Canadian Food Inspection Agency
President
Ottawa, Ontario
K1A 0Y9

Agence canadienne d'inspection des aliments
Président
Ottawa (Ontario)
K1A 0Y9

SEP 0 6 2012

PRC 010295

Ms. Lucy Sharratt
Coordinator
Canadian Biotechnology Action Network
Suite 206, 180 Metcalfe Street
Ottawa, Ontario K2P 1P5

Dear Ms. Sharratt:

Thank you for your letter of July 9, 2012, and for your questions surrounding the Canadian Food Inspection Agency (CFIA) and Health Canada's Notice of Submission process. I will attempt to answer your questions by dealing with the science-based Assessment of Novel Plant Products and the Notice of Submission processes separately.

Assessment of Novel Plant Products

As you are aware, any novel product (such as a genetically engineered agricultural or food product) must be assessed and approved by Health Canada and the CFIA before it can be used as food or feed or released into the environment in Canada. The objective of these science-based assessment processes is to ensure that novel products are safe for humans, livestock and the environment. As you note in your letter, there are strict requirements that describe the criteria for the safety assessment that must be addressed, and how government evaluators must examine the information. Decisions are based on the data provided by the proponent, as well as on other relevant information, such as peer-reviewed publications and advice from subject matter experts. Given that the CFIA's role is limited to assessing the safety of these novel products for use as feed or for release into the environment, it is not able to consider social or economic factors as part of its assessment.

.../2

Canada

Notice of Submission Process

As part of its effort to provide transparency to the novel products being assessed, the CFIA negotiated a voluntary Notice of Submission project with Croplife Canada. While I recognize your comparisons to the regulatory processes in the U.S., and the public posting of submission information in that jurisdiction, please note that in Canada there is no legal requirement that developers participate in this Notice of Submission process nor any ability for the CFIA to require developers to participate. The project was designed to provide increased transparency as to the novel products being assessed by the CFIA and Health Canada, and to allow interested parties to provide comment. The Notice of Submission project was not designed to provide a mandatory public consultation process for individual novel product submissions. The materials provided in the notice are published at the sole discretion of the developers. All comments received in response to the Notice of Submission are reviewed by the Government of Canada (GoC), but only those comments providing science-based evidence are considered by the GoC as part of the assessment of the novel product. All comments received, with the consent of the author, are forwarded to the developer. It is important to note that the submission to the regulators for authorization of novel plant products must contain all the required data to address the regulatory requirements before a decision regarding authorization can be made. For further details regarding the Notice of Submission project, you are invited to visit the CFIA website at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/notices-of-submission/eng/1300143491851/1300143550790. I have taken note of your expressed interest in having access to a greater amount of information through such Notices. The CFIA is prepared to further engage industry with respect to expanding the information provided in the Notice of Submission Initiative as part of our ongoing commitment to expand transparency.

GE Apple

The Government of Canada believes that industry is best positioned to make market-based decisions regarding the commercialization of products approved as safe for food, feed and the environment, and that the role of the CFIA and Health Canada is to assess only the safety of these novel products. In this regard, the CFIA plays an impartial role in conducting its science-based safety assessments. Consideration of social or economic factors are outside of the Agency's regulatory mandate. Consequently, the CFIA cannot place the regulatory assessment of the GE apple on indefinite hold as per your request.

Transparency

The CFIA continues to strive for openness and transparency in all its activities. However, it is also obligated to protect the confidential business information submitted by developers and adhere to the regulations that govern the assessment of novel plant products. As part of the Agency's commitment to greater transparency, we will engage our partners at Health Canada as well as the industry to consider differing regulatory regimes in other jurisdictions and look for opportunities to bring greater clarity and openness to our assessment of novel products. We would welcome your organization's participation.

Again, thank you for writing with your concerns.

Yours sincerely,

George Da Pont