EU-SAGE comments to the NGT regulatory proposal

EU-SAGE welcomes the NGT regulatory proposal, in particular as a means to create a more proportionate regulatory framework for specific types of genome-edited crops, thereby enabling the responsible use of genome-edited crops for sustainable agriculture. The proposal is also important in an international context, as it aligns more closely with most of the regulatory approaches taken in other parts of the world. This will contribute to the prevention of difficulties in international trade of genome-edited plant products.

EU-SAGE does still have a number of questions and comments on the regulatory proposal and these are discussed in more detail below.

Complexity of the GMO regulatory framework

The proposed regulation creates an overly complex regulatory framework for genetically modified plants. On top of the GMOs covered by the current GMO regulatory framework, it creates two additional categories of genetically modified plants for each of which specific requirements apply. It also creates these categories outside of the current GMO legislation, instead of incorporating them into this legislation.

Definitions

It is noteworthy that the GMO definition in the proposal differs from the GMO definition in Directive 2001/18/EC and equals the one in Regulation 1829/2003 and Regulation 2018/848. This leads to the remarkable situation that the 2001/18/EC GMO definition is the only one in which plants resulting from mutagenesis or cell fusion are regarded a GMO. This 2001/18/EC GMO definition also remains in conflict with the Living Modified Organism (LMO) definition of the Cartagena Protocol on Biosafety.

The definition of *targeted mutagenesis* could be improved by replacing the word 'precise' by 'pre-determined'.

The category 1 NGT criteria (annex I)

- *20 modifications*

  The proposal to allow a total of 20 modifications is discriminatory for polyploid plants such as potato (4X), rapeseed (4X), wheat (6X) and strawberry (8X). Rather than the quantity of the modifications, it is the quality of the modifications that counts. If there must be a limit to the number of modifications, this should be formulated per monoploid genome.
- *Sequence similarity*

  It is not clear what level of sequence similarity is meant as there is neither a homology percentage mentioned, nor is it specified which types of bioinformatic tools the Regulation refers to. It should

be clear that this is referring to the current bioinformatic tools that are used to predict the number of off-target sites for a specific guide RNA.
It should be noted that possible off-target sites can only be predicted if a good reference genome for the crop species is available. This is currently not the case for a significant number of crop species. One can therefore question whether potential off-target modifications should be considered, also because they rarely occur, especially in comparison to their occurrence in conventional random mutagenesis breeding.

- *Interruption of an endogenous gene*

Criterium (3)a seems to suggest that the targeted and deliberate introduction of a very short stretch of DNA into the coding sequence of a gene cannot fall into category 1, which would be in conflict with the criterion (1). This can be prevented by adding 'other than the ones mentioned under (1)' between 'sequence' and 'existing'.
It is not fully clear what is meant by interruption of an endogenous gene. Does this only refer to interruptions of the coding sequence of a gene? We assume that the intention is to prevent that plants in which a native gene would be unintentionally knocked out as a result of the insertion could qualify as a category 1 NGT plant. It would then be better to replace 'does not interrupt an endogenous gene' by 'does not knock out an endogenous gene'.

- *Conventional crosses between category 1 NGT plants*

It should be clarified that a conventional cross between two different category 1 NGT plants will always remain a category 1 NGT plant, even when in the offspring the total amount of modifications exceeds 20.

The category 1 NGT verification process

- *The data requirements*

The proposal does not contain specific data requirements for substantiating that a certain plant fulfils the category 1 NGT criteria. This creates the danger of different levels or an inflation of data requirements in different Member States. The data requirements should be proportionate and science-based and uniformly applied by the Member States and the European Commission.

- *Two different verification procedures*

We see no difference in performing a category 1 NGT verification prior to the deliberate release for any other purpose than placing on the market (now described in article 6) and performing a category 1 NGT verification prior to the placing on the market of NGT products (now described in article 7). Either the plant fulfils the criteria for a category 1 NGT or it does not. And if a Member State is able to perform that verification for a deliberate release for any other purpose than placing on the market, they are also able to do that for plants and plant products intended for placing on the market. The most important thing – as already stated above – is that the data requirements for substantiating that a plant fulfils the category 1 NGT criteria are proportionate, science-based and uniformly applied. In other words, we believe the two different verification procedures can be replaced by one.

- *Article 6.7*

In the current procedure it is problematic that any 'comment' by another Member State is enough to have to lift the verification decision to the level of the European Commission. This should only be in cases of serious reasoned objections.

- *The role of EFSA in the verification process*

It is proposed that the European Commission will consult EFSA in the verification process. EFSA is the food safety authority that has a mandate to perform risk assessments in the context of thesafety of the food and feed chains. EU-SAGE contends that it is not correct to suggest that the

check whether a plant fulfils the category 1 NGT criteria is a risk assessment process. It is not – it is a technical administrative matter – , and therefore one can question whether EFSA must be involved.

Category 1 NGT plants and organic agriculture
EU-SAGE does not understand the need to explicitly state in article 5.2 that category 1 NGT plants are not allowed to be used in organic agriculture. Because even without mentioning this, given the ruling of the CJEU in 2018 and the interpretation given to it by the European Commission, such plants would fall into the category of GMO plants which would not be allowed to be used in organic agriculture. EU-SAGE therefore thinks it is better to delete article 5.2. Thus which organisms areallowed to be used in organic agriculture is determined by what is written in Regulation 2018/848, and not determined by two different pieces of legislation.

Cisgenesis
In the current proposal cisgenic plants can only fall into category 1 NGT plants if they are the result of a targeted introduction (see formulation of criterium (3)b and (5) in annex I). This is too stringent. Also when cisgenic plants are not the result of a targeted introduction, they can be plants in which the cisgene has not interrupted an endogenous gene. Such plants are therefore perfectly comparable with a conventional plant and should also fall into category 1 NGT plants.

The requirements for category 2 NGT plants
The regulatory proposal for category 2 NGT plants creates the possibility to have simplified data requirements for the risk assessment. It also contains incentives for SMEs to lower the threshold for them to develop and market category 2 NGT plants. However, the proposal requires that category 2 NGT plants and products are labeled and traced throughout the food and feed chain as is currently the case for transgenic crops. This creates an insurmountable regulatory threshold for SMEs leading to complete failure of the mentioned SME incentives. The most important reason why food processors, food producers and retailers do not develop and sell GM products is exactly this requirement to label and trace them as GMO. It is for this reason that EU-SAGE is of the opinion that the proposed category 2 NGT plants will be without any effect. It will not lead to a wider variety of crops and traits being developed and marketed beyond what we see under the current GMO legislation. One can therefore question the usefulness/inclusion of this category in the current proposal.

An additional point is that for category 2 NGT plants Member States are required to take appropriate measures to avoid the unintended presence of such plants and their products in non-GMO products. This is more strict than what applies for current transgenic plants for which this is not a requirement. This is not logical.