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11.02.20

Betting on the wrong horse –

why new Genetic Modification Techniques are not suited to overcome hunger and tackle the environmental and social challenges of our times

Arguments in favour of a strict regulation of new GMOs

There is a heated public debate ongoing and millions of dollars are being spent on lobbying for the promotion of the new genetic modification techniques. It is in these very months that the course is set for the future of our all food safety, biodiversity, consumer rights and power distribution.
Will we invest in sustainable systems that work WITH nature or will we rely on technical fixes that bring a lot of money to the few and endanger biodiversity?

Agrichemical corporations like Dow (Corteva), Bayer and Syngenta are heavily lobbying the European Commission to exclude genetically modified organisms (GMOs) derived from the new techniques, like CRISPR-Cas, from EU GMO regulations. They argue that these techniques are no genetic engineering, which is clearly wrong from a technical point of view, as underpinned also by the European Court of Justice (CJEU) in its judgment of 2018.

Exempting the new techniques from GMO regulations would mean that EU requirements for risk assessment, traceability and labelling no longer apply to them. However, more and more uncertainties in regards to the impacts of these new GMOs have been documented by biotechnologists in recent years; therefore it is also advocated by experts that new GMOs need to be subject to risk assessment. Moreover, many consumers, breeders and farmers want to be able to avoid GMOs, so these new GMOs need to be traceable and labelled.

This briefing introduces the new genetic modification techniques, outlines why we question the promotion and application of these new techniques and reasons that as a very minimum a continued proper regulation of these techniques must be secured to guarantee their risk assessment, traceability, labelling and safety monitoring.

1. New Genetic Modification Techniques - what for:

To SUPPOSEDLY adjust plants and animals to one's needs
The objective of genetic modifications is to modify an organism, by it a plant, animal or bacteria. In this briefing, we will focus on genetic modifications of plants.

The **first generation of genetic modifications -** *here called 'old GMOs', their proponents like to speak of 'classical GMOs'* - the predecessors of 'new GMOs' which are the focus of this briefing - was characterised by a modification of a genome by transferring a gene from one species into the genome of another species. This procedure is known as transgenesis, the resulting species as 'transgenic'.

Almost all GMOs that have been produced by transgenesis and are authorised for use in the EU have

been modified to be either herbicide tolerant or to produce insecticides (Bt toxins), or both[1]. Currently, there are only two EU countries[2] that grow genetically modified maize.

The **new generation of GMOs** has been developed over the last decade and works by modifying the genome by adding or removing genes in a targeted manner. In this briefing they are referred to as **New Genetic Modification Techniques** (NGMTs)[3]. Their proponents prefer the term '*new breeding techniques*' or '*novel genomic techniques*', attempting to dissociate their resulting products from genetic modifications. The most prominent example of new genetic modification techniques are genome editing techniques[4] as CRISPR-Cas.
The first plant that has been modified with the new genetic engineering techniques and which is already in cultivation is a herbicide-tolerant oilseed rape. In the pipelines of companies are among others:

- a soybean with a modified fatty acid composition
- a potato with improved storage capacity at cool temperatures
- the so-called waxy maize with a modified starch composition
- a flax which is herbicide-tolerant[5]

Proponents of the new genetic engineering claim that the new methods are safe and very precise, which is not correct. The consequences of the DNA changes are completely unclear. Whether the modified organism reacts and develops in the same way as a natural organism, whether it has unwanted side effects or develops differently, is not yet known and more and more uncertainties of the impact of these new GMOs have been documented by biotechnologists in recent years.

2. New Genetic Modification Techniques: Regulatory context

The EU legal framework on Genetically Modified Organisms ('GMOs') aims to, inter alia[6]:

- **protect human and animal health and the environment** by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market;
- ensure **clear labelling** of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice; and
- ensure the **traceability** of GMOs placed on the market.

