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IHRE NACHRICHT VOM

AKTENZEICHEN  
(bitte bei Antwort angeben)

DATUM 28. September 2015

**Interpretation of §2 (2) of Directive 2001/18/EC in order to clarify legal status of  
organism created by New Plant Breeding Technologies (NPBT)**

Dear [REDACTED],

In response to your kind offer to MS during the recent SCoPAFF meeting of September 2015 we wish to send information (Annex I) containing a legal interpretation of § 2 (2) of Directive 2001/18/EC. In the light of this interpretation it becomes clear that the GMO definition within the Directive relies on both, a product AND a process related component. The necessity to contain both components is in our opinion crucial for the clarification of the legal status of organisms created by NPBTs. This interpretation was put together by an exchange of views from the UK Government and the Irish and German Competent Authorities under Dir. 2001/18/EC. We would appreciate if this interpretation could be handed over to your legal service for discussion.

Yours sincerely

[REDACTED]

[REDACTED]

## Annex I

The definition of "genetically modified organism" is as follows according to Article 2 (2) of Directive 2001/18/EC:

"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"

Article 2 (2) defines a GMO by reference to both: (i) the technique (process) used to generate an alteration in the organism's genetic material and; (ii) the genetic alteration (product) that the technique has generated. The use of the words 'altered in a way' applies to both the process and the product. This is evidenced by:

a) Process: The references in the definition to techniques listed in Annexes I A Part 1 (1) and (2) establish that the process/ technique is one of the criteria for determining whether something is being genetically modified «within the terms of this definition».

b) Product: The use of the word «naturally» in Article 2 (2) establishes that the definition also relates to the genetic alteration in the organism (product), i.e. whether the resulting product is something that is genetically modified. This is apparent when the Article is broken down into component phrases.

The wording in the definition is as follows:

...the genetic material has been altered in a way that does not occur naturally by mating and / or natural recombination...

There is no particular reason why «mating» appears before «natural recombination». If the two terms are swapped, this becomes:

...the genetic material has been altered in a way that does not occur naturally by natural recombination and/or mating...

This highlights that the inclusion of the word 'naturally' is redundant if the definition applied only to the techniques/ processes used (i.e. «mating», which is a natural process and «natural recombination», which already contains the term «natural»). The definition would effectively be stating that the process does not occur naturally by a natural process, which makes little sense.

Therefore, the Article establishes that for an organism to be a GMO, its genetic material has to be altered in a way that does not occur naturally by mating and/ or natural recombination

(product) and it has to have been altered through the use of a technique that is considered to result in genetic modification (i.e. a technique that is not listed in Annex I A, Part 2, subject to the associated conditions) (process). The definition is stating that the end product's genetic make-up does not occur naturally and that it has not come about by a natural process (i.e. by mating or recombination).

Processes/techniques that are not mating and/or natural recombination are techniques of genetic modification in the meaning of Article 2 (2) (a), Article 3 (1), Annex I A, Part 1, and Annex I B. However, techniques of genetic modification do not necessarily generate GMOs regulated under the Directive; this will depend on whether they meet the terms of the definition in Article 2 and/ or whether they are listed as being exempt from the Directive in Annex I B (and the exclusion criteria apply). This approach is consistent with the wording of Article 3 (1), which excludes «organisms» obtained through the techniques of genetic modification listed in Annex I B, rather than excluding «genetically modified organisms» obtained by such means (it is notable in this regard that «genetically modified organisms» is used for the exclusion in-stead in Article 3 (2), suggesting that the Article 2 definition must be met before this exclusion applies, but not the exclusion in Article 3 (1)).

Therefore, the GMO legislation does not control:

- novel organisms generated through traditional breeding techniques
- non-novel organisms generated by novel breeding techniques (i.e. those organisms that could have been developed using traditional breeding techniques)
- organisms generated by techniques excluded in accordance with Annex I B

It follows: Only modifications of genetic material that do not occur naturally by mating and/ or natural recombination (product) and which occurred through the use of a technique of genetic modification (a technique that is not listed in Annex I A, Part 2) would, therefore, create a GMO.

ODM: Generates an organism in which the genetic material has been altered in a way that can occur naturally during the process of mating. The technique used is a technique of genetic modification; but mutagenesis is a technique that yields organisms that are excluded from the Directive. (Therefore, organisms generated by ODM do not fall under the definition of GMO given in Article 2 (2) of the Directive because the genetic material is altered in a way that can be the result of natural mating. In addition, the technique is listed in Annex I B (and the exclusion criteria are met), meaning that the Directive does not apply to organisms gen-

erated by this technique, under Article 3. This ties together the definition of genetically modified organisms under Article 2 and the list of techniques for genetic modification in Annex I B.