level, the release of new GMOs would also undermine existing ecological breeding and farming approaches, since these would have to deal with GMO contaminations.

* Under which conditions do you consider this would be the case?

We expect this to happen under current regulatory and economic conditions. It would be even worse if EU GMO regulations are weakened to accommodate the wishes of the global seed industry.

* Are these challenges/concerns specific to NGTs/products obtained by NGTs?

- (●) Yes
- ( ) No

* Please explain

The market uptake of old-style GMOs has plateaued. In fact, the number of countries growing GM crops has been shrinking since 2010. [1] In the European Union, these products never knew much success anyway. Large seed companies are therefore looking to new GM approaches to foster their business.

[1] International Service for the Acquisition of Agri-biotech Applications (ISAAA), 2010, 2012, 2018

*** 22. Do you see particular challenges for SMEs/small scale operators to access markets with their NGTs /NGT-products?**

- (●) Yes
- ( ) No

* Please explain and provide concrete examples and data

In fact, SMEs will have to deal with “onerous, very expensive licencing arrangements” to be able to use technologies such as CRISPR-Cas, according to a scientist who has worked for such an SME. The “standard business practice in the SME biotechnology sector” is that an SME, which builds a good patent portfolio, is then taken over by a larger company. Ultimately, this
results in the concentration of patent ownership and products in a few large companies. [1]

[1] Euractiv, Gene-editing regulation not the biggest hurdle for SMEs in EU, says academic, 27 February 2020. Available at: https://www.euractiv.com/section/agriculture-food/news/gene-editing-regulation-not-the-biggest-hurdle-for-smes-in-eu-says-academic/

*** 23. Do you see challenges/concerns from patenting or accessing patented NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please describe and provide concrete examples/data

Big seed companies are in the position to control access to genome editing technologies. For example, Corteva Agrisciences has managed to acquire licenses for CRISPR-Cas from all big players, including Broad Institute, ERS Genomics, Caribou Biosciences and Vilnius University. It now offers sublicenses for agricultural applications to interested parties. [1]

In 2019, according to Testbiotech, Corteva Agrisciences had 60 international patent applications running for specific applications of genome editing in plant breeding, followed by 30 patents for Bayer/Monsanto. [2]

Control over new GM technologies and products is likely to enhance the economic and political power of big seed companies, with negative repercussions on farmers, consumers and the environment.

[1] Pionier. DuPont Pioneer Expands CRISPR-Cas9 Patent Portfolio with License from Broad Institute of MIT and Harvard, 18 October 2017. Available at: https://www.pioneer.com/home/site/about/news-media/news-releases/template.CONTENT/guid.EA02CAA5-07DA-AA4D-D17A-E2C6AE20D9FF

[2] Testbiotech. Patent cartel for the large companies. 24 June 2019. Available at: https://www.testbiotech.org/en/news/patent-cartel-large-companies

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E - Safety of NGTs/NGT-products

*** 24. What is your view on the safety of NGTs/NGT-products? Please substantiate your reply**

As Greenpeace, we are concerned that safety issues of new GM techniques are not receiving sufficient attention. (See also our response to Question 15)

Genome editing is far from being “precise” and outcomes are far from “controlled”. In fact, of three steps involved in genome editing – gene delivery, editing, and regeneration with the help of tissue culture – the first and last are essentially the same as with old-style GM technology.

These steps can lead to unintended genetic alterations including the integration of unwanted DNA sequences originating from the DNA-transferring bacterium or from cell culture - a problem that occurs in genome editing as in old-style genetic engineering. [1] [2] The most prominent example is Recombinetics' hornless cattle, the oft-cited poster child of genome editing in animals. [3]

The editing step has its own, specific problems. With so-called Site-Directed Nucleases (SDN), such as CRISPR-Cas, the DNA is cut not only at the targeted site but also in other places. The subsequent repair leads to deletions and rearrangements not only around the DNA cuts but also further down in the DNA, affecting the functions of multiple genes. [4] This has mostly been documented in mammals but there is no reason why it would not also happen in plants.

