THE GREENS/EFA in the European Parliament

Genome editing in agriculture

A Greens/EFA perspective

Introduction

Biodiversity and ecosystems are under extreme threat, with around one million species facing extinction. To avert the worst consequences of runaway climate change, urgent action needs to be taken now.

In order to respond to these unprecedented and closely interlinked crises, our food and agricultural systems need to be rapidly transformed. High input, industrial farming based on monocultures and factory farming must be replaced by high biodiversity, locally adapted food production systems, ones which produce healthy food while respecting animal welfare and the environment.

Indeed, according to the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), 'feeding the world in a sustainable manner, especially in the context of climate change and population growth, entails food systems that ensure adaptive capacity, minimize environmental impacts, eliminate hunger, and contribute to human health and animal welfare'. Sustainable agricultural production options include agro-ecological practices and organic agriculture[1].

On the horizon, a new set of genetic engineering techniques, collectively known as 'genome editing', are being touted as part of the solution to the climate crisis. Despite the hype, however, these techniques are not compatible with agro-ecological and organic agriculture. Furthermore, since genome-edited crops and animals are being patented, small farmers and breeders will not be able to save and exchange their seeds, ruling out the possibility of them developing locally adapted crops and breeds. On the other hand, conventional breeding has already provided many useful traits, such as drought resistance and increased yield.

Patents on transgenic genetically modified crops have led to the monopolisation of the commercial seed sector by a handful of companies. Transgenic crops are, almost without exception, either herbicide tolerant or produce their own toxic insecticides, or both. Both traits have led to harmful impacts on biodiversity whilst posing risks to human health. With the seed giants profiting from the joint marketing of their patented herbicide tolerant GM seeds and the 'complementary' herbicides, this trend is likely to continue with genome editing. Indeed, the first commercially available genome-edited crop is herbicide tolerant.

[1] https://ipbes.net/sites/default/files/inline/files/ipbes_global_assessment_report_summary_for_policymakers.pdf

Genetically modifying farm animals can have serious consequences for animal welfare as well as aiding intensive agricultural systems in pushing animals even further beyond their physiological limits. It often involves cloning, which leads to birth defects, spontaneous abortions and early postnatal death. For this reason, a ban on both the cloning and genetic engineering of animals is needed.

A growing body of scientific research highlights the unintended off-target and on-target genetic changes brought about by genome editing, both in plants and animals. These changes may impact food safety as well as having environmental impacts. In order to protect human health and the environment, therefore, genome-edited crops and animals should be subject to stringent risk assessment. They should also be labelled and traceable throughout the food chain. Such requirements are already laid down in EU GMO legislation, applicable to genome-edited products as ruled by the European Court of Justice (ECJ) in 2018.

It is clear, as ruled by the ECJ, that these techniques create GMOs as defined in the GMO legislation. Any legislative proposals from the European Commission which attempt to differentiate between the products of genome editing and more established genetic engineering techniques should be opposed.

This paper outlines why trying to 'edit' the genome of crops and animals does not provide a meaningful solution to the climate and biodiversity crises and, therefore, why we are opposed to the use of GMOs for agricultural purposes. It also outlines why, in order to uphold the precautionary principle, as well as the ECJ ruling, swift and full implementation of EU GMO legislation in relation to genome-edited crops and animals is urgently needed. Whilst this paper focuses on the use of agricultural products for food and feed purposes, the Greens/EFA group remain cautious about the use of GMOs to produce medicinal proteins; even if they could be accepted in vitro, we cannot accept them when their medical or commercial use leads to field cultivation.

The dangers of gene drives, a particular application of CRISPR technology, is also examined. The paper concludes with a set of demands to the European Commission and Member States.

Part one: Implementation of EU GMO laws urgently needed

The Greens/EFA group calls for full and swift implementation of the EU legislation governing genetically modified organisms (GMOs). This legislation requires, among other things, a risk assessment to take place before genetically modified (GM) crops can be grown in, or imported for food and feed into, the EU. The law also requires that GM crops are labelled and can be traced through the food chain[2].

These obligations have been put in place to help ensure a high level of protection of human health and the environment. Currently, there are no GM animals commercially available in the EU, but the requirements for a risk assessment, traceability and labelling also apply to GM animals.

[2] This labelling requirement relates to GM food crops but not to eggs, dairy, meat and other products from animals fed GM feed, which is a loophole that needs closing

Gene editing techniques fall within the scope of the GMO Directive

Until now, EU GMO legislation has been mostly implemented in relation to the import and cultivation of transgenic GM food and feed crops[3]. Over the last decade, however, a new generation of genetic engineering technologies have been developed and are being applied in labs to food crops, trees, farm animals and insects[4]. They include so-called[5] genome editing techniques[6] such as CRISPR, which is comparatively cheap and versatile, and therefore the focus of a lot of research.

Genome editing techniques and other new genetic engineering techniques are often misleadingly referred to as New (Plant) Breeding Techniques (NBTs or NPBTs) although they have little in common with traditional breeding techniques.

