Response of GMWatch to European Commission's Inception Impact Assessment on "Legislation for plants produced by certain new genomic techniques"

Sustainability: Commission relies on promises, not evidence

The Commission claims that plants developed with new genetic engineering techniques could contribute to sustainability goals. However, this claim is not substantiated and the Commission relies far too heavily on promises by GMO developers and associated lobby groups.

In its working document published in April 2021, the Commission mentioned an unspecified Joint Research Centre (JRC) "review" as identifying "several" new GM plant products that could contribute to sustainability goals (p52) and elsewhere mentions the "JRC review on market applications" (p14), so it can be assumed that the JRC report "Current and future market applications of new genomic techniques" is the source.[1]

At the ad hoc advisory group meeting organised by DG SANTE, JRC said its report was based on a survey of developers (private companies and research institutes), underlining that "this was the only way" to find information on potential products. However, the JRC did not reveal names of developers, but only mentioned that they are mostly private companies in the US, Canada and China, making it impossible to check claims of closeness to market.

Neither the JRC report nor its associated database[2] contain any published references that could provide more information about the alleged products. Also, in the report, no specific criteria are presented for allocating a plant product to a specific development stage.

These shortcomings mean that the Commission's conclusions on the potential of these techniques are entirely based on unverifiable claims by developers.

While other sources are mentioned in the JRC report, such as the Genetic Literacy Project website, the US National Science Foundation Plant Genome Editing Database, and the Julius Kühn Institute,[3] all these sources will rely on information given by the developers, so they cannot be considered to be independent verification of developers' claims. Therefore the statement that new GMOs can contribute to the objectives of the European Green Deal and Farm to Fork strategy is based on confidential business information and relates more to commercial goals (including attracting investment) than objective evidence.

[1] JRC (2021). Current and future market applications of new genomic techniques. https://publications.jrc.ec.europa.eu/repository/handle/JRC123830
[2] JRC (undated). New genomic techniques. https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/
[3] JRC (2021). Current and future market applications of new genomic techniques. https://publications.jrc.ec.europa.eu/repository/handle/JRC123830

Commission falsely downplays herbicide tolerance

In spite of the JRC report's reliance on biased sources, its findings call into question the Commission's claim that new GM products can improve sustainability, because they show that the main trait of gene-edited GM plants in the pipeline is herbicide tolerance. This trait allows seeds to be sold in a package with custom-fit agrochemicals. It further consolidates a chemical input-intensive agricultural system and does not contribute to reduced need for pesticides or to sustainability.

For the report, the JRC surveyed GMO developers and classified their products according to how close they are to market. The JRC identified a single plant product that is on the market: Calyxt's high oleic soybean. This soybean, however, has reportedly failed in the US, suffering from poor farmer takeup due to low yields.[4] The JRC ignored another commercial product, Cibus' SU Canola, a herbicide-tolerant (HT) canola (rapeseed).

For years, Cibus claimed that SU Canola was gene-edited via the oligo-directed mutagenesis (ODM) technique. Only when a detection technique was published did Cibus deny that it was a gene-edited GMO (any presence in EU imports would be illegal as it has not been authorised for food and feed use under the EU's GMO regulations). Now Cibus publicly claimed that the canola was the product of somaclonal variation – an accidental mutation in the petri dish.[5] Thus either Cibus did not tell the public the truth about the origin of SU Canola, or the ODM technique appears not to be reliable or precise.

In excluding this commercialised HT product from its investigation, the JRC relied more on the company's sudden denial that its product is not a genetically modified organism than on the EUginius database or the Convention on Biological Diversity (CBD) Clearinghouse, both of which list the product as a genetically modified plant.[6] In this way the JRC downplayed the dominance of HT plants among new GMOs – and the Commission repeated the JRC's omission.

