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Biased from the outset: The EU Commission's "working document" on new GM techniques fails to uphold environmental and consumer protection standards

Critical response by NGOs and farmer and business associations to the Commission's document on new GMOs

September 2021

Summary

In April 2021 the health branch of the EU Commission (DG SANTE) published a "staff working document" calling the EU's genetically modified organism (GMO) regulations "not fit for purpose". In the document, the Commission makes suggestions that could lead to a proposal to exempt some crop plants produced with "new genomic techniques" such as gene editing from the requirements of the regulation. Such deregulation could mean that there would be no safety checks, GMO labelling for the consumer, traceability requirements, or post-market monitoring.

We, the undersigned non-governmental organizations (NGOs), peasant farmer organisation, and business and trade associations strongly oppose the proposals in the Commission's document, on the grounds that deregulation of new GM techniques would pose unacceptable risks to human and animal health and the environment. Deregulation would also prohibit citizens from knowing what they are eating and farmers from knowing what they are sowing. The Commission's proposals cross red lines regarding biosafety, transparency of information, and consumer protection. They should be rejected.

In the event that something went wrong – if, for example, consumers of new GM foods suffered allergic reactions or toxic effects, or if there were unintended effects on wildlife – the removal of labelling and traceability requirements would mean that the cause could not be identified.

Our objections to the document and the consultation that gave rise to it are listed below.

The Commission's consultation was biased: The consultation process that led to the document was biased from the outset, with the vast majority of inputs (74%) coming from the agricultural GMO industry.

The Commission relies too much on the unverifiable promises of the industry: The Commission claims that plants engineered with new GM techniques could contribute to sustainability goals. However, this claim is not substantiated and relies on unverifiable promises by GMO developers and associated lobby groups. According to the Commission's source, the Joint Research Centre (JRC), the vast majority of the promised plant products identified in the JRC survey of GMO developers are in research and development stages, which could be far from commercialisation or never be commercialised at all.

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.

The Commission misleadingly downplays the dominance of herbicide tolerance in new GM crops: Out of the new GM plants that the JRC classifies as at the pre-commercial stage, the largest trait group – six out of 16 plants – is herbicide tolerant. Of these 16, 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.

The Commission ignores a large body of scientific evidence and analysis pointing to the risks of new GM techniques. Gene-editing techniques are not precise and can cause off-target mutations (at locations in the genome other than the intended edit site) and unintended on-target mutations (at the intended edit site of the genome), with unpredictable consequences – potentially including unexpected toxicity or allergenicity.

The mutations induced by gene-editing processes are different from those that occur in random mutagenesis breeding and those that occur in nature or with conventional breeding, since gene editing can access areas of the genome that are otherwise protected from mutations.

There is no scientific basis for deregulating whole classes of new GM techniques and their products. The risks of these techniques were fully acknowledged by the pharmaceuticals sector during the Commission’s consultation, which warned, in the Commission’s paraphrasis, that “the technology is not without risk and that products should undergo risk assessment”. Yet we are expected to believe that deregulating these same techniques in the food and agriculture sectors would be safe.

The Commission uncritically follows the GMO industry’s “wish list” for deregulation. GMO developers and associated lobby groups (such as ALLEA, EU-SAGE, EuropaBio, EPSO, Euroseeds, Plants for the Future European Technology Platform (ETP), and the “big farmers’” lobby organisation COPA claim that there should be ‘non-discrimination’ between conventional and gene-edited products because the mutations induced by gene editing could also arise in nature or during conventional breeding programmes, so gene-edited products are no riskier than natural or conventionally bred products. The Commission's document comes to a strikingly similar conclusion.

But this argument is false and misleading. New GM techniques may induce a single base change that could also occur in nature – but they can also induce changes that do not occur in nature. Gene-editing applications can target several genes at once, or be used in repeated applications, resulting in changes that would be extremely difficult or impossible to achieve using chemical- or radiation-based mutagenesis or in nature. However, risk is not dependent on the size of the intended change – large risks can result from small changes, and vice versa.

