



Canadian Food
Inspection Agency

Agence canadienne
d'inspection des aliments

Canadian Food Inspection Agency



Our vision:

To excel as a science-based regulator, trusted and respected by Canadians and the international community.

Our mission:

Dedicated to safeguarding food, animals and plants, which enhances the health and well-being of Canada's people, environment and economy.

Update of Ongoing Regulatory Activities in Canada for Biotechnology

Canola Industry Meeting

***Gordon Berg, Plant Biosafety Officer, Western Area,
Canadian Food Inspection Agency***

December 10, 2008

Canada

Update of Ongoing Regulatory Activities in Canada

1. Revision of the Confined Research Field Trial Program
2. New Directive, entitled “Plants Regulated Under Part V of the *Seeds Regulations*”
3. Activities from the Working Group entitled, “Increasing Transparency and Efficiency in the Regulatory Assessment of Novel Products” (ITERANP)
4. Addressing Low Level Presence
5. Bilateral work

1. Revision of the Confined Research Field Trial (CRFT) Program

Revised Directive has been posted.

Directive Dir2000-07: Conducting Confined Research Field Trials of Plant with Novel Traits in Canada

Key modifications include:

- i. Communication with applicants on compliance
- ii. Assessment of proposed confinement measures
- iii. Requirements for record-keeping
- iv. Post-harvest land use restrictions
- v. Exemptions from field trial limitations

Refer to website for details of the revised Directive2000-07:

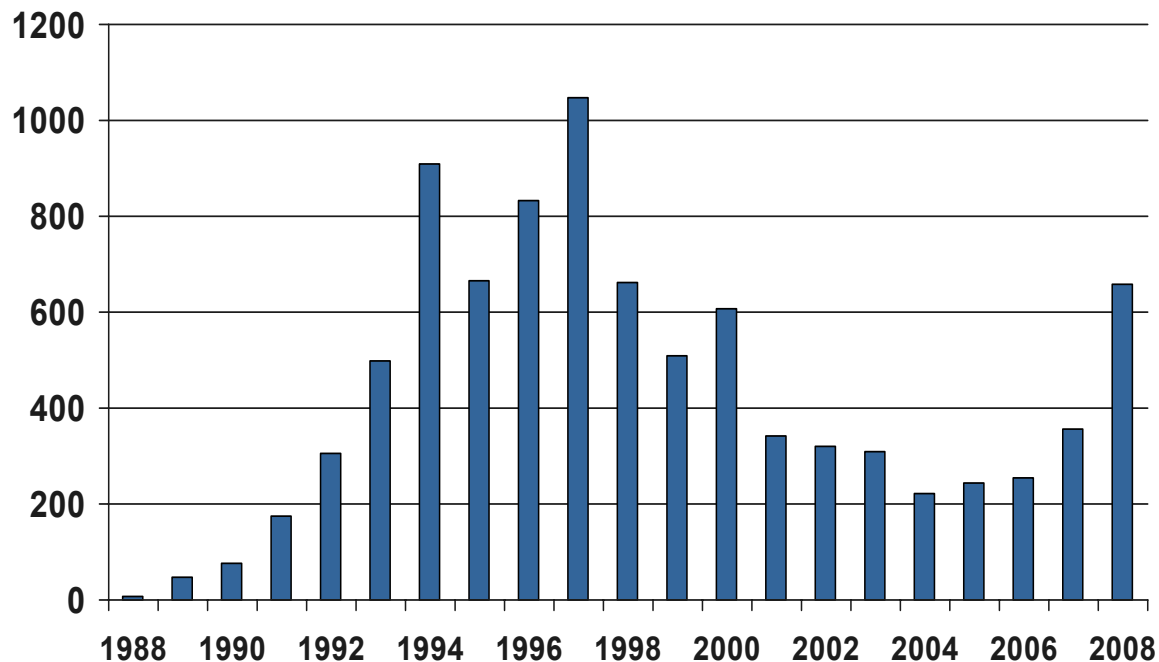
<http://www.inspection.gc.ca/english/plaveg/bio/dir/dir0007e.shtml>



CRFT Program: Trends

Applications received for more than 650 trials in 2008

- Almost double the number from 2007



2. New Directive, entitled “Plants Regulated Under Part V of the *Seeds Regulations*”

- PBO has drafted a directive to provide more clarity and guidance on determining whether a plant has a novel trait to breeders/importers
- Discussed new directive at the NFS Meeting (October 27, 2008):
 - presented the draft directive and received feedback
 - participants felt that draft was a step in the right direction but further guidance is required
 - a working group with breeders established to further clarify draft directive
 - once revised, further feedback on the directive will be solicited through an e-mail questionnaire
- Stakeholder feedback to occur early 2009

3. ITERANP Working Group (Increasing Transparency and Efficiency in the Regulation and Assessment of Novel Products)

- **Completed projects**
 - Two workshops with industry on optimizing submission quality
- **Current projects:**
 - Data package life cycle diagram - interactive diagram that outlines the steps in the evaluation of a regulatory submission for food, feed and environmental release
 - Development of a pre-submission consultation guidance document
 - to raise awareness of this optional step in the regulatory system

4. Addressing Low Level Presence (LLP)

Managing the issue through:

I. Publication of a policy statement describing the current CFIA/HC response to non-compliance

- Will outline steps taken when unauthorized agricultural products of biotechnology are found
- Expected publication early 2009

II. LLP project in the Organization for Economic Cooperation and Development (OECD)

- Project proposed in 2007 by the OECD's Business and Industry Advisory Committee (BIAC) to examine LLP of biotech traits in seed

5. Bilateral Work - China

- Technical and Working Group Meetings alternate locations between Canada and China annually
- Chinese regulators have signalled openness to harmonizing molecular characterization requirements toward symmetry of assessments
- Next meeting will be in Canada, Winter 2009



Bilateral Work - India

- Following the Canada-China cooperative model, efforts have recently begun with India
- In February 2008, a successful first Canada-India technical workshop on agricultural biotechnology cooperation was hosted by India in New Delhi
- The next meeting is proposed for mid-2009



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