Comments to the EFSA-Meeting 2022-12-12

EFSA recently published a ► Statement on criteria for the risk assessment of plants obtained by targeted mutagenesis and cisgenesis as advice for the European Commission. While EFSA does not recommend a particular regulatory framework for such plants, as it is not in its remit, the statement might give the impression that a mandatory risk assessment step is necessary for all plants obtained by targeted mutagenesis, cisgenesis and intragenesis.

EFSA appears to take the risk assessment approach to GMOs as the reference point for genome edited plants. While on the contrary EFSA repeatedly stated that such plants obtained by targeted mutagenesis and cisgenesis resemble plants produced via conventional breeding methods. This does not provide risk managers with options to consider the framework for conventional plants as a starting point and seems to suggest a GMO-like framework. New genomic techniques allow to introduce desired changes in a more targeted manner than was possible in the past. A verification / notification process to determine the regulatory status would be more suitable plants developed with NGT. Plants derived from NGTs that could have been obtained by conventional breeding or occur spontaneously in nature should be treated in the same manner as conventional plants. The fact that breeders have safely introduced variability from within the breeder's gene pool or via spontaneous or induced mutagenesis should be the pillar of a future policy initiative. Also, for plants produced with NGT, plants breeders will employ the same processes that have ensured putting on the market safe and nutritious plant varieties through selection and elimination processes.

On Monday the 12th December during the ► EFSA event on NGT, EFSA stated that the main justification to subject plants developed using targeted mutagenesis and cisgenesis to risk assessment requirements are linked to the increased speed to introduce changes. The introduction of variability within a line (via random or targeted techniques) is only the first step in the production of a variety. For any developed lines the breeder will test them to ensure they have the desired characteristics and to eliminate those lines having undesired traits. This process will also be employed for NGT plants and furthermore, the plants will need to comply with all requirements applicable to conventionally bred varieties (including official variety registration testing).

EFSA's current proposed criterion of **history of safe use is not appropriate** for the following reasons:

(1) EFSA seems to suggest that changes in the DNA that are not documented or that induce a change in exposure cannot be considered to result in products that are evaluated via a history of use approach. This is to be neither proportionate nor fit-for-purpose, even conventional breeding products would in many cases not fulfil this criterion. This concept, as interpreted by EFSA, would limit to a great extent the number of products and variety of crops that would benefit from reduced data requirements in the risk assessment proposed by EFSA in its statement and would disincentivise developers;

(2) The concept of history of safe use has no official and universally accepted definition. Its interpretation in the statement is contradictory to an earlier definition from the ► 2012 EFSA opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. It appears that a broad range of stakeholders, including the independent panellists, do not support this concept as seen in the recent EFSA online event on NGT.

The existing regulatory frameworks available for conventional products have shown to provide a high level of protection of humans, animals and the environment also when new variability has been introduced via natural or induced mutation processes. EFSA refers to the GMO framework when discussing plants with multiple edits. Plant breeders are, on a regular basis, combining alleles to improve varieties. For this reason, the GMO framework is not an appropriate basis to regulate these plants and the existing framework available for conventional breeding has shown to provide a high level of protection.