In accord with the lobby groups’ demand for new GM products not to carry GMO labels, the Commission makes no statement supporting labelling, leaving the door open to ending consumer and farmer choice by the removal of GMO labelling from new GM foods and seeds.

Deregulation of new GMOs would leave consumers and the environment unprotected. GMO developers and associated lobby groups argue that existing alternative legislation governing food, environmental protection, and seed quality is sufficient for ensuring safety and establishing liability in case things go wrong with a new GMO. However, these laws do not provide for a health and environmental risk assessment. And seed testing is only for distinctness, uniformity, and stability (DUS) – not for food or environmental safety.

Prof Dr Tade M. Spranger was commissioned by the German Environment Ministry to conduct an analysis to ascertain whether such alternative legislation would 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".

Food processors and traders seem to demand contradictory outcomes – a contradiction that the Commission fails to address. The food processors and traders want to have it both ways: Easier access to new GM products (therefore deregulated), but still with full guarantees of safety and without any risk for their consumers and markets. They argue for a differentiated regulatory framework, but not clearly for full deregulation. However, these arguments run counter to the warnings of numerous independent scientists that gene-edited GM plants pose different risks from conventionally bred plants and all (without exception) need to be subjected to a detailed risk assessment that is not restricted to the intended trait but also recognises the inherent risks of gene-editing processes.

The Commission falsely claims that new GMOs cannot be detected. This is in spite of evidence from the plant breeding sector that identification of plant varieties is already being done using biochemical and molecular techniques. There is no reason why new GMO varieties would be different. Indeed, the Commission states in its own Implementing Regulation on crop varieties that use of these techniques "enables certification authorities to identify the plant variety on the basis of laboratory analysis". While it is not yet possible to identify the method by which the variety was generated, this has never been a requirement of the EU's GMO regulations.

While unknown new GMOs would prove more of a challenge to detect, this is not a new problem, nor is it unique to new GMOs. Unknown GMOs have likely been missed for some time, but the inability to detect all GMOs does not justify abandoning attempts to apply the GMO legislation. Also, crucially, detection of GMOs does not rely only on laboratory detection methods, but also on documentation and traceability throughout the supply chain – just as with organic and fair trade products.

The Commission has over many years refused to fund the EU's GMO detection laboratories to work on developing detection methods for new GMOs[1] – yet now 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.

Although the Commission has accepted at face value industry's argument that new GM is about adapting to climate change and reducing pesticides, it is, in reality, about patents. The patent landscape is currently dominated by Corteva, which controls access not only to its own patents, but also to many other patents needed by breeders who want to use CRISPR/Cas technology. While the Commission claims that deregulation would benefit small- and medium-sized enterprises, in practice, it would simply promote the quasi-monopoly of Corteva.

In conclusion, the planned changes in the GMO legislation are disproportionate, since they will have a serious impact on the interests of consumers, farmers, breeders and food producers, but any potential benefits are likely to be minor or insignificant.

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.

The EU Commission and governments should step back from promoting and deregulating the new generation of GMOs and instead prioritise public and political support for sustainable farming 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.

The Commission should also mandate the development and application of already available biochemical and molecular plant variety identification techniques to detect all known new GMOs entering the marketplace.

END OF SUMMARY. SEE FULL TEXT BELOW.

1. Process biased from the outset

In April 2021 the EU Commission published a "staff working document" making suggestions that could lead to a proposal for the deregulation of new GM techniques.[2] In compiling the document, the European Commission seemed to ignore its own guidelines on a fair and balanced process. Instead, the consultation feeding into the document was secretive and dominated by industry. The European Commission chose the stakeholders for the closed consultation, with just 14% of stakeholders representing civil society groups – while 74% came from industry and thus have a vested interest in exempting new GMOs from safety laws. A number of GMO companies were represented multiple times, both individually and as part of umbrella organisations.[3]

Key issues around the protection of the environment and consumer safety and choice were ignored. The result is a working paper that is biased towards the interests of the agricultural biotech industry. It repeats the arguments of the sustained campaign by industry-linked lobbyists to win exemptions from safety regulations for new GMOs.