In terms of food and feed crops, genome editing is being used to create plants with different traits. These include tolerance to herbicides (crops include oilseed rape, soybean, potatoes, rice, tobacco, cotton and cassava), including to glyphosate. Indeed, the first commercially available genome-edited crops, an oilseed rape grown in the US and Canada, is herbicide tolerant. Crops tolerant to more than one herbicide are also being developed.

Other traits being developed include increased tolerance to different viral, bacterial and fungal pathogens, plants with changed composition (e.g. reduced browning in mushrooms and more fragrant rice), and plants with enhanced fitness against environmental stressors. No genome-edited products have yet been commercialised in the EU.

Until recently there has been a fierce debate over whether the products of genome editing, such as CRISPR, result in GMOS and therefore fall within the scope of EU GMO legislation. This was finally settled by an important ruling of the European Court of Justice (ECJ), which in 2018 concluded that new mutagenesis techniques, which encompass genome editing, result in GMOs which fall within the scope of EU GMO law and should therefore not be exempt from its obligations. Whilst the ruling is not a ban (it simply means that genome-edited products are regulated and that any cultivation or import of food and feed must follow existing EU rules) the Greens/EFA group opposes the placing on the market of these GMOs, either under the 2001 GMO Directive or the 1997 novel food regulation.

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[3] Transgenic' means that foreign DNA, often genes from another unrelated species, have been inserted into the organism

[4] Unlike the previous techniques, genome editing is used as much on animals as plants. Whilst the focus of this paper is genome editing, other new genetic engineering techniques are increasingly being used, and many of the comments and conclusions in this paper also apply to them.

[5] The term genome editing gives the misleading impression that such interventions are no different from e.g. editing a text, in which an individual letter is deleted or replaced. However, genome editing is the genetic engineering of DNA of living organisms, which are subject to biochemical rules as well as interactions with the environment and epigenetic regulation factors, and is far more complex than the concept of 'editing' a piece of text.

[6] Genome editing is a type of genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism. Genome editing covers a wide range of techniques often used in combination, and classified into three types: SDN-1, SDN-2 and SDN-3. SDN-3 involves the insertion of new genes ('transgenesis'). In addition to CRISPR/Cas, genome editing techniques include zinc finger nucleases (ZN), TALENS, meganucleases and oligonucleotide-directed mutagenesis (ODM).

According to the ECJ, the main premise for exempting a genetic engineering technique from the requirements under EU GMO legislation is that, prior to 2001, it has been conventionally used in a number of applications and has a long safety record. Since this is not the case for genome editing techniques, including CRISPR, they are therefore subject to the legal requirements which include risk assessment, labelling and traceability.

Older techniques exempt from the scope of the law

Contrary to genome editing techniques, most organisms derived from a technique called random in vivo mutagenesis are considered to be exempt, since this technique has already been used in a large number of applications. Indeed, the EU's Scientific Advice Mechanism estimates that more than 3,200 different commercially available crop varieties have been developed worldwide using random in vivo mutagenesis, with examples including common rice and banana varieties, which are cultivated and consumed in large quantities[7]. The decision to exempt this technique was made on the basis that it had already been used in such a wide range of crops.

Risk assessment

Proponents claim that the products of genome editing could arise in nature without human intervention or through the use of more established techniques. However, in the case of in vivo random mutagenesis, as with spontaneous mutations that occur in nature, some regions in the genome undergo changes less frequently than others because they are particularly protected by repair mechanisms in the cell. CRISPR applications, on the other hand, which involves direct intervention at the molecular level, can bypass these naturally occurring processes, resulting in organisms with new genetic combinations that would not occur naturally.

Furthermore, a growing body of research shows that genome editing results in both off-target and on-target unintended changes to the genome. Whilst some of these changes may be subtle and not easy to detect, they could impact the nutritional quality or even be associated with allergenic or toxic effects in genome edited crops, with potential implications for food safety and biodiversity. These unintended changes can occur whether or not genes encoding a novel trait (e.g. herbicide tolerance), are inserted. This is an important point, since some stakeholders insist that regulation is only needed in cases where genes are inserted.

The effects of SDN-1 and SDN-2 gene editing (both intended and unintended) may be multiplied since genome editing techniques are being developed to be used simultaneously and/or sequentially. Therefore, even in cases where each single intended change is small, the totality of changes applied could produce a plant or animal that is substantially genetically different from the original. It is also important to remember that even small 'edits' can have wide-ranging consequences with single 'point mutations' knocking out or modifying gene functions, resulting is missing or malformed proteins. Furthermore, many processes to develop genome-edited plants typically involve a combination of techniques, including, in many cases, the insertion of transgenic genes (SDN-3).

