EFSA suggests a detailed risk assessment for conventional-like plants derived from targeted mutagenesis and cisgenesis

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Euroseeds participated in an EFSA Stakeholder event on 'The safety of plants derived from New Genomic Techniques: looking into future risk assessment challenges' which was hold on 12 December. The event was organized in conjunction with the publication of the recent EFSA statement that proposes criteria for the risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. The statement suggests a detailed risk assessment and would introduce the same burdensome and politicized pre- market approval system for conventional-like NGT plants as for transgenic GMOs.

While the Commission requested technical advice from EFSA under the General Food Law with a focus on the (food) product without specifically referring to the current GMO framework, EFSA only delivered its advice under the perspective of the current GMO framework with setting up risk assessment requirements from a pure process-based angle without considering the product and the importance of the similarity to outcomes from conventional breeding or natural processes.

"We reiterate that the seed sector is considering any GMO-like approach as unworkable, specifically for SMEs. Under such conditions NGTs will not be able to deliver in terms of sustainability, productivity and diversity of crops. The EU will practically undermine the goals of its own farm to fork and biodiversity strategies", states Petra Jorasch from Euroseeds.

EFSA proposes criteria to assess the history of safe use/familiarity as well as the structure and function of a genetic change introduced by targeted mutagenesis and cisgenesis in a way that would discriminate those products against similar products resulting from conventional breeding.

"Any potential pre-assessment process that concludes that a plant resulting from NGTs is conventional-like and has a similar risk profile should therefore result in a decision to also treat those plants as conventional varieties under the respective regulatory framework for conventional breeding", says Jorasch.

In addition, the efficiency gain in breeding with NGTs compared to conventional breeding methods will likely be neutralized by regulatory requirements as suggested by EFSA. Currently a GMO import approval takes more than 5 years, the last cultivation approval dates back to

the end of the 1990ies. These aspects are crucial for the EU's competitiveness and companies to make investment decisions either in the EU or outside.

While EFSA acknowledges that there is no clear and workable definition of "history of safe use", it suggests in its opinion that a period of at least 25 years is needed to allow a product to be considered safe. In contrast to this, new plant varieties that can include many genetic changes also from conventional breeding are often only on the commercial market for a few years before they are again replaced by superior lines.

"We therefore support the EFSA conclusion from 2012 that the concept of history of safe use was not developed with respect to plant breeding but for the assessment of imported food. In the case of plant breeding any "history of safe use" should be associated with the plant species in a generic sense, e.g. with wheat, maize potato, etc., rather than with individually derived varieties or gene sequences", concludes Jorasch.

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