More often than not, unintended changes pass unnoticed because developers are not properly looking for them. Most genome editing studies use biased methods to screen the genome at predicted sites for off-

target effects, whereas only a small number of studies use unbiased methods such as whole genome sequencing. [5] This is because whole genome sequencing would increase the time and cost of development, nullifying the supposed benefits of genome editing. For example, Recombinetics scientists were unaware that their hornless cattle was in fact transgenic, carrying bits of DNA from the bacteria used to deliver the genome editing machinery. It was US authorities who found out. [6]

The fact that developers pay too little attention to these issues means regulatory oversight is urgently needed. In the US, where genome editing in plants is routinely 'deregulated', the FDA decided after the Recombinetics 'incident' that genome edited animals had to be regulated. [7]

The safety implications of unintended outcomes of the genetic engineering process can be felt at different levels. For example, genome-edited plants or animals could produce new toxins or allergens, affecting food safety. However, no safety studies have been carried out so far. Studies in animals have only been done with old-style transgenic GM crops. They have brought to light unexpected toxicity and/or allergenicity from GM food crops. [8]

[1] Latham J, Gene-editing unintentionally adds bovine DNA, goat DNA, and bacterial DNA, mouse researchers find. Independent Science News, 23 September 2019. Available at: https://www.independentsciencenews.org/health/gene-editing-unintentionally-adds-bovine-dna-goat-dna-and-bacterial-dna-mouse-researchers-find/

[2] Ono, R., Yasuhiko, Y., Aisaki, K. et al. Exosome-mediated horizontal gene transfer occurs in double-strand break repair during genome editing. Commun Biol 2, 57 (2019). https://doi.org/10.1038/s42003-019-0300-2

[3] 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

[4] Kosicki, M., Tomberg, K. & Bradley, A. Repair of double-strand breaks induced by CRISPR–Cas9 leads to large deletions and complex rearrangements. Nat Biotechnol 36, 765–771 (2018). https://doi.org/10.1038/nbt.4192

[5] Modrzejewski, D., Hartung, F., Sprink, T. et al. What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map. Environ Evid 8, 27 (2019). https://doi.org/10.1186/s13750-019-0171-5

[6] MIT Technology Review, Gene-edited cattle have a major screwup in their DNA. 29 August 2019. Available at: https://www.technologyreview.com/2019/08/29/65364/recombinetics-gene-edited-hornless-cattle-major-dna-screwup/

[7] FDA, FDA Expertise Advancing the Understanding of Intentional Genomic Alterations in Animals, 7 February 2020. Available at : https://www.fda.gov/news-events/press-announcements/fda-expertise-advancing-understanding-intentional-genomic-alterations-animals

[8] Hilbeck, A., Binimelis, R., Defarge, N. et al. No scientific consensus on GMO safety. Environ Sci Eur 27, 4 (2015). https://doi.org/10.1186/s12302-014-0034-1

*** 25. Do you have specific safety considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

Genome editing enables the genetic modification of a living organism at a level and speed unheard of previously. It can be applied several times over or simultaneously at different target sites. The resulting changes can go far beyond what is possible with old-style GM methods, therefore adverse effects may also be greater.

So-called ‘environmental genetic engineering’ raises particular concerns with regard to the uncontrolled spread of these GMOs and the fact that unintended effects that cannot be investigated inside the laboratory prior to release. [1] [2]

With regards to gene drive, a recent report has pointed out that: “The potential of these novel genetic approaches to genetically modify or eradicate wild populations is as yet unprecedented.” [3]

[1] Sirinathsinghji, E (2019). Transferring the laboratory to the wild: An emerging era of environmental genetic engineering. Available at: https://biosafety-info.net/wp-content/uploads/2019/11/Biosafety-briefing_From-lab-to-wild.pdf

[2] Heinemann JA (2019). Should dsRNA treatments applied in outdoor environments be regulated? Environ Int 132, 104856. https://doi.org/10.1016/j.envint.2019.05.050

[3] Dolezel, Marion & Simon, Samson & Otto, Mathias & Engelhard, Margret & Zúghart, Wiebke. (2020). Gene Drive Organisms: Implications for the Environment and Nature Conservation. Available at: https://biosafety-info.net/articles/assessment-impacts/ecological/gene-drive-organisms-implications-for-the-environment-and-nature-conservation/

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F - Ethical aspects of NGTs/NGT-products

* **26. What is your view on ethical aspects related to NGTs/NGT-products? Please substantiate your reply**

By definition, GM techniques will alter organisms in a way “that does not occur naturally”, disregarding the integrity of living organisms.

