



#### **IFOAM EU position paper on New Plant Breeding Techniques**

Since the last review in 2001 of the EU Directive on the deliberate release of genetically modified organisms (GMOs) in the environment (Directive 2001/18/EC, which was initially adopted in 1990), a number of new plant breeding techniques (NPBTs) have been experimented by researchers and biotech companies, and sometimes already released in the environment through open field trials.

The European Commission is expected to provide a legal interpretation on which of these NPBTs fall within the scope of Directive 2001/18/EC which provides a definition of GMOs in its article 2(2): ("genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination") and a definition of techniques leading to genetic modification in its Annex I. This decision will have far reaching consequences on the development of the organic sector.

The IFOAM EU Group considers that the NPBTs discussed below should be, without question, considered as techniques of genetic modification leading to GMOs according to the existing EU legal definition and that the Commission should explicitly confirm that they fall within the scope of the GMO legislation (Directive 2001/18/EC and Regulation 1829/2003). It is of crucial importance for the organic sector that these new techniques that engineer living organisms through technical, chemical or biotechnological intervention in the cell and/or nucleus be a) subject to a risk assessment and b) if authorised for release in the environment and the food chain, be subject to the mandatory traceability and labelling requirements that apply to other GMOs (Regulation 1829/2003 and Regulation 1830/2003).

# 1) Breeding techniques and applications considered as genetic modification to fall within the scope of the EU legislation on GMOs

The IFOAM EU Group considers that the Commission should urgently clarify that the following NPBTs<sup>1</sup> fall within the scope of the GMO legislation:

- Oligonucleotide directed mutagenesis (ODM)
- Zinc finger nuclease technology types I to III (ZFN-I, ZFN-II, ZFN-III)
- CRISPR/Cas
- Meganucleases
- Cisgenesis
- Grafting on a transgene rootstock
- Agro-infiltration
- RNA-dependent DNA methylation (RdDM)
- Reverse Breeding
- Synthetic Genomics

<sup>&</sup>lt;sup>1</sup> For more information regarding these techniques, see Steinbrecher (2015), available at: <a href="https://www.econexus.info/sites/econexus/files/NBT%20Briefing%20-%20EcoNexus%20December%202015.pdf">www.econexus.info/sites/econexus/files/NBT%20Briefing%20-%20EcoNexus%20December%202015.pdf</a> and Ledford (2015), available at: <a href="https://www.nature.com/news/crispr-the-disruptor-1.17673#/b1">www.nature.com/news/crispr-the-disruptor-1.17673#/b1</a>



1

These new techniques, and the products obtained through them, fall within the scope of Directive 2001/18/EC on the basis of its article 2(2), which defines a genetically modified organism (GMO) as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

The list of techniques in Annex 1A, part 1, of Directive 2011/18/EC is not exhaustive and cannot be used as a valid reference point since these new breeding techniques were not known 15 years ago, when the Directive was adopted.

The exclusions listed in Annex 1A, part 2 and Annex 1B do not apply to any of these new techniques. Recital 17 of Directive 2001/18/EC makes it clear that the exclusions from the scope of the Directive listed in Annex 1B were included to exclude products which had at the time already been on the market for a certain time: "This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record". None of the techniques listed above have gone beyond the experimental stage, and their use in other parts of the world is extremely recent and has not been subject to any risk assessment. Therefore, none of the above techniques can claim to have a "long safety record".

The Commission should clarify the situation quickly, before plants bred with such techniques start being released into the environment on a commercial scale.

#### 2) Other techniques using GM methods

Reverse breeding, agro-infiltration and grafting are not themselves new techniques, but as ways of using a GMO, are new applications of genetic modification techniques such as transgenesis, and involve new ways of using GMOs, and therefore fall within the scope of the GM legislation. IFOAM EU considers that the use of all GM techniques fall in the scope of the GMO legislation and has to remain traceable, labelled, subject to a risk assessment and to the precautionary principle, even though the GMO might not be the end product, in accordance with the process-based approach laid out in Regulation 1829/2003.

#### 3) Techniques of genetic modification are not compatible with organic farming

**Organic farming**, which is legally defined at the EU level Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, **excludes GMOs** and products produced from or by GMOs from its production process<sup>2</sup>.

<sup>&</sup>lt;sup>2</sup> Article 9.1 states that "GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material, micro-organisms and animals in organic production."



2

The NPBTs listed above and the breeding techniques involving GMOs use technology that interferes at the sub-cellular and genomic level. Therefore, IFOAM EU considers that they are not compatible with the principles of organic farming and must not be used in organic farming.

Although GMOs are only cultivated in small areas in a very limited number of countries in the EU, addressing the risk of contamination has nonetheless already triggered technical complications and increased economic costs for operators in the organic sector<sup>3</sup>. Moreover, consumers of organic products and organic farmers clearly reject the use of GMOs and hold as a key principle the right to know that what they eat and grow is GMO-free.

Organic agriculture is based on the four principles of ecology, health, fairness and care. It focuses on promoting biodiversity, soil quality, closed production cycles and overall enhancing ecological processes based on care and respect of the health principle. It is a systemic and process oriented approach that acknowledges the importance of the precautionary principle.