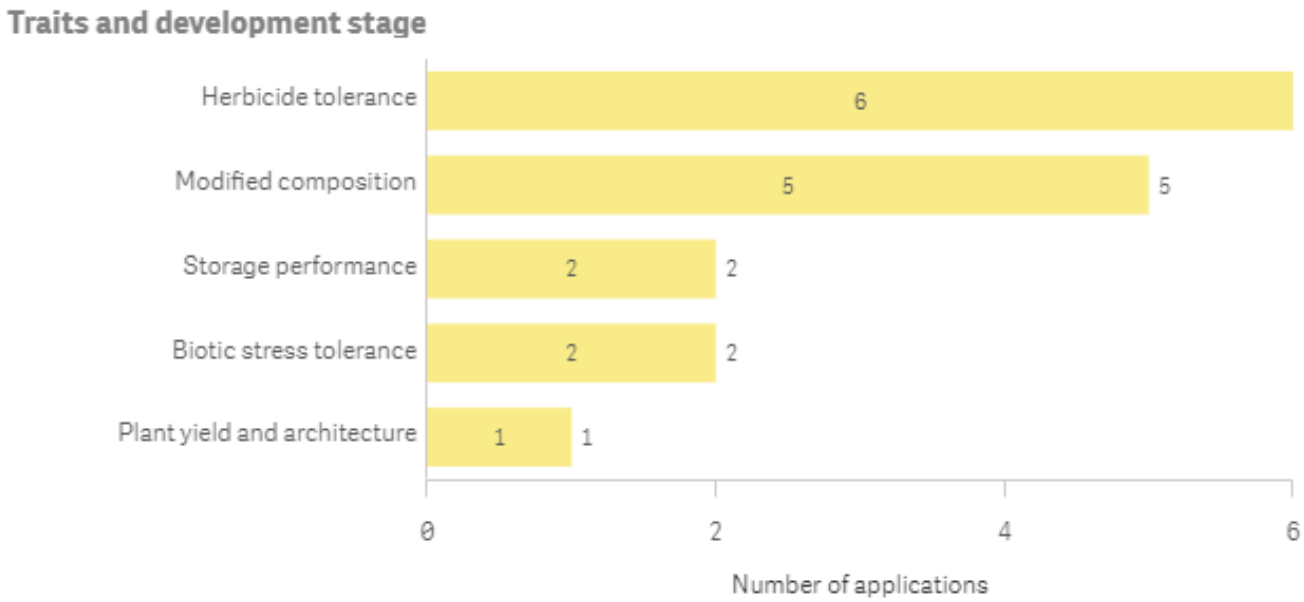
In spite of this inconsistency, the JRC's results are sobering. It identified only 16 plant products at "pre-commercial stage". According to the JRC, this means that they are "ready to be commercialised in at least one country worldwide" and that "commercialisation mainly depends on the developer's decision and a 5-year horizon is estimated". The vast majority of the promised plant products are classified as being in research and development stages. That will include basic research, which is far from commercialization.

Out of the plants that are classified as at the pre-commercial stage, the largest trait group – six out of 16 plants – is HT.

[4] Issa B (2020). Calyxt to exit farming operations and focus on seed science. Seeking Alpha. 10 Dec. https://seekingalpha.com/article/4394048-calyxt-to-exit-farming-operations-and-focus-on-seed-science

[5] Robinson C (2020). Company claims first commercial gene-edited crop wasn't gene-edited after all. GMWatch. https://www.gmwatch.org/en/news/latest-news/19535

[6] In its report (JRC (2021), as above), but not its data visualisation tool, "New genomic techniques" (https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/), the JRC also listed a tomato with altered composition (Sanatech's Sicilian Rouge High GABA Tomato).



Source: JRC
https://datam.jrc.ec.europa.eu/datam/mashup/NEW_GENOMIC_TECHNIQUES/

Of these 16 plant products, two were engineered for biotic stress tolerance (stress due to living organisms such as plant pests and fungal diseases) and none for abiotic stress tolerance (stress due to non-living factors, such as extreme weather and saline soils), compared to the six modified for herbicide tolerance. These numbers counter claims by the agricultural biotech industry that new GM crops could help agriculture adapt to climate change.

Overall, then, the JRC has identified many more applications for HT plants than for plants that can better withstand biotic or abiotic stresses – even though it left out an existing HT product for unknown reasons.

GMO "vapourware"?