The level and speed of the genetic alterations made possible by new GM techniques, and the new realm of ‘environmental genetic engineering’, raise questions that go beyond environmental and consumer safety.

Importantly, these techniques can also be employed for malicious purposes, including biological warfare. [1] Whilst our submission focusses on agricultural applications, the full scale of possible uses needs to be considered and discussed.

This is particularly true for novel tools such as CRISPR-based gene drives. Considering that most people have never heard about this technology, and that the European Parliament has voted for a global moratorium on it [2], the Commission’s explanation that the EU has funded “six projects researching gene drives with a budget of EUR 25,748,224” is surprising, to say the least. [3]

[1] DiEuliis, D., Giordano, J. Gene editing using CRISPR/Cas9: implications for dual-use and biosecurity. Protein Cell 9, 239–240 (2018). https://doi.org/10.1007/s13238-017-0493-4

[2] European Parliament resolution ‘COP15 to the Convention on Biological Diversity’, 16 January 2020. Available at: https://www.europarl.europa.eu/doceo/document/TA-9-2020-0015_EN.html

[3] Parliamentary question and Commission response on ‘EU funding of gene drive research’. Available at: https://www.europarl.europa.eu/doceo/document/P-9-2020-000025_EN.html

*** 27. Do you have specific ethical considerations on NGTs/NGT-products?**

- (●) Yes
- ( ) No

* Please explain

New GM techniques require a precautionary approach, by which decision-makers adopt protective measures when scientific evidence about an environmental or health hazard is uncertain, and the stakes are high.

However, the precautionary principle, that guides such an approach, has been under assault in recent years. Perhaps Covid-19 has provided a moment of opportunity to rediscover the precautionary principle, as governments abiding by it have fared better than those that did not. [1]

[1] New Statesman, How coronavirus has led to the return of the precautionary principle. 7 April 2020. Available at: https://www.newstatesman.com/international/2020/04/how-coronavirus-has-led-return-precautionary-principle

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G - Consumers' right for information/freedom of choice

*** 28. What is your view on the labelling of NGT-products? Please substantiate your reply**

According to applicable EU law, products of new GM techniques must be labelled according to the EU GMO labelling rules. [1] These rules provide for a single label: “This product contains genetically modified organisms" or “This product contains genetically modified [name of organism(s)]". It represents simple, clearly understandable information for consumers.

Consumers have a right to know how their food has been produced. The Commission has recognised that and announced, as part of its European Green Deal, that it will “explore new ways to give consumers better information, including by digital means, on details such as where the food comes from, its nutritional value, and its environmental footprint”. [2]

In this context, the EU GMO labelling rules should not only be upheld but also strengthened to close existing gaps, due to which milk, eggs and meat from animals reared on GM feed do not have to be labelled. Most consumers are unaware of this and may choose to avoid such food if they had the opportunity.

[1] Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32003R1830

[2] Communication COM(2019) 640 final, The European Green Deal, 11 December 2019. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX:52019DC0640

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H - Final question

*** 29. Do you have other comments you would like to make?**

- (●) Yes
- ( ) No

Please provide your comments here

In the light of the information we have about new GM techniques, it is extremely worrying that some EU governments, and parts of the Commission, should be considering a weakening of EU GMO legislation, by which new organisms produced with these techniques would escape the EU GMO regime.

It is argued that such a move would facilitate the development of new agricultural crops that can better withstand the ravages of climate change.

However, the reason that GM technology has failed to deliver on relevant traits such as resistance to pathogens or droughts has nothing to do with “burdensome” regulation. Even in North and South America, where GMOs are practically unregulated, GM developers have not delivered on these promises. [1]

GMOs have no place in sustainable farming. They come with unacceptable risks created by the genetic engineering process and the traits they are engineered to express. To protect the environment and our health, the European Union should ban GMOs and promote ecological farming methods. [2]

[1] Greenpeace International (2015). Twenty Years of Failure. Why GM crops have failed to deliver on their promises. Available at: https://www.greenpeace.org/international/publication/6966/twenty-years-of-failure/

