



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Biotechnology

Brussels,
SANTE/E1/IC/nn sante.ddg2.e.1(2015) 270852

Dear Competent Authority for Directive 2001/18/EC,

Subject: Herbicide tolerant oilseed rape produced using oligonucleotide directed mutagenesis

We have been informed that some Member States authorised, as exempted from the GMO legislation, field trials of herbicide tolerant oilseed rape produced using an oligonucleotide directed mutagenesis technique.

You are aware that the Commission is carrying out a legal analysis of a group of new plant breeding techniques, in order to evaluate whether they lead to organisms falling under the scope of Directives 2001/18/EC on the deliberate release into the environment of genetically modified organisms and 2009/41/EC on the contained use of genetically modified micro-organisms. Among these techniques, oligonucleotide directed mutagenesis (ODM) is also considered.

As you know, the deliberate release (field trials or placing on the market) of products which are subject to the rules of the EU GMO legislation without appropriate prior authorisation, is illegal.

This is why, even if we acknowledge the interest of companies to develop and market new products within the best timeframes, we would like to ask you, in the context of the current legal uncertainty, to await, as much as possible, the outcome of the Commission legal interpretation before authorising a deliberate release of organisms obtained with new plant breeding techniques. For the products which could be currently be subject to field trials with the agreement of the competent authorities of the Member States concerned, we recommend that, until the status of the techniques is clarified, a protective approach is implemented in order to be able to adapt to the requirement of EU legislation on GMOs should it be concluded that the organisms produced by these techniques are subject to its rules.

Being aware that the current legal uncertainty is unsatisfactory, the Commission' services are committed to present their legal analysis to the Competent Authorities and stakeholders before final adoption by the Commission foreseen before the end of the year.

Yours sincerely,

Dorothée André
Head of Unit

To all Permanent Representations of Member States of EU

Sent only by email