

**From:** [redacted] <[redacted]@mapama.es> on behalf of Ciomg <ciomg@mapama.es>  
**Sent:** 11 October 2018 16:51  
**To:** SANTE CONSULT-E3  
**Cc:** [redacted] (SANTE); Ciomg  
**Subject:** RE: Follow-up PAFF meeting 11/09/2018 on new mutagenesis techniques

Dear [redacted] and colleagues,

Following your request during the Committee meeting of 11 September, you can find below information about **Spain**:

-**17 notifications** to carry out activities with organism modified by CRISPR-CAS9 under **containment measures** were submitted to Competent Authorities. 12 notification with cells, 3 notification with virus, 2 notifications with animals.

Spain applies the precautionary principle and we have evaluated the notification on a case by case basis.

- **Inscription of varieties to the national list:** We are not aware of any variety. However, currently it has to be mentioned if the variety is GM, but is not mandatory to specify the technique.

- **Detection and control:** methods for the detection of GMO produced with NBT are not available, so we can't give specific instructions to our control bodies. We are aware about the possibilities and limitations of analytical methods to determine if the crop have emerged with NBT or with spontaneous or conventional mutation. It is also important to keep in mind the costs and resources needed to perform the controls.

-**Scope of judgement:** the ruling court raises some questions about GMO regulation that need to be clarified.

- There is no equivalence to recital 17 in Directive 2009/41 on the contained use of GMO.
- It should be explain what is meant by "have conventionally been used in a number of applications" and "long safety record".

**Trade:** Considering that in some cases there are not differences between mutation resulting from NBT and spontaneous mutation or mutation resulting from conventional techniques, it is necessary to analyze the impact on WTO agreements.

**Impact analysis:** the consequences of the ECJ ruling in relation to R&D sector and agriculture sector in EU should be analyzed, taking into account that the global stage has changed since the year 2001. In addition, research and development in new techniques also aims to produce safer products with more precise changes (reduction of unintended effects)

Kind regards

[redacted]  
SDG de Medios de Producción Agrícolas y OEVV  
Ministerio de Agricultura, Pesca y Alimentación  
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Enviado el: miércoles, 03 de octubre de 2018 15:57

Para:





CC: [@ec.europa.eu](mailto:ec.europa.eu)

**Asunto:** 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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