The JRC report (as well as the Commission) ignores key facts about the reality of GM plant commercialisation prospects:

- New GM plant products that have been announced by the companies for commercialization frequently disappear from the companies' pipelines, with no reasons given
- Companies repeatedly postpone the commercialization of new GM plant products
- With regard to countering the effects of climate change, it is questionable whether new GM plants with promised traits such as abiotic stress tolerance will work as well in the fields as they may appear to work in the lab or research greenhouse. Plants react to stress in many different ways, and stress reactions are often the result of a complex interaction of many genes and cellular mechanisms, as well as the environment.[7] This network of different reaction mechanisms is still poorly understood.[8] This is why GM-free conventional and organic breeding techniques

[7] Lamers J et al (2020). How plants sense and respond to stressful environments. Plant Physiology 182(4):1624–1635. https://academic.oup.com/plphys/article/182/4/1624/6116416
[8] Saijo Y (2019). Plant immunity in signal integration between biotic and abiotic stress responses. New Phytologist. 17 June. https://doi.org/10.1111/nph.15989

such as cross-breeding have proven to be more successful in producing plants with such complex traits.[9]

Therefore the claim that new GM crops will have the potential to contribute to sustainable food systems is not substantiated. This potential is not a matter of fact, as presented by the Commission, but a matter of unsubstantiated promises of stakeholders with strong vested interests in deregulation. The term “vapourware” comes to mind: In the computer industry, this is hardware or software that is announced but not yet available to buy, typically because it is still in the research and development phase – and may never appear at all.

Sustainability claims must be based on independently verifiable evidence, not claims and promises.

Moreover, the Commission and EU decision-makers should explore evidence-based ways to meet the challenges of climate change and reverse biodiversity loss. The financial and political support hitherto given to research associated with new GM applications needs to be redirected into researching and fostering GM-free, organic and agroecological land use systems and procedures. However, both organic and GM-free production already benefit from evidence, as well as a consistent line of successful marketed products, showing that they can contribute to a more sustainable agriculture.

Even if evidence did exist that new GM products could contribute to sustainability (which is not the case), this would not be a valid justification for weakening or abolishing safety checks on these products before they enter our fields or our plates. These safeguards must be maintained, in accordance with the precautionary principle enshrined in the Treaty on the Functioning of the European Union.

Commission ignores scientific evidence of risks

The Commission ignores a large body of evidence and analysis pointing to the risks of new GM techniques. The Commission writes, ““[EFSA] concluded that plants obtained by targeted mutagenesis [gene editing] and cisgenesis can have the same risk profile as plants produced with conventional breeding”, and “These techniques can be used to produce alterations of the genetic material that can also be obtained by natural mutations and conventional breeding techniques, or can be used to produce alterations that are more complex”.

However, the Commission fails to define a change that "can also be obtained by natural mutations and conventional breeding”.

Indeed, new GM techniques *may* induce a single base change that could also occur in nature. But the genetic modification (GM) processes of cisgenesis and gene editing are different from conventional breeding and can produce unintended mutations that differ in type as well as number, potentially affecting many, or all, of the genes of the organism. They can induce changes in hundreds or thousands of nucleotides, the totality of which changes does *not* occur in nature. Gene editing can access areas of the genome that are otherwise protected from mutation. It can target several genes at once, or be used in repeated applications, resulting in changes that would be extremely difficult or impossible

[9] Gilbert N (2014). Cross-bred crops get fit faster. Nature News 513(7518):292. http://www.nature.com/news/cross-bred-crops-get-fit-faster-1.15940 ; GMWatch (1999–2021). Non-GM successes. https://www.gmwatch.org/en/articles/non-gm-successes

to achieve using chemical- or radiation-based mutagenesis or via conventional breeding.[10] Unintended consequences of such gene editing interventions could include unexpected toxicity or allergenicity.[11] However, risk is not dependent on the size of the intended change – large risks can result from small changes, and vice versa.[12]

EFSA has dismissed the importance of off-target effects resulting from gene editing, saying, "The analysis of potential off-targets would be of very limited value for the risk assessment".[13]

However, scientists working for national regulatory agencies in EU member states and Switzerland disagree. In a scientific review, Eckerstorfer and colleagues state, “The identification and characterization of off-target modifications in the final plant product is relevant for the assessment of unintended effects".[14]

EFSA states that strategies are available to increase the precision of editing and to remove off-target modifications in subsequent crossbreeding steps, using this argument to minimize the importance of off-target effects.[15] But Eckerstorfer and colleagues note, "Not all GE [gene editing] approaches can be designed to minimize the occurrence of off-target modifications". They add that sometimes, intentionally "dirty" gene-editing approaches are used by developers, in order to target a number of sites in the genome with slightly different target sequences.[16]