The European Commission should recognise that the working paper was flawed in its scope and setup and cannot be used to justify changes in GMO safety regulations.

2. Commission relies too much on promises

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.

The document is poorly referenced, so it is not possible to verify specific claims by checking sources. However, the Commission mentions 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.[4]

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[5] 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,[6] 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.

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.

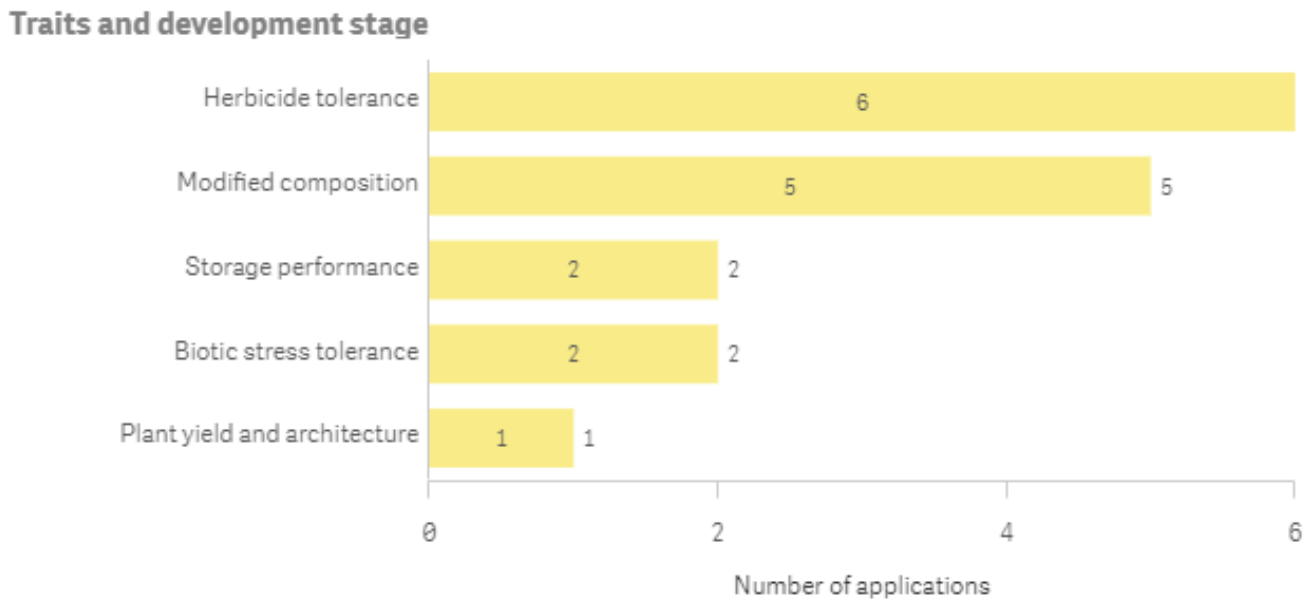
For the report, the JRC surveyed GMO developers and classified their products according to how close they are to market. The JRC identified a single plant product that is on the market: Calyxt's high oleic soybean. This soybean, however, has reportedly failed in the US, suffering from poor farmer takeup due to low yields.[7] 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.[8] 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.[9] 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.



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 report 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.[10] This network of different reaction mechanisms is still poorly understood.[11] This is why GM-free conventional and organic breeding techniques such as cross-breeding have proven to be more successful in producing plants with such complex traits.[12]

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.

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.

