Briefing
May 2016

European Parliament

New plant-breeding techniques
Applicability of GM rules

SUMMARY

New plant genetic modification (GM) techniques have evolved rapidly in recent years, allowing much faster and more precise results than conventional plant-breeding techniques. They are seen as a promising new field for the agri-food industry, offering great technical potential.

There is, however, considerable debate as to how these new techniques should be regulated and whether some or all of them should fall within the scope of EU legislation on genetically modified organisms (GMOs).

There are two sides to the discussion. Those who take the view that the new techniques should be exempt from GMO legislation generally argue that the end product is very similar to products generated using conventional breeding techniques. Those who consider that the new techniques should fall within the scope of GMO legislation contend that the processes used mean that plants bred using the new techniques are in fact genetically modified.

The Commission is currently working on a legal interpretation of the regulatory status of products generated by new plant-breeding techniques, which should be published in the course of 2016. The Commission has highlighted that its legal interpretation is intended to give guidance to national authorities on the scope of GMO legislation, but that it is the sole prerogative of the European Court of Justice to render a final and binding opinion on the interpretation of EU law.

The scientific community remains divided over the issue, and various published legal analyses differ, as do the opinions of other stakeholders.

In this briefing:

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PE 582.018

The uncertain status of new plant-breeding techniques

EU legislation on genetically modified organisms dates back to 1990. It has been revised more recently, but the definition of GMOs has remained unchanged since then.

In traditional plant breeding, mutations producing variation in the plant genome are introduced using radiation or chemicals. This way of modifying genetic material, called mutagenesis, is explicitly exempt from the scope of GMO legislation on the basis that it has a long history of safe use. Many varieties of plant species cultivated today, including for example barley, wheat and grapefruit, were modified in this way.

New breeding and genetic modification techniques have evolved rapidly, and nowadays biotechnologies are applied in plant breeding largely with the aim of introducing new traits bringing desirable characteristics to the plants. Another important objective is to achieve this in a precise and cost-effective manner, allowing rapid identification of plants carrying the desirable genotypes.

The first new plant variety developed using one of the new techniques (a herbicide-tolerant oilseed rape) has already been marketed in North America, and companies have also requested permission to start field trials in some EU Member States.

Some of the newest plant-breeding techniques are in an uncertain situation concerning their classification within legislation. There is considerable debate as to how these new techniques should be regulated and whether some or all of them should fall within the scope of EU legislation on GMOs.

The Member States have asked the Commission to issue guidance on the regulatory status of products generated using the new techniques. The Commission is currently working on a legal interpretation meant to give guidance to national authorities, and has asked Member States to wait for the outcome before authorising field trials or cultivation. This legal interpretation was expected by the end of 2015, then postponed to first quarter of 2016. It is now expected during the course of 2016. The Commission has stressed that the legal analysis is intended to give guidance to national authorities on the scope of the legislation, but that it is the 'sole prerogative of the European Court of Justice to render a final and binding opinion on the interpretation of EC law'.

Background

The EU seed and plant reproductive material market is the third biggest in the world – worth around €6.8 billion a year – and the EU is the world's second largest seed exporter. According to a study by the European Commission's Joint Research Centre (JRC), conducted in 2011, Europe's plant-breeding industry and researchers have been very active in the field of new plant-breeding techniques, and have carried out almost 50% of the research done globally. These new techniques allow targeted gene modifications to be obtained more precisely and faster than by conventional plant-breeding techniques.

Potential applications

- Precise and rapid alteration of crops to boost yields
- Plants with herbicide tolerance (oilseed rape variety created using ODM technology cultivated in the USA since 2014)
- Plants with pest or insect resistance (field trials in the Netherlands and in Belgium of potatoes bred using cisgenesis, to make them resistant to fungus causing 'late blight')
- Plants with drought or flood resistance
- Enhanced nutritional quality of food crops
- Changes in composition of nutrients in plants, for example vitamins or fatty acids
- Food crops with reduced allergenicity (for example wheat without gluten)

They are seen as a promising new field for the agri-food industry. The study notes that because the regulatory costs for plants classified as GMOs are much higher than those for non-GMO plants and because public acceptance of them is lower, biotechnology companies and plant breeders have been 'particularly concerned' by the legal uncertainty relating to the applicability of GM rules to these new techniques.