[7] EU's Scientific Advice Mechanism 'New techniques in Agricultural Biotechnology' (2017), p33
https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf

In terms of risks to the environment of genome-edited crops, these will depend on the technique used as well as the intended trait. For example, the use of herbicide-tolerant transgenic crops have led to an increase in the use of the herbicides, especially glyphosate, with negative impacts on different plant and insect species, as well as aquatic organisms and the composition of soil bacteria. Herbicide tolerant genome-edited crops will inevitably pose the same risks.

Other changes due to the genetic modification, such as a change in flowering time, may impact pollinators, whilst genome-edited crops which have been developed to produce toxic compounds will also affect biodiversity.

Further, in regard to environmental risk assessment, there are several risk scenarios that need to be considered including: changes in the composition of plants that may impact the food web; changes in the composition of plants that may impact plant communication and interaction with the environment, and changes in the biological characteristics of the plants that concern their invasiveness. As with transgenic crops, cross-contamination with wild relatives or neighbouring non-gene edited crops is very likely and next generation effects can occur if those plants have the potential to persist and propagate in the environment.

Risk assessment of genome-edited crops should thoroughly investigate whether the techniques(s) used can lead to unintended genetic or epigenetic changes and any associated adverse effects on human and animal health as well as the environment. To decide whether an organism is safe, a detailed examination of an organism's genetic and overall biological characteristics is needed, starting with the process that was used to generate the organism. It should also address whether the intended trait, such as herbicide tolerance or changes in plant composition, might result in adverse effects.
When it comes to on and off target unintended changes, there are currently many more papers being published in the medical research field, whilst plant research predominantly focuses on product development. This knowledge gap in relation to plants further underlines the need for strict oversight and regulation of genome editing in crops, as well as in animals.

The Precautionary Principle and genome-edited foods

The Precautionary Principle, enshrined in the Treaty on the Functioning of the EU as well as underpinning the GMO legislation, lawfully justifies decision makers taking precautionary measures in order to avoid harm to human health, the environment or biodiversity, where scientific certainty is lacking. The ECJ found, in its 2018 ruling, that to exempt techniques resulting in GMOs which don't have a long safety record, such as genome editing techniques, from the scope of GMO law would be a failure to respect the Precautionary Principle.

Case studies in the Late Lessons project by the European Environment Agency illustrated, in relation to ignoring the risks associated with new technologies, just how damaging and costly to human health and the environment neglect of the Precautionary Principle can be.

Not subjecting these products to a thorough risk assessment in line with GMO legislation would be contrary not just to the Precautionary Principle, but also to the oath of 'do no harm' as outlined in the European Commission's European Green Deal and endorsed by the European Parliament.

Unfortunately, many scientific studies on which EU GMO risk assessments are based are either directly or indirectly led or financed by the applicants themselves, who generally belong to the agro-industrial sector. Therefore, due to the lack of comprehensive knowledge on the risks of genome editing, and a growing body of scientific evidence that shows that these techniques can result in many unintended genetic effects, it is clear that genome-edited crops and animals should be banned from the EU market, in order to uphold the precautionary principle.

Labelling

The labelling of GM food is essential to help protect the rights of consumers so that they can choose and know what they are eating. Farmers also have the right to know how the seeds they are growing have been created.

Without the labelling of genome-edited seeds, measures taken to segregate GM crops from non-GM crops[8], as required under EU GM law, will not take place, risking cross-pollination of non genome-edited crops. Furthermore, farmers and breeders might use the seeds without knowing that they are products of genome editing. This could have devastating impacts on farming systems which are not compatible with genetic engineering techniques, such GMO free farming including the organic sector.

The European Green Deal endeavours to provide consumers with better information about their food - this can only be achieved by making sure that genome edited foods are clearly labelled, in compliance with the law.

Traceability

Traceability guarantees that if there is a problem identified with the genetic engineering technique and product in question, then it can be traced and recalled. At the moment, EU-wide protocols on traceability and detection methods for genome-edited products have not been developed, yet this is crucial to ensure that the law can be fully implemented, especially to check imports for potential non-authorized new GMOs.

Legally, the responsibility for providing detection methods lies with the company wanting to market their gene-edited product. However, the validation of detection methods is done by the EU Reference Laboratory for GM Food and Feed (EURL-GMFF), assisted by the European Network of GMO Laboratories (ENGL). In a 2019 report they state that several aspects concerning detection, identification and quantification of genome-edited products remain unresolved and require further consideration.

Thankfully, the development and adaptation of new protocols and techniques is likely to facilitate better, cheaper and more reliable detection of small changes in genome-edited organisms. Another approach is to look for patterns of genetic change within the genome, a trademark sign of most genome editing techniques, rather than specific DNA sequences. Whatever the methods used, there is an urgent need to develop such detection capacities and to put in place systems, more broadly, which make easy and unambiguous traceability of genome-edited products possible. Above all, this requires political will and the allocation of sufficient resources.

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[8] Measures taken to do this vary between Member States, but typically involves the setting up of minimum distances between GM crops and non-GM crops. Only one GM crop has to date been authorised for cultivation in the EU: a transgenic maize cultivated in Spain.

