



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL  
JOINT RESEARCH CENTRE  
Directorate F - Health, Consumers and Reference Materials  
**Food & Feed Compliance**

## **Information on the preparation of the EURL GMFF Technical Report on the detection of genome edited products**

Immediately after the ruling of the Court of Justice of the European Union (ECJ) on 25 July 2018 the EU Reference Laboratory for Genetically Modified Food and Feed (EURL GMFF) had been contacted by DG SANTE (Unit E.3) with the request to be informed about consequences of the ECJ ruling with regards to traceability and labelling. This request was related to the two legal mandates of the EURL GMFF: the validation of detection methods, supplied by GM producers in the course of their application for EU market authorisation of their products (Regulation 1829/2003), and the EURL GMFF tasks in the frame of official food and feed controls (Regulation 2017/625). This initial request has been further specified by SANTE.E.3 in an email request of 13 August 2018 (see Annex 1).

After internal JRC.F Management consultation it was agreed to write a technical report in form of an explanatory note on possibilities and limitations of analytical methods for the detection, identification and quantification of food and feed products obtained by genome editing techniques. Moreover, representatives of the EURL GMFF ( [redacted] ( [redacted] and [redacted] ( [redacted] attended in person ( [redacted] and by telephone ( [redacted] respectively, a brainstorming meeting with colleagues of Unit SANTE.E.3 in Brussels on 22 August 2018. At this occasion the first outline of the intended technical note was shared and discussed.

As requested by DG SANTE the meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF), Section Genetically Modified Food and Feed, was attended by [redacted] (in person) and [redacted] (by video conference) on 11 September 2018. In preparation of this meeting the Member State representatives had been informed by DG SANTE that the EURL GMFF is studying the impact of the ECJ ruling on the detection and quantification aspects and is preparing a document for discussion at the plenary meeting of the EU Network of GMO Laboratories (ENGL) (see Annex 2). This information was repeated by DG SANTE at the PAFF meeting and the EURL GMFF outlined the approach for the technical note as well as answered technical questions from Member States. The upcoming consultation with Member State experts at ENGL level was announced again.

In parallel JRC.F has been approached by a Commission colleague of DG RTD, who is managing the Group of Chief Science Advisors (GCSA, formerly SAM), with the information that they are preparing a statement on implications of and challenges arising from the ECJ ruling on gene editing. The colleague had followed the PAFF Committee meeting on 11 September 2018 and was therefore aware of the drafting of the EURL GMFF technical note. At that point in time a draft version could not be shared with her as it was not finalised and approved.

In preparation of the ENGL Plenary Meeting where the issues on detection of genome edited food and feed products had been put on the agenda, as requested also by DG SANTE, the ENGL members received the draft of the above specified technical note. This draft had been sent to SANTE.E.3 on 17 September 2018 with the request to submit comments or suggestions to the EURL GMFF to be taken into the final revision process (Annex 3).

The draft version of the technical note has been discussed with experts from the Member States at the annual ENGL Plenary meeting on 3 October 2018. The lively discussion was also attended by a representative of SANTE.E.3 who outlined in an agenda point before the current view of SANTE regarding the ECJ ruling. The final revision process for the draft document has been explained during that ENGL meeting and all meeting participants were requested to send further comments, if any, to the EURL GMFF until 5 October 2018.

In addition to the comments and suggestions obtained and discussed during the ENGL Plenary meeting, several Member State experts provided written input until the deadline. No comments have been received from DG SANTE on the draft document.

The discussion at the ENGL Plenary Meeting, the written contributions from Member State experts and internal input from within JRC.F have been taken into account for the final revision process of the technical note until 9 October 2018. The final version has been submitted into the normal publication authorisation workflow of PUBSY at the end of that day.

The final Technical Report has been distributed to SANTE.E.3 on 11 October 2018 and has been put as promised to the ENGL (and as originally requested by DG SANTE in the discussions of August/September 2018) on the public webpage of the EURL GMFF. Therefore, the RTD colleague managing the GCSA obtained also the published document.

Moreover, on 10 October 2018 DG SANTE requested to [REDACTED] to attend a meeting of the Standing Committee for Directive 2001/18/EC on 18 October 2018 as the ECJ ruling will be on the agenda. They asked also for sharing the explanatory note with the Member States (see Annex 4).

*PS: JRC.F received on 9 and 10 October 2018 requests from the DG Office to contribute to a briefing for a lunch meeting of the DG with Commissioner Moedas and the Group of Chief Science Advisors on gene editing. Part of the submitted briefing contribution was the technical report which at that point was still in the PUBSY workflow, but did not undergo changes afterwards.*

[REDACTED]

Geel, 12 October 2018