Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Plant Health and Biosecurity Directorate
1400 Merivale Road
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Canada

December 23, 2020

Lucy Sharrat
Coordinator
Canadian Biotechnology Action Network
902-209-4906

Dear Ms. Sharratt,

Thank-you for your letter dated December 16, 2020 regarding your request for information on changes made to *DD 2013-100: Determination of the Safety of Cibus Canada Inc. (Incorporated)'s Canola (Brassica napus L. (Linnaeus)) Event 5715*. As the responsibility for publishing Decision Documents lies within my division, Dr. Komal has asked me to reply on behalf of CFIA.

Firstly, I'd like to emphasize that CFIA considers issues of safety to be of the utmost importance. Our rigorous regulatory system is focused on the characteristics of the final product, regardless of the methods used in development. Products subject to the regulations must undergo a comprehensive science-based approval process involving both Health Canada and the Canadian Food Inspection Agency (CFIA).

With respect to the specific questions you have regarding DD 2013-100, we have prepared the following responses.

1. **When was the review of the initial determination/Decision Document initiated and who was involved in evaluating information leading to this change in the regulatory record?**

   The review of the decision document was initiated in February of 2020, and the development of the clarified text included input and review by the CFIA's Plant Biosafety Office, the Plant and Biotechnology Risk Assessment Unit, and the Animal Feed Division.

2. **How was the need to change the Decision Document brought to the attention of the CFIA? Was this re-examination a response to a request or other communication from the proponent, or was it the result of an internal process that brought new information to light?**

   The CFIA was notified by Cibus that the text could be erroneously misinterpreted to mean that Cibus canola event 5715 was developed as a direct result of an oligonucleotide-directed mutagenesis approach known as the Rapid Trait Development System™ (RTDS™). The description now states clearly that this canola was selected during the tissue culture process. This wording is also consistent with the novel foods decision that Health Canada has posted online

The CFIA decided to clarify the decision document to ensure that it more clearly described the development of canola event 5715. The CFIA did not review any new information to develop the clarified text in the decision document.

3. **What scientific evidence supports the changes made by the CFIA? Specifically, what evidence was provided or identified that demonstrates that event 5715 (and 5720) are exclusively products of "a spontaneous somaclonal variation that occurred during the tissue culture process"?**

   Cibus Canada Inc. used an oligonucleotide-directed mutagenesis approach known as the Rapid Trait Development System™ (RTDS). This process included the use of tissue culture techniques to generate plant cells that are more receptive to mutagenesis. Following treatment of protoplasts of the parental canola line with the RTDS, a canola event known as BnALS-57 was isolated.

   Sequencing confirmed that the BnAHAS1 gene of BnALS-57 contains a single nucleotide mutation, which confers tolerance to AHAS-inhibiting herbicides such as the sulfonylureas and imidazolinones.

   Although BnALS-57 was isolated following treatment of cells with the RTDS, the mutation in BnALS-57 was created as a result of a spontaneous somaclonal variation that occurred during the tissue culture process, rather than due to the oligonucleotide used in the RTDS, as evidenced by the DNA sequence of the event.

4. **Is the identification and detection method provided by Cibus still relevant to uniquely identify canola cultivars engineered with the company's events 5715 and 5720? What evidence has been provided or identified to assure the CFIA that this is the case.**

   Cibus Canada Inc. provided the CFIA with a method for the detection and identification of canola event 5715 in 2011. As per the applicable policies, Cibus provided appropriate test methodologies and reference materials to detect and identify canola event 5715 and the remutation event 5720. As always, the CFIA reviewed all methods to ensure that they were suitable to detect the event.

I trust that this information will be of assistance to you. Thank you for writing with your comments and concerns.

Sincerely,

Dr. William Anderson
Executive Director
Policy and Programs Branch
Canadian Food Inspection Agency

Cc: Dr. Jaspinder Komal