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Berlin, 22.10.2020
Unser Zeichen: 000447-10/GB/GB
Ihr Zeichen:

Verband Lebensmittel ohne Gentechnik e.V. (VLOG, Association Food without Genetic Engineering, Germany)
Detection Method for Cibus SU Canola
ENGL Evaluation of 02.10.2020

Dear Ms Jülicher,
dear [redacted]

we write to you on behalf of our client VLOG, the German Association Food without Genetic Engineering (Verband Lebensmittel ohne Gentechnik). VLOG is a German industry association that represents food manufacturers and retailers as well as sectors across the food supply chain. VLOG promotes food manufacture without GMOs and awards licences for use of the standardized, state owned seal "Ohne GenTechnik" on food products that meet its standard. More than 14,000 food products currently bear the "Ohne GenTechnik" seal. VLOG currently represents more

than 750 members and licensees with combined annual sales of 8.8 billion euros in certified products.

At present, the possible presence of GMOs developed by genome-editing poses a serious risk to the integrity of the European food chain as a whole. Such GMOs are grown and used in North America but are not authorised in the EU. Seeds, food and feed with traces of these GMOs may therefore not be placed on the market in the EU.[1] The competent authorities are obliged to ensure that necessary measures are taken to terminate the placing on the market of unauthorised GMOs (Art. 4(5) of Directive 2001/18/EC). It is understood that at least two such GMOs are already in production in North America but have not been authorised for placing on the market in the EU. However, to date, no official controls with recognised testing methods have been developed for those genome-edited GMOs. Therefore, it is completely unclear whether and to what extent these unauthorised GMOs may already be on the market in the EU.

Non-GM food producers have a particular responsibility to ensure the absence of GMOs in their products. Therefore, together with NGOs and other business operators, VLOG has supported the development of a detection method for Cibus SU canola, one of the first genome-edited GMOs placed on the market in North America. The method has been validated by the Austrian Reference Laboratory for GMO Analysis of the Umweltbundesamt GmbH and was recently published, following peer review.[2]

The European Network of GMO Laboratories (ENGL) evaluated this publication.[3] It concludes that the method cannot identify the origin of one of the detected single nucleotide variants (SNV) and can therefore not prove that it has been caused by genome editing. ENGL also states that the publication does not provide a strategy for how to detect an unknown genome-edited based mutation, if the developer has not supplied any information on that.

Our position, on behalf of VLOG, on the evaluation of the ENGL is as follows:

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1 Art. 4 (1) and Art. 13(1) of Directive 2001/18/EC on the deliberate release into the environment of GMO, Art. 4(2) and Art. 16(2) of Regulation (EC) No 1829/2003 on GM food and feed.

2 Chhalliyil et al., A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant, Foods 2020, 9 (9), 1245, https://www.mdpi.com/2304-8158/9/9/1245/htm.

3 https://gmo-crl.jrc.ec.europa.eu/ENGL/docs/ENGL%20Evaluation%20of%20the%20scientific%20publication%2002-10-2020.pdf.

1. It is primarily the responsibility of the competent authorities to protect consumers and food businesses in the EU from the placing on the market of unauthorised GMOs.

   To this end, competent authorities should have asked the developer Cibus or the competent authorities of Canada to make available the detection methods and reference material. Cibus provided the CFIA with a method for the detection and identification of canola event 5715 according to Canadian seed law.[4] Further information may be available according to US or Canadian patent or plant variety law. No such information request appears to have been made since the ENGL is itself unable to advise on how to detect products derived from Cibus SU canola. Therefore, there is currently no analytical detection method used in the EU to monitor and enforce EU law concerning unauthorised Cibus GM products or trace contamination thereof. This, even after the Grand Chamber of the ECJ clarified in 2018[5] that the application of new genome editing techniques falls within the scope of Directive 2001/18/EC; and despite the lack of authorisation for SU Canola in the EU and the company's statement to the Commission five years ago that the presence of SU canola in imports to Europe could not be excluded.[6] It is for the Commission, as the guardian of the Treaties, to provide for the implementation of EU GMO law.

