Access to Information and Privacy Centre
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K1A 0K9

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A-2001-0180 / hh

July 16, 2001

Mr. Bradford Duplisea
Researcher
Canadian Health Coalition
2841 Riverside Drive
Ottawa, Ontario
K1V 8X7

Dear Mr. Duplisea:

This is a follow up to your request dated April 27, 2001 under the Access to Information Act for the following information: **Information pertaining to written correspondence between Health Canada and the Royal Society of Canada (time period 2000 - present).**

I am pleased to send you the information requested noting that some information has been severed pursuant to section 19(1), personal information, of the Act. With the provision of this information Health Canada now considers this file closed.

Please be informed that you have the right to make a complaint to the Information Commissioner about this request, at the following address:

The Information Commissioner
Tower B, Place de Ville
112 Kent Street
Ottawa, Ontario
K1A 1H3

Please refer to our file number **A-2001-0180 / hh** on all future correspondence pertaining to this request.

Sincerely,

Hans Helleman
Special Assistant

Health Canada
Santé Canada

Deputy Minister
Sous-ministre

Ottawa Canada
K1A 0K9

FAXED 2/2/01

Your file Votre référence

Our file Notre référence

February 2, 2001

Dr. William Leiss
President
The Royal Society of Canada
FAX 991-6996
Ottawa, Ontario

Dear Dr. Leiss

I am writing due to serious concerns I have regarding a fundamental misunderstanding the Expert Panel may have had concerning our application of the Substantial Equivalence concept at Health Canada.

As described in publicly-available information, our safety assessment process includes the following aspects.

1. We consider how the food crop was developed, including the molecular biological data which characterizes the genetic change.
2. We review the composition of the novel food as compared to the non-modified counterpart.
3. We review nutritional information for the novel food compared to non-modified counterparts.
4. We consider the potential for production of new toxins.
5. We consider the potential for causing allergic reaction.

Please note that, in considering the molecular biological data, we review data related to DNA, RNA and protein expression. We do consider the potential for secondary or unexpected impacts.

These considerations are made based on data and information provided by the petitioner which are carefully reviewed by scientists within Health Canada. After reviewing this data, the comparative analysis, based on the application of Substantial Equivalence as described by the FAO-WHO Expert Consultation 2000, we direct the assessment to those elements of the product which are novel.

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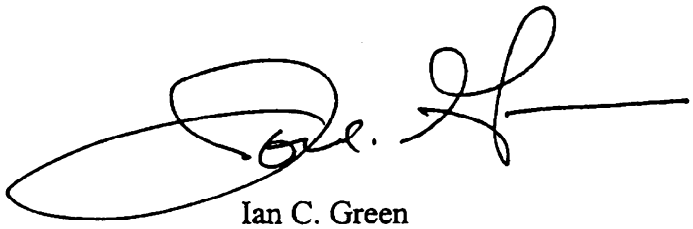
In other words, in the system at Health Canada, Substantial Equivalence is an approach, not an endpoint and there are never assumptions of Substantial Equivalence. All internal decision documents regarding currently approved genetically-modified foods substantiate this approach.

I trust that the Panel would want to ensure the factual validity of any of their statements.

Should you require any further clarification of Health Canada's approach in this area, Dr. Karen Dodds (830-5033) would be pleased to speak with you.

Yours truly



Ian C. Green

The Royal Society of Canada
The Canadian Academy of the Sciences and Humanities
La Société royale du Canada
L'Académie canadienne des sciences, des arts et des lettres

February 5, 2001

Ian C. Green
Deputy Minister
Health Canada
Ottawa Canada
K1A 0K9

Dear Mr. Green:

Thank you for your letter to Dr. William Leiss concerning the RSC Expert Panel and its interpretation of the use of the Substantial Equivalence concept at Health Canada. Dr. Leiss forwarded your letter to us, and asked us to respond.

We understand, both from the published documents and from interviews with Health Canada personnel, that the Health Canada safety assessment process does include some consideration of the five aspects listed in your letter. Those formal procedures are referenced in our Report (Chapter 3). We also understand that data related to DNA, RNA and protein expression derived directly from the transgene are reviewed.

However, in our direct discussions, Health Canada personnel did not provide sufficient information to allow us to assess the extent or rigour of the protocols used. Our request at the time for detailed data pertinent to those protocols produced no subsequent response. The Expert Panel was therefore unable to verify the overall consistency or appropriateness of the assessment process. It did, however, appear that examination of molecular biological data during the Health Canada assessments did not routinely extend to possible pleiotropic impacts of the transgene.

We appreciate that the basis of the approach used by Health Canada is an analysis of whether a claim of Substantial Equivalence can eventually be justified. However, that analysis is based solely on data and information provided by the petitioner, and the decision documents describing and validating the outcome are, as you point out, internal, and thus not readily available to either the scientific community or general public.

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In the view of the Expert Panel, this situation does not meet the expectations of either stakeholder group for a full, rigorous and transparent evaluation of GM crops and foods. Our Report details our concerns about the existing regulatory process, and offers constructive suggestions for ways in which the credibility and reliability of that process could be improved. We hope that the work of the Expert Panel will be of value in designing a regulatory process that will more effectively serve the needs of Canadian society.

Sincerely yours,

Conrad Brunk and Brian Ellis
Co-Chairs, RSC Expert Panel on the Future of Food Biotechnology

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