

Minister of Health



Ministre de la Santé

Ottawa, Canada K1A 0K9

OCT 07 2009

Ms. Lucy Sharratt
Coordinator
Canadian Biotechnology Action Network
Second Floor
431 Gilmour Street
Ottawa, Ontario K2P 0R5

Dear Ms. Sharratt:

Thank you for your correspondence of July 28, 2009, concerning SmartStax corn.

Health Canada's mandate is to ensure that all novel foods, including those derived from biotechnology, are safe prior to entering the Canadian food supply. The Department rigorously assesses the safety of all biotechnology-derived foods in order to protect the health and safety of Canadians.

In your correspondence, you indicate that your organizations are concerned that a food safety assessment of SmartStax corn has not been conducted, and have asked the Canadian Food Inspection Agency (CFIA) to rescind its authorization of SmartStax until Health Canada conducts a food safety assessment.

Once genetically modified crop lines are approved for environmental release and for food and feed use in Canada, they can be used in breeding programs to develop new varieties. The use of traditional breeding techniques to combine two or more previously authorized products is referred to as stacking. Health Canada's policy regarding foods derived from plants with stacked traits is described section 4.1.3.2 of the *Guidelines for the Safety Assessment of Novel Foods*, available at <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php#4.1.3.2>.

SmartStax is produced from the conventional breeding of four corn lines approved by the Department. Each of the four lines has been thoroughly assessed and has been deemed to be safe. When developing a plant with stacked traits, such as Smartstax, if the proponent does not note a novel characteristic resulting from the stack, changes in the stacked characteristics in comparison to the approved parental lines, or changes in the composition of the stacked plant which would have an impact on food safety, a notification under Division 28 of Part B of the *Food and Drug Regulations* is not required.

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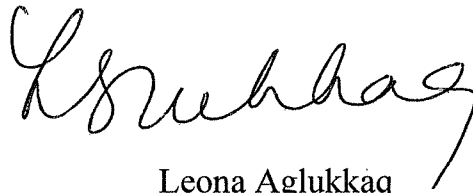
The Codex Alimentarius guidelines do not make reference to stacked products. The line you refer to in paragraph 14 is taken out of context. Paragraph 14 is intended to highlight that unintentional changes can occur as a result of any crop breeding, whether using modern biotechnology or traditional methods, and that these changes are not specific to genetically engineered crops.

Furthermore, you refer to paragraph 17 of the same document, which states that crops should be screened by breeders for unintended effects and that varieties which pass this screen should then be subject to the safety assessment described in the Codex document. Health Canada agrees fully with this statement and expects that breeders are conducting complete characterizations of their varieties to ensure that no unintended effects exist, whether the crops are genetically modified or not. As previously noted, in cases where a new variety is created by traditional breeding from previously approved lines, and the new variety did not exhibit new or altered expression of traits, the variety would not require an assessment. Only if the variety exhibited new or altered expression of traits would it then be subject to a food safety assessment.

The Department's approach to assessing SmartStax is consistent with its own policies as well as with the Codex guidelines. As there are no known food safety concerns, and SmartStax did not exhibit new or altered expression of traits, Health Canada does not see a need to ask the CFIA to rescind its authorization. It remains the responsibility of a developer to ensure that their products are in compliance with all applicable statutory and regulatory requirements. Health Canada's Food Directorate expects that any post-market information obtained that has potential health and safety implications will be forwarded to the Department for consideration.

Thank you for writing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Leona Aglukkaq', written in a cursive style.

Leona Aglukkaq