   ENGL's task is to provide technical support to the authorities. Its attempt to discredit a functional test for SU canola, based on incorrect legal assumptions, is inappropriate.

2. The ENGL evaluation is based on incorrect legal assumptions when it implies that a detection method must be able to prove that the detected mutation is caused by genome editing.

   In fact it is sufficient that a detection method can uniquely identify a GM organism based on detection of certain DNA sequences. Evidence that the particular sequences used to identify the GMO arise from the application of a regulated genetic engineering

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4 CFIA, DD 2013-100: Determination of the Safety of Cibus Canada Inc.´s Canola (Brassica napus L.) Event 5715, https://www.inspection.gc.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669. See also CFIA, Detection and Identification Method Criteria, https://www.inspection.gc.ca/plant-varieties/plants-with-novel-traits/applicants/detection-and-identification/eng/1338224521085/1338229770701.

5 ECJ, judgment of 25.07.2018, C-528/16, Confédération Paysanne, ECLI:EU:C:2018:583.

6 Cibus Europe B.V., letter of 27.01.2015 to European Commission, https://corporateeurope.org/sites/default/files/attachments/12.pdf, published via https://corporateeurope.org/en/food-and-agriculture/2016/02/us-company-railroads-eu-decision-making-new-gm#footnote18_tqpr3y1.

technique may be provided by other means. According to Regulation (EU) 2017/625 on Official Controls (OCR), methods and techniques of official controls include not only analyses and tests, but also, inter alia, an inspection of traceability, an examination of documents, traceability records and other records which may be relevant to the assessment of compliance, as well as any other activity required to identify cases of non-compliance (Art. 14(b)(iv), (e), (h) and (j) of OCR 2017/625).

As regards Cibus SU canola, the fact that the gene editing technique, oligonucleotide-directed mutagenesis (ODM) was used in the development of the trait is sufficiently documented in regulatory decisions in Canada,[7] in the scientific literature[8] and patent filings,[9] among others.

For the classification of Cibus SU canola as a GMO it does not matter if one of the two detected DNA sequences were a direct or indirect result of the use of ODM techniques. Only if the SU canola was produced without using any techniques that fall within the scope of Directive 2001/18/EC, would it not be a GMO. Therefore, since it is a matter of public record that ODM techniques were used, the Cibus SU canola is a GMO.

The legal requirements for detection tests used for official controls are laid out in Art. 34 of OCR 2017/625. According to that the requirements for the tests depend on the quality of tests available. For example, if there are no specific EU rules, international rules or rules recommended and validated by the EU Reference Laboratories, methods developed or recommended and validated by national reference laboratories or other methods are applicable.

The SU canola test meets these requirements. The Austrian Reference Laboratory for GMO Analysis of the Umweltbundesamt GmbH validated the test and performed tests with DNA from 17 canola varieties (8 wild-type, 3 Clearfield and 6 GM canola varieties) and DNA from corn, soy, rice, potato, and cotton, and confirmed the specificity of the

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7 See the authorisation as a novel food by Health Canada, Novel Food Information – Cibus Canola Event 5715 (Imidazolinone and Sulfonylurea Herbicide Tolerant), modified 26.05.2016, https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products/novel-food-information-cibus-canola-event-5715-imidazolinone-sulfonylurea-herbicide-tolerant.html.

8 D. D. Songstad, J. F. Petolino, D. F. Voytas & N. A. Reichert (2017) Genome Editing of Plants, Critical Reviews in Plant Sciences, 36:1, 1-23, DOI: 10.1080/07352689.2017.1281663

9 See for example US Patent 2012/0178628 A 1 of 12.07.2012, Mutated Acetohydroxyacid Synthase Genes in Brassica, https://www.lens.org/lens/patent/165-880-127-747-710/fulltext.

test during the validation procedure.[10] Therefore the test fulfils all requirements for tests according to Art. 34 of OCR 2017/625.