At the request of the Member States, the European Commission set up a working group in 2007, composed of nationally appointed scientists, to assess whether or not a number of new breeding techniques should fall within the scope of GMO legislation (see 'Legal basis' section below for more details).

The working group considered the following eight new breeding techniques:[1]

- oligonucleotide directed mutagenesis (ODM), also known as the Rapid Trait Development System (RTDS);
- zinc finger nuclease (ZFN) technology (ZFN-1, ZFN-2 and ZFN-3);
- cisgenesis and intragenesis;
- grafting;
- agro-infiltration;
- RNA-dependent DNA methylation (RdDM);
- reverse breeding; and
- synthetic genomics.

The working group completed its work in 2012. The experts all agreed that organisms developed through cisgenesis[2] and intragenesis[3] fell under Directive 2001/18/EC,[4] but remained divided on the regulatory status of most of the other new techniques.

The European Food Safety Authority (EFSA) has issued two opinions on the new breeding techniques: a scientific opinion on the safety assessment of plants developed by cisgenesis and intragenesis, and another on the safety assessment of Zinc Finger Nuclease 3. EFSA concluded that the existing guidelines for risk assessment applicable to GM plants were also appropriate for cisgenic and intragenic plants, and for the ZFN-3 technique. EFSA also considered the hazards associated with cisgenic plants to be similar to those linked to conventionally bred plants, but that novel hazards could be associated with intragenic and transgenic[5] plants. All these breeding methods could, however, 'produce variable frequencies and severities of unintended effects, the frequency of which cannot be predicted and needs to be assessed case by case'.

There are other new techniques that have only recently come into more frequent use. Nuclease-based genome editing has emerged as an effective genetic-engineering method that allows the precise modification of the nucleotide sequence of the genome by adding, replacing or removing DNA bases. This is obtained using artificially engineered enzymes called nucleases that act as molecular scissors to split open the DNA double-stranded helix, then allowing the cell's own endogenous repair machinery to repair the break. Many different types of nuclease have been developed that can be directed to the exact place where a DNA break is to be introduced. Different results are obtained depending on the method used to repair the DNA breaks: insertions or deletions of nucleotides, gene inversions or translocations, changes in the nucleotide sequence. They are quick, precise and cheap to use, and experts say they have revolutionised gene-editing technology since 2012. The Commission working group examined zinc finger nuclease technology (ZFN-1, ZFN-2 and ZFN-3) but no other nuclease-based techniques (TALENs, Meganucleases or CRISPR/Cas for instance).

Developing new plant varieties or protecting old ones?

Innovation in agriculture and plant breeding can play a key role in responding to challenges such as feeding the growing world population, adapting to climate change and protecting natural resources. The United Nations Food and Agriculture Organization (FAO) estimates that agricultural production needs to grow by approximately 70% by 2050 to feed the world population, while the area suitable for agricultural cultivation is limited. As a result of climate change, the world may need plant varieties that can adapt to changing conditions.

At an FAO-hosted international symposium on agricultural biotechnologies in February 2016, stakeholders, including scientists and government, civil society and farmers' group representatives discussed the benefits of biotechnologies, such as improving crop and vegetable resource efficiency, building climate change resilience, increasing fruit and vegetable storability and shelf life, increasing yields, improving plants' nutritional qualities and transforming food systems so that they need fewer inputs and have less of an environmental impact.

Paradoxically, the intensification of plant-breeding activity may reduce biodiversity, and hence resilience. Plant genetic diversity is threatened by the loss of landraces (local varieties of plant species that have adapted over time to their ecological and cultural environments) and the domination of genetically uniform modern varieties in many agricultural production systems. The FAO points out that 'since the 1900s, some 75% of plant genetic diversity has been lost as farmers worldwide have left their multiple local varieties and landraces for genetically uniform, high-yielding varieties'. Yet, according to the FAO, maintenance of genetic diversity is key to adapting to changing conditions. In Europe, only a few farmers cultivate locally adapted traditional crops and much of this genetic variation has been lost.