Eckerstorfer and colleagues also explain that the presence of off-target modifications has not been well studied for a number of gene-editing applications. Thus the notion that gene-editing methods induce off-target modifications with a low probability is based on very limited data.[17] Kawall and colleagues found that “the vast majority” of studies on gene-edited plants use biased methods to search for off-target effects, meaning that most such effects could be missed.[18]

Eckerstorfer and colleagues state, “The existing guidance developed by EFSA and their initial work on GE applications is not sufficient to address these challenges, but rather a starting point for further efforts.” They recommend that EFSA drafts “further guidance for the assessment of unintended effects of GE modifications”.[19]

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

[11] Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Sciences Europe 32(1):106. https://doi.org/10.1186/s12302-020-00361-2

[12] Eckerstorfer MF et al (2021). Biosafety of genome editing applications in plant breeding: Considerations for a focused case-specific risk assessment in the EU. BioTech 10(3). https://www.mdpi.com/2673-6284/10/3/10

[13] Naegeli H et al (2020). Applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide- directed mutagenesis. EFSA Journal 2020;18(11):6299.

[14] Eckerstorfer MF et al (2021). Biosafety of genome editing applications in plant breeding: Considerations for a focused case-specific risk assessment in the EU. BioTech 10(3):10. https://www.mdpi.com/2673-6284/10/3/10

[15] Naegeli H et al (2020).
https://www.efsa.europa.eu/sites/default/files/scientific_output/j.efsa_.2020.6299.pdf

[16] Eckerstorfer MF et al (2021). https://www.mdpi.com/2673-6284/10/3/10

[17] Eckerstorfer MF et al (2021). https://www.mdpi.com/2673-6284/10/3/10

[18] Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environmental Sciences Europe 32(1). https://doi.org/10.1186/s12302-020-00361-2

[19] Eckerstorfer MF et al (2021). https://www.mdpi.com/2673-6284/10/3/10

No scientific justification for weakening regulations for whole classes of GMOs

It is not scientifically justifiable to exempt certain classes of GMO from the GMO regulations based on arbitrary and non-evidence-based criteria, such as if the intended changes are claimed to be reproducible in conventional breeding or if no transgenes (foreign genes) have been deliberately inserted.

Eckerstorfer and colleagues warn that the type and size of mutations introduced by gene editing “may differ quite significantly from those mutations which may arise spontaneously during conventional breeding”. They also state that risk is not dependent on whether or not foreign DNA is inserted.[20]

Their conclusion is that, considering the wide range of plant species and the gene editing methods and traits, "there is no safety by default for whole groups" of gene editing applications or products. Thus they state: “The precautionary approach of the existing EU GMO regulations should not be weakened by excluding whole groups of GE applications from their scope without having regard to the characteristics of the individual GE plants.” Instead, "a case-specific risk assessment within the current regulatory frameworks for GMOs should be conducted” prior to release into the environment. They recommend specific sources as references for establishing science-based risk assessment guidance.[21]

Cisgenesis cannot be assumed to be safer than transgenesis

As for cisgenesis, peer-reviewed evidence summarised by Wilson and Latham (2007) notes that cisgenic plants are "created using the same highly mutagenic plant transformation techniques used to create other transgenic plants".

Regarding the "no foreign DNA" claims made for cisgenesis, Wilson and Latham state, "According to some definitions, cisgenes, like transgenes, may include anti-sense sequences, sequence changes to elude feedback inhibition and combinations of gene coding and regulatory components from different genes and species (Rommens, 2004). Indeed, the cisgenic plants engineered by Rommens et al. (2004), who claim to have made 'the first genetically engineered plants that contain only native DNA', were produced using Agrobacterium-mediated transformation of potato (via tissue culture and transient selection on kanamycin) and the cisgenes were composed of sense or anti-sense plant DNA from three distinct genes."

[20] Eckerstorfer MF et al (2021). https://www.mdpi.com/2673-6284/10/3/10 : “The theoretical comparison of spontaneous mutations with modifications introduced by GE [gene editing] does not consider the specific hazards that may be associated with a particular mutational change. The occurrence of hazards thus would not be correlated in all cases with an exogenous origin of the introduced DNA sequences.” p5.