As to whether further validation might be necessary since there were more than 160 species of weeds in which mutations in the relevant gene resulted in SU resistance, as ENGL states, it is for the competent authorities to ask Cibus or the Canadian authorities for more specific tests or to further validate the test presented by Chhalliyil et al., if necessary. As long as there is no better test available, this one meets all legal requirements for official controls according to Art. 34 of OCR 2017/625.

As far as ENGL states that the conditions of Regulation (EU) No 503/2013 were not met, this is not relevant for official controls. Regulation (EU) No 503/2013 only applies for applicants for a GMO authorisation, but not for official controls of unauthorised GMOs. Therefore, as long as there is no validated detection method presented by the developer in an authorisation procedure, the competent authorities are allowed and obliged to use the best test available (Art. 34 of OCR 2017/625).

Furthermore, even validated detection methods do not need to identify the technique applied. It is sufficient that they are specific to the transformation event and thus are only functional with the genetically modified organism considered and not functional if applied to other transformation events already authorised (No 3.1 Part C of Annex III to Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of GM food and feed).

3. The ENGL evaluation further ignores that, according to food and feed law, the competent authorities do not only have to act when a violation of the law is proven, but already when there is a suspicion that this might be the case.

According to the OCR, in the event of suspicion of non-compliance the competent authorities shall perform official controls or an investigation in order to confirm or to eliminate that suspicion (Art. 65(1) and Art. 137(2) of OCR 2017/625).

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[10] See Chhalliyil et al., A Real-Time Quantitative PCR Method Specific for Detection and Quantification of the First Commercialized Genome-Edited Plant, Foods 2020, 9 (9), 1245, page 11, https://www.mdpi.com/2304-8158/9/9/1245/htm with reference to the Umweltbundesamt GmbH validation report, which is provided as a supplementary material to the peer reviewed paper: https://www.mdpi.com/2304-8158/9/9/1245#supplementary.

Therefore, even if the SU canola test presented by Chhalliyil et al. was not sufficient to conclusively prove the presence of a GMO, because there might, theoretically, exist another, non-GMO canola variety with the same two DNA sequences the test is based on, the test would at least justify reasonable suspicion of the presence of an unauthorised GMO. It would then be the task of the competent authority to clarify the origin of the product, e.g. the seed varieties actually or probably used, and to verify, e.g. by considering the information given in seed variety catalogues and by testing, whether one of these varieties was a non-GMO seed variety with the DNA sequences detected by the test. The competent authorities would also have to ask Cibus or US or Canadian authorities for the detection method the developer presented in the authorisation procedure (see above 1.). It would further be the obligation of the operators to give staff of the competent authorities access to the documents and any other relevant information to the extent that this is necessary for the performance of official controls or other official activities (Art. 15(1)(d) of OCR 2017/625). For the time needed to clarify the origin of the product the competent authorities would have to place the suspect products under official detention pending the outcome of the official controls (Articles 65(3) and 137(3)(b) of OCR 2017/625).

4. The ENGL further discussed limitations for processed food/feed materials that may contain oilseed rape. This is a general issue concerning all GMOs and therefore needs no specific discussion as to genome-edited plants.

5. Finally, the ENGL states that the SU canola test presented by Chhalliyil et al. is based on prior knowledge about the genetic modification of the plant and does not provide a strategy on how to detect an unknown genome-edited based mutation if the developer has not supplied any information. This is true. But it is no reason not to apply the test to monitor for the presence of Cibus SU canola in seeds as well as in food and feed.

As a consequence, we ask you, on behalf of the VLOG, to consider these legal requirements and provide for the enforcement of EU GMO law to genome edited SU canola as well as to conventional, transgenic GMOs.[11]

[11] See the test methods recommended by the ENGL for other GMO which are not authorised in the EU, https://gmo-crl.jrc.ec.europa.eu/emerg-unauth.html and which refer to testing methods submitted by the developer, competent authorities of states outside of the EU (e.g. for LL Rice 601, the US Department of Agriculture) or private laboratories (e.g. for CDC Triffid Flax, Genetic ID NA, Inc).

We would be pleased if you could inform us and/or the VLOG directly about your view on this topic and the next steps planned by the Commission.

Yours sincerely,

[redacted]