3. Commission's rationale for changing regulation is invalid

The EU Commission concludes in its working paper: "A purely safety-based risk assessment may not be enough to promote sustainability and contribute to the objectives of the European Green Deal and in particular the 'farm to fork' and biodiversity strategies; benefits contributing to sustainability would also need to be evaluated, so an appropriate mechanism to accompany risk assessment may be required."

However, policy decisions based on societal values such as "benefits contributing to sustainability" can only be considered as an additional element within the approval process. They must not replace the current process-oriented risk assessment, labelling, traceability, and monitoring, as required by EU law for the whole food chain, from breeders to consumers.

Moreover, the scientific rigour of the GMO evaluation process would be severely compromised by basing any part of it on claims of benefits by GMO developers. The first generation of transgenic plants was promoted on the basis of claims that they would contribute to sustainability by reducing pesticide use and provide benefits to consumers. However, these promises have never materialised.[13] Thirty years after their release onto world markets, there is still no consensus amongst scientists, industry, farmers, and food producers on the sustainability impact of transgenic plants in food production.

Forecast benefits, such as the Commission foresees being used in GMO evaluations in a deregulated system, cannot be stringently assessed. And any claims of benefits could not be balanced by an assessment of the potential negative impacts of the GMO on the environment, biodiversity, and the social side of farming, since these are also impossible to assess prior to release. Indeed, they are difficult to calculate even after the damage has occurred.

While industry can calculate the potential cost of a lost or delayed market for a GMO product, it is not possible to put a price on a cancer caused or the destruction of a species.

Therefore taking claimed benefits of a GMO into consideration in the regulatory evaluation will neither help sustainability nor increase the societal consensus around GMOs. In addition, the EU Commission, in its role as risk manager, can already take any potential advantages and disadvantages of GMOs into consideration in its decisions on

authorisations. Also, risk assessment standards can be stipulated through risk assessment guidance documents, without having to change the legal framework.

Given the above, he proposed changes in the GMO legislation are disproportionate, since they will have a serious impact on the interests of consumers, farmers, breeders, food producers, and retailers, but any potential benefits are likely to be minor or insignificant – and restricted to the large biotech companies that control the patents.

4. EU Commission ignores scientific evidence of risks

In its working paper, the Commission ignores a large body of evidence and analysis pointing to the risks of new GM techniques.

Gene-editing techniques are not precise and can cause off-target mutations (at locations in the genome other than the intended edit site) and unintended on-target mutations (at the intended edit site of the genome), with unpredictable consequences – potentially including unexpected toxicity or allergenicity.[14] The mutations induced by gene-editing processes are different from those that occur in traditional mutagenesis breeding and those that occur in nature or with conventional breeding, since gene editing can access areas of the genome that are otherwise protected from mutation.[15]

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".[16]

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".[17]

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.[18] 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.[19]

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.[20] 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.[21]

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”.[22]

Commission's conditions for exemption from GMO regulations are contrary to scientific facts

The Commission's document suggests that new GM plants would be exempted from the GMO regulations if they meet certain conditions – for example, if their intended characteristics are already known from conventional breeding and no transgenes (foreign genes) have been inserted.

However, 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.[23]

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.[24]

Pharmaceuticals stakeholders acknowledge risks of gene editing

The Commission cites the opinion of the European Food Safety Authority (EFSA) in concluding that certain new GM techniques, notably "targeted mutagenesis and cisgenesis" carry "the same level of risk as conventional breeding techniques".

Yet the pharmaceuticals stakeholders to the EU Commission consultation, discussing exactly the same techniques – SDN-1, SDN-2 and cisgenesis – in medical applications consider, in the Commission's paraphrasis, that "the technology is not without risk and that products should undergo risk assessment".[25]

In its input to the consultation, the pharmaceutical industry lobby group, the European Federation of Pharmaceutical Industries and Associations (EFPIA), was more explicit. The EFPIA said, "There is uncertainty of safety risk of NGTs/NGT [new genomic technique]-products... We also support the collection of long-term safety data on these products to better understand potential risks."[26]

The EFPIA also said, "NGTs can have unintended effects that are unknown and not predictable based on animal data. Long term safety follow-up is needed for some product categories in order to monitor for delayed adverse reactions… The true long-term environmental aspects and safety aspects for patients and their relatives remain an uncertainty."

