

LEGAL DRAFT FOR DIRECTIVE 2001/18/EC

There is a need for the clarification of the scope and definitions in Directive 2001/18/EC. Therefore, additional definitions of the following concepts shall be specified in Article 2.

PART A

GENERAL PROVISIONS

Article 2

Definitions

- () ...
- () Long safety record: This should be defined as having a safety record of X years before the ratification of this Directive. Recital (17) of Directive 2001/18/EC shall also be adapted accordingly.
- () ...
- () Mutagenesis: The process of generating mutations in the genetic material of an organism. For the purpose of this directive, the definition should entail the differentiation between conventional mutagenesis techniques which are further exempt through Annex I B, and new mutagenesis techniques which do not introduce foreign transgenic DNA and are exempt via the proposed Annex I C.
- () ...
- () Traditional breeding (as referred to in Annex I B (2)): The definition should clearly state a positive exhaustive list of breeding methods which are considered "traditional", and may be supported by provision of a cut-off date such as the ratification date of this Directive.
- () ...
- () Traits (as referred to in several provisions of the Directive): The definition should specify the notion of a "novel" trait (e.g. A trait that is not listed in the exhaustive positive list of species-specific traits and which cannot be introduced into a species through traditional breeding techniques alone).
- () ...

Article 3

Exemptions

1. This Article shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B and Annex I C.

Whereas:

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3 (1)

- (1) Mutagenesis: It shall be specified that this article's exemption only applies to "conventional" mutagenesis techniques, and that such techniques must have been safely applied before the Directive entered into force.
- (2) Shall there be any reasonable belief that such an introduced novel trait renders an organism a safety risk with regards to human and animal safety or the environment, the applicant or the competent authority shall require a full risk assessment of the new product in line with Annex II requirements.

New annex:

ANNEX I C

TECHNIQUES REFERRED TO IN ARTICLE 3 (1)

- I. The provisions of this Directive shall not apply to techniques of genetic modification as referred to in Article 3(1), on the conditions that:
 - (i) The technique only results in modifications of the genetic material of an organism which could have been obtained by traditional breeding methods defined in Article 2 of this Directive and Annex I B, including via breeding with other species with which the resulting organism could naturally exchange genetic material. The compliance with this provision is to be established by comparison with a database established in Annex I C III and IV;
 - (ii) The method only yields organisms from which any recombinant nucleic acid molecules that were introduced during the modification procedure were subsequently removed using traditional breeding techniques, so that the organisms to be placed on the market and/or to be released into the environment no longer carry the recombinant nucleic acid molecules or copies thereof used during the modification phase;
 - (iii) The resulting organisms do not contain genetically modified organisms other than those produced by techniques, methods or applications compliant with this Annex I C, subparagraphs (i) and (ii).
- II. All known traits that existed in the EU or had been introduced by any breeding techniques until the ratification date of this Directive, and that were not connected to any safety concerns requiring further risk assessment, shall be listed in a database which as such constitutes a positive list of species-specific traits.
- III. Organisms that have been modified to exhibit only species-specific traits listed in the positive list established in Annex C III shall not fall into the scope of this Directive and thus, do not require the risk assessment required by this Directive.
- IV. Organisms with traits which are not included in the database (positive list) fall under the same provisions as genetically modified organisms, irrespective of the method of production with an exemption of those methods listed in Annex I B, and must undergo

the risk assessment as provided for in this Directive Annex II and all other applicable provisions.

- V. Products exhibiting novel traits resulting from any techniques referred to in Annex I C, and not listed in the positive list established in Annex I C III, shall undergo the risk assessment procedure described in this Directive, Annex II and all other applicable provisions.
- VI. The notification procedure in Annex III is to be adapted to the novel provisions.

