Dr. Dirk Inze
European Sustainable Agriculture
Through Genome Editing - EU-SAGE

Dear Dirk,

the Italian Society of Agricultural Genetics (SIGA) and the Italian Federation of Life Sciences (FISV) believe it is time to propose a revision of the EU regulatory framework of plants produced using recombinant DNA technology, mainly established by Directive 2001/18/CE. The aim of such revision is to exempt products of genome editing techniques from the Directive, as fast as possible.
We believe that such proposal should first come from the EU scientific community, who has the competences to set a framework based on the advancements of knowledge relevant to this topic. After several years of public discussions and dozens of documents that underline the urgency of revising the legal framework, it is time to clearly propose a revision.

Our proposal follows the strategy illustrated during recent years by many EU scientific societies and organizations, including ourselves. This strategy has been recently summarized in a joint statement by the German National Academy of Sciences Leopoldina, German Research Foundation and Union of the German Academies of Sciences and Humanities (2019), as well as in a statement by EASAC (2020), and can be briefly explained as follows:

1. Given the urgency to exempt form the GMO regulations a number of genome editing products, a first, short term action should amend ANNEX I B of Directive 2001/18/CE
2. A probably long term step should develop a completely new legal framework, based on the traits of the new variety instead of the technology used to introduce that trait. This will imply abolishing any legal use of the term Genetically Modified Organism, which has no scientific or merely rational meaning.

Our proposal regards step 1, and it is conceived to be as simple and clear as possible, to avoid entering into unfruitful, and probably not very scientific, discussions on number of bases modified or specific nucleic acids used. It is instead based on the simple principle that gene inactivation and the introduction of natural gene variants from the same species or a species that can be interbred have been, serendipitously or based on rational knowledge, the aim of any plant selection or breeding programme, since the origin of agriculture. It thus links the new techniques to the historical tradition of exploiting natural biodiversity, in this case with unprecedented precision and safety.

We therefore consulted with other plant science Scientific Societies and came to an agreed proposal among SIGA, the Italian Society of Plant Biology (SIBV), the Italian Society of Plant Pathology (SIPAV), and the Italian Federation of Life Science (FISV).

We propose the following modification of ANNEX I B for a discussion by the Societies, Academies and Organizations that support EU-SAGE. Our proposal is obviously open to improvements, but we think that EU-SAGE should promote an initiative for an amendment of ANNEX I B to stimulate the EU institutions to take initiative.

Sincerely yours.

Mario Enrico Pè,
President, Italian Society of Agricultural Genetics

Gennaro Ciliberto,
President, Italian Federation of Life Sciences

Pisa, Italy, Sept 21, 2020

PROPOSAL OF MODIFICATION OF ANNEX I B OF DIRECTIVE 2002/18

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of organisms other than those produced by one or more of the techniques/methods listed below, and that the recombinant DNA molecules possibly used to introduce the modification have been completely eliminated, are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods,

(3) the induction of targeted DNA breaks in selected sites, without the use nucleic acid molecules as template for DNA repair,

(4) the induction of targeted DNA breaks in selected sites, with the use of a nucleic acid molecule as template for DNA repair that introduces a targeted single base substitution,

(5) the induction of targeted DNA breaks in selected sites, with the use of a nucleic acid molecule as template for DNA repair that introduces a sequence already present in the species' gene pool, or a modification identical to a known allele of the same gene or to a known structural variant present in the gene pool of the species, or of a species with which it can be interbred.

ORIGINAL 2001 TEXT

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods.