From: [redacted] (LFST) <[redacted]@lbst.dk>
Sent: jeudi 24 janvier 2019 10:05
To: SANTE CONSULT-E3; [redacted] (SANTE)
Cc: [redacted] (LFST); [redacted] (LFST); [redacted] (LFST); [redacted] (LFST); [redacted] (LFST); [redacted] (FVST)'; [redacted] (FVST)'; [redacted]; [redacted] ([redacted]@fvst.dk)'; [redacted]; [redacted]; [redacted]
Subject: SV: Follow up PAFF 03/12/2018 - new mutagenesis techniques

Dear Sante E3 and competent authorities on deliberate release of GMO (Directive 2001/18/EC) in other member states

Please find below the reply from the Danish CA regarding responses upon the ECJ ruling C-528/16. This supplements our previous reply on the ruling of 15 October 2018.

The following feedback was asked from the EU Commission:
Provide to the JRC and reference laboratories **any questions and information concerning analytical issues.**

- See reply below.

Provide timely **input to EURL GMFF/ENGL** in view of finalising the draft report.

- Comments have been coordinated with the Danish reference laboratory who send comments on January 15th 2019.

Provide information on **difficulties** Member States are confronted with (including impact on resources) **for** both **inspections and analytical testing** and to **share practices on inspections**

- In the report mentioned above, JRC will provide an overview of the detection issue as seen from a purely scientific/technical point of view. This is very helpful for MS. However, JRC will not provide an estimate of the cost involved in implementing the various suggested types of controls. MS need such a cost estimate before they decide on a future model of control. We would welcome if COM initiated an analysis of the cost involved in the various proposals presented by JRC.

Communicate ongoing and future application for **field trials** with new techniques

- No applications for field trials are currently in pipeline in Denmark.

Communicate Member States' experience with **contained uses.** N.B. The Commission will also contact directly Competent authorities of Directive 2009/41 on this question.

- The Commission will receive a reply from the CA on contained use when the commission send the questions to the CA in this area.

Liaise with national competent authorities on **seeds** to consider possibilities and challenges in ensuring that all **registered varieties** fulfil the relevant requirements

- For registrations *ex nunc* the Danish CA on deliberate release of GMO has liaised with the CA on seed and the holder of the national variety list (TystofteFoundation (TystofteFonden)). The TystofteFoundation has included in their application form a precision of the definition of a GMO to include a reference to the ECJ ruling in case C528/16, see mail from November 27 from [redacted] (CA in DK). TystofteFoundation and the Danish Agricultural Agency have informed stakeholders about the change through news feeds on both homepages (lbst.dk[1] and tystofte.dk[2]).
- For registration in retrospect, we encourage the Commission to coordinate a discussion in the Committee under directive 2001/18/EC where member states agree on a common process to discuss with national breeding companies on how to make sure, those varieties in the common catalogue (CC) are not GMO's according to the ECJ ruling C528/16.

Provide clear examples of **products challenging the implementation** of the legislation.

- Problems related to detection and control of imported products are important and difficult, but these awaits the JRC-report previously mentioned.
- As mentioned in the Annex III of Directive 2001/18/EC: "Future developments in genetic modification may necessitate adapting this Annex to technical progress or developing guidance notes on this Annex". There is a need to adapt the demands for information in the dossier in connection to filing applications for deliberate release. E.g.:
    - Annex III B point C 2 and 3 do not apply for gene edited plants ("2. Nature and source of the vector used and 3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion").
    - Applicant is not able to provide information related to Annex III B point D point 12 ("12. Description of detection and identification techniques for the genetically modified plant").
- We would welcome a clarification from the Commission on the interpretation of the GMO-definition and the mutagenesis-exemption vis a vis all the new techniques and applications that are currently available. A New Techniques Working Group has previously addressed such questions, but following the ECJ-ruling they need to be addressed again. We need a common understanding and interpretation on a more technical level than what is provided by the ECJ-ruling.

Communicate any information on **products readily available** in third countries

- We have not made an assessment of this yet but would welcome information from others who have.

Provide information on available **patented products**

- No information available.