Commission and Member States must implement the law

Despite the ECJ ruling being immediately binding on the Commission and Member States, they have so far failed to give themselves the means to implement it, leading to the possibility that food and feed crops produced using genome editing are being imported, for example from the USA and Canada, without any EU pre-marketing assessment or authorisation. Since these crops have not undergone a safety assessment carried out by the European Food Safety Authority, their import into the EU would be illegal, and carries potential risks to consumers who could be consuming them unknowingly.

Part Two: Gene Drives = using genome editing techniques to modify or eradicate entire species

One particular application of CRISPR is gene drive technology, which is designed to genetically modify, replace or eradicate populations or entire species in the wild. Gene drive organisms (GDOs) are intended to mate with their wild relatives and spread their engineered genes to all of their offspring. This forced inheritance pattern circumvents normal rules of inheritance and triggers a genetic chain reaction in which the CRISPR/Cas9 component and sometimes an additional new gene are passed from generation to generation.

Genetic changes induced by a gene drive can lead to sterility or the change of sex ratio of descendants, leading to a crash in populations. Species considered potential targets include insects, small mammals, fish, birds, plants, molluscs, nematodes, flatworms and fungi, including yeasts, and in many cases laboratory work on constructing gene drives in these organisms is already under way.

Unlike other genetic engineering technologies used to date, GDOs are designed to spread through ecosystems. Once released, GDOs could spread uncontrollably and irreversibly over time and distance and there are currently no means of recalling GDOs or reversing their effects in nature. For this reason, the release of GDOs poses severe threats of harm to biodiversity and the web of life with a high level of uncertainty regarding undesired side effects that could potentially affect the functioning of entire ecosystems, impacting human health and food security. Gene drive technology is, effectively, genetic engineering at ecosystem scale, with long-term effects across many different life forms.

Genetically engineered GDO applications are being developed in four main areas: medical (e.g. the elimination of infectious diseases such as malaria via the modification/elimination of mosquitos), agriculture, conservation and military applications. Many insects are the subject of gene drive research with the aim of eliminating or modifying their populations, either in agricultural crops or for the purpose of eliminating infectious disease such as malaria. However, as with other uses of GDOs, the impacts on the wider ecosystem are not thoroughly understood, the data are insufficient and the complexities too intricate to currently, if ever, allow for clear and reliable predictions of the outcomes and the impacts of their release.

Whilst one of the intended applications of genetically engineered GDOs is to eliminate invasive species in a bid to protect biodiversity, a group of leading conservationists argue that the ‘powerful and potentially dangerous technology such as gene drives, which has not been tested for unintended consequences nor fully evaluated for its ethical and social impacts, should not be promoted as a conservation tool'. Gene Drive technology is also dual-use, meaning it is being developed for military purposes - research for 'civilian' purposes cannot be separated from military uses.

There is currently no sufficiently robust methodology available for conducting an environment risk assessment of genetically engineered GDOs, and it is questionable whether realistic risk assessment will ever be possible, given the unprecedented, unpredictable and potential catastrophic impacts of GDOs on biodiversity. The development of gene drive applications and the release of GDOs into nature are not compatible with the Precautionary Principle.

We join the international call for a moratorium on gene-drives[9] and see any new scientific research into this field as a waste of time and money.

Part Three: Genome editing does not belong in a truly sustainable and socially just food system

The Greens/EFA group's vision for a food and agricultural system is one which supports the transition towards a social and agro-ecological model: one which delivers sufficient amounts of healthy, nutritious, quality food to all, respects social and labour rights of agricultural workers and migrants, ensures a fair income for farmers and supports micro, small and medium sized farms, while maintaining long term fertility, productivity and efficient resource use.

We aim to restore agriculture and rural economies as an attractive prospect for farmers and rural businesses in all areas, not just the most geographically favoured regions, and to develop a food policy which delivers public goods including local jobs and vibrant economies, on-farm biological diversity, animal welfare, clean air and water and healthy, living soils. Seed freedom, based on farm-saved seed systems and seed exchanges that ensure genetically diverse and locally adapted crops that can rapidly evolve to help meet the challenges of biodiversity loss and climate change, is an essential component of this vision.

Such an approach, which recognises the links and interconnections across the food chain, is urgently needed if we are to address the deepening biodiversity and climate challenges that we face. Shorter food chains and sovereignty of our food systems are also needed if we are to remain resilient in the face of pandemics, which, as we are currently witness to, have the power to disrupt food supply chains across the globe including by closing borders.

Genome-edited crops and farm animals cannot help achieve the urgently needed transition to this food system for two main reasons.

Firstly, the patent regime under which genome-edited crops and animals will be commercialised, as with transgenic GM crops, will only serve to further entrench the current highly concentrated nature of the seed market in the hands of ever fewer companies.

Secondly, genetically tweaking a plant or animal in order to a develop a desired trait, however seemingly sophisticated, cannot address the underlying problem – our highly

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[9] See https://www.etcgroup.org/sites/www.etcgroup.org/files/files/forcing_the_farm_sign_on_letter_english_web.pdf

industrialised, wasteful and polluting agricultural model, which requires systemic transformation.