Legal basis

The EU's GMO legislation stems from 1990 when the first two directives concerning GMOs[6] came into force. Both original directives have since been updated,[7] although the definition of a GMO has remained unchanged. This is causing problems for new techniques developed since then.

Under EU law, the definition of GMOs states that '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' – Directive 2001/18/EC, Article 2(2).

The annexes to the Directive further define the techniques that (a) result in genetic modification (listed in Annex I A, Part 1); (b) are not considered to result in genetic modification (Annex I A, Part 2); and (c) result in genetic modification but yield organisms that are excluded from the scope of the Directive (Article 3 and Annex I B): these techniques are mutagenesis and cell fusion (of plant cells of organisms that can exchange genetic material through traditional breeding methods).

Recital 17 states that the 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'. Mutagenesis – a method used in traditional plant breeding, where variations in the plant genome are introduced using radiation or chemicals – is explicitly exempt from the scope of GMO legislation, on the basis that it has a long history of safe use.

In replies to parliamentary questions, the Commission has stressed that the decision to include or exclude a technique from the scope of Directives 2001/18/EC and 2009/41/EC depends only on the interpretation of the definition of genetically modified organisms (and genetically modified microorganisms) and of the conditions for

exemption provided for in the two Directives. The Commission has also noted that the evaluation is complex, because the definition of GMO under EU legislation refers both to the characteristics of the organism obtained and to the techniques used.

If the new techniques were to be exempted from GMO legislation, they would also then be exempt from the obligations of pre-market assessment and authorisation, as well as from labelling requirements concerning GMOs.

EU legislation requires that GMOs be identifiable using detection methods.[8] But plants grown using many of the new methods can hardly, if at all, be distinguished from conventionally bred plants if no foreign DNA has been introduced. It is often impossible to tell whether the modification was natural or triggered by a new breeding technique.

Regulatory status in some non-European countries

Since cisgenic plants include only genes from cross-compatible species, it has been argued that these should be regulated less strictly than transgenic plants. In Australia, cisgenic plants are excluded from GMO legislation, and in Canada and the USA they are considered to be similar to any other new plant variety.

The United States Department of Agriculture has indicated that crop varieties generated through genome editing do not constitute GMOs as they do not contain foreign DNA from plant pests[9]. On the contrary, in New Zealand the government has decided to keep all new breeding techniques under GMO law. In Argentina a final decision was published in May 2015, determining that all crops derived through new breeding techniques were to be reviewed on a case-by-case basis.

Regulating the new techniques

There are two sides to the debate on how the new techniques should be regulated. Those who take the view that new techniques should be exempt from GMO legislation generally argue that the end product is very similar to products generated using conventional techniques. Those who take the opposing view contend that the processes used make plants bred by the new techniques very similar to GMOs.

The case for exempting the new techniques from GMO legislation

In its statement on new breeding techniques published in July 2015, the European Academies' Science Advisory Council (EASAC), a body of national science academies of the EU Member States, argues that the products of new breeding techniques should not fall under GMO legislation when they do not contain foreign DNA. EASAC notes that in some cases the product cannot be distinguished from one generated by conventional techniques. This, according to EASAC, calls into question the definition of what is meant by genetic modification, and calls for EU regulatory frameworks to be modernised so as to regulate the trait and/or the product rather than the technology. EASAC also argues that the new techniques enable much more precise and targeted changes compared with mutagenesis used in traditional breeding, where changes in the genome are induced by chemicals or radiation, creating multiple, unknown, unintended mutations.