Provide information on **other techniques, economic and trade impacts, ongoing research and research needs** at national level

- The Danish Agricultural Agency has asked their experts for an assessment of consequences of the ECJ ruling on education, research and innovation in Denmark. The report will be published medio March 2019 and will be shared with the Commission at this point.

Provide **formal position** of government (if any)

- DK has no government position on the subject.

Other feedback and **concerns following the court ruling from stakeholders in Denmark**

- The Danish Agricultural Agency hosted a meeting on January 9th 2019 with a broad spectrum of stakeholders in Denmark to gather feedback on the consequences of the court ruling. A summary of the feedback is given here:
    - **Regulation:** Stakeholders from business and research generally found that the current regulation is outdated and need a revision. There is a need to open the directive. Future regulation should be based on product, not technique. Changing the directive will take many years. Meanwhile there is a need to change appendix 1B and clarify the definition of a mutation and for GMO. We have 2-3 years to do this before the new gene edited varieties are on the market. [On the other hand, some biotech companies fear/speculate, that opening the directive could result in an even more restricted regulation than the current directive]. Maybe we need a "breeder's directive".
    - **Research & Innovation:** Scientists already experience difficulties in obtaining funding for applied research where the goal is exploitation of gene editing in crop innovation. One university already experienced decline from both industry participation and public funding to applied research. This ruling will reduce the opportunity to exploit the possibilities that the new techniques provide.
    - **Breeding:** Danish breeding will survive, but competition will be harder. Organic farmers were concerned about the effect on Danish plant breeding. Changes made by gene editing will come, but European plant breeders will not be the ones that decide what challenges are solved with the use of gene editing. From breeding companies there was a concern that the ruling will undermine the "open source" system (breeders exemption) that prevail within the plant breeding community. How can a breeder be certain, that the shared material at no time in history was developed using gene editing?
    - **Market:** From a market perspective there was concern that Danish agriculture would be controlled by multinational seed/chemical companies and the possibilities these companies see a marked for. Not the Danish marked needs. The ruling strengthen multinational companies' power/dominance in the seed market.
    - **Consumers:** The consumers' organisation is pleased with the ruling because companies are forced to label food which ensure consumers can make a choice (GMO or no GMO food).
    - **NGO's:** The environmental organisation (NOAH/Friends of the Earth) is pleased with the ruling because new plant varieties developed with gene editing will be assessed with respect to risk for humans and the environment.

Best regards

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Ministry of Environment and Food
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[1] https://lbst.dk/nyheder/nyhed/nyhed/organismer-frembragt-ved-nye-mutagenese-teknikker-er-gmoer/
[2] https://www.tystofte.dk/en/reviews/application-forms/