3a: Gene editing and patents

The intended aim of the patent system, originally developed for chemical and industrial products, is to enable innovation and make sure that research costs can be recuperated by innovators. Once a patent is granted, an invention is protected and in exchange, there is an obligation to disseminate the invention and the patented processes. Patent holders charge money for the use of their product.

The seeds, plants and even parts of genetically engineered crops can be patented, often leading to higher prices for farmers. Patents also limit possibilities for further breeding and seed reproduction and particularly disadvantage small-scale seed breeding businesses and farmers, who are those most able to provide biodiverse and climate-adapted agriculture with local traits.

Farmers and breeders can also be taken to court for infringement of patents, even where this was completely unintentional. In the US, for example, where transgenic GM crops are widely grown, many farmers have been sued for unknowingly infringing patent rights. In developing countries, in particular, patents also restrict experimentation by individual farmers while undermining local practices that enhance food security and economic sustainability.

The EU Directive on Biotechnology as well as the European Patent Convention, an international treaty of which all EU Member States are members and which forms the basis for European patent law, exclude, at least in theory, conventionally bred plants and animals from patentability. On the other hand, products of genome-editing can be, and are already being, patented.

Patent applications to the World Intellectual Property Organization (WIPO) for genome-edited plants and animals were analysed in a 2016 report. It found that, between 2010 and the end of 2015, 35 patents on genome-edited plants were registered by big seed companies and some of their cooperation partners. Patents applications covering genome-edited animals included the use of genome editing techniques to increase muscles in cows and pigs, to create hornless cows, to block genes for production of sperm cells and to create animals with multiple genetic changes.

According to the report, we should expect, in relation to genome editing technologies, 'a continuum of the development that started with the first introduction of genetic engineering in the breeding sector. For the foreseeable future, IP (Intellectual Property)-strategies will continue to drive market concentration, the acquisition of smaller companies and the increasingly predominant position of the so-called seed giants.' In 2018, just a handful of companies owned over half of the commercial global seed market.

In summary, patents in the area of food, seeds and agriculture are paving the way for privatisation of life and the monopolisation of nature by a handful of global companies, to the detriment of breeders and farmers, including peasants and those working on a small scale. The introduction of patented genome-edited plants and animals into agriculture will foster further market concentration in plant and animal production and this change could be particularly dramatic for the EU, where until now, only one (transgenic) GM crop is authorised for cultivation and no genetically engineered animals are authorised.

Patenting is also relevant in regard to wild genetic resources. An international legally binding instrument is currently being negotiated under the UN Convention on the Law of Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. The wording of the current draft document foresees that marine genetic resources “shall not be subject to patents except where such resources are modified by human intervention resulting in a product capable of industrial application”. This and other related parts are still under discussion, but show the importance of the topic at an international level.

3b: Systemic transformation of our food systems needed

Claims that we need genome-edited crops to help tackle climate change ignore that, to deal with the climate and biodiversity crises together, simply creating more varieties to continue to grow in mono-cultures or further intensifying animal husbandry is not the answer. Claims that they are needed to help feed the world ring hollow - we know that food production today is sufficient to satisfy global needs but that around a third of it is lost or wasted along the food chain. The fact that conventional breeding has already delivered traits such as drought resistance and higher yields is conveniently overlooked.
In order to tackle the ecological crises that we face, that of climate change and biodiversity collapse, we need to radically transform our agricultural system in a way that contributes to solving both at the same time. This means much less meat and dairy farming, wasting a lot less food, shorter supply chains, and many more smaller farms based on agro-ecological and organic principles. We need to reverse the general trend of the growing industrialisation of farming systems and bring them back to working more closely with nature.

Genome-edited crops and animals designed to treat symptoms of intensive agriculture

Instead of tackling the root problems, genetic engineering risks only treating the symptoms caused by intensive agricultural practices and promoting further intensification.
One example is research on genome editing cattle so that microorganisms in their gut produce less methane, a greenhouse gas, thereby attempting to reduce the contribution that cattle farming makes to climate change. Other examples include developing crops with traits such as pest resistance and increased yield.
Yet, all of these ‘solutions’ are being proposed in the context of industrialised agriculture. Rather than investing know how and valuable resources into the current predominant approach, we need to focus on overhauling our farming systems all together by investing more research into, for example, how agro-ecological approaches can be optimised including through participatory breeding programmes.

Reducing methane emissions via genetic engineering of cows might sound promising, but tinkering with the intestinal flora of cattle may have a major impact on their general health and well-being and increase susceptibility to disease. Furthermore, methane is only one of several greenhouse gases emitted by agriculture - feeding cows on an industrial scale also requires the production of concentrated feed, of which the EU imports vast quantities and which, in the case of GM soy, contributes to deforestation in countries such as Brazil. Deforestation is a major driver of biodiversity loss and emissions from land-use and land-use change, mostly due to deforestation, are the second biggest cause of climate change after burning fossil fuels.