The view that the safety of new crop varieties ought to be assessed according to their characteristics, rather than the method by which they are produced, is shared by a range of bodies, including the UK Biotechnology and Biological Sciences Research Council (BBSRC), the German Academies, the European Plant Science Organisation (EPSO) and the French High Council for Biotechnology (HCB).[10]

When it comes to the various techniques, opinions differ. The UK Advisory Committee on Releases to the Environment (ACRE) indicated in its advice that only products of cisgenesis and intragenesis should be regarded as GMOs. On the contrary, the Dutch Commission on Genetic Modification (COGEM) has argued that cisgenic plants should be exempt from GMO legislation, since only genetic elements from the same species or a cross-compatible species are introduced. Germany's Central Committee on Biological Safety (ZKBS) has classified organisms modified by means of ZFN and ODM as not being genetically modified. The Swedish Board of Agriculture has, meanwhile, concluded that CRISPR/Cas9 should not be subject to European GMO legislation.

In February 2015, the German Federal Office for Consumer Protection and Food Safety (BVL) stated that plants generated by the ODM (including the RTDS) and CRISPR/Cas9 techniques do not constitute GMOs within the meaning of Directive 2001/18/EC, as the modifications could also be generated through conventional mutagenesis techniques and are not distinguishable from them. Therefore, field trials of a herbicide-resistant rapeseed generated with the RTDS could be carried out without the approval required for GMOs.[11] The BVL stated, however, that the decision would be reversed if the legal interpretation of the European Commission produced a different result.

The plant-breeding industry in general takes the view that new breeding techniques should not be subject to GMO legislation. The European Seed Association (ESA) argues that classifying the new techniques under GMO legislation would prevent Europe's predominantly small and medium-sized plant-breeding companies from developing and using them, and drive research outside Europe. In its paper on 'Regulatory approaches to modern plant breeding', it points out that the changes induced by gene-editing techniques can occur naturally, and do not result in insertion of foreign DNA into the final product. It highlights that the precautionary principle need not apply as the degree of scientific uncertainty linked to the new techniques is lower than the degree of uncertainty associated with mutagenesis. The New Breeding Techniques Platform, a coalition of SMEs, large industry and academic and research institutes, argues that recognition by the EU that products developed with new plant-breeding techniques do not fall within the scope of GMO legislation would give strong impetus to the European plant breeding sector. Their position is supported by a legal briefing paper.

The case for classifying the new techniques under GMO legislation

A legal analysis of genome-editing technologies commissioned by the German Federal Agency for Nature Conservation concludes that the organisms produced using the new techniques fall within the scope of the EU's GMO legislation. The analysis argues that the fact that mutations also occur naturally is of no importance in this context: most crucial is that the modifications are carried out purposefully and lead to the incorporation of material into a host organism in which these nucleid acid molecules do not occur naturally. In addition, these interventions can be applied many times over to the same plant, possibly leading to extensive modifications. Most importantly, as the analysis highlights, the term mutagenesis used in Annex I B explicitly covers only conventional mutagenesis.

In a report on the assessment of the potential risks associated with crops obtained through new plant-breeding techniques, Environment Agency Austria points out that the individual new techniques differ widely in their approaches and characteristics. It further emphasises that these techniques are used mostly in combination. The potential risks are associated with the intended modifications, or with unintended effects

resulting from application. This means that a case-specific risk assessment is necessary, as well as application of the precautionary principle.

EcoNexus, a not-for-profit public-interest research organisation, concludes that there is a scientific case for classifying all the new breeding techniques as GM, and that their use should be regulated as rigorously as current GM techniques. EcoNexus points out that all of these techniques, though claiming great precision, can also have unintended effects and unpredictable consequences.

A legal analysis commissioned by several German agricultural and environmental associations concludes that both ODM and the CRISPR/Cas technique constitute GM technology. The analysis takes the view that the classification of a specific technique does not depend on whether or not the modified organism can be distinguished from an organism that mutated naturally or with the help of traditional breeding, because Directive 2001/18 is process-oriented, not result-oriented.

