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L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT

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FACT SHE
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PLANT MOLECULAR FARMING (PMF)

WHAT IS PLANT MOLECULAR FARMING (PMF)?

Plant molecular farming is the use of genetically modified plants to produce pharmaceutical products or industrial chemicals.

These "plants with novel traits" (PNTs) have been developed by inserting new genes, usually from other species, that instruct the plant to produce the desired substance. The plant can be directed to make that substance accumulate in specific parts of the plant, such as seeds or leaves. The compound can then be extracted from the "platform" plant species crop and refined for use; the remaining plant material is destroyed.

Platform species commonly used in the research today include corn (maize), tobacco, tomatoes and potatoes; these are advantageous because their production techniques are well known and their genetics have been well-studied.

More recently, non-crop species like duckweed and mouse-eared cress (Arabidopsis) have also been used in research trials.

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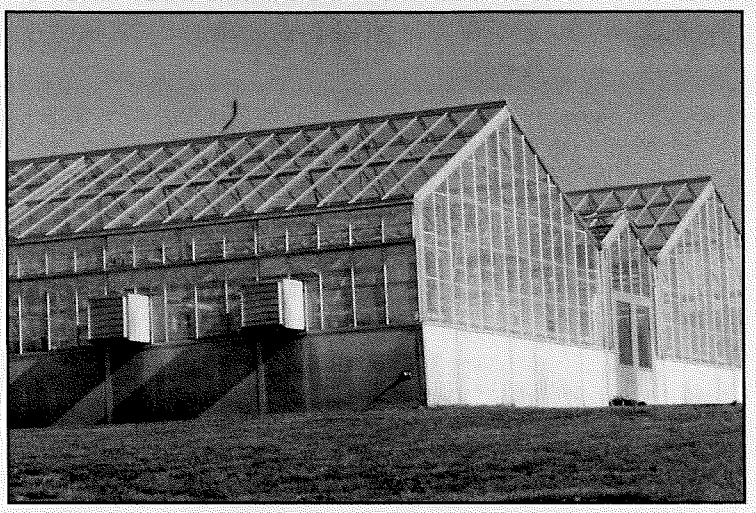

CLAIMED BENEFITS AND CONCERNS

WHAT POTENTIAL BENEFITS ARE CLAIMED FOR PMF?

Socioeconomic

A major claim is that much pharmaceutical production done in this way would be substantially cheaper and would result in significantly increased availability and lowered drug costs and prices. This is because the source of many products used in medicine, including drugs, diagnostic materials, blood products and hormones, is biological in origin and expensive to produce in conventional ways from plants, animals, or from microbes in bioreactors. Using plants to manufacture these compounds could increase the quantities produced, and do it more quickly and cheaply. This technology could also

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WHAT IS THE STATUS OF THESE TECHNOLOGIES IN TERMS OF COMMERCIALIZATION?

Currently there are no commercial applications approved for use in Canada. Only confined field trials have been allowed here. Some pharmaceutical PMF products in the U.S. have reached the stage of clinical trials.

WHAT ABOUT GOVERNMENT OVERSIGHT AND POLICY?

Research and Development (R&D)

The bulk of Canada's millions of dollars spent on biotechnology research is in the health field. More than half of its biotechnology companies are in this sector, and in 2003 there were over 10,000 health-related biotechnology products or processes that were at some stage of approval. However, little of this health-related biotechnology R&D is specifically for PMF applications.

Canada does not have a legislated liability regime for any biotechnology applications, including PMF.

Regulatory Framework

Health Canada and the Canadian Food Inspection Agency (CFIA), along with Environment Canada and possibly other government departments that make up the patchwork of Canadian agencies responsible for different aspects of biotechnology regulation have key roles for PMF applications.

Liability

Canada does not have a legislated liability regime for any biotechnology applications, including PMF. In Canada, biotechnology issues are subject to the traditional common law rules of civil liability. If the use of biotechnology causes damage to a person, their property or their economic interests, the producer or user of that biotechnology might or might not be held liable for that damage by a court.

Because of potential benefits and the possibility of indoor production in greenhouses, there is probably less opposition to PMF than to many other applications of biotechnology.

The common law, as it has developed in Canada, may not be flexible enough to meet the novel challenges raised by the potential for harm that biotechnology applications may cause. These technologies bring up general policy issues that are better resolved by legislators rather than judges. A strict liability regime, entrenched in legislation, would hold producers of biotechnology responsible for damage to human or environmental health.

Transparency and Citizen Engagement

The formal avenue of public input into government policy is the Canadian Biotechnology Advisory Committee, though its involvement from civil society has primarily been from the scientific community and commercial interests. Because of potential benefits and the possibility of indoor production in greenhouses, there is probably less opposition from environment and other groups to

GOVERNMENT OVERSIGHT (contd.)

PMF applications, despite their risks, than to genetically modified trees and food crops intended for widespread, unconfined use.

WHAT INTERNATIONAL IMPLICATIONS ARE THERE?

The potential for more widely available and much cheaper pharmaceuticals offers promise from this technology to many poorer countries. However, the risks to biodiversity and human health are also arguably great, particularly if PMF is practiced in countries with less capacity for scientific monitoring and stringent regulatory oversight.

ADDITIONAL SOURCES OF INFORMATION

Specific to Plant Molecular Farming:

- **The Canadian Food Inspection Agency** www.inspection.gc.ca

Concerned about Biotechnology

- **Union of Concerned Scientists** www.ucsusa.org/
- **Greenpeace Canada** www.greenpeace.ca

Pro-Biotechnology

- **Biotechnology – Good to Grow** www.biotechgoodtogrow.com/
- **BIOTECanada** – www.biotech.ca/
- **Council for Biotechnology Information** http://whybiotech.com/

Government of Canada

- **The Government of Canada's BioPortal** www.bioportal.gc.ca/
- **The Government of Canada's Bio-Strategy** http://biostrategy.gc.ca/
- **Canadian Biotechnology Advisory Committee** www.cbac-cccb.ca/

CIELAP gratefully acknowledges funding from the International Development Research Centre, Canada, to support our factsheet publications. The views expressed in this document, however, are those of CIELAP.

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