



## Traducere EN

### 1. Field trials involving organisms obtained through targeted/oligonucleotides-directed mutagenesis and cisgenesis

No field trials have been carried out so far involving organisms obtained through targeted mutagenesis or cisgenesis, in the national institutes, the R&D institutes and the R&D units operating in agriculture and coordinated by/subordinated to the “Gheorghe Ionescu Șișești” Academy of Agriculture and Forestry Sciences.

### 2. The existing varieties obtained through mutagenesis

According to the Romanian State Institute for Variety Testing and Registration (ISTIS), based on the information that the Institute gets from documents it receives from beneficiaries upon registering their varieties into the Official Catalogue (which need to undergo an examination beforehand), the breeding method used in obtaining the varieties that are presented for testing and Catalogue registration consists of mutant form selection and *hybridization*. No mutagenesis techniques are used.

### 3. Member State information on the possible techniques used by the ENGL (the European Network of GMO Laboratories) to develop methods of analysis, detection, and measure

The national institutes, the R&D institutes and the R&D units operating in agriculture and coordinated by/subordinated to the “Gheorghe Ionescu Șișești” Academy of Agriculture and Forestry Sciences do not have any research infrastructure allowing them to apply such techniques, nor to develop any methods of analysis, detection, and measure. Technically speaking, any genome rearranging that is done without inserting exogenous genomic fragments makes it impossible to identify products obtained through the new mutagenesis techniques - except for when previous scientific information exists on the modification that was introduced through the breeding method.

### 4. Information coming from the Member State databases regarding the intellectual property and patents, with a view to identify products that are launched on the market and which have been obtained through mutagenesis or other New Breeding Techniques

Specific databases containing domestic and international patent literature - such as *RoPatentSearch*, *Espacenet* or *Epoquenet* - may be accessed to find out whether a specific patent application has been approved by the Romanian State Office for Inventions and Trademarks (OSIM) and whether the item in question has acquired a patent status, or not. However, one cannot determine whether a product has been launched on the market, or not. OSIM does not hold any information on whether the patent-covered products are being marketed or have been launched on the market.

The databases of the national institutes, the R&D institutes, and the R&D units operating in agriculture and coordinated by/subordinated to the “Gheorghe Ionescu Șișești” Academy of Agriculture and Forestry Sciences include no information on intellectual property and patents that may be used to find out which specific organisms derived from such techniques might be on the market.

### 5. Other aspects regarding the European Court of Justice (ECJ) ruling of July 25, 2018, to be discussed in future meetings

We believe that the ECJ ruling of July 25, 2018, which equates the new techniques of targeted mutagenesis and other recent plant breeding techniques with *genetically modified organisms* may substantially hamper progress in certain areas of plant breeding, focused on specific objectives.

As a result of the ECJ ruling of July 25, 2018, the academia and the seed production companies in Romania have expressed their deep concern regarding its implications. Based on the experience that stakeholders have had with the current GMO legislation, they fear that the ECJ ruling will halt any research work based on NBT - which have proven so far to be the only economically-viable methods of diminishing/reducing/eliminating the climate change impact throughout the food security systems.

Agricultural academia in Romania have expressed their fears regarding the ECJ ruling, which will block research efforts in plant breeding aimed at adapting plants to climate stress, maximise protein content, reduce allergens and non-food content, etc.

Within that context, we believe that a discussion about the ECJ ruling within the Standing Committee on Plants, Animals, Food and Feed - GM Food and Feed Section, is a must, in the light of the overwhelming arguments that exist both in technical and scientific terms, their doubtless objectivity, and the consequences that such a ruling will trigger, economically and socially. The Romanian academia and professionals in the variety and seed production industry therefore declare themselves firmly against any EC court interference in the field of scientific knowledge.

We also appreciate that an evaluation of the costs of the public policies is required - in terms of the strategies that will need to be developed in order to implement the ECJ ruling -, as well as a regulatory timeline related to these strategies.

Equally, the impact of this ruling upon the WTO agreements should be analysed, given that no detection methods exist to distinguish between products resulting from spontaneous mutagenesis and products obtained through NBT mutagenesis.

We appreciate that a new European legislation on genome-editing technologies would be necessary, since the ECJ ruling of July 25, 2018 states that the organisms obtained through mutagenic techniques/methods are GMOs and therefore must be covered by the legislation on transgenesis. There is a need for a legislation that would distinguish between diffuse spontaneous mutagenesis, induced mutagenesis, and gene transfer.