In fact, the European Union is the world's second largest importer of soya, the majority of which is imported for animal feed and analysis by the Commission itself has found that soya has historically been the Union's number one contributor to global deforestation and related emissions, accounting for nearly half of the deforestation embodied in all Union imports.

Biological and genetic simplification resulting from our current farming practices destroy the balance between pests and their natural enemies, e.g. through the use of pesticides and because of habitat loss, making crops more vulnerable to pests. More diverse farming systems based on agro-ecology provide a natural defence against pests (along with other benefits), representing a more efficient and holistic alternative to, for example, crops which have been genetically engineered to produce toxic insecticides.

Genome editing of animals further entrenches intensive farming

Until now, farm animals have so far not been widely genetically engineered, but genome editing makes this easier, meaning that many more patent applications will be filed for genome-edited animals. The introduction of patented animals will lead to major changes in the animal breeding sector and traditional breeders and farmers in areas such as the production of cattle and dairy may be particularly impacted.

Examples of genome-edited animals under development include pigs resistant to respiratory disease, cattle without horns and ultra-muscular pigs and cows. Genetically modifying farm animals can have serious consequences for animal welfare as well as aiding intensive agricultural systems in pushing animals even further beyond their physiological limits. Genetic engineering of animals often involves cloning, which leads to birth defects, spontaneous abortions and early postnatal death.

The engineering of animals therefore disregards animal welfare by contributing to an agricultural model of factory farming. It is also incompatible with tackling climate change nor with helping to prevent the emergence of new infectious zoonotic diseases in the future, the origins of which have been linked to intensive farming.

In many cases, genome editing purports to solve something that can be done in a simpler, low-tech way. For example, the use of genome editing to develop disease resistance in farm animals, thereby reducing antibiotic use, is under development. However, dangerously high antibiotic use would be much better addressed by moving away from intensive farming, resulting in healthier animals with strengthened immune systems which are less vulnerable to disease in the first place.

In addition to the animal welfare and ethical questions surrounding the development and use of genome-edited farm animals, they may pose risks to human health as well. This was highlighted by the case of genome-edited hornless cattle which contained unintended DNA inserts, including an antibiotic resistant gene. This was due to an unintended effect of the genome editing process that was only picked up by research conducted by a US regulatory agency, despite claims by the developer that their product was safe. Unexpected effects in genome-edited animals also include the production of abnormal proteins, potentially affecting food safety.

Climate friendly agriculture needs local seed saving and exchange

For farmer and breeders to be able to adapt crops and farm animals to a changing climate, they need to be able to save and exchange seeds and breeds which are best suited to their local climatic and agronomic conditions. Genome-edited plants and animals preclude this possibility because they are patented.

Conventional breeding has already achieved many beneficial traits including drought resistance for many crops, but they are not promoted as they do not lead to patents to the same extent and the subsequent huge profits for multinationals. They are also usually developed for local use, which may reduce their marketability but makes sense in terms of climate adaptation. Furthermore, complex traits such as drought tolerance, which involves the interaction of many different genes as well as epigenetic factors, can more easily be achieved with conventional breeding techniques.

Indeed, transgenic GM crops have not achieved complex traits such as drought resistance or increased yield, despite decades of promises. Instead, the major seed companies chose to focus on producing herbicide tolerant (HT) crops and insecticide producing crops ('Bt' crops) in a handful of crop varieties.

The problem with transgenic GM crops and why we cannot expect a paradigm shift

Out of the 39 GM crops that the European Commission has authorised for import since December 2015, 38 are either HT crops or Bt crops, or both. The intended trait of the remaining one, Maize MON 87403, produced by Monsanto, is increased biomass and yield. However, in its risk assessment, the European Food Safety Authority itself 'acknowledges that the change due to the intended trait is known to be of limited amplitude'.

Both HT and Bt transgenic crops have had negative impacts on biodiversity, through the increased use of herbicides (especially where crops have been made resistant to multiple herbicides) and through the ingestion of the toxic Bt insecticide by non-target organisms. Impacts on biodiversity and risks to human health from these GM crops are among the reasons why the Greens/EFA Group remain at the forefront of opposing their cultivation and import in the EU.

Experience from transgenic GM crops shows that in a scenario dominated by patents, small and medium sized breeders cannot survive in the long term and the larger seed giants will continue to dominate the market. Since developments in the application of genome editing in plants and animals used for food production will similarly be driven by patents, it is likely that research and development will be dictated by the priorities and business models of the dominant companies and that herbicide resistant genome-edited crops will continue to be an important objective for future commercial plant development.

Viewing biotechnologies through a care ethics lens

Although scientific studies highlight the need for rigorous risk assessment, decision making on genome editing and other genetic engineering techniques should not only boil down to the risks to human health and the environment, but should also take into account and genuinely assess broader considerations.