[2] Greenpeace International (2015). Ecological Farming: The seven principles of a food system that has people at its heart. Available at: https://www.greenpeace.org/international/publication/7009/ecological-farming-the-seven-principles-of-a-food-system-that-has-people-at-its-heart/

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Contact

SANTE-NGT-STUDY@ec.europa.eu

Greenpeace e.V., Hongkongstraße 10, 20457 Hamburg

Mr Michael Flueh
Acting Director
DG Sante, Directorates E Safety of the food chain
Rue Breydel 4/Breydelstraat 4
1049 Bruxelles/Brussel

Contact person:
Dr. Dirk Zimmermann
Tel.: +49 (0)40- 30618-339
E-Mail: dirk.zimmermann@greenpeace.de

Sent by email and mail

Hamburg, 30 March 2015
NaLaWi/PV

URGENT request to intervene to halt German authorisation of GM oilseed rape

Dear Mr Flüh,

We would like to bring to your attention a recent decision by the German competent authority on GMO approvals, the Federal Office of Consumer Protection and Food Safety (BVL), to authorise a genetically modified oilseed rape for cultivation.

The oilseed rape plant, developed by US company Cibus, has been genetically modified using a new gene editing technology termed Rapid Trait Development System (RTDS). Under this technology, so-called oligonucleotides (small molecules of synthetic DNA) are inserted into a plant's cell so that the cell's own DNA-repair system will modify its DNA. How the cell's DNA is actually altered by this process, which does not occur in nature, is not fully understood. Several publications document unintended effects.

We consider that the Cibus RTDS oilseed rape constitutes a genetically modified organism (GMO) according to EU law. Directive 2001/18 defines a GMO as "*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*". The Directive specifically mentions "*techniques involving the direct introduction into an organism of heritable material prepared outside the organism*". Furthermore, the technology is clearly different from random mutagenesis that has been applied in plant breeding for many years, and that is excluded from the scope of Directive 18/2001.

However, upon request of the company Cibus, BVL has unilaterally decided that the Cibus RTDS oil seed rape plants fall outside the scope of German GMO law (see Annex). Based on this decision, Cibus would be allowed to release its RTDS herbicide resistant oilseed rape into the environment without any detailed risk assessment, registration or labelling.

We strongly believe that the German authority's decision contravenes EU law on genetically modified organisms (GMOs), and in particular EU Directive 2001/18 and Regulations 1829/2003 and 1830/2003. National interpretations of EU legislation appear inappropriate, especially as a process is currently underway at EU level to assess whether new breeding technologies, including RTDS, produce GMOs.

We are concerned that the release of the RTDS oilseed rape could result in an uncontrolled spread of its genetic material into the environment. Oilseed rape can spread its pollen over kilometres, cross pollinate with wild relatives and its seeds remain viable in the soil for more than ten years. There would be no possibility to protect GMO-free farmers and food producers against gene flow from these plants. This would potentially also concern other EU countries, since the RTDS oilseed rape is likely to spread beyond Germany's borders.

We are asking you therefore to urgently intervene in order to prevent that the RTDS oilseed rape is cultivated in Germany before the EU has ruled whether it is a GMO and falls under EU law on GMOs. Furthermore, we are asking you to ensure that no plants or animals derived from RTDS technology are released or brought onto the market anywhere in Europe until such a decision has been taken.

We count on your support to stop the BVL decision and remain at your disposal should you require any further information, either by email or in a meeting.

This letter is signed by:

Georg Janßen
Bundesgeschäftsführer
Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) e.V.

Peter Röhrig
Geschäftsführer
Bund Ökologische Lebensmittelwirtschaft e.V. (BÖLW)

Prof. Dr. Hubert Weiger
Bundesvorsitzender
Bund für Umwelt und Naturschutz Deutschland e.V. (BUND)

Dr. Alexander Gerber
Vorstand Demeter e. V.

Christof Potthof
Gen-ethisches Netzwerk

Dr. Dirk Zimmermann
Greenpeace e.V.

Dr. Eva Gelinsky
Koordinierungsleiterin
Interessengemeinschaft für gentechnikfreie Saatgutarbeit (IG Saatgut)

Benedikt Härlin
Direktor Save our Seeds

Dr. Christoph Then
Geschäftsführer Testbiotech