[redacted] (JRC-GEEL)

From: [redacted] (SANTE)
Sent: 13 August 2018 17:00
To: [redacted] (JRC-GEEL); [redacted] (JRC-ISPRA)
Cc: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: FW: Court Ruling and contribution of EURL GMFF to implementation of GMO legal framework

Dear [redacted]

I hope this email finds you well. I am writing to you in relation to the implementation of the recent court ruling. A first discussion on it will take place in our next Standing Committee meetings : 11. September 2018 (GM food /feed) and 04 October (deliberate release). I understand that the ENGL plenary meeting is scheduled in the first week of October 2018.
Member States are likely to raise questions on detection/quantification/traceability in all these meetings.

One of the consequences of the ECJ ruling C528/16 – classifying the products of new mutagenesis techniques (ODM, SDN1 and SDN2) as GMO – is that all requirements of the GM authorisation procedure, including the submission of a reliable method for detection and quantification, traceability and labelling of the GM product apply.

To help the discussions with Member States and ensure proper implementation of the GMO framework, it would be extremely useful to get the EURL GMFF' views on the following:

- whether and under which conditions the current analytical possibilities allow detection and quantification of all types of mutagenesis events and other "new breeding techniques" ; and
- if not what are possibilities of the available or new future scientific knowledge to overcome these issues.

Ideally we would need a paper from you summarising the issues, which could then be distributed to Member States, when appropriate. Please let us know whether this is possible. To be of help, my colleagues have started a very first attempt below and would be very happy to meet with you in Brussels as you kindly suggested coming over to our offices in August.

It would also be good if you could be present in the respective Standing Committee meetings on 11/9 and possibly also on 4/10 to participate in the likely discussion on the above. [redacted] will attend the ENGL meeting you chair early October; in this regard have you put this point already on the agenda?

I am happy to discuss these ideas over the 'phone with you this week (as I will be on hols from next onwards until 10/9) and I do look forward to a continued good cooperation on these interesting issues,

Kind regards,

[redacted]

Applicability of current detection methods on products obtained through new mutagenesis techniques

The current analytical approach for detection, identification and quantification of GMO is real-time Polymerase Chain Reaction. The event-specific detection method is developed by the applicant, and validated by the EURL GMFF. Qualitative methods (detection and identification) are used for verification of absence of non-authorised GM events. Quantitative methods (determining percentage present) ensure enforcement of the labelling thresholds.

- For products obtained with mutagenesis techniques (ODM, SDN1 and 2):

a) *detection* : the current detection methods are suitable for detection purposes under the condition that *the mutated DNA sequence* contains a modified DNA sequence of at least 10 consecutive base pairs. For any mutation event that would be smaller than that threshold, the detection would be challenging if not impossible, as the method would also recognise the conventional counterpart. For a mutagenesis technique resulting in *a deletion in the DNA sequence*, the size of the deletion would equally be the limiting factor for current analytical methods to be reliable.

b) *quantification* : the lack of availability of a suitable detection method (for small size deletion and mutation) or the lack of specificity of the current detection methods will not allow a correct quantification of the event within the batch, which would be needed for proper enforcement of labelling requirements.

- For products obtained by other new techniques in agricultural biotechnology :

a) For products obtained through cisgenesis, intragenesis, SDN3, and GM microorganism used for agro-infiltration, the current analytical methods are in principle suitable for the detection, identification and quantification of the GMO under the condition they induce an altered DNA sequence in the final products.

b) However, products obtained with RNA dependent DNA methylation, reverse breeding, and in agro-infiltration will not be distinguishable from a conventional counterpart: as the DNA sequence is not modified, the products can neither be detected nor quantified.