**Potential impact of the judgment of the Court of Justice of the European Union in Case C 528/16 within the framework of existing legislation**

In Bulgaria, an interinstitutional working group comprising experts from: the Ministry of Agriculture, Food and Forestry, the Ministry of Environment and Waters, the Ministry of Health, the Agricultural Academy, the AgrobioInstitute, the National Center for Public Health and Analyzes and the Executive Agency for Variety Testing, Approbation and Seed Inspection discussed the impact of the judgment of the Court of Justice of the European Union (CJEU) in case C 528/16 regarding: control and traceability when placed on the market; field experiments and work in a controlled environment; the production of seeds and propagating material; patent protection and its impact on traceability; and research and development.

According to the judgments of the CJEU in case C 528/16, the new mutagenesis techniques (NMTs) lead to the creation of genetically modified organisms (GMOs) and their products are subject to: health and environmental risk assessments, market approval, labeling, traceability and monitoring.

The approach used in this CJEU decision, impacts also other methods included in the new selection techniques (NST) as presented in the publication of the Joint Research Center (2011) "New Planting Techniques: State and Prospects for Commercial Development"[1] and The EC Scientific Researches (2017) for "New Techniques in Agricultural Biotechnology"[2], since it considered all techniques/methods, which alter the genetic material of an organism in a way that does not occur naturally.

In addition, the CJEU decision enables Member States (MS) in their national legislation to categorize classical (chemical and physical) mutation as leading to the creation of GMOs or to continue to exclude it from the scope of GMO legislation.

The judgment of the Court of Justice in Case C 528/16 is largely based on Recital 17 of Directive 2001/18, therefore we need a strict definition when a technique is "traditionally used in a number of applications, and its safety has long been known ".

**1. Control activities and traceability: conducting official laboratory tests.**

The Control of NMTs products, in accordance with current GMO control, will be based on risk assessment and requires official identification and quantification methods or, in other words, there must be official methods to distinguish between NMT's plants and conventional ones. In addition, mutations derived from NMTs and from those with classical mutagenesis, which are often included in traditional selection programs and are often not fully documented, will also need to be reliable distinguished.

In this respect, we rely on the technical document, developed by the European Network of GMO Laboratories and the European Reference Laboratory for GM Food and Feed.

[1] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/new-plant-breeding-techniques-state-art-and-prospects-commercial-development

[2] https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf

From a technical point of view, any changes in the genome, which are done without introduction of a foreign genetic fragment, makes them virtually impossible to be reliable identified, such as the products obtained through NMTs, unless there is preliminary information on the modification. It is becoming even more difficult in the case of point mutations (replacement of single nucleotides) or deletion of part of the genome. And when it is not possible or very difficult to have an analytical protocol for detecting these small genome mutations, this could be considered as a technical barrier on the use of NMT's products under the rules of the World Trade Organization. Therefore, in that point a thorough legal analysis by the EC is needed with the active involvement of the MS.

Laboratory control of NMT's products can be performed if detailed information on the mutation is available. In the case of products with an edited genome, which are applied for placement of EU market, the mutation is known and the applicant provides a method and positive control. The only additional task, which possible needed is establishment of proper performance criteria of analytical methods for detection, identification and quantification for these products.

In a case of lack of certified reference materials, another issue will be metrological traceability conduction.

For unauthorized NMT's products questions are significantly more. Sequencing analysis to detect unknown products developed by genome editing with subsequent bioinformatic analysis is required. It will be necessary to build a new infrastructure and significant capacity building to meet the requirements for detection of unauthorized NMT's products, which require considerable time, financial and human resources.

In this respect, a thorough discussion is needed between the MS coordinated by the EC on the rationality, appropriateness and proportionality of the proper control analyzes, required.

In addition, when complex products (such as most foods and feeds) have to be controlled, the task becomes even more difficult.

**2. Conducting field trials and working in controlled conditions.**

According to the decision of the CJEU, organisms obtained by gene editing are covered by GMO legislation. The main challenges with regard to the application of this legislation to the contained use and the release of organisms, developed by NMTs, into the environment are linked again to the lack of effective and efficient methods for their detection and identification. As noted above, a serious problem will be when the nature of the modification is not known in advance and the expected genetic changes are minor in comparison to the unmodified parental variety or strain. It will be extremely difficult to monitor for unregulated work or release into the environment. It is necessary to analyze a relatively large number of samples, when the nature of the GMO present is unknown. In general, detection and identification in this case would be difficult and sometimes impossible.

Potential monitoring costs would often be disproportionate to potential risks.

**3. Production of seeds and propagating material;**

The CJEU decision, which defines NMTs and other NSTs as leading to GMOs creation, will inevitably impact their application in European breeding programs.

For the varieties available, is known whether or not a classical mutagenesis is used in their breeding, but there is no specific technical information. Thus, for example, the vast majority of the forms obtained in a number of important crops - maize, vegetables, and orchards include classical mutagenesis, which may lead to a new review of their risk assessment.

**4. Patenting and its impact on traceability.**

In the case where NMTs lead to the creation of GMOs, the differences in the possible patent protection in the EU and US of the products thus obtained could create additional obstacles to traceability.

**5. Scientific research and development**;

For the current research and development, as is well known, work with GMOs is only allowed after appropriate authorization in laboratory premises, indoor cultivation and field trials. This restricts the opportunities for work on projects that are practice-oriented or are associated with larger-scale studies. Given these constraints, there is a real self-restraint that leads to non-participation in such projects. Thus, our scientific institutions lose seriously overall competitiveness, they are lagging behind more than modern science and in practice are losing opportunities for capacity building.

**Conclusion**

Based on the above, we support an in-depth discussion between the MS coordinated by the EC regarding the impact of the application of the CJEU's judgment in case C 528/16 .