EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
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Dear Mr Sarvas and Ms Törmäkangas,

Subject: Commission's view on the regulatory status of the oligonucleotide mutagenesis (ODM) techniques

Thank you for your letter of 17 February 2014.

As you mentioned in your letter, oligonucleotide-directed mutagenesis (ODM) is already widely used by research laboratories for the induction of targeted mutations in both prokaryotes and eukaryotes. In the plant breeding sector, it is considered, together with other newly developed techniques, within the group of the so called "new plant breeding techniques" (NPBT), whose regulatory status in the European Union has to be clarified.

The Commission has launched different actions with the objective to clarify the legal status of these NPBTs.

The first action, as mentioned in your letter, was the setting up of a Working Group (NTWG) on the establishment of a list of techniques which might fall under the scope of Directive 2001/18/EC and Directive 90/219/EEC, with the objective of evaluating these techniques in the light of the GMO/GMM definition, of the techniques listed in the Annexes of the Directives and of the most recent available scientific data.

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The second action was the study on "New Plant Breeding Techniques: state-of-the-art and prospects for commercial development" carried out by the Institute for Prospective Technological Studies (IPTS) of the European Commission Joint Research Centre (JRC) in cooperation with the JRC Institute for Health and Consumer Protection (IHCP).

The third action was the request to the EFSA Panel on GMOs to deliver a scientific opinion on three techniques, namely cisgenesis, intragenesis and site directed nuclease technique, in terms of the risks they might pose and the applicability of the existing EFSA guidance documents on GM plants for their risk assessment.

The fourth action is the legal analysis of these techniques which is currently ongoing within the Commission Legal Services.

I would like to stress that including or excluding a technique from the scope of the Directive depends on the interpretation of the definition of GMO set out in Art. 2(2) of Directive 2001/18/EC and of the techniques of genetic modification exempted from the Directive as provided for in Art. 3(1); this evaluation is complex and requires a thorough legal analysis by the Commission, which is currently ongoing and is addressing not only ODM, but also other New Plant Breeding Techniques.

In this respect, I would like to assure you that the Commission, having well in mind your concerns, is committed to perform this analysis and, although unable yet to provide a defined timeline for the delivery of its legal opinion, intends to share its conclusion with the Member States in a close future.

With respect to your concern on major difficulties which could be encountered by Competent Authorities in the risk assessment and risk management of products obtained through the use of NPBT, we would be able to address this issue once the legal status of these techniques is clarified.

Finally, with regards to your request to include the Final Report of the NTWG in the agenda of the next CA meeting, the Commission would like to consider this report for discussion with Member States' Competent Authorities together with the result of the legal analysis, as soon as this will be completed by the Commission Services.

I look forward to our continued cooperation on these sensitive issues.

Yours sincerely,

For the Director General **absent,**
Martin SEYCHELL
Deputy Director General

p.o. Paola Testori Coggi