Genetic modifications are **regulated** by five main pieces of legislation in Europe[7]:

- **Directive 2001/18 on the deliberate release into the environment of genetically modified organisms** (central and most important legal act)
- Regulation 1829/2003 on genetically modified food and feed
- Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

[1] See here for an overview of the traits of 36 GMOs that have been objected to by the European Parliament in its 8th term (all of them except the three authorisations for cultivation have been subsequently authorised by the Commission): https://www.greens-efa.eu/files/doc/docs/e491b1b487e5c6b48f553e1ef027bccf.pdf
[2] Spain and Portugal
[3] Proponents of new genetic modification techniques prefer to frame the techniques as "new breeding techniques" respectively "novel breeding techniques" ore "gene editing"; supposedly to create an artificial distinction between this generation of GMOs and the previous generation of GMOs (‚old GMOs')
[4] New genetic techniques include zinc finger nucleases (ZFN), TALENS, CRISPR/Cas, meganucleases and oligonucleotide-directed mutagenesis (ODM)
[5] as in 13
[6] https://ec.europa.eu/food/plant/gmo/legislation_en
[7] https://ec.europa.eu/food/plant/gmo/legislation_en

- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
- Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs

It is these strict legal requirements that have led developers of new genetic modification techniques[8] to argue, in a push for de-regulation, that these techniques were not GMOs and therefore would not need to be covered by existing GMO Law.
The European Court of Justice has ruled otherwise in July 2018: It made clear, that the legislation covers all technical changes in DNA, even if no foreign DNA is being introduced.

In the EU, old genetic engineering has remained a supply without demand, failing due to the resistance of civil society and the rejection of farmers and consumers. For its protagonists from research, business and politics this is a story of defeat. A history that they do not want to repeat with new genetic engineering. Hence the concealment of genetic engineering with the word 'genome editing', hence the constant presence of terms like 'precise', 'safe', 'natural', 'undetectable'.
Following the ruling of the European Court of Justice, classifying the new genetic engineering processes as genetic engineering, the proponents of new GMOs are increasingly pursuing one goal: the current EU genetic engineering law is to be undermined - instead of the allegedly disturbing "precaution", more "innovation" is to be promoted. Their lobbying work was successful: The European Council has requested from the European Commission in November 2019 to submit a study by April 2021 in light of the Court of Justice's judgement regarding the status of new GMOs. The European Commission will do so and also cater for stakeholder consultation in early 2020 - detailed input is welcome especially on why the new GMOs are supposedly safe.

3. Going for new GMOs is betting on the wrong horse

New GMOs are divesting research and development resources for sustainable food-systems that are badly needed elsewhere, be they time or money. In times of climate change, biodiversity loss and water and soil destruction we simply cannot afford this narrow focus on technical fixes. What we need to tackle the burning issues is a system change and real ecological innovation and not the illusion of a techno-fix attempting to remedy the problems caused by a wrong agricultural system. We need to focus on the reorganisation of the food distribution system (notably through an EU protein plan), spreading low-input agriculture, supporting participative breeding of locally adapted and robust varieties and connecting ancient varieties with modern knowledge about ecosystems. We also need to respect animals' needs, and agro-ecology at large. We need numerous, well-remunerated, autonomous farmers. The potential of new genetic engineering to meet these challenges is much smaller than the potential of agro-ecological techniques, as outlined in the following:

3.1. GMOs are not effective in addressing urgent environmental and social issues

The 'old' genetic modifications were promoted with many promises: they were marketed by the agro industry as a tool to end world hunger, produce more food and to reduce pesticide use. None of these promises has been kept. In the contrary.