[21] These sources are: 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 7 (2019). https://doi.org/10.3389/fbioe.2019.00031 ; Haut Conseil des Biotechnologies (2017). Scientific Opinion on New Plant Breeding Techniques. tinyurl.com/2nf3khsr; Kawall K et al (2020). Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture. Environ Sci Eur 2020(32). https://doi.org/10.1186/s12302-020-00361-2 ; Lema M (2021). Regulatory assessment of off-target changes and spurious DNA insertions in gene-edited organisms for agri-food use. J Regul Sci 2021(9):1. https://journals.tdl.org/regsci/index.php/regsci/article/view/136

Wilson and Latham point out, "While categorizing transgenes according to their origins may have merit, changes to risk assessment and regulations need to be based on scientific data not semantics."

Based on a review of experimental data on cisgenic plants, Wilson and Latham conclude, "Trait introduction via a cisgene can result in plants which differ in unanticipated and dramatic ways from their conventionally bred counterparts. Furthermore, the observed differences would likely have important agronomic and ecological implications for commercial varieties."[22]

Existing alternative legislation is not sufficient

In the first round of consultation that led to the April 2021 publication of the Commission's working document:

- EU-SAGE,[23] EuropaBio[24] and others wanted post-market safety liability to be regulated through the General Food Regulation[25] and the Environmental Liability Directive[26] – which, however, do not provide for a health and environmental risk assessment. This means deregulation.

- EuropaBio argued for product-based, not process-based legislation. However, the problem with this type of legislation is that it focuses only on the intended trait. Unintended effects of new GM techniques would be missed, even though they could crucially affect the safety of the GMO for health and the environment. As scientists have cautioned, to protect public health and the environment, each GMO must be evaluated in a detailed risk assessment that considers the processes used to develop it.[27]

- COPA stated that the seed legislation already requires pre-market testing and approval for plant varieties.[28] In effect, COPA was proposing deregulation. FoodDrinkEurope claimed that if SDN-1 and SDN-2 applications of gene editing are excluded from the GMO directive, this does not mean they would go unregulated, as they would be covered by seeds legislation.[29] But seed testing is only for

[22] Wilson A, Latham J (2007). Cisgenic plants: Just Schouten from the hip? Independent Science News. 23 Feb. https://www.independentsciencenews.org/health/cisgenic-plants/
[23] EU Commission (2020). Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council. Response of EU-SAGE. 13 May. Contribution ID: 70ce3ccf-0036-4a9d-9ce7-fe281b070883. https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_stake-cons_stake-reply-69.pdf
[24] EU Commission (2020). Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council. Response of EuropaBio. 15 May. Contribution ID: 1d2f2073-ab05-46af-bb5b-7063db2dd0ce. https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_stake-cons_stake-reply-23.pdf
[25] EC 178/2002.
[26] 2004/35/EC.
[27] Eckerstorfer MF et al (2021). Biosafety of genome editing applications in plant breeding: Considerations for a focused case-specific risk assessment in the EU. BioTech 10(3). https://www.mdpi.com/2673-6284/10/3/10
[28] EU Commission (2020). Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council. Response of COPA. 12 May. Contribution ID: f2cc858c-c4a2-4134-a6f9-834aa92e42e7. https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_stake-cons_stake-reply-11.pdf
[29] EU Commission (2020). Stakeholder questionnaire on new genomic techniques to contribute to a Commission study requested by the Council. Response of FoodDrinkEurope. 19 May. Contribution ID:

distinctness, uniformity, and stability (DUS). Testing and assessment for health and environmental safety is not carried out.

Prof Dr Tade M. Spranger was commissioned by the German Environment Ministry to conduct an analysis to ascertain whether alternative legislation, such as that applied to the cultivation of crops, animal breeding, safety of food and feed, and the protection of the environment, would indeed mean that GMOs are still regulated. Spranger concluded “that the various European directives and regulations do not guarantee a level of protection comparable to that of genetic engineering law neither individually nor collectively”.[30]

Public want strict regulations and GMO labelling for new GM foods to be maintained

An Ipsos opinion poll shows that the vast majority (86%) of Europeans who have heard of GM crops want food produced from these plants to be labelled as such. It also shows that the majority (68%) of respondents who have heard of new GM techniques, including gene editing, want food produced with these techniques to be labelled as GM.[31]

