Please find bellow information about the situation in the the Republic of Lithuania regarding the new mutagenesis techniques:

1. Provide to the JRC and reference laboratories **any questions and information concerning analytical issues.**
Harmonised EU strategy for detection, identification and validation of new mutagenesis techniques would be welcome.

2. Provide timely **input to EURL GMFF/ENGL** in view of finalising the draft report.

The implementation of methods for the detection of genome-edited crops depends strongly on the prior knowledge of the sequence alteration. If the analytical procedure for detection and identification of a genome-edited product would be assessed by the EURL.

3. Provide information on **difficulties** Member States are confronted with (including impact on resources) **for** both **inspections and analytical testing** and to **share practices on inspections.**

National Reference GMO laboratory of Lithuania (National Food and Veterinary Risk Assessment Institute) needs more workshops and training for detection and identification of a genome-edited product.
In the meantime, Lithuania does not carry out control and surveillance of organisms obtained by new mutagenesis techniques because the comprehensive data on the species to which these methods were applied and the nature of alterations made to the genome are lacking. Another issue – it is essential to have harmonised EU procedure for detection and identification of the organisms obtained by new mutagenesis techniques.

4. Communicate ongoing and future application for **field trials** with new techniques.

The Competent Authority of Directive 2001/18/EC (The Ministry of Environment of the Republic of Lithuania) hereby would like to inform you that Lithuania has no field trials with plants produced with new techniques of mutagenesis. The Ministry of Environment of the Republic of Lithuania has not received any applications for approval of varieties for cultivation under Dir. 2001/18/EC that have been developed with new mutagenesis techniques.

5. Communicate Member States' experience with **contained uses.** N.B. The Commission will also contact directly Competent authorities of Directive 2009/41 on this question.

The Competent Authority of Directive 2009/41 (The Ministry of Environment of the Republic of Lithuania) has not received any application linked to new mutagenesis techniques yet. So, there is no experience how to handle such type of applications and what criteria to use for risk assessment and how to assess the risk itself. It would be helpful better explanation of the list of new mutagenesis techniques and what risk assessment methodology and safety measures to use for each new mutagenesis technique. Harmonised EU legislation of new mutagenesis techniques would be welcome.

6. Liaise with national competent authorities on **seeds** to consider possibilities and challenges in ensuring that all **registered varieties** fulfil the relevant requirements.

Before the inclusion of the plant variety to the National list of plant varieties, all applicants must provide data on the methods which were used to produce variety in question. According to the Competent Authority of the Directive on seeds (The State Plant Service under Ministry of Agriculture of the Republic of Lithuania), Lithuania has no registered varieties in national catalogues, which have been produced by using new techniques of mutagenesis.

7. Provide clear examples of **products challenging the implementation** of the legislation.

The comprehensive data on the species to which these methods were applied and the nature of alterations made to the genome are lacking. It is essential to have harmonised EU procedure for detection and identification of the organisms obtained by new mutagenesis techniques.

Need for further clarification.
CJEU judgment: "1. Article 2(2) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC must be interpreted as meaning that organisms obtained by means of techniques/methods of mutagenesis constitute genetically modified organisms within the meaning of that provision.

Article 3(1) of Directive 2001/18, read in conjunction with point 1 of Annex I B to that directive and in the light of recital 17 thereof, must be interpreted as meaning that only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive".

The Lithuanian authorities consider that the CJEU judgment requires a complementary interpretation of the terms from recital 17 of Directive 2001/18 / EC, in order to specify according to which criteria the notion of "have conventionally been use", "in a number of applications", with "a long safety record", must be assessed.

8. Communicate any information on **products readily available** in third countries.

The State food and veterinary service of the Republic of Lithuania (Competent Authorities for food/feed control) does not have information about products available in the third countries because we control only such products which are on the Lithuanian market and products imported under existing EU requirements.

9. Provide information on available **patented products.**
According to the information given by GMO expert committee:

1. Patents. Šikšnys V, Gasiūnas G, Karvelis T. RNA-directed DNA cleavage by the Cas9-crRNA complex . US patent.9 637 739 2017.05.02.

2. Patent applications:
1) Šikšnys V, Gasiūnas G, Karvelis T. RNA-DIRECTED DNA CLEAVAGE BY THE Cas9-crRNA COMPLEX. WO/2013/141680, PCT/LT2013/000006. 2013.03.15;
2) Siksnys V, Gasiunas G, Karvelis T, Lubys A, Zaliauskiene L, Glemzaite M, Smith A. RNA-DIRECTED DNA CLEAVAGE BY THE Cas9-crRNA COMPLEX. WO/2013/142578, PCT/US2013/033106. 2013.03.20;
3) Cigan AM, Gasiunas G, Karvelis T, Siksnys V, Young JK. NOVEL GUIDE RNA/CAS ENDONUCLEASE SYSTEMS. US20180346895; PCT/US2016/032073. 2016.05.12;
4) Cigan AM, Gasiunas G, Karvelis T, Siksnys V, Young JK. RAPID CHARACTERIZATION OF CAS ENDONUCLEASE SYSTEMS, PAM SEQUENCES AND GUIDE RNA ELEMENTS. US20180258417;PCT/US2016/032028. 2016.05.12.

10. Provide information on **other techniques, economic and trade impacts, ongoing research and research needs** at national level.

The State food and veterinary service of the Republic of Lithuania (Competent Authority for food/feed control) does not notice any trade disturbances that could occur after revision of the existing legislation covering the GMO revision according Decision of the European Court of Justice.

11. Provide **formal position** of government (if any).

Provide informal position:

According to the Decision of the European Court of Justice Lithuania suggests to revise the legislation that covers the area of GMOs

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