ROMANIA'S POSITION REGARDING EUROPEAN COMMISSION REQUEST OF 18th DECEMBER, 2018

In addition to the information previously submitted by Romania to the European Commission in the context of the Court of Justice of the European Union decision of July 25th, 2018, we would like to add the following:

The Romanian Biosafety Commission mentioned that the new targeted mutagenesis technologies and the cisgenesis one have not yet been used on the level of experimental field trials, and researches in this area have not been completed with such products.

The Romanian Biosafety Commission states that it doesn't know about the existence of varieties obtained through induced mutagenesis that have been registered and marketed in Romania in the last 10 years.

Regarding this subject, Romania considers it opportune to draw up at the EU level, based on Member States' experience, a list (catalog) of products obtained through NBTs, that could be placed on the Union market by Member States or non- EU countries.

At the same time, we mention that the National Environmental Protection Agency (NEPA), the competent authority under the Directive 18/2001/EC, did not receive applications for notification/authorization for studies that are using new mutagenesis or cisgenesis techniques for field trials. Instead, NEPA registered a notification under the Directive 2009/41/EC on the contained use of Listeria monocytogenes, in order to *obtain a genetically modified strain of Listeria monocytogenes in containment conditions to establish the high pressure stress response mechanism.* This activity with genetically modified microorganisms that was authorized in 2018, uses classical mutagenesis and CRISPR - Cas 9 (NT) technique, but the purpose of microorganisms obtained by new techniques in this project is not to be used in fields trials or to obtain genetically modified plants.

The National Sanitary Veterinary and Food Safety Authority (NSVFSA), the competent authority for the implementation of provisions under the Regulation 1829/2003/CE on food and feed, does not have information on the existence of plant products obtained through mutagenesis at national level. To date, specific methods for detecting products obtained through mutagenesis techniques and genetic editing, have not been developed. When the EURL GMFF will make

available to the European network the method to validate detection methods for mutagenesis events, NSVFSA through the Institute of Diagnosis and Animal Health, having expertise on GMO for food and feed and specialists from the National Reference Laboratory Genetically Modified Organisms, will support the development of the necessary detection methods, taking into account the laboratory's facilities.

At the national level, there is still no position adopted by the government, but officially, the public authorities with responsibilities in the GMOs area (the Ministry of Environment/National Environmental Protection Agency, Ministry Of Agriculture And Rural Development and National Sanitary Veterinary and Food Safety Authority), as well as the Romanian Biosafety Commission draw attention that in the context of the CJEU ruling on July 25th 2018, an amendment of the European legislation regulating organisms obtained through new mutagenesis techniques / methods used in genome editing is needed, as well as a specific transgenic legislative provision, both based on the scientific progress of biotechnology and plant breeding.