This raises fundamental questions about how the use of the same techniques can be declared safe for new GM plants but not for pharmaceuticals. Such declarations are made even though unlike GM foods, pharmaceuticals are targeted to the individual patient, who accepts the risks, often for a limited time period, in exchange for expected benefits, with informed consent, and monitoring is carried out post-release. In contrast, if new GM techniques were deregulated, consumers could unknowingly buy and eat plants developed using new GM techniques. And without labelling or traceability, there would be no recourse if something went wrong, such as an allergic or toxic reaction.

As the EFPIA correctly stated, “These technologies are still in their infancy and most methods have relatively low on-target efficiency and some off-target effects.”

5. Commission blurs line between GMOs and conventionally bred organisms

In its document, the EU Commission uses and defines the term “conventional GMOs”, equating these to “transgenic organisms”. This may have serious regulatory implications, since the new terminology introduced by the EU Commission might be interpreted in a way that exempts GMOs from the EU’s GMO regulation and mandatory approval processes.

During the consultation process for the Commission document, some stakeholders, such as EuropaBio,[27] used the term “conventional GMO” with a specific regulatory meaning, falsely implying that genetic engineering techniques have no specific or inherent risks. That said, neither the EU scientific services, EFSA, the Joint Research Center (JRC), nor the vast majority of experts participating in the consultation, used this terminology. Nevertheless, the term “conventional GMO” was integrated in the document – with the meaning of “transgenic”, exactly as proposed by industry.

The EU Commission must reconsider the term or clarify why and how it was introduced, as well as what effects it may have on GMO regulation. It appears to aim at blurring the lines (which are legally and scientifically clearly drawn) between GM and conventional breeding, thus paving the way for deregulation of new GM – and possibly all GM – techniques.

6. Commission follows industry and GM developers’ “wish list”

Agricultural GMO corporations, public-private GMO developers, and associated lobby groups (such as ALLEA, EU-SAGE, EuropaBio, EPSO, Euroseeds, Plants for the Future European Technology Platform (ETP), and the “big farmers’” lobby organisation COPA claim that there should be ‘non-discrimination’ between conventional and gene-edited products.[28] They argue that these products are the same because the mutations induced by gene editing could also arise in nature or during conventional breeding programmes, so “safety concerns should not differ”, and products that have the same likelihood of safety should be governed by the same legislation.[29] To treat them differently, we are told, is “discriminatory”.[30]

The Commission’s document comes to a strikingly similar conclusion: “Furthermore, as concluded by EFSA, similar products with similar risk profiles can be obtained with conventional breeding techniques, certain genome editing techniques and cisgenesis. It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk.”

But this argument is false and misleading. Indeed, new GM techniques *may* induce a single base change that could also occur in nature. But they can also induce changes in hundreds or thousands of nucleotides, the totality of which changes does *not* occur in nature. Gene-editing applications can target several genes at once, or be used in repeated applications, resulting in changes that would be extremely difficult or impossible to achieve using chemical- or radiation-based mutagenesis or in nature.[31] Unintended consequences of such gene editing interventions could include unexpected toxicity or allergenicity.

However, risk is not dependent on the size of the intended change – large risks can result from small changes, and vice versa.[32]

Clearly, gene-editing tools can produce a product that could be very different from its conventionally bred parent(s), in terms of risk profile. Yet lobbyists are arguing that health or environmental assessments, as well as monitoring or labelling, should be abolished for these products. EU-SAGE and Euroseeds argue that this will align EU policy and rules with those established and being developed in the rest of the world. But this would entail deregulating to the lowest level: There would be no regulation that takes account of the special risks associated with gene-edited techniques and products.

