AT input to the follow up PAFF 03/12/2018 – new mutagenesis techniques

• Provide to the JRC and reference laboratories any questions and information concerning analytical issues

- *AT sees an urgent need to follow a proactive approach for solving the challenges regarding detection of products produced by NBT. We expect that the EURL GMFF/ENGL report provides substantial input as well as clear recommendations for the next steps in this issue*

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

- *Input from AT is provided directly via* [redacted] *who is member of the drafting team of the EURL GMFF/ENGL report*

• 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

- *AT is of the opinion that there is an urgent need for developing of analytical methods and strategies to identify and inspect products developed with new mutagenesis techniques. Until this methods and strategies are available, the only way to conduct controls will solely depend on the documents provided and total traceability.*

• Communicate ongoing and future application for field trials with new techniques

- *Based on the Austrian Genetic Engineering Act only methods of non directed mutagenesis are exempted. Therefore all products made with the new mutagenesis techniques will fall under the scope of the Austrian law and would need an approval for a field trial. So AT can state that there are no ongoing field trials with GMO and no further applications are in the pipeline.*

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

- *In the contained use there are ongoing projects with new mutagenesis techniques. Mostly in the field of development of therapeutics and vaccines. This work is mainly done on microorganisms and is basic research.*

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

- *During the seed certification process in AT the applicant has to fill out a technical questionnaire. Within this questionnaire the applicant has to declare if the variety or the parental material is genetically modified. As mentioned before based on the Austrian law, products developed with new mutagenesis techniques fall under the scope of the Austrian Genetic engineering act. Based on this it can be assured that all certified seed varieties approved in AT are non GMO.*

• Provide clear examples of products challenging the implementation of the legislation.

- *All products, where the genetically modification consists of point mutations will challenge the implementation of legislation. Although it is possible to detect such a point mutation, it will be difficult to distinguish if this mutation is the result of a natural mutation, non directed mutagenesis or new mutagenesis techniques until there will be new detection methods are developed.*

• Communicate any information on products readily available in third countries

- *In Canada a number of products subject to the PNT regulations have been evaluated for Environmental and Livestock Feed Safety by CFIA. Determinations of Safety were issued for herbicide resistant (ALS-inhibitors) Sorghum, Wheat (8 lines developed by chemical-induced mutagenesis), Oilseed Rape (3 lines developed by chemical-induced mutagenesis or site-directed mutagenesis/ODM), Rice (4 lines developed by (chemical-induced) mutagenesis), Lentils, Mustard and Sunflower (1/1/2 lines developed by mutagenesis). In addition the safety was determined for Potato (4) and Alfalfa lines (1) developed by Cisgenesis/Intragenesis.*

- *In the USA a number of applications developed by New Techniques (new Genetic Modification Techniques) have been reviewed by USDA-APHIS for their status of regulation under the agency´s statute:*
  Most of the applications are modified by Genome Editing (21, incl. 10 CRISPR-based, 7 TALEN, 2 Meganuclease, 1 ZFN; applications for Camelina, Pennycress, Tomato, Maize, Tobacco, Soybean, Alfalfa, Setaria, Mushrooms, Wheat, Rice). Others are modified by Cis/Intragenesis (5; Potato, Rice, Apple, Grapevine) or Null-Segregants (6, e.g. an application for accelerated breeding; Plums, Tobacco, Potato, Soybean) and an RNAi-modified Soybean for transposon mutagenesis.
  The applications are in various stages of development (field testing or subsequent stages); no concrete information is available for the time of commercialisation for most of the applications; only a few cisgenic / intragenic

potato lines (9) have passed the voluntary FDA consultation for food safety which precedes market introduction.
An Overview as of 10.09.2018 is also provided in Modrzejewski, Dominik; Hartung, Frank; Sprink, Thorben; Krause, Dörthe; Kohl, Christian; Wilhelm, Ralf (2018). Übersicht über Nutz- und Zierpflanzen, die mittels neuer molekularbiologischer Techniken für die Bereiche Ernährung, Landwirtschaft und Gartenbau erzeugt wurden: Julius Kühn-Institut. Available: https://www.bmel.de/SharedDocs/Downloads/Landwirtschaft/Pflanze/GrueneGentechnik/NMT_Stand-Regulierung_Anlage4-Aktualisierung.pdf?__blob=publicationFile

- *Until June 2018 12 requests were evaluated in Argentina according to Resolution No. 173/2015, incl. 10 applications of genome editing, mostly in plants, mostly determined not regulated by the Argentinian authorities (OECD, 2018). Further information on status of commercial development or use is only available from Argentinian authorities*

  For more detailed information two documents are attached

• Provide information on available patented products

- *No patents for nGM applications were submitted to the Austrian Patent Office in 2016-2018; such patents however may be available from the EPO*

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

- *Economic and trade impacts as well as research needs are important topics within the process of finding a formal position of the AT government. Since this process is not finished now(see point below), AT can not answer this question now*

• Provide formal position of government (if any)

- *AT is currently in the process of finding a formal position of the government. Involved CAs are the Federal Ministry of Labour, Social Affairs, Health and Consumer Protection, the Federal Ministry of Sustainability and Tourism and the Federal Ministry of Education, Science and Research. We expect an arranged and formal position in April or May 2019*