Dr Jaspinder Komal, Vice-President, Science, Canadian Food Inspection Agency
CC: Sarah Davis, National Manager, Plant and Biotechnology Risk Assessment Unit;
Dr William Anderson, Executive Director, Plant Health and Biosecurity Directorate

December 16, 2020

RE: Request for information regarding changes made to *DD 2013-100: Determination of the Safety of Cibus Canada Inc. (Incorporated)'s Canola (Brassica napus L. (Linnaeus)) Event 5715*

Dear Dr Komal,

We are writing to ask the Canadian Food Inspection Agency (CFIA) to explain changes made, in 2020, to Decision Document *DD 2013-100: Determination of the Safety of Cibus Canada Inc. (Incorporated)'s Canola (Brassica napus L. (Linnaeus)) Event 5715* (Produced in 2013 and updated in 2015 and 2017, and 2020). The document was changed to remove reference to oligonucleotide-directed mutagenesis (ODM) and to the company's trade-marked Rapid Trait Development System (RTDS) as the development method of the Cibus canola event.

The earlier Decision Document (2017) that was current until July 2020 introduced the development method as follows: "*Cibus Canada Inc. utilized an oligonucleotide-directed mutagenesis approach known as the Rapid Trait Development System™ (RTDS™).*" The document further stated that "*although [the mutated line] was isolated following treatment of cells with the RTDS, the mutation [in this line] is thought to have been created as a result of a spontaneous somaclonal variation that occurred as a result of the tissue culture process, rather than due to the oligonucleotide used in the RTDS.*" However, the document was edited in 2020 to remove any reference to ODM and RTDS and now states that *"the mutation […] has been created as a result of a spontaneous somaclonal variation that occurred during the tissue culture process."*

We are concerned that the CFIA issued a decision and published the associated Decision Document despite uncertainty and confusion surrounding the development method.

The company has consistently stated, in peer-reviewed science literature and the media, that commercial canola lines engineered with 5715 (and the re-transformation 5720) are a product of gene editing.

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We are also concerned that the CFIA changed the Decision Document without public notification of the edits. Decision Documents are the only document made available to the public to describe the risk assessment of an approved Plant with Novel Trait (PNT). These documents constitute the only public record of scientific evaluations and therefore need to be reliable, to provide accurate and detailed transparent information. (Our long-standing concerns over the lack of transparency in regulation including the lack of detail in Decision Documents are outlined in our report "Are GM Foods and Crops Well Regulated?" www.gmoinquiry.ca/regulation)

The changes made by the CFIA also have potential impacts for Canadian producers and exporters. The CFIA needs to report accurate information on the PNT transformation process.

We ask the CFIA to explain the changes made to the Decision Document:

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?

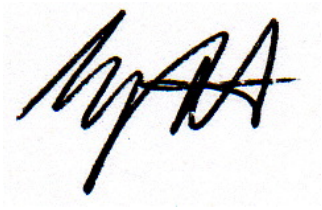
2. How was the need to change the Decision Document brought to the attention of the CFIA? Was this re-examination a response to a request or other communication from the proponent, or was it the result of an internal process that brought new information to light?

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"?

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?

Thank you for your attention our request. We look forward to your response.

Sincerely,



Lucy Sharratt
Coordinator

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