eusage
European Sustainable Agriculture Through Genome Editing

# Proposal for a proportionate regulatory framework for plants resulting from targeted mutagenesis and cisgenesis

**Main principles of the EU-SAGE regulatory proposal for plants resulting from targeted mutagenesis and cisgenesis**

1. Plants that result from targeted mutagenesis and cisgenesis are exempted from GMO directive 2001/18/EC.
2. Plants that result from targeted mutagenesis and cisgenesis must be notified to the authority.
3. The notification requirement does not apply to a pre-defined category of plants. This category of plants will be treated as conventional (just like plants resulting from conventional random mutagenesis)
4. Based on a limited number of pre-defined risk hypotheses, the authority may request additional information about the notified crop. The crops and derived food and feed are allowed to be placed on the market when the authority has no (further) questions within 3 months after having received the notification, or the additional information provided leads to the conclusion that the crop is not expected to lead to harm to human and animal health and/or the environment.
5. Plants resulting from targeted mutagenesis and cisgenesis do not have to be labeled.

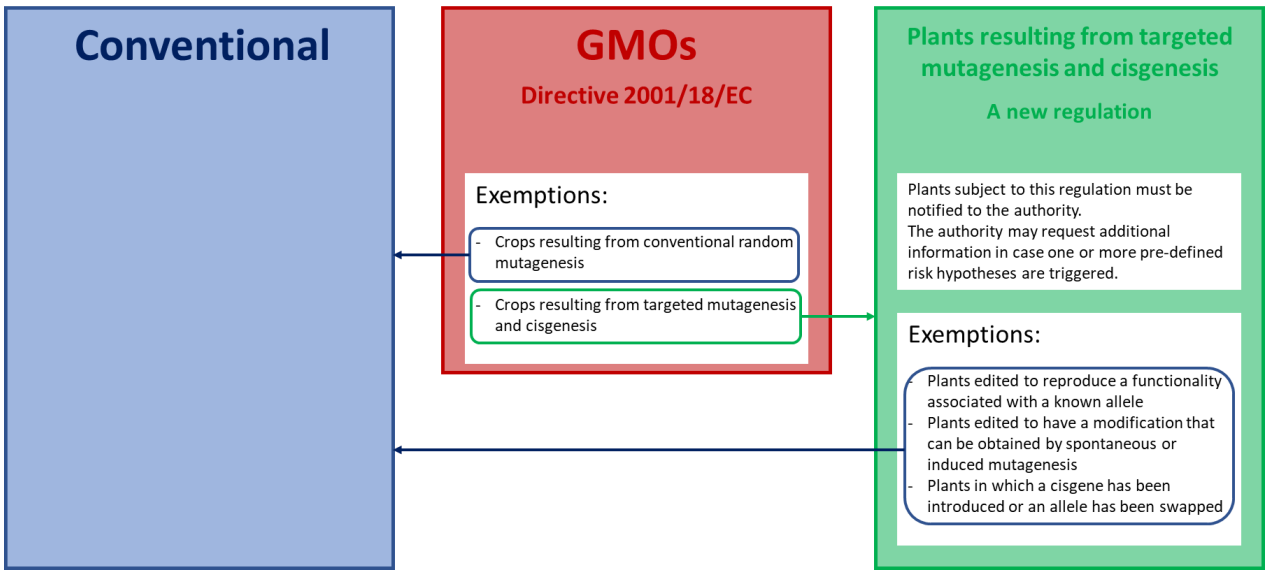


Figure 1: schematic representation of the principles of the EU-SAGE regulatory proposal

**Additional information concerning the EU-SAGE regulatory proposal**

Plants resulting from targeted mutagenesis and cisgenesis can be exempted from GMO directive 2001/18/EC by adding these categories of plants to Annex IB of the directive. Alternatively, one could also change the GMO definition in Directive 2001/18/EC to align with the scope of the LMO definition in the Cartagena Protocol on Biosafety. If the latter is done, then plants resulting from targeted mutagenesis and cisgenesis are legally no longer a GMO.

It is suggested to use the following definitions of targeted mutagenesis and cisgenesis in the legislation:

- *Targeted mutagenesis* is the targeted introduction of heritable genetic changes that do not result in the integration of functional genes into the genome, that are foreign to the plant's gene pool.
- *Cisgenesis* is the additional introduction of a gene that exists in the plant's gene pool, or the replacement of a gene by an existing other version of that gene. The cisgene is allowed to include flanking sequences of no more than 30 bp each.
- *A plant's gene pool* is the genes and their sequence and structural variants that can be introduced into that plant through crossing (including bridge crossing) / hybridization.

A separate legislation would be set up for plants resulting from targeted mutagenesis and cisgenesis. Within that legislation a certain category of plants would be exempted, resulting in treating this category of plants as conventional. This stays true to the original position of EU-SAGE and is based on the principle that one should avoid that plants with the same type of alteration but made using different technology would be treated differently by the legislation. The following plants could be part of that category:

- Plants having a native allele that has been edited to reproduce a functionality associated with a known allele present in its natural gene pool
- Plants having a native allele that has been edited to reproduce a functionality associated with a known allele present in a plant species that is outside the plant's natural gene pool
- Plants having a native allele that has been edited to reproduce a new functionality, of which the sequence modifications obtained by genome editing are of the same type as those which can be obtained by spontaneous or induced mutagenesis
- Plants in which a cisgene has been inserted into its genome either randomly or at a chosen locus, and in the latter case in the form of an extra copy or a swap

Plants that would not fall in the category of exempted plants would have to be notified to the authorities. It is suggested that this notification should contain the following information:

- Information about the notifier
- Name of the crop species
- Method used to introduce the targeted change into the genome
- Description of the introduced change
- Description of the altered propert(y)(ies) resulting from the change

It is suggested that the authority evaluates the information provided in the notification within a timeframe of maximum three months and that this authority will only request additional information when one or more of a limited number of pre-defined pathways to harm is triggered, such as:

- The plant may have significant increases in levels of antinutrients, toxins and/or allergens.

The notifier would not be allowed to introduce the plant on the market until the authority has either confirmed that no further information will be requested, or has concluded that the additional information that has been provided has led to the conclusion that the introduction of the plant on the market is not expected to lead to harm to human or animal health or the environment. If the authority has not requested additional information within three months after having received the notification, the product is considered approved.