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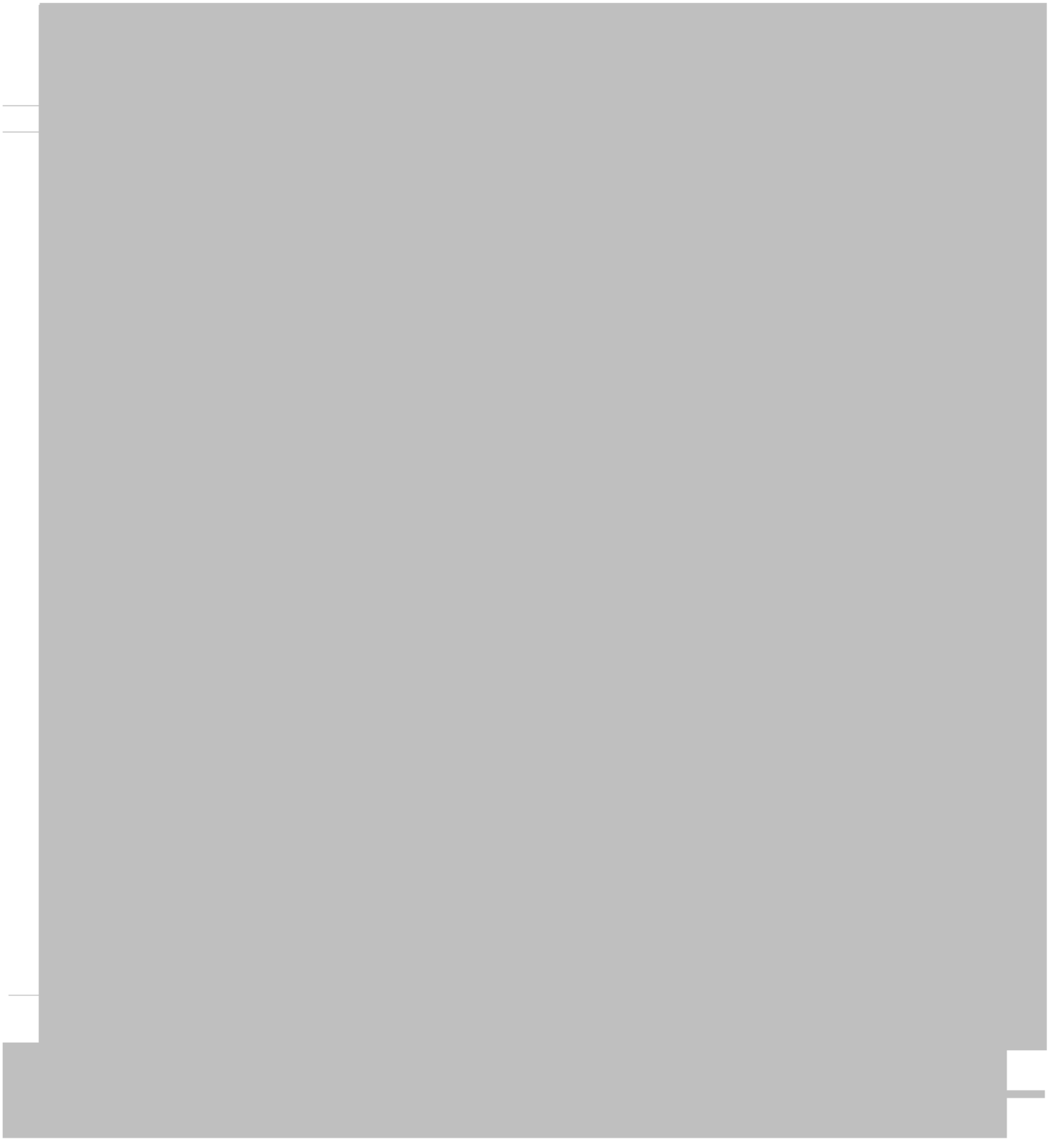
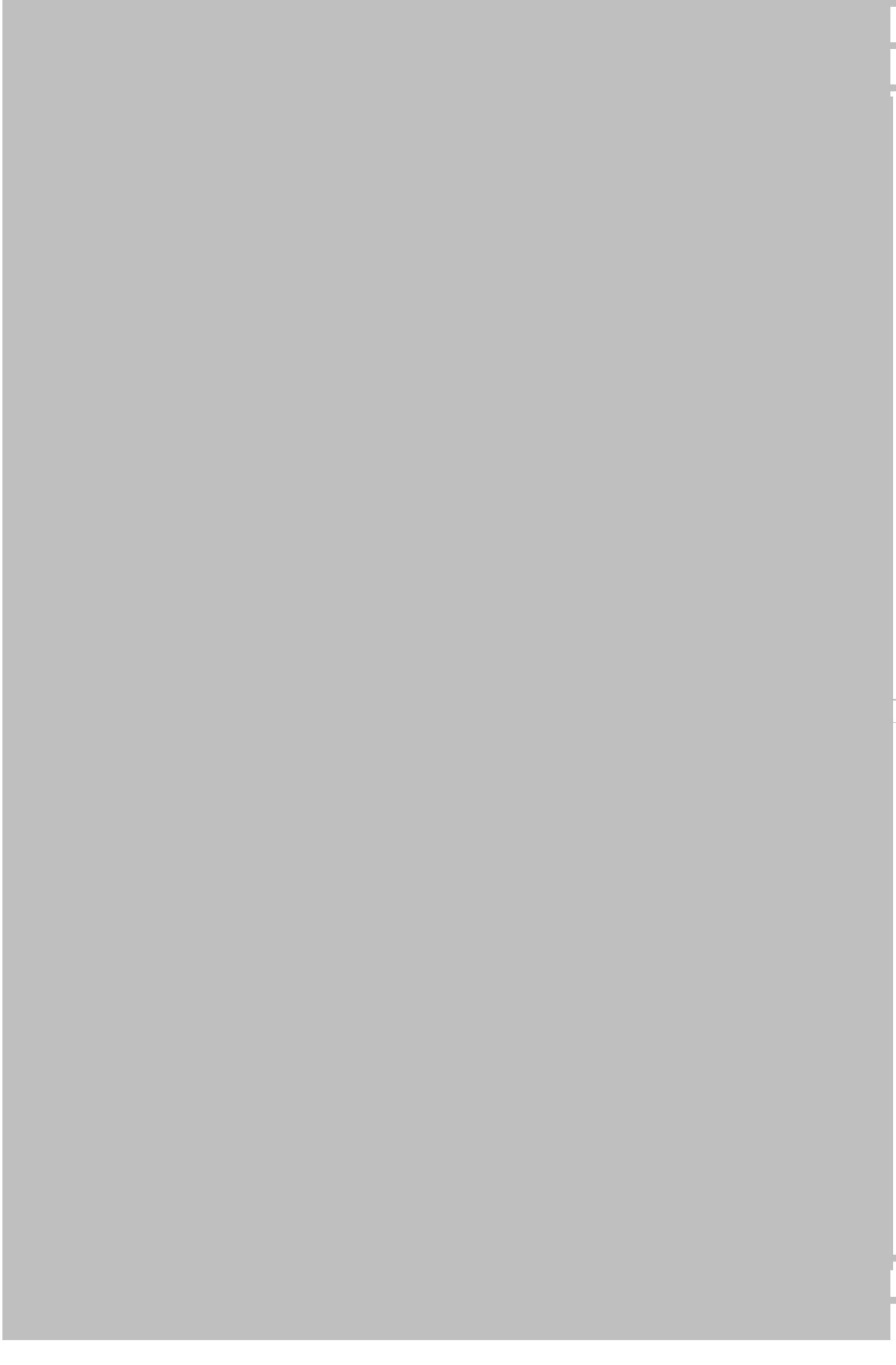
Sendt: 18. december 2018 16:01





