



Reply to SANTE E3 regarding ECJ case C-528/16 on new mutagenesis techniques

Prior to the ECJ-decision, new plant breeding techniques and their future regulation have been discussed in Denmark in a broadly composed working group with representatives from academia, breeders-, consumers- and farmers organizations and NGO's.

The discussions showed that the new plant breeding techniques – as described by *i.a.* Danish scientists – potentially could support the development of a more sustainable and environmentally friendly agriculture. The new plant breeding techniques could also benefit small and medium sized breeding companies in the EU. However, concerns were also raised about the potential risks posed by the new techniques. The future regulation should strike a proper balance between these elements.

Following the ECJ-decision on 25 July, various stakeholders, including members of the working group, have expressed serious concerns about the implications of the Court's decision. Based on the experience with the current GMO-regulation, they fear that the Court's decision in practice will ban the use of the new techniques in plant breeding within the EU.

The Danish Agricultural Agency has been informed that a number of European breeding companies, including two large Danish breeding companies, are seriously considering to move their breeding activities outside of Europe after the ECJ ruling. Stakeholders from industry has suggested that the EU should seek to resolve the situation following the ECJ-ruling, including through considering if time has come to seek a review of the current GMO-legislation.

- On this background, Denmark believes there is a need to analyse and discuss the overall political, economic and environmental consequences of the ECJ-ruling regarding plant breeding. We suggest that the Commission initiates a discussion among Member States about the consequences of the ECJ-ruling.
- We would also welcome an analysis from the Commission on the socio-economic consequences of the ECJ ruling (plant breeding companies moving out of EU, loss of environmental benefits with new crop varieties, loss of agricultural biodiversity, loss of national crops that are not feasible to develop with NBT etc.)

In addition, we find that the ECJ-ruling raises a number of questions on a more technical level that also need to be resolved, as described below. Firstly, we provide the information asked for by the Commission at the PAFF-meeting on 11 September 2018.

Applications for approval of varieties for cultivation under Dir. 2001/18/EC

Denmark has received no applications for approval of varieties for cultivation under Dir. 2001/18/EC that have been developed with new mutation techniques.¹

Details on field trials under Dir. 2001/18/EC

Denmark has no ongoing field trials under Directive 2001/18/EC with regulated GMO's or any applications for field trials in the pipeline.

Status of current national variety listing related to new mutation varieties

The Danish Agricultural Agency has no records on the Danish variety list of varieties that have been developed with the use of the new mutation techniques. However, limited information is available on varieties that are multiplied in Denmark based on a variety listing in another EU-member state or another OECD-country.

Details of the advice given to control bodies/local enforcement authorities

Denmark has not prepared any guidelines for national and local control bodies regarding control of mutations in seed and vegetative propagation material. We are waiting for the European National Reference Laboratories (ENGL) to have control methods in place before we find it relevant to initiate a control effort directed at mutations.

Specific questions received following the ECJ-decisions

The Danish Agricultural Agency has received one question regarding the status of the GMO definition after the EJC ruling. The question concerns applications under contained use on whether the ruling will change regulation of GMO's (mutants) that fall under the mutagenesis-exemption and therefore currently are not regulated.

Questions that need to be resolved

The ECJ court ruling gives rise to the following questions from the Danish competent authority (CA) regarding plant breeding and control:

- We would welcome a clarification from the Commission about how competent authorities should fulfil their responsibility as regards the control of food, feed and seed for presence of unauthorised GMO's if some products in the future technically do not allow detection of the changes that have been introduced with the new mutagenesis techniques.
- To make a risk based control, the competent authorities in individual member states need an updated variety list, with global coverage, on authorised gene edited crops. Who will host and update such a list? And how can such a list be made if countries outside the EU do not regulate these crops as GMO's?
- We would welcome a clarification from the Commission about how the Commission suggest that plant breeding companies who want to market a GM crop developed with one of the new mutagenesis-techniques should live up to the requirement of providing a technique for identification of this GMO, if the changes introduced could also occur naturally or by traditional mutagenesis.
- We would also welcome a clarification from the Commission about how traceability and labelling can be ensured when tools to identify changes are lacking and there is no means of control.

¹ However, Denmark has received a number of applications for approval of trials and production of microorganisms under Dir. 2009/41/EC that have been developed with the new mutation techniques. Denmark has handled these as GMOs and Denmark will continue with this, according to the decision of the EU judiciary

- We would welcome a clarification from the Commission about how competent authorities can control for unintended or deliberate release of not approved crops developed with one of the new mutagenesis techniques, e.g. ornamental species like Petunia.
- The ECJ ruling clarifies the opportunity for MS to implement national legislation related to annex 1 B (the mutagenesis exemption). We would welcome a clarification from the Commission about how MS should handle the situation if part of the EU MS makes national regulation and another part does not (lack of harmonization).

The ECJ ruling is said to clarify the GMO status of the techniques referred to as New Breeding Techniques. Looking at the court case and the French case, the question raised to the ECJ relates only to a subset of techniques, that is the new mutagenesis techniques.

- How does the Commission suggest that the remaining new plant breeding techniques should be regulated, e.g. apples from trees where the root stock is GM and the branches that grew the apples are not GM or other techniques as described in e.g. the 2017 Explanatory Note on new breeding techniques from the Scientific Advice Mechanisms (SAM)?

Since 2001 when the directive entered into force there has been research on developing traditional mutation techniques as well. Some research has resulted in the new breeding techniques; others have made new discoveries and modifications to the known traditional mutagenesis techniques.

- How does the Commission suggest that developments in traditional mutation techniques (chemical and physical) should be regulated and controlled? How should e.g. plants mutated with a chemical substance that was not used in 2001 be regulated?