Latest with the world agricultural report (2008) it has become evident that **hunger exists first and foremost due to a problem of availability and distribution**. 70 to 80 percent of hungry people live in the countryside. They need access to land, water, education, agricultural knowledge and to regionally

[8] The term new genetic modification technique is taken from a 2017 statement on this topic by The European Network of Scientists for Social and Environmental Responsibility (ENSSER):
https://ensser.org/publications/ngmt-statement/

adapted, reproducible and patent free seeds. [9]

Genetic modification has not resulted in rising yields. Reason is that it is technically difficult to manipulate the genes for yields. Properties such as resistance to drought or salt are not embedded in a single gene but are regulated by many genes. Drought or salt resistant plants are more efficiently obtained through the use of classical breeding methods using traditional and regionally adapted species and varieties. Finding old varieties can also lead to success even without breeding: For example, the MASIPAG[10] network has collected more than 2000 different varieties of rice, 12 varieties that survive if flooded for a few days, 18 varieties that cope well with drought, 20 varieties that are tolerant to salt water and 24 that are resistant to certain local pests. Evidence from research and practice suggests that a food production system that is able to adapt to a changing climate, needs an approach based among others on short supply chains, soil improvement, crop genetic diversity and locally adapted varieties that respect farmers' and breeders' rights.

It is also very important to realise that so far plants modified with new genetic modification techniques have still to prove themselves on the field. Techniques as CRISPR, make it possible to produce all kinds of experimental lines within a short period of time but it is questionable if and how quickly marketable varieties can be developed from these lines that can actually perform in farmers' fields. Knock-out plants[11] are produced in approximately 90% of the current applications of CRISPR that are useful only for basic research, such as gene functioning, no commercialisation of the yet again promised 'super plants' is to be anticipated in the near future[12] [13] Renown scientists deem it little likely that eventually the genetically modified plants will have the capacity to exceed the successes of conventional breeding[14].

3.2. GMOs disempower farmers, breeders and consumers

As with old GMOs, again the large corporations hold most of the patent applications in the field of new genetic engineering. As patent holders agrochemical companies decide who can use their products and charge good money for any usage made. This system speeds up the privatisation of life and the monopolization of nature itself by a handful of global agrochemical companies.
Today, three companies, DuPont-Dow, ChemChina-Syngenta and Bayer-Monsanto dominate more than 60% of the global seed market. Patents can cover methods, seeds, plants and often also their harvest.

The fact that patents are applied for and granted contradicts the alleged 'naturalness' of genetic modification. According to the European Patent Convention, patents may not be granted on plants and animals "*obtained by essentially biological breeding techniques*". And the EU Patent Directive (98/44/EC) states: "*A process for breeding plants or animals is essentially biological if it is based entirely on natural phenomena such as cross-breeding or selection*".

Patents mean higher prices and further concentration of an already highly concentrated market. They also constrain further breeding and seed reproduction and particularly disadvantage small-scale seed

[9] The "Welthungerhilfe" stated in 2010: "A sustainable increase in income for the benefit of small farmers in developing countries through green engineering has not yet been demonstrated, nor has it contributed to the fight against hunger."
Deutsche Welthungerhilfe (2010): „Gensaat ist keine Lösung". In: Welternährung, 2. Quartal
[10] http://masipag.org/about-masipag/
[11] A **gene knockout** is a genetic technique in which one of an organism's genes is made inoperative ("knocked out" of the organism). Knockout organisms or simply knockouts are used to study gene function, usually by investigating the effect of gene loss. Researchers draw inferences from the difference between the knockout organism and normal individuals. Source: Wikipedia
[12] as in 13
[13] Gelinsky, Hilbeck (2018): European Court of Justice ruling regarding new genetic engineering methods....
[14] as in 13

breeding businesses and farmers.
Indeed, without proper labelling, farmers and breeders might use patented seeds without even knowing it, and face court cases, as has happened several times in the USA and Canada with old GMOs.

4. Why a strict regulation of new genetic modification techniques is absolutely necessary

If further investment into new GMOs is done the absolute minimum is to strictly regulate these high risk techniques. The best way of doing so is to have them covered by the current EU-GMO legislation. That is also what the European Court of Auditors ruled in 2018. The reasons for strictly regulating new GMOs are outlined in the following:

4.1 Techniques come with a number of risks

With the new genetic modification techniques we have to reckon with a much larger number of organisms that have somehow been genetically modified. Their releases could be accompanied by a multitude of possible, unresearched, unpredictable and unwanted changes - if the users and applicants are not obliged by law to document such releases and conduct a thorough pre-release risk assessment[15].

