

Legal arguments to keep plants from novel breeding techniques such as cisgenesis outside the GMO regulation

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Content

- Definition of a *GMO*
- Small nucleotide sequences
- Other legal argument why cisgenic plants should not be under the *GMO* Regulation

Definition of a GMO

2001/18/EC, 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"

“has been altered” can be interpreted in three ways:

1. The process of altering
2. The result (being altered)
3. Both process AND result

What is meant?



“has been altered”

What is meant? Three sources help us.

1. The Directive itself :

Annex 1A, Part 1

Techniques of genetic modification referred to in Article 2(2)(a) are *inter alia*:

recombinant nucleic acid techniques involving the formation of new combinations of genetic material

by the insertion of nucleic acid molecules

produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system

and their incorporation into a host organism

in which they do not naturally occur

but in which they are capable of continued propagation;

Result

Process

Foreign DNA

Here, the Result AND the Process are important.

“has been altered”

2. The Cartagena Protocol

Article 3 (g):

Living modified organism means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Result

Process

Here also, the Result AND the Process are important.

The EU agreed in 2003 on the Protocol.



“has been altered”

3. The experts of the New Techniques Working Group

Paragraph 4.4 refers to progeny that does not contain foreign DNA although a parent was a GMO:

- *All experts agreed that once it is established that the 'foreign' genetic material is no longer present in the resulting organism it is no longer considered a GMO.*

Here also, the Result AND the Process are important.



“has been altered”

Conclusion:

The wording “*the genetic material has been altered*” in 2001/18/EC, Article 2, refers to both the process AND the result.

Organisms that do not contain foreign DNA, should NOT be considered as GMOs, even if during the process a technique of genetic modification was used.



“...has been altered in a way that does not occur naturally by mating and/or natural recombination”

The genes that are introduced via cisgenesis can also be present because of natural mating.

‘Genomic disruption’ (resulting from the introduction of natural genes) is a natural process that occurs on a regular basis because of transposons, natural mutations and genomic rearrangements, and natural gene copying.

Gene families are very common in plants, and are a result of copying genes and inserting them elsewhere in the genome. A natural kind of cisgenesis.

Conclusion: **Cisgenic plants can be a result of natural processes.**



Small nucleotide sequences

- Foreign DNA?
- How many nucleotides could constitute a new combination of genetic material?

- Expert Working Group, par. 4.2:

A majority of experts concluded that in order to form a new combination, a nucleotide sequence of at least 20 bp is required.

Cisgenic plants should not be regarded as GMOs, on the condition that no foreign nucleotide sequences of 20 bp or longer are inserted.



Other legal argument

EFSA: Cisgenic crops are as safe as conventionally bred crops.

- Goal of 2001/18/EC is biosafety.
- EFSA Report:
 - Cisgenic plants are as safe as conventionally bred plants.
 - Intragenic plants and transgenic plants may lead to additional risks.
- For transgenic plants, biosafety studies have to be performed to show that these additional risks do not occur.
- For cisgenic crops such studies are not needed, as cisgenic crops are within the range of conventional bred crops.
- Bringing cisgenic plants under 2001/18/EC would be against the goal of the Directive, and would needlessly frustrate innovation, mainly by SMEs.



Thank you
for your attention