In the UK government’s consultation on the deregulation of gene editing, out of 6,440 submissions to the consultation, most individuals (87%) and businesses (64%) felt that gene-edited organisms pose a greater risk than naturally bred organisms. Most individuals (88%) and businesses (64%) supported continuing to regulate the products of gene editing as GMOs.[32]

Plant varieties (including new GMOs) can be detected

The Commission suggests that detection of new GMOs might be difficult or impossible. However, the current law (Directive 2001/18EC) requires that the applicant for a GMO authorisation provides a "description of identification and detection techniques" as a prerequisite for market approval. The particular genetic modification technique used to make the GMO has never been required to be identifiable. Therefore the existing GMO legislation is sufficient to maintain the detectability of all new GMOs that pass through the authorisation process.

Detection of known GMOs is clearly possible because they are patented – and patents require that companies can distinguish their products from others. This is generally known and acknowledged to be feasible in the plant breeding sector. In 2018 the International Union for the Protection of New Varieties of Plants (UPOV) published a draft report explaining that a plant variety can be identified by its characteristic molecular markers, as

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7ee4ffda-53c1-44f2-886e-8ddac7c14ed6. https://ec.europa.eu/food/system/files/2021-04/gmo_mod-bio_stake-cons_stake-reply-80.pdf

[30] Spranger TM (2017). Summary of key findings resulting from the legal opinion prepared by Professor Dr Tade M. Spranger, “In-depth analysis of various European directives and regulations with regard to their potential to regulate environmental effects of New Technologies besides Genetic Engineering Law”. German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN). 27 Nov. https://www.bfn.de/fileadmin/BfN/recht/Dokumente/NT_Auffangrechte_RGutachten_Zusammenfassung_en.pdf

[31] Greens/EFA in the European Parliament (2021). GMO survey data. http://extranet.greens-efa.eu/public/media/file/1/6912

[32] UK Government (2021). Consultation outcome: Genetic technologies regulation: government response. Updated 29 September 2021. https://www.gov.uk/government/consultations/genetic-technologies-regulation/outcome/genetic-technologies-regulation-government-response#summary-of-consultation-views-and-our-response

well as phenotype, which in combination constitute a kind of signature.[33] This information is used in plant breeding and for variety description and tracing.

In 2019, UPOV released a report on DNA-based methods for variety testing, so as to protect the ownership of breeders.[34] As early as 2015, the International Organization for Standardization (ISO) published and adopted standards to be followed to analyse the fingerprints of the maize and sunflower species and to verify the identity of the varieties.[35] Two standards using such "horizontal methods for molecular biomarker *analysis*" were evolved by the same ISO working group that previously published the standards currently used to detect transgenic GMOs.[36]

In 2019 the International Seed Testing Association (ISTA) concluded on methods for variety testing that “DNA-based techniques are 1) developed and used by breeding companies and seed companies 2) mature and available for seed testing, already used in many laboratories, in many countries”.[37]

In 2021 the Commission acknowledged the effectiveness of biochemical and molecular techniques (BMT) in the identification of plant varieties by issuing Implementing Directive (EU) 2021/971. The Directive contains amendments to legislation concerning various food crop seed varieties. It states, “The use of BMT enables certification authorities to identify the plant variety on the basis of laboratory analysis instead of visual phenotypic observation of the plants in the field.” The Directive adds, “BMT in plant breeding and seed testing are developing fast and their use in the seed sector is increasingly important.”[38]

It is not credible to imply that new GM varieties would be uniquely unidentifiable via these techniques.

Identification and detection of new GMOs would be facilitated if developers and the EU authorities would acknowledge what is scientifically known about new GM techniques – that they not only produce the intended change in the genome, but also a range of unintended changes that, if characterized, could be used as molecular markers to distinguish different varieties.

All that is needed to detect known GMOs entering the marketplace is the political will to roll out the appropriate protocols. If companies can distinguish their plant varieties, why should the Commission refuse to consider the possibility?

