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Sent: vendredi 18 janvier 2019 17:06
To: SANTE CONSULT-E3
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Subject: VS: Follow up PAFF 03/12/2018 - new mutagenesis techniques
Attachments: ECJstatements_FIsupervisoryauthorities_en.docx

Dear Sir/Madam,

Please find the following report on the state of play in Finland:

- The Board for Gene Technology GTLK (the Finnish Competent Authority for Directives 2001/18/EC and 2009/41/EC) asked 6.11.2018 from the national supervisory authorities for their views on the implementation of ECJ decision on new mutagenesis techniques. Please see attached an unofficial translation of their statements. In their statements the supervisory authorities bring up their approaches and challenges in the supervision of organisms modified with new mutagenesis techniques.
- GTLK sent 15.11.2018 a letter to the Commission asking for clarification on the interpretation of the Directives regarding certain types of deletion mutagenesis as well as on certain aspects on the ECJ Court ruling.
- During 2018, the Committee for the Future of the Parliament of Finland and the Advisory Board for Biotechnology brought up in their reports the need to update the regulation genetic technologies.
- GTLK sent 18.1.2019 a letter to the Ministry of Social Affairs and Health, which is responsible for the implementation of the above mentioned Directives, informing minister Saarikko about the situation and asking for her support for possible initiatives to update the Directives.
- The officials responsible for maintaining national catalogues of registered varieties have been liaised with, and they are aware of the consequences of the ECJ decision.
- Finnish Medicines Agency Fimea officials reported that ECJ decision has not yet been discussed widely in EMA. However, the issue has been discussed in the Commission ad hoc GMO-Pharma Working Group.
- On requesting the views of the Finnish Bioindustries FIB (Finland's biotechnology industry association), the organization reported that in Finland the consequences of the ECJ decision are likely to primarily affect the plant breeding sector.
- Universities Finland UNIFI (a co-operational organisation for Finnish universities) has expressed their concern about the consequences of the ECJ decision (<http://www.unifi.fi/suomalaiset-yliopistot-huolissaan-eun-ratkaisusta-rajoittaa-voimakkaasti-geenisaksien-hyodyntamista-kasvinjalostuksessa/>)
- Negotiations have been initiated as for a formal position of the government, but due to the forthcoming elections their progress will probably be slow.

[REDACTED]
[REDACTED]
[REDACTED]

Should you need further information about the situation in the food and feed sector, please contact my colleague [REDACTED] in the Ministry of Agriculture and Forestry ([REDACTED]@mmm.fi).

Yours Sincerely,

[REDACTED]

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Further information on the Board for Gene Technology:
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Lähetetty: tiistai 18. joulukuuta 2018 17.01

[REDACTED]



Kopic

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Aihe: 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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