

From: [REDACTED] [REDACTED]@mos.gov.pl>
Sent: 08 October 2018 15:27
To: [REDACTED] (SANTE)
Cc: SANTE CONSULT-E3
Subject: Re: Follow-up PAFF meeting 11/09/2018 on new mutagenesis techniques

Dear [REDACTED]

I am sending You respond as Competent Authority (Ministry of Environment).

Following request by EC to Member States at the PAFF meeting of 11/09/2018 to provide information and data on field trials with GMOs, new genetically modified plant cultivars and new mutagenesis techniques as Competent Authority (Directive 2001/18/EC, Directive 2009/41/EC) we present below information.

Now within country we have only one experimental field with genetically modified poplar plants. The aim of project is a morphological and physiological analysis of genes. Field experiments are for study of correlations occur on each level of basic plant living processes regulation. Genes that influence on above processes are: LSD1, PAD4, EDS1, CAO1, MPK4. In the future, application aim of the project is production of wood, paper and ethanol (bio-fuel) using plants confer higher pathogen resistance and biomass production and reduction in the use of plant protection toxic chemicals. GMO poplar plants come from Umea Plant Science Center laboratory in Sweden.

No application for genetically modified plants for release into the environment or any entry into the catalog of the Research Centre for Cultivar Testing has been received.

The European Court of Justice (case C-528/16) ruled in July 2018 that organisms obtained by new mutagenesis techniques and methods and have not traditionally been used for various applications and whose safety has not been confirmed so far (oligonucleotide-directed mutagenesis or nuclease-directed mutagenesis) are the subject of the Directive 2001/18/EC, like other GMOs that fall under this legislation, only the organisms obtained by mutagenesis techniques and methods that have traditionally been used for various uses and whose safety has already been confirmed are excluded from the scope of the directive.

According to the Court's ruling, accidental mutagenesis is excluded from the scope of application of GMO law. In the light of this ruling, the technique of directed mutation, which allows to achieve the same effects as introducing a foreign gene into the body and allows to produce new varieties at such a rate and to the extent that could not be imagined using traditional methods of random mutagenesis should be treated as a transgenesis - technique leading to the creation of GMOs.

Ministry of Environment as Competent Authority for Directive 2001/18/EC and Directive 2009/41/EC will proceed in accordance with the judgement in case C-528/16 of the European Court of Justice.

In case of any further questions please contact us,

Kind regards,

[Redacted]

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[Redacted]

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Departament Ochrony Przyrody
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GMO Unit
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From: sante-consult-e3@ec.europa.eu [<mailto:sante-consult-e3@ec.europa.eu>]

Sent: Wednesday, October 03, 2018 3:57 PM

To:

[Redacted]



ec.europa.eu

Subject: Follow-up PAFF meeting 11/09/2018 on new mutagenesis techniques

Dear Member States Competent Authorities for Regulation (EC) 1829/2003,

Following our request to Member States at the PAFF meeting of 11/09/2018 to provide information and data on new mutagenesis techniques, we have received feedback from four Competent Authorities so far.

We would like to thank these Member States for their valuable contribution and kindly remind the other Authorities to send their feedback by 11 October, in order to allow an informed discussion at the next PAFF and Regulatory Committee 2001/18/EC meetings. To this end, we also invite you to consult the relevant national authorities for Directive 2001/18/EC and Directive 2009/41/EC.

We intend to share Member States' contribution through CIRCA BC.

Thank you in advance for your cooperation.

Best regards,



DG SANTE/E/3
Health & Food Safety



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