[redacted]

Cc [redacted]@ec.europa.eu; [redacted]@ec.europa.eu; [redacted]@ec.europa.eu
Emne: Follow up PAFF 03/12/2018 - new mutagenesis techniques

Dear Member States Competent Authorities for Regulation (EC) 1829/2003 and for Directive 2001/18,

Following our discussion during the PAFF meeting on 03/12/2018, we would like to thank you for the valuable information already provided after September PAFF meeting and October 2001/18 meeting.
We kindly invite you to continue providing us information on practices and issues linked to new mutagenesis techniques in order to promote further discussion in upcoming meetings.
For sake of clarity and completeness, please find below a summary of the information that would help us all for the future discussions:

- Provide to the JRC and reference laboratories **any questions and information concerning analytical issues**

- Provide timely **input to EURL GMFF/ENGL** in view of finalising the draft report.
- Provide information on **difficulties** Member States are confronted with (including impact on resources) **for** both **inspections and analytical testing** and to **share practices on inspections**
- Communicate ongoing and future application for **field trials** with new techniques
- Communicate Member States' experience with **contained uses.** N.B. The Commission will also contact directly Competent authorities of Directive 2009/41 on this question.
- Liaise with national competent authorities on **seeds** to consider possibilities and challenges in ensuring that all **registered varieties** fulfil the relevant requirements
- Provide clear examples of **products challenging the implementation** of the legislation.
- Communicate any information on **products readily available** in third countries
- Provide information on available **patented products**
- Provide information on **other techniques, economic and trade impacts, ongoing research and research needs** at national level
- Provide **formal position** of government (if any)

We would appreciate receiving this information by **20 January 2019**. If this is not possible, we would be grateful if you could provide us with a timing estimate for your answer.

The next PAFF meeting will take place on 14 January. Please note that, while no specific agenda point for new mutagenesis techniques is planned, any relevant issue can be raised under AOB.

Finally, we would like to wish you, your families and colleagues a merry Christmas and a happy and peaceful new year.

Kind regards,

DG SANTE/E/3
Health & Food Safety

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