4.1.1) Techniques pose risks to health

A genetic engineering intervention can lead to plants unintentionally producing modified proteins, potentially resulting in their becoming toxic or allergenic. [16]

4.1.2) Techniques pose risks to environment

When applied in agriculture, these new GMOs cause changes that do not occur naturally. They carry a risk of collateral damage since they can induce unintended changes in genetic material (in other words, unintended mutations or changes in the genome expression that can cause unwanted changes in the plant). Furthermore, these techniques pose similar and additional risks to the environment: reducing both cultivated and wild biodiversity, increasing pollution linked to the use of pesticides and herbicides or promoting herbicide resistance in wild plants.

Doing biotech research in a lab is one thing, releasing the results in the environment is a different matter altogether. The genetic contamination of other plants is as probable with these techniques as it is with old GMOs, inevitably leading to biodiversity loss. The modified new properties can also result in plants having increased survivability (fitness) in comparison to other plants[17], thereby stirring up the ecological balance. Effects on agro biodiversity will inevitably lead to a decline of dependent insects, mammals and birds.

For organic farmers, contamination of their plants by gm-plants would be especially problematic, as these new biotechnologies are incompatible with organic principles.

4.2 Precautionary principle must rule

As outlined above the new genetic modification techniques come with considerable risks and uncertainties. '*Better safe than sorry*' should be the guiding principle in handling them.
This does not mean, as often wrongly communicated, that that their research and development would no longer be possible. But it means that their research needs to take place under secure conditions.
It is likewise an absolute necessity that organisms resulting from genetic modification are accordingly labelled so that their usage by farmers, breeders and consumers can happen consciously.

[15] as in 13
[16] as in 13
[17] as in 13

All these safeguard mechanisms are part of the precautionary principle that is the guiding principle of the EU health and environment policy. It basically represents a system for navigating possible risks in situations where scientific understanding is lacking or incomplete.
The precautionary principle stands in strong opposition to the so-called innovation principle, being pushed for by industry. Proponents of the innovation principle generally place big trust and hopes in any technical innovation without safeguarding their 'innovation' against potential risks.

4.3 Organic farming has to be secured

If the new genetic modification techniques were not to be covered by GMO law, they would not be subject to an approval procedure with risk assessment, labelling or coexistence regulations. Seeds would not be labelled as genetically modified. The farmer would no longer have a choice and genetically produced plants would be allowed to enter conventional GMO-free and organic production (which by definition is GMO-free) without being subject to control. If, for example, herbicide resistance is created with the new processes, there would be neither protection against outcrossing nor liability claims as there would be no release regulations, there would also be no location register. Due to the intersections with conventionally bred seeds, organic agriculture is dependent on the labelling of new breeding technologies if it does not want to use certain technologies or their products.

5. Green demands

- Apply the precautionary principle consequently
- Cover new genome editing techniques by the current EU legislation, as ruled by the European Court of Auditors
- Keep a suitable comprehensive risk assessment for each and every gmo as part of the authorisation procedure; make sure that the risk assessment is independent from economic interests
- Secure freedom of choice to farmers, breeders, consumers by maintaining the process-based labelling obligation of gmos.
- Intensify efforts to guarantee traceability of genetically modifed products
- Support the further development and implementation of processes of detectability of new gmos
- Establish an international registrar that keeps track of all organisms (plants, animals, microorganisms) that have been genetically modified and that allows for deciphering the precise sample of the genetic modifications. That is a necessity if the EU wants to prove gmos in imports that do not have any EU authorisation
- Protect farmers and producers from contamination of their produce with gmos; secure that according to the polluter pays principle the polluters are liable for any potential damage caused
- Support more strongly independent research into risks and technological impact assessment of new gmos. For the production and release of gmos as well as for gene-drive organisms effective in wild populations
- Intensify the use of GMO-free methods for the breeding of robust, yield-safe and resistant species for conventional and ecological cultivation; make corresponding research money available
- Increase research resources for agro-ecological means of production, as well as for agroforestry and an agriculture adjusted to climate change