History of the Novelty and PNT Concept

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GMOs in Europe

LMOs in Biosafety Protocol

PNTs in Canada

- **Whose approach is correct?**
  Probably everyone for their own political and socio-economic reasons !

- **Whose approach is most defensible internationally?**
  Probably Canada's since it is science based !

- **17 years after the first discussions took place in Canada over how we should be regulating products of biotechnology "a lot of water has flowed under the bridge"**

History to Canada's Approach

- **Canada's approach is based on a four letter word "CEPA" (Canadian Environmental Protection Act)**

- **CEPA was first promulgated in 1988 and amended 10 years later in 1999**

- **It requires that any person who wants to import, manufacture or sell any new substance to notify the appropriate Canadian regulatory authority so the new substance can be evaluated for potential effects on the environment and human health**

- **Products of biotechnology are deemed to be "new substances" within the Canadian regulatory framework**

- **Biotechnology is defined as "the application of science and engineering to the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms**

- **CEPA is the key legislative authority for the federal government to ensure all new substances are assessed**

- **CEPA exempts those aspects of biotechnology regulated under other Acts (e.g. Seeds, Feeds, Fertilizers) but it does give Environment Canada (EC) residual powers to regulate any areas other Acts do not regulate**

Let's go back 17 years:

- **In 1987/88 with promulgation of CEPA on the horizon, several activities were happening:**

1. Agricultural companies were making pitches to Agriculture and Agri-food Canada (AAFC) regulators (FP&I Branch) asking us to regulate them, not EC

2. They wanted to be allowed to initiate confined field trials in 1988 (U of S ran their first field trial for transgenic flax in 1988 as well as 3 biotech companies for modified canola)

3. CARC organized a scientific workshop December 1988 on the Regulation of Agricultural Products of Biotechnology (Chaired by Dr. Harvey and attended by researchers and academia from Universities, industry & government)

- **The CARC workshop arrived at agreement on several key recommendations for the government to consider, which set the stage for the direction the Canadian regulatory system would take in the coming years:**

1. **"Those plants which possess characteristics or traits sufficiently different from the same or similar species should require an assessment of risk"**

2. **"the product, not the process should be regulated"**

3. **Several categories of concern were raised:**
   - plants with novel herbicide tolerance
   - plants with novel pesticidal properties
   - plants with novel stress tolerances
   - plants with novel compositional changes

   (Noteworthy that all PNTs that have been approved in Canada to date by CFIA &/or Health Canada fit one of the above categories

Direction from CARC in 1988 was pivotal in assisting the government in developing regulatory framework for what/how to regulate products of biotechnology

- **Policy decision made to use the terms "novel" and "PNTs" instead of new substances**

- **Guidelines were developed by FP&I for allowing field testing of PNTs**

- **1988 - first field tests of PNT canola by 3 biotech companies and HT flax by U of S**

Since there were no Regulations in place, FP&I authorized confined field trials under the Environmental Assessment and Review Process from 1988 - 1995

- **1989 and 1990 - FP&I held Advisory Committee meetings with key stakeholders to get input on refining Confined field testing protocols and direction for requirements for Unconfined release of PNTs**

Key Activities in Early 90s:

FP&I met with representatives of various Provincial departments in key provinces where Confined field trials were going to be grown (Agriculture, Environment, Health, Labour)

FP&I contracted in 1992 with Dr. Wally Beversdorf (on sabbatical from Chair of Crop Science Dept., University of Guelph) to develop via consultation draft protocols/assessment criteria for unconfined release of PNTs

1993 - Government of Canada established Federal Regulatory Framework for Biotechnology

•Key Principles to assure practical benefits of biotech derived products would be balanced with need to protect human and animal health and the environment:

1. Maintain Canada's high standards for the protection of health and the environment

2. Build on existing legislation and regulatory institutions and avoid duplication

3. Regulation should be based on the characteristics of the product

4. Use science based risk assessments

February 1993

- **Cross Canada consultations with AAFC researchers and regulators**

- **Discussed risk based approach to regulation of biotech products**

- **Concepts of familiarity and substantial equivalence in order to determine “novelty” were key part of the discussions**

- **November 1993 Workshop on Regulation of Agricultural Products of Biotech**

- **covered seed, livestock feed, fertilizers, animals, veterinary vaccines and biologics, food**

- **broadest representation at a consultation meeting to discuss regulatory issues ever experienced during my career**

- **outcome of the consultation formed the basis of FP&I drafting Regulations under existing Acts (e.g. Seeds, Feeds, Fertilizers) and HC (Novel Food Regulations)**

- **consultation involved representatives from the following:**

Major seed companies
Biotech companies
Universities
Cdn. Federation of Agriculture
Cdn Society of Agronomy
Provincial Departments
Consumer groups
Farm producer groups (corn, canola)
Environmental groups
Food manufacturers
Livestock industry groups
Private sector lawyers
Health Canada
Industry Canada
FP&I regulators
Organic organization
AAFC (researchers, policy)

•1994-1996 FP&I worked on obtaining agreement on draft Seeds Regulations Part V, Feeds Regulations, etc. to regulate PNTs

• Since FP&I's goal was to make our regulations CEPA equivalent, they were under severe scrutiny by Environment Canada for CEPA compliance

•Finally after 3 years of consultation and negotiations, the Gazetting process was completed and in the case of the Seeds Regulations, Part V came into effect December, 1996

• The Seeds Regulations had to be amended in 2000 to reflect 1999 amendments to CEPA to include the definition of toxic

- **During the 3 year period (1994-1996) while Regulations were under development, FP&I worked very closely with the industry to facilitate the development, innovation and testing of their biotech products (while there was significant political pressure to put a moratorium on all field testing and releases)**

- confined field trials continued to be authorized and site inspections carried out

- guidelines were implemented for developers of PNTs to make submissions for unconfined release based on concept of "familiarity" and "substantial equivalence"

- applications for unconfined release were accepted by FP&I and the first unconfined release of HT canola was in 1995

- CDC Triffid flax was granted unconfined environmental and feed release in 1996

- Part V was drafted in such a manner that it grandfathered in biotech products that had already been released into the environment (Health Canada did not implement a grandfathering clause so some PNTs that may have been exempt under the Seed Regulations were not necessarily exempt under the Novel Foods Regulations)

- **without the Part V exemption, many products which fall within the "novel" category would have required assessment even though they may have been grown and/or commercialized for many years and found to pose minimal risk to the environment**

- **Examples are: triticale first released in Canada in 1969**
  Canola since it was not substantially equivalent to rapeseed
  Traizine tolerant canola released in the mid 80s
  B. juncea canola

Summary:

- **17 years later since we first discussed how products of biotechnology should be regulated we are still discussing the topic**

- **Issue now is using the knowledge and experiences gained (not all of them positive) over the past 17 years, what adjustments should/could be made to the Canadian system without negatively affecting human health and the environment?**