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[33] UPOV (2018). Document TGP/15 Guidance on the use of biochemical and molecular markers in the examination of distinctness, uniformity and stability (DUS). https://www.upov.int/edocs/mdocs/upov/en/twa_47/tgp_15_2_draft_1.pdf

[34] [UPOV (2019). DNA-based methods for variety testing: ISTA approach. https://www.upov.int/edocs/mdocs/upov/en/bmt_18/bmt_18_3.pdf

[35] ISO (2015). ISO/TR 17622:2015: Molecular biomarker analysis — SSR analysis of sunflower. https://www.iso.org/standard/60170.html ; ISO (2015). ISO/TR 17623:2015: Molecular biomarker analysis — SSR analysis of maize. https://www.iso.org/standard/60171.html

[36] ISO (undated). ISO/TC 34/SC 16: Horizontal methods for molecular biomarker analysis. https://www.iso.org/committee/560239.html

[37] UPOV (2019). DNA-based methods for variety testing: ISTA approach. https://www.upov.int/edocs/mdocs/upov/en/bmt_18/bmt_18_3.pdf

[38] EU Commission (2021). Commission Implementing Directive (EU) 2021/971 of 16 June 2021. Official Journal of the European Union 17.6.2021. https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021L0971

Unknown GMOs

Detection of unknown GMOs through laboratory methods will be more challenging or impossible. But the problem of unknown GMOs entering the market is not new or confined to "new GM" products. Some will be missed, but this is not a reason to give up on enforcing the GMO regulations and deregulate all new GMOs. By analogy, just because all burglaries cannot be solved, is not a reason to legalise burglary.

Also, crucially, detection of GMOs does not rely only on laboratory detection methods, but also on documentation and traceability throughout the supply chain. Similarly, organic, fair trade, and "protected designation of origin" foods cannot be verified by laboratory detection methods, but they are still labelled and rules governing these food standards are enforced for the benefit of consumers and producers – and the integrity of the food chain.

Commission has refused to fund detection methods for new GMOs

The Commission has consistently and over many years refused to fund the EU's GMO detection laboratories to work on developing detection methods for new GMOs[39] – yet now it argues that new GMOs cannot be detected. This is a self-fulfilling prophecy based on the Commission's inaction. It must commit to mandating and funding such work, in order to protect food safety standards.

New GMOs will not democratize plant breeding

Whilst the GMO industry wants us to believe that new genetic engineering techniques (especially gene editing) are about adapting to climate change, reducing pesticides, and democratizing plant breeding, in reality they are about maximising profits through patents.

The patent landscape is currently dominated by Corteva (resulting from a merger of Dow AgroScience and DuPont/Pioneer). Corteva controls access not only to its own patents, but also to many other patents needed by breeders who want to use CRISPR/Cas technology. Corteva established a patent pool in 2018, which at that time already comprised around 50 patents. Other breeders who want to have access to this pool are required to sign contracts; this puts Corteva in an extremely strong market position that could be seen as a hidden cartel, with possible implications for competition (the text of the contracts is confidential).[40] Weakening regulations around gene editing and cisgenesis would not benefit small- and medium-sized enterprises, but would simply promote the quasi-monopoly of Corteva.

Conclusion and recommendations

In conclusion, the EU Commission's plan to deregulate new GM techniques and cisgenesis is contrary to the precautionary principle and will threaten public health and the environment. It will also endanger the non-GMO, conventional, and organic agricultural

[39] Meunier E (2021). Detection of new GMOs: Not a priority for the Commission. Inf'OGM, 25 June. https://www.infogm.org/7229-detection-new-gmos-not-a-priority-for-commission

[40] Testbiotech (2021). New GE and food plants: The disruptive impact of patents on breeders, food production and society. June. https://www.testbiotech.org/sites/default/files/Patents_on%20new%20GE.pdf

and industry sectors. There is no scientific basis for deregulating whole classes of new GM techniques and their products. The Commission is uncritically following industry lines of argument in favour of deregulation. These arguments are based not on scientific evidence but on marketing considerations.

New GM techniques must be kept under the existing GMO regulations, which must not be weakened but strengthened (via additional risk assessment guidance) in order to maintain and improve protections for human and animal health and the environment, as well as for our agriculture and food systems.

The Commission should prioritize the development and application of biochemical and molecular techniques, which are already used to identify plant varieties, to detect new GMOs.

The Commission and governments should step back from promoting and deregulating the new generation of GMOs and instead prioritise public and political support for sustainable agriculture systems like agroecology and organic farming. These farming approaches have been proven to preserve biodiversity and adapt to extreme weather conditions. By their very nature, they contribute to the aims of the Farm to Fork strategy to reduce the use of pesticides and artificial fertilizers.