Claims that genome-edited crops and animals will help solve the climate crises should be rigorously assessed, also in relation to their impact on biodiversity. As with any other proposed tech-based solution to climate change, these products should be evaluated against other possible solutions, such as greater investment in agro-ecology and other sustainable systemic approaches.

Further considerations should include, but are not limited to, impacts on agricultural practices including the organic sector; the risk of increased concentration in the breeding sector; access to seeds for farmers; capacity to contribute to food sovereignty; what kind of innovation strategy we want to promote (top-down versus bottom up); the rights of consumers, breeders and farmers to make informed choices and the need for a broad societal and ethical debate on these technologies, including through a care ethics lens.

'Our ability to make ever greater changes to the genetic make-up of living organisms should not blind us to the reality: our incomplete knowledge of these organisms and their interactions and the dangers involved in trying to adjust nature to our needs and 'improve' it by engineering it'[10] .

Just as transgenic GMOs have not provided a panacea for the climate and biodiversity crises we face, but in effect take us further in the wrong direction, it is difficult to see how genome-edited plants and animals will help either. The development of genome-edited crops and animals raises many questions which cannot simply be brushed under the carpet.

Unfortunately, whilst many of these questions remain largely undiscussed and unscrutinised, genome editing and other new genetic engineering techniques are diverting a significant amount of scarce research and development resources, as well as political will and attention, from truly sustainable food systems, which we need now more than ever.

The Greens/EFA group in the European Parliament:

- Reiterates our strong opposition to the use of GMOs in agriculture, be it in crops or animals

- Insists that the Precautionary Principle, as enshrined in the Treaty on the Functioning of the EU as well as underpinning EU GMO legislation, must be fully respected and upheld

- Warmly welcomes the 2018 ECJ ruling which found that genome editing techniques, such as CRISPR, result in GMOS which fall within the scope of EU GMO law. All such techniques are therefore subject to the legal requirements which include risk assessment, labelling and traceability

- Calls for full and swift implementation of EU GMO law, as required by the ECJ ruling

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[10] Taken from ''New Breeding Techniques' and synthetic biology - genetic engineering by another name', Helena Paul, Elizabeth Bücking and Ricarda A. Steinbrecher, April 2017, The Ecologist https://theecologist.org/2017/apr/04/new-breeding-techniques-and-synthetic-biology-genetic-engineering-another-name

- Insists that existing national bans on the cultivation of GMOs should be implicitly extended to genome-edited products without requiring the adoption of new legislation

- Insists on the need for stringent risk assessment of genome-edited products to be undertaken on a case-by–case basis, covering the technique used as well as the final product

- Calls on the European Commission to urgently coordinate and lead national governments as well as the EURL-GMFF/ENGL[11] in developing protocols to trace and detect genome-edited products, in order to help detect illegal imports that may already be on consumers' plates and to ensure that traceability and labelling is possible

- Calls for initial efforts to be focused on detecting, and stopping, the import of known commercially grown genome-edited crops, including through the reinforcement of border checks and controls where necessary

- Calls on national governments to ensure that any outdoor field trials of genome-edited crops adhere to EU and national GM legislation. Any field trials that have not been approved under the GMO legislation are illegal and must be stopped immediately

- Calls on the Commission to launch infringement proceedings against Member States who conduct field trials of genome-edited crops which do not comply with the law

- Calls on the European Commission not to propose changes to the EU GMO or seed laws which could result in a weakening of requirements for genome editing techniques or other new genetic engineering techniques

- Calls on the Commission to take measures to prevent any releases of genome-edited or other genetically engineered organisms, including gene drives, if their spatio-temporal spread cannot be controlled

- Are opposed to the use of crops to produce genetically engineered medicinal proteins, due to the risk of cross-pollination of neighbouring non-GM crops

- Calls on the Commission and Member States to provide sufficient funding for independent research into health and environmental risks of genome-edited crops and animals and to develop strong incentives for research driven by protection goals, rather than by the interests of developing, applying or profiting from the use of genetically engineered organisms

- Considers it essential that genetically modified crops are clearly labelled, in order to ensure traceability throughout the food chain and transparency for consumers

[11] EU Reference Laboratory for GM Food and Feed/European Network of GMO Laboratories

- Notes that, at present, animal products (e.g. eggs, milk and meat) from animals fed GM feed are not required to be labelled. Neither are food or feed additives, including those created with the use of GM microorganisms, such as GM yeasts

- Calls for these labelling loopholes to be closed, possibly through an amendment revision of the Food Information to Consumers Regulation.

