

## EUROPEAN CITIZENS' INITIATIVE - GROW SCIENTIFIC PROGRESS: CROPS MATTER!

- a. With regard to Article 114 of the Treaty on the Functioning of the European Union (TFEU) and in accordance with the ordinary legislative procedure;
- b. Directive 2001/18/ EC of the European Parliament and of the Council of March 12, 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, establishes a legal framework for the authorization of genetically modified organisms (GMOs), which does not apply to organisms obtained through techniques of genetic modification listed in Annex I B;
- c. Vagueness, lack of workable definitions and legal certainty block the implementation of this Directive;
- d. Scientific and technical innovation have developed to an extent that requires a revision of the present Directive, with special regard to new plant breeding techniques (NPBTs);
- e. Indispensable evaluation of the protection of human and animal health and the environment must be taken into account;
- f. The objective is to improve the opportunities regarding scientific progress in the European Union (EU);

### OUR GUIDING PRINCIPLES FOR REVIEWING THE DIRECTIVE

In light of recent technical and scientific advancements, Annex I B of Directive 2001/18/EC is outdated. This can be attributed to the fact that a procedure to review and update the Directive is missing. In addition, a definition of "long safety record" as referred to in recital 17 of the Directive is absent. The lengthy and costly market authorization process, which several products are subject to, as a result impedes opportunities regarding scientific progress and innovation in the EU. Therefore, we as students of the Life Sciences consider it important to revise the current exemption mechanism stipulated in the Directive, with regards to NPBTs. NPBTs, as regarded in this proposal, will be further defined in the legal draft.

Our proposal is based on the following guiding principles:

1. Annex I B should serve the same regulatory purpose as before, but it should be specified that "mutagenesis" refers to techniques invented before the creation of the present Directive (referred to as "conventional mutagenesis").
2. A new Annex, Annex I C, should be introduced that encompasses an exemption-mechanism for NPBTs, in which recombinant nucleic acid molecules may be used during the procedure, but do not result in end products containing these recombinant nucleic acids.
3. In view of possible scientific and technological progress, timely revision and adaptation of Annex I C should follow.
4. The party placing the organism resulting from NPBTs on the market and making use of the exemption mechanism outlined in Annex I C is responsible for providing proof of compliance with the exemption criteria to the competent authorities.
5. The new Annex I C requires product-based evaluation of NPBTs, followed by case-by-case evaluation if the product could not have been reached with traditional breeding methods.

The case-by-case evaluation thus shall only be required if the new resulting organism has traits that are not included in a positive list which is to be established in the form of a database (based on existing databases, e.g. worldwide plant varieties or EU database) of naturally existing traits.

6. The database should become legally binding to ensure the well-founded existence of the traits.