IFOAM EU, representing the organic food and farming sector, argues that plants bred using the new techniques should be subject to the risk assessment and mandatory traceability and labelling requirements applying to GMOs. IFOAM stresses that Recital 17 of Directive 2001/18/EC makes it clear that the exclusions from the scope of the Directive are meant only for products that have been on the market for a long time and have a long safety record. Moreover, traceability and labelling are of paramount importance to the organic sector, as GMOs are not to be used in organic production. Eight NGOs sent an open letter to the Commission, insisting that all non-traditional breeding processes that change the structure of DNA using genetic engineering technologies should fall within the scope of GMO legislation. They stress that cisgenesis, using genes from the same species, remains genetic engineering and therefore is subject to unexpected and unpredictable effects. They highlight that the precautionary principle should be applied, as there is not yet sufficient information to assess the risks associated with most of these techniques. A number of environmental NGOs published a joint position paper in March 2016, arguing that EU GMO law must be applied in full to the new plant-breeding techniques, as otherwise European consumers, farmers and breeders would have no way to avoid GMOs.

European Parliament

In its resolution of 25 February 2014 on 'plant breeding: what options to increase quality and yields', Parliament noted that it was important to develop and use new plant-breeding techniques and to be open to the technologies available. Parliament expressed concern at the Commission's delay in assessing new breeding techniques, and called on the Commission to clarify their regulatory status. Parliament stressed that in order to respond to forthcoming challenges, such as future food-supply needs and climate change, it was important to have an effective and competitive plant-breeding sector. It called on the Commission to use the Horizon 2020 Framework Programme to fund research that supported the development of new, innovative plant-breeding techniques such as accelerated breeding. In its resolution of 11 March 2014 on 'the future of Europe's horticulture sector – strategies for growth', Parliament called on the Commission to differentiate between cisgenic and transgenic plants and to create a different approval process for cisgenic plants.

Over the past year, MEPs have posed several questions to the Commission concerning progress on completing the legal analysis (E-001802/15, P-003377/2015, P-014731/15).

Further reading

Technology options for feeding 10 billion people – Plant breeding and innovative agriculture, Science and Technology Options Assessment (STOA), European Parliament, October 2013.

The opportunities and limits of genome editing, Nationale Akademie der Wissenschaften Leopoldina et al., September 2015.

The precautionary principle, European Parliamentary Research Service, December 2015.

The regulatory status of New Breeding Techniques in countries outside the European Union, Schuttelaar & Partners, June 2015.

Endnotes

1 Definitions and descriptions of these techniques can be found for example in Chapter 3 (pp. 23-27) of the study by the Joint Research Centre (JCR) on 'New plant breeding techniques'.

2 Cisgenesis is the genetic modification of a recipient organism with a gene (cisgene) from the same species or closely related (crossable) species.

3 Intragenesis is the genetic modification of a recipient organism that involves the insertion of the reorganised, full or partial coding region of a gene from another gene (intragene) of the same species or a crossable species.

4 They also indicated, however, that cisgenesis is similar to self-cloning and may in some cases meet the criteria of self-cloning as described in Annex II, Part A of Directive 2009/41/EC on the contained use of genetically modified micro-organisms, and that when that is the case it may be considered as falling outside the scope of Directive 2009/41/EC. They also noted that co-legislators treated self-cloning differently in Directive 2001/18/EC and in Directive 2009/41/EC, excluding self-cloning from Directive 2009/41/EC but not from Directive 2001/18/EC.

5 Transgenesis means the transfer of an exogenous gene (derived from another unrelated species) from one organism to another. Conventional genetically modified organisms are usually produced in this way.

6 Directive 90/220/EEC on the deliberate release of GMOs into the environment and Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

7 Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and Directive 2009/41/EC on the contained use of genetically modified micro-organisms. Regulation (EC) No 1829/2003, concerning genetically modified food and feed, was added in 2003.

8 Commonly used genetic engineering breeding methods used to leave easily detectable traces of genetic material from the bacteria or viruses (used as gene shuttles) in the genome of the plant.

9 DNA from plant pests, such as viruses or bacteria, were used in traditional GM-plants.

10 In April 2016 seven associations announced that they were suspending their membership of the HCB's Economic, Ethical and Social Committee (CEES), claiming that their opinions had been ignored in the Council's report on new plant breeding techniques.

11 Several NGOs objected to this decision in 2015.

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