EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
**The Director**

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Dear Dr Buchholz,

Thank you for your letter of 27 October 2020[1], addressed to Director-General Sandra Gallina, on the ENGL evaluation of the recent scientific publication in the journal *Foods* about a detection method for Cibus SU Canola. Director-General Gallina has requested me to reply on her behalf.

Non-authorised GMOs and GM food and feed, including those developed through genome editing, should neither be deliberately released nor placed on the EU market. As stated in Regulation (EC) No 178/2002 on general food law[2], operators have the primary responsibility for ensuring that products placed on the EU market are not only safe, but also comply with all relevant regulatory EU requirements, regardless whether these operators are operational in or outside of the EU. Member States are responsible for the enforcement of the EU legislation.

Since the judgement of the Court of Justice of the EU on mutagenesis in 2018, the Commission has discussed with Member States the implementation of the GMO legislation in several meetings of the Standing Committee on Plants, Animals, Food and Feed and of the Regulatory Committee under Directive 2001/18/EC. During these meetings, the Commission has recalled the national competent authorities' responsibility to enforce the GMO legislation in accordance with the Court's judgement, including control of products to be placed on the EU market and imported.

With the same objective of properly enforcing the GMO legislation, the Commission has also requested the European Network of GMO laboratories (ENGL) and the European Union Reference Laboratory for GM Food and Feed (EURL GMFF) to assess current and future possibilities and limitations regarding the detection of food or feed obtained

1 Our reference Ares(2020)6795577.

2 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24

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by new mutagenesis techniques. As mentioned in your letter, the 2019 report of the ENGL addresses these challenges and possibilities.

I would like to specify that the ENGL comprises around 60 national reference laboratories that are appointed by the relevant Competent Authority from each EU Member State and other laboratories from Europe designated to collaborate with the EURL GMFF and to coordinate the activities of official control laboratories.

The ENGL plays an eminent role in the development, harmonisation and standardisation of means and methods for sampling, detection, identification and quantification of GMOs in a wide variety of products, ranging from seeds to food and feedstuff.

As your letter focuses on potential imports of non-authorised GMOs, I would like to add that the Commission has regularly informed and will continue to inform third countries that only EU-authorised GM products as understood under EU legislation can be exported to the European Union. Third countries are aware of this requirement and are confident that their exporters are as well.

Proper enforcement verifies compliance against a specific legal framework, followed by corrective measures against the non-compliant products. Therefore, enforcement practices have to be able to discriminate products falling within the scope of the relevant legal framework from products that are out of scope. In this respect, the title of the publication of Chhalliyil et al. suggests that the proposed detection method could be applied by enforcement laboratories to specifically detect and quantify a genome-edited plant product. We would like to clarify that the analytical method as published is able to detect and quantify the targeted single nucleotide variants (SNV) in the acetolactate synthase gene (AHAS1C). However, it does not identify unequivocally the 'genome-edited' characteristic of the product, since the same nucleotide variation might also originate from a natural mutation or from conventional breeding techniques. The method proposed by Chhalliyil et al. is thus not fit for regulatory compliance as it fails to discriminate in an unambiguous manner whether products under consideration are within the scope of the relevant legislation or not.

Regarding method validations in the frame of official controls, Art. 34(1) of Regulation (EU) 2017/625 prescribes that "*Methods used for sampling and for laboratory analyses, tests and diagnoses during official controls and other official activities shall comply with Union rules establishing those methods or the performance criteria for those methods.*" In accordance with the latter provision, the performance criteria for GMO detection methods are established in the ENGL document '*Definition of minimum performance requirements for analytical methods of GMO testing*' (MPR guidelines)[3]. However, as described in the publication by Chhalliyil et al. the laboratory of the Environment Agency Austria has not performed the method validation according to these validation criteria, but has rather applied the more limited approach of the ENGL guidance document "*Verification of analytical methods for GMO testing when implementing interlaboratory validated methods*". Method validation and verification have different objectives (see ISO/IEC 17025) and therefore further validation activities, as mentioned in the ENGL evaluation, would have to be performed on top of what has been reported in the publication.

[3] https://gmo-crl.jrc.ec.europa.eu/guidancedocs.htm

The detection method proposed by Chhalliyil et al. is based on the amplification of a considerably large sequence (334 base pairs), which is much larger than the recommended amplicon size for quantitative PCR methods (50-150 base pairs).

Since processing methods may degrade the DNA in a product to sizes that could be smaller than the amplicon size targeted in the proposed Cibus canola method, there is a high probability that the performance of the method may be affected when applied to processed products.

Debode et al. (2017)[4] have analysed the effect of larger amplicon sizes on qPCR quantification and concluded "*These results also show that the use of larger fragments could impact the limit of detection and that targets present at low levels could not be detected due to the loss of efficiency.*"

Finally, I would like to underline that the Commission welcomes all efforts in the development of detection methods for products from new genomic techniques and will continue exploring, together with the Member States' Competent Authorities, new or improved approaches to enforce the existing GM legislation in the European Union. The Commission has discussed this detection method and its potential for enforcement with the Member States during the meeting of the Regulatory Committee under Directive 2001/18/EC. In view of the findings of the EURL/ENGL, the Commission and all Member States concluded that the Member States that would like to use this detection method should be aware of its limitations, notably that the method does not distinguish regulated products from non-regulated ones, and complement it with appropriate official control measures.

Yours sincerely,

Sabine Jülicher

c.c.: Mr Alexander Hissting (VLOG)
Mr G. Van Den Eede (JRC)

[4] Debode, F., Marien, A., Janssen, E., Bragard, C., Berben, G. (2017): The influence of amplicon length on real-time PCR results. Biotechnol. Agron. Soc. Environ. 21, 3-11.