In line with the precautionary principle, IFOAM is opposed to the release of GMOs into the environment and to their use in agriculture because GM techniques can lead to unpredictable side effects. Living genetically modified organisms cannot be recalled once a problem is identified, and their release can lead to negative and irreversible environmental impacts. Their use in agriculture leads to genetic contamination of the gene pool and indirectly to reduced agro-biodiversity. Most GMOs available on the market are herbicide-tolerant plants to be used in combination with chemicals, incompatible with organic farming. Through intellectual property rights, GMOs also contribute to further consolidation in the agri-food sector, at the expense of farmers and consumers.

Organic farming supports the use of plant varieties produced under organic conditions complying with the legal organic standards and principles. According to IFOAM Organics International standards, for varieties used in organic farming the genome and the cell should be respected as impartible entities and breeders shall disclose the applied breeding techniques.

### 4) Potential impacts of deregulation of techniques leading to genetic modification

Deregulation of the new breeding techniques will threaten the freedom of choice for breeders, farmers and consumers.

If for some reason the Commission decides to exclude some of these new techniques from the scope of the legislation on GMOs, the organic sector will have to face a situation where genetic modification techniques, excluded from organic farming, could be released into the environment and the food chain but be exempted from any traceability and labelling requirements. This would have serious consequences on the costs incurred by economic

<sup>&</sup>lt;sup>3</sup> Preventing GMO contamination – An overview of national "coexistence" measures in the EU, IFOAM EU, <a href="http://www.ifoam-eu.org/sites/default/files/ifoameu\_policy\_gmos\_dossier\_201412.pdf">http://www.ifoam-eu.org/sites/default/files/ifoameu\_policy\_gmos\_dossier\_201412.pdf</a>



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operators in the sector (farmers, processors, traders and retailers) and unavoidable contamination cases would negatively affect the image and reputation of organic products towards consumers<sup>4</sup>.

This would also jeopardise the development of the organic market and sector in the EU. Organically managed land has doubled in the last decade and represented in 2013 5.7% of the total agricultural area in the EU. Organic farming represents a market value of 22.2 billion euro in the EU-28, with a growth of 6% per year. In particular, the EU Action Plan on organic farming COM(2014) 179 final<sup>5</sup> recognises the importance to develop the use of organic seeds and the organic breeding sector. DG Research has launched a 20 million euro call for projects to contribute to this objective. Organic seed companies and organic breeders would be most severely affected if new genetic engineering techniques are authorised for release with no traceability requirements. This would hamper innovation in the organic plant breeding sector. IFOAM EU urges the Commission to take into account the impact on innovation in the plant breeding sector.

Another aspect is that many companies producing varieties with these NPBTs have claimed patents on the varieties. As a consequence, the production costs for the farmers will increase, and other breeders will no longer be allowed to use released cultivars for their own breeding without agreement of the patent holder (restriction of the breeder's privilege).

A final reason to subject those techniques to the GMO legislation is to guarantee the application of the precautionary principle. At the moment, there is not enough scientific data and no long term studies available to properly evaluate the risks that these techniques might present<sup>6</sup>, and in most cases there are currently no tools available to identify and trace organisms derived through means of above techniques.

## 5) Traceability and labelling are the preconditions for freedom of choice for consumers

Since GMOs and products produced from or by GMOs shall not be used in organic production, traceability and labelling is indispensable to avoid unintentional use of cultivars derived from NPBTs listed above by the organic sector. It is even more important that these new techniques are subject to traceability requirements because, at the moment, methods to detect their use in the final product are not available for all techniques. As long as no methods for tracing these

http://www.umweltbundesamt.at/aktuell/publikationen/publikationssuche/publikationsdetail/?pub id=2054; Agapito-Tenfen, S.Z. & Wikmark, O.-G. 2015. Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis. GenØk Biosafety Report 02/15, 43p. http://genok.com/arkiv/4288/



<sup>&</sup>lt;sup>4</sup> <u>Preventing GMO contamination – An overview of national "coexistence" measures in the EU</u>, IFOAM EU, http://www.ifoam-eu.org/sites/default/files/ifoameu policy gmos dossier 201412.pdf

<sup>&</sup>lt;sup>5</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Action Plan for the future of Organic Production in the European Union, European Commission, COM(2014) 179 final

<sup>&</sup>lt;sup>6</sup> Eckerstorfer, M., Miklau, M. & Gaugitsch, H. 2014. New plant breeding techniques and risks associated with their application. Environment Agency Austria

techniques in the end products are available, plants produced with these techniques should not be released in the environment. It is important for farmers in general and organic farmers in particular to know if any of these techniques have been used to develop the cultivars that they buy. Transparency is needed as well as a legally binding obligation for breeding companies to disclose the applied breeding methods. Otherwise, seed producers and farmers cannot make an informed choice and this might cause unwanted contamination of organic seeds and fields.

#### 6) Alternative breeding programmes should be developed

The agricultural sector should promote alternative breeding programmes like organic plant breeding, in order to foster the development of suitable and efficient varieties that are GMO-free and patent-free.

Innovation is necessary in order to improve productivity and resolve the issues that the organic sector faces. The European Commission has also acknowledged the fact that there is a need to develop the organic breeding sector. The European Innovation Partnership (EIP) focus group on organic farming has explicitly mentioned "the programming of delocalised and participatory breeding systems" and "the re-framing of breeding criteria" as important research topics<sup>7</sup>. IFOAM EU believes that the above mentioned NPBTs that focus on single genes are not the solution to the complex challenges that the agriculture sector faces.

<sup>&</sup>lt;sup>7</sup> https://ec.europa.eu/eip/agriculture/sites/agri-eip/files/fg1\_organic\_farming\_final\_report\_2013\_en.pdf



5