More specifically:

- EU-SAGE,[33] EuropaBio[34] and others want post-market safety liability to be regulated through the General Food Regulation[35] and the Environmental Liability Directive[36] – which, however, do not provide for a health and environmental risk assessment. This means deregulation.

- EuropaBio argues 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.[37]

- COPA states that the seed legislation already requires pre-market testing and approval for plant varieties.[38] In effect, COPA is proposing deregulation. FoodDrinkEurope claims 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.[39] But seed testing is only for distinctness, uniformity, and stability (DUS). Testing and assessment for health and environmental safety is not carried out.

Existing alternative legislation is not enough

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”.[40]

Food processors and traders want contradictory outcomes

Food processors and traders seem to demand contradictory outcomes – yet the Commission fails to address the contradiction. The food processors and traders want to have it both ways: Easier access to new GM products (therefore deregulated), but still with full guarantees of safety and without any risk for their consumers and markets. They argue for a differentiated regulatory framework, but not clearly for full deregulation.

For example, FoodDrinkEurope states, “In principle these products would be as safe as conventional, provided that the safety has been comprehensively assessed, the products have been authorised, and a tailored regulatory framework, other than the GMO framework, has been developed if appropriate.”[41]

The origin of these arguments (industry lobby groups) would not matter if they were based on objective and verifiable criteria that take into account the public interest. But they run counter to the warnings of numerous independent scientists that gene-edited GM plants pose different risks from conventionally bred plants and all (without exception) need to be subjected to a detailed risk assessment that is not restricted to the intended trait but also recognises the inherent risks of gene-editing processes.[42]

For a referenced overview of these risks, see Testbiotech, "Deregulation of New GE: Reasonable? Proportional?"[43]

Commission opens door to ending GMO labelling for new GM foods

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.[44]

However, this view is opposed by pro-GMO lobby groups. For example, EU-SAGE says labelling is "discriminatory" and gives a "stigma".[45] EuropaBio says labelling should be scrapped as it is "unnecessary, inappropriate and even counter-productive".[46] EPSO believes that labelling should be voluntary.[47]

The Commission, in its document, concedes the widespread disagreement on labelling, stating, "Consumers' understanding and awareness enable them to make informed choices, so the provision of consumer information (e.g. via labelling) is key. However, stakeholders have opposing views, both on the need to continue labelling NGT products as GMOs and on the effectiveness of such labelling in informing consumers."

The Commission makes no statement supporting labelling, leaving the door open to ending consumer and farmer choice by the removal of GMO labelling from new GM foods and seeds.

7. Commission falsely claims that new GMOs cannot be detected

The Commission repeatedly refers to the claimed inability to distinguish plants produced using new GM techniques from plants produced using conventional breeding or mutagenesis breeding, using this as a reason why the GMO legislation cannot be enforced for new GMOs. It cites a EURL/ENGL report as saying that even where detection methods exist, they cannot prove whether a specific DNA alteration was made via gene editing, conventional breeding, or mutagenesis breeding: "Although existing detection methods may be able to detect even small specific DNA alterations, this does not necessarily confirm the presence of a genome-edited plant product. The same DNA alteration could have been obtained by conventional breeding or random mutagenesis techniques, which are exempted from the GMO legislation."[48]

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. But 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.

Plant breeders can distinguish and identify their varieties

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 well as phenotype, which in combination constitute a kind of signature.[49] 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.[50] 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.[51] 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.[52]

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”.[53]

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.”[54]

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?

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 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[55] – 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.

8. GMOs are about patents

Whilst the GMO industry wants us to believe that new genetic engineering techniques (especially gene editing) are about adapting to climate change and reducing pesticides, 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).[56] While the Commission claims that deregulation would benefit small- and medium-sized enterprises, in practice it would simply promote the quasi-monopoly of Corteva.