Genetically Engineered Gene Drives Organisms (GDOs)

- Calls on the Commission to clarify that no releases of genetically engineered GDOs are permitted in the EU, in line with the precautionary principle, since there are no sufficiently effectively methods to retrieve them from the environment once released

- Emphasises that research into and development of gene drive organisms brings with it the high risk of accidental release of gene drives into the environment with potentially devastating effects on ecosystems and the conservation of species; Notes with great concern that gene drive technologies have the potential to be used for military and hostile purposes;

- Calls on the Commission and the Member States to advocate at the UN Convention on Biological Diversity COP15 for a global moratorium on gene drive research linked to the development of applications and on releases of gene drive organisms into nature, including field trials, in order to prevent these new technologies from being released and to uphold the precautionary principle which is enshrined in the Treaty on the Functioning of the European Union as well as the CBD

- Calls on the Commission and the Member States to call for the COP15 to adopt provisions on horizon scanning, technology assessment and the monitoring of new technological developments, including those emerging from synthetic biology

- Calls on the Commission and the Member States to push for the COP15 to ensure that free, prior and informed consent of indigenous peoples and local communities is sought and obtained prior to the release of any technologies which may impact on their traditional knowledge, innovation, practices, livelihoods and use of land, resources and water; stresses that this must be done in a participatory manner involving all potentially affected communities prior to any deployment

- Calls on the Commission and the Member States to call for the post-2020 Global Biodiversity Framework to enshrine, as key pillars, the precautionary principle, a rights-based approach and horizon scanning, technology assessment and monitoring with regard to the adoption of new technologies

Investing in sustainable farming systems

- Calls for the strengthening of biodiversity protection in order to legally safeguard it as a protected common good for the future

- Insists that all public funds for agriculture, at EU and Member State level, serve the overall goal of transitioning towards sustainable and ecological agricultural systems that support animal welfare and the preservation and restoration of biodiversity and public health

- In that regard, insists that no EU funding is used for the development of genome editing applications in agriculture

- Calls for the Common Agricultural Policy and Farm to Fork Strategy to support greater investment in the use of GMO-free methods for the breeding of robust, resistant species for conventional and ecological agriculture

- Opposes the cultivation of all crops which have been made herbicide tolerant or which produce their own pesticides, regardless of whether they have been genetically modified or developed using conventional breeding techniques

- Following a recent French Court ruling, calls on the Commission to subject to risk assessment all crops that have either been made herbicide tolerant or that produce their own pesticides, either for import or cultivation in the EU, no matter which technique was used to produce them, due to the negative biodiversity and health impacts

- Recognises the devastating environmental impacts of imported GM soya for animal feed; Calls for a reduction of the number of animals farmed in the EU in order to reflect the natural resource boundaries of the EU

- Calls on the Commission to swiftly move forward with a European vegetable protein production and supply strategy which would enable the Union to become less dependent on GM feed imports, and to create shorter food chains and regional markets

- Calls on the EU and Member States to prevent imports of genome-edited organisms, be they plants or animals, thereby helping bring to an end the current EU practice of driving harmful agricultural practices in other parts of the world

- Calls on the Commission and Member States to work to prevent the development and release of genome edited crops and animals, both in the EU and elsewhere, thereby leading global efforts for the genuine protection of nature and climate

- Calls for research on seed breeding to be more participative and to include farmers from the start

- Calls for increased funding for the agricultural European Innovation Partnership (EIP AGRI), which aims to foster sustainable farming

- Calls for the abolition of all patents on crops, plants, fungi and animals

- Oppose any changes to other models of Intellectual Property Rights on plants and animals which are detrimental to farmers and consumers
- Calls on the Commission to ensure that public funding or patent regimes do not trigger financial incentives that could be detrimental to animal welfare

- Calls for an ban on the genetic engineering of animals and for a ban on the import into the EU of genetically engineered animals and all related products

- Calls for an ban on the cloning of animals and for a ban on the import into the EU of cloned animals and all related products

EU GMO decision making process

- Calls on the Commission to close gaps in the current implementation of risk assessment as performed by the European Food Safety Authority (EFSA)[12]

- Calls on the Commission to refrain from simply rubberstamping EFSA's GMO risk assessments and to consider 'relevant provisions of Union law and other legitimate factors', as required by the law, such as the health and environmental impacts of cultivation outside the EU

- In that regard, calls on the Commission to take into account the EU's commitments to halt and reverse global biodiversity loss under the UN's Sustainable Development Goals, as well as the commitment of keeping global warming to below 1.5C when making its decision on whether to authorise GMOs, or not

- Calls on the Commission to no longer authorise GM crops that are either herbicide tolerant or which produce their own pesticides, either for import or cultivation in the EU, due to biodiversity damage and health risks

- Calls on the Commission to no longer authorise GMOs which do not have a qualified majority of Member States in favour and/or where the European Parliament has voiced its opposition[13]

- Calls on the Commission to make the voting position of each Member State in the GMO authorisation process public

[12] For examples of gaps in the risk assessment and how they could be addressed, see the international research project 'Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland' https://www.testbiotech.org/sites/default/files/RAGES_%20Factsheet_Overview_0.pdf

[13] The Commission has authorised around 40 different GMOS for import as food and feed into the Union since December 2015. The plenary of the European Parliament adopted resolutions opposing the authorisation of all of these GMOS, whilst there has never been a qualified majority of Member States in favour of authorisation. The Commission itself has acknowledged the lack of democratic legitimacy of its decisions.

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