GIET,
Groupe International
d'Études Transdisciplinaires

Legal status of products derived from « new techniques of genetic modification of plants »

11 – 18 – 2015

In 2008, the European Commission listed eight new techniques of genetic modification of plants:
- Oligodirected mutagenesis
- Cisgenesis / Intragenesis
- Site directed Nucleases (SDN): zinc finger nucleases
- RNA dependant DNA methylation
- Grafting
- Reverse breeding
- Agro-infiltration
- Synthetic biology

The European Commission first asked a group of experts to say whether those techniques are producing GMOs or not. Facing scientific controversies, this group was unable to reach a unanimous conclusion for each technique. DG Health, in charge of this policy in the European Commission, decided to release a legal opinion on the first seven techniques. This opinion aims at preparing a « communication from the European Commission » to be approved by all the commissioners and to be published before the end of 2015. Regarding synthetic biology, the European Commission considers that there's a need to better define the extent of this concept. By the end of 2013, the European Commission hoped – and its communication have not changed since then – that this work could also be the reference for other techniques that might emerge in the future, which is already the case for Talen / CrisprCas9 / meganucleases techniques, added to the list from 2008.

Which legal arguments can answer the European Commission's question?

Those seven techniques of genetic modification aim either at modifying the plants' genetic material "in a way that does not occur naturally by mating and/or natural recombination" (GMO definition according to 2001/18 Directive, article 2.2[1]) or at using GMOs.

None of the new techniques is strictly limited to the techniques listed in part 2 of Annex 1A of 2001/18 directive and which "are not considered to result in genetic modification"[2] . Those new

1 "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.

2 "Techniques referred to in Article 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B: (1) in vitro fertilisation, (2) natural processes such as: conjugation, transduction, transformation, (3) polyploidy induction ».

techniques do give rise to GMOs according to directive 2001/18.

All those new techniques are about applying “in vitro techniques to nucleic acid” in at least one of their steps and then, are giving rise to GMOs, or products derived from GMOs, according to the Cartagena Protocol[3].

1. Gene-editing techniques.

Gene-editing techniques allow the direct modification of plant genetic material at specific locations in the genome. Some of these techniques cleave the DNA at specific sites and trigger the plants own repair mechanism (ZFNs, TALENs, meganucleases and CRISPR/Cas). Another technique, oligonucleotide-directed mutagenesis (ODM), inserts short DNA fragments into the cells where they trigger modifications of the cells’ own DNA to match the introduced fragments.

Mutagenesis produces GMOs. But these GMOs are exempt from the directive's scope of application “on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms” (Annex 1B of 2001/18 directive[4]). The ODM techniques are using DNA or RNA which will not be found in the final product and for which the use of the term “recombinant nucleic acid” is subject to scientific controversy. Companies (1) contest that an oligonucleotide is to be considered as a recombinant nucleic acid because it is, according to them, a molecule synthesized in vitro by adding nucleotides one by one, and (2) underline that no additional DNA is found in the final product.

But the legal opinion cannot be based on this sole argument to define the status of products obtained through the use of those techniques, or to consider whether they fall under the scope of application of the directive. The directive itself is the text of reference allowing to know what were the motivations of the legislator when excluding some GMOs from the scope of application of the directive. Such reasons are given in whereas 17: “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”.

All these techniques of mutagenesis do give rise to GMOs and are new. None of them have been conventionally used for different applications and therefore they cannot be considered as having a long safety record. Consequently, organisms derived from these techniques cannot be excluded from the scope of application of the directive.

2. The other techniques.

Cisgenesis / intragenesis are “techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation” considered to give rise to GMOs in accordance with Annex 1A part 1, point 2) of directive 2001/18 and not techniques considered to produce organisms to be excluded from the scope of application of the directive in accordance with the restrictive list of Annex 1B. Grafting,

3 Article 3, i) « Modern biotechnology" means the application of: a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. »

4 “Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are: (1) mutagenesis, (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.”

reverse breeding and agro-infiltration do give rise to either GMOs, or organisms produced from GM plants or bacteria falling under the scope of application of the directive.

All those techniques do give rise to GMOs which have intended or unintended effects that need to be assessed prior to any environmental release and commercialisation as stated in whereas 5 of 2001/18 directive (“The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMOs)”) and whereas 19 (“A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment”). None of the last four techniques of genetic modification have been conventionally used for different applications and therefore they cannot be considered as having a long safety record. Consequently, organisms obtained through the use of these techniques cannot be excluded from the scope of application of the directive.

Legal conclusion: The answer to the question of the European Commission is that all listed techniques are giving rise to GMOs or products derived from GMOs which fall under the scope of application of the directive. Any other answer would be against the motivations of the legislator and citizens who largely approved his decision.

Amis de la Terre
Confédération Paysanne
Fédération Nationale d'Agriculture Biologique
Fondation Sciences Citoyennes
France Nature Environnement
GIET, Groupe International d'Études Transdisciplinaires
Greenpeace
Nature & Progrès
OGM dangers
Réseau Semences Paysannes
Union Nationale de l'Apiculture Française