Monopolistic claims on patented technologies and seeds linked to the introduction of new GM crops render disruptive processes in plant breeding, agriculture and food production a highly likely consequence. This development is in strong contradiction to repeatedly voiced arguments stating that CRISPR/Cas technology would be cheap, and therefore more accessible for small- and medium-sized breeding companies.

At the same time, the interest in proprietary technologies are also having an impact on political decision making and trust in science. This puts the precautionary principle and the place of science at risk and increases the pressure on ecosystems: short-term profit maximisation is, amongst others, driven by the duration of the patent and pressure on the companies to sell as many of their patented seeds as possible. This means that ecosystems may be impacted within a short period of time by an increasing number of organisms not derived from evolutionary processes and mechanisms. The pressure to generate profit may therefore also impact food safety.

Conclusion and recommendations

In conclusion, the EU Commission’s attempt to deregulate new GM techniques 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 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.

Signatories

EU-based organisations:

1. Agroecology in Action (Belgium)
2. Agrotrade Group Spol. S.R.O. (Slovakia)
3. Arbeitsgemeinschaft bäuerliche Landwirtschaft (AbL) e.V. (Germany)
4. ARCHE NOAH (Austria)
5. Association Demeter Czech & Slovakia
6. Association of Feed Producers, Warehouse-Keepers and Trade Companies (Slovakia)
7. Biodynamic Association Denmark
8. Biodynamic Federation Demeter International
9. Biogros s.àr.l (Luxembourg)
10. Centrum environmentálnych aktivít-CEA (Slovakia)
11. Compassion in World Farming EU
12. Confédération Paysanne
13. Corporate Europe Observatory
14. Demeter Associazione Italia (Italy)
15. Demeter Denmark
16. Demeter France
17. Druživa, o.z. (Slovakia)
18. Ekotrend Slovakia - Zväz ekologického poľnohospodárstva (Slovakia)
19. European Coordination Via Campesina
20. Foundation AgriNatura for Agricultural Biodiversity (Poland)
21. France Nature Environnement (France)
22. Friends of the Earth Europe
23. Fundacja Strefa Zieleni (Poland)
24. Gazdovský spolok Hont-Tekov (Slovakia)
25. Générations Futures (France)
26. Greenpeace
27. IFOAM
28. IG Saatgut (Germany, Austria, and Switzerland)
29. Instytut Spraw Obywatelskich/The Civil Affairs Institute (Poland)
30. Inter-Environnement Wallonie ASBL (Belgium)

31. Magház Association (Hungary)
32. Mouvement d'Action Paysanne (Belgium)
33. Natagora (Belgium)
34. Naturata s.àr.l (Luxembourg)
35. Nature & Progrès Belgique (Belgium)
36. NOAH Friends of the Earth Denmark
37. Občianska iniciatíva Slovensko bez GMO/Citizens' initiative Slovakia without GMO (Slovakia)
38. OGM dangers (France)
39. ÖMKi/Hungarian Research Institute of Organic Agriculture (Hungary)
40. OZ Vidiecky parlament na Slovensku (Slovakia)
41. Sciences Citoyennes (France)
42. Slow Food Europe
43. Social Ecological Institute (Poland)
44. SOSNA (Slovakia)
45. STRUK (škola permakultúry) (Slovakia)
46. Svenska Demeterförbundet (Sweden)
47. Umweltinstitut München e.V. (Germany)
48. UNAB - Union Nationale des Agrobiologistes Belges (Belgium)
49. Velt (Belgium)
50. Vereenegung fir Biolandwirtschaft Lëtzebuerg a.s.b.l. (Luxembourg)
51. Za Zemiata (FoE Bulgaria)

Non-EU-based organisations:

1. Beyond GM (UK)
2. Biologisk-dynamisk Forening (Biodynamic Association in Norway)
3. GM Freeze (UK)
4. GMWatch (UK and International)
5. Schweizer Allianz Gentechfrei (Switzerland)
6. Schweizerischer Demeter-Verband (Switzerland)

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