The Effect of Plants with Novel Traits (PNT) Regulation on Mutation Breeding in Canada

G G Rowland

Abstract

The Canadian Environmental Protection Act (1988) has within it a definition for biotechnology. This definition would have allowed the government department, Environment Canada, to regulate all genetically modified organisms (GMOs) in Canada. In response to this, the Canadian Food Inspection Agency (CFIA), which reports to the Minister of Agriculture and Agri-Food Canada, developed the concept of a Plant with Novel Trait (PNT). Not only does this definition capture GMOs, it also includes induced mutations, natural mutations and exotic germplasm that have not previously been grown in Canada. It is a system that is product, not process based. However, apart from questions regarding the novelty of traits in new plant varieties, breeders are asked by CFIA to identify the process used to develop the trait or traits in question. Field trials involving breeding lines with a PNT may be subject to confined testing. This conference celebrated 80 years of unconfined development and testing of induced plant mutations. This regulation is time consuming, expensive and an innovation barrier for Canadian plant breeding. It can only be hoped that other nations, and particularly those that have successfully used induced mutations, will not emulate Canada's approach.

Introduction

The announcement for this meeting summarized the use of mutation techniques in plants over the past 80 years and the positive economic impact this has had throughout the world. During the meeting we have learned of the direct release of varieties of crop plants from mutation breeding and varieties developed with genes identified in mutant crop plant populations. We have also heard about the use of site directed mutagenesis, which would avoid the regulatory hurdles associated in most countries with genetically modified organisms (GMOs). We were told that TILLING (Targeted Induced Local Lesions IN Genomics) would also not be caught in the regulatory trap. However, this use of mutations does not avoid regulation in Canada. How Canada came to be in this position and the regulation's effect on plant breeding is the subject of this presentation.

CEPA

In 1988 the Parliament of Canada passed the Canadian Environmental Protection Act (CEPA) into law. Within this Act is a definition for biotechnology, which reads: *the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms*. The definition was placed in CEPA to deal with concerns regarding genetically modified organisms (GMOs) and allow Environment Canada to regulate all GMOs as well as varieties arising from traditional plant breeding techniques. It is interesting that biotechnology is the only technology defined in CEPA, and this reveals the shaky ground on which the definition was built and its spurious danger to the environment.

CFIA response to CEPA

Government departments do not like to have responsibilities taken from them and, in this case, the danger that it poses is towards production agriculture in Canada. From 1988 and onwards, Environment Canada had the potential to regulate the registration of crop varieties in Canada, a responsibility that was then held by a branch of Agriculture Canada. In anticipation of the regulatory issues CEPA would cause, Agriculture Canada and the Ministry of State for Science and Technology sponsored a Workshop on the Regulation of Agricultural Technology organized by the Canadian Agriculture Research Council (CARC). CARC was a council of agriculture researchers from industry, universities and federal and provincial governments and they invited a number of respected Canadian scientists to the workshop. The workshop developed 18 recommendations that were sent to various government ministries including Agriculture Canada. The two key recommendations that applied to crops were:

- *The products of biotechnology should be regulated, not the process that produces them and*
- *The definition of biotechnology in use by the regulatory agencies is too broad and must be redefined with more focus. The plant sector, for example, would limit it to genetic engineering.*

By 1997 the responsibility for registering crop varieties had passed on to a reorganized group of Agriculture Canada known as the Canadian Food Inspection Agency (CFIA). The CFIA has organized a number of workshops over the years to explain the regulation of GMO's in Canada, one of which took place at the University of Saskatchewan in 2004. An official of the CFIA in his presentation stated:

1. *The CARC workshop arrived at several key recommendations*
2. *The product, not the process should be regulated. Those plants which possess characteristics or traits sufficiently different from the same or similar species should require an assessment of risk. (http://www.inspection.gc.ca/english/plaveg/bio/consult/novnou/watsone.shtml)*

However, as regards point 2, the CARC meeting actually recommended:

Products Subject to Regulation:

"Genetically modified organisms (GMO), which possess characteristics or traits that are 'sufficiently different' from the characteristics or traits of previous members of the same or similar species so as to require a separate assessment of risk".

Definitions for the above

Genetically modified organisms: organisms which are obtained by in vitro alteration of genetic material including, but not restricted to, recombinant DNA, nuclear and organelle transplantation, or genetic manipulation of viruses.

Crop Development Centre, Department of Plant Sciences, College of Agriculture and Bioresources, University of Saskatchewan, Saskatoon, Saskatchewan, Canada
E-mail: gordon.rowland@usask.ca

Despite the best advice of CARC and members of the Canadian Plant breeding community, in 1994 Agriculture Canada issued regulatory directive 94-08, which contained the following concept and definition:

Plant with Novel Trait: A plant variety possessing a characteristic that is intentionally selected or created through a specific genetic change and is either not previously associated with a distinct and stable population of the cultivated plant species in Canada or expressed outside the normal range of a similar existing characteristic in the plant species.

So what exactly is a plant with a novel trait (PNT) in Canada? CFIA defines it as:

A PNT is a plant that contains a trait that is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, mutagenesis, or conventional breeding techniques and have some potential to impact weediness, gene flow, plant pest potential, non-target organisms, or biodiversity. (http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml)

Canada now has a system that not only regulates GMOs but also is able to regulate traditional breeding techniques as well as induced mutation! This, despite there being no evidence that induced plant mutations have caused harm to humans, animals or the environment. We are told that Canada's variety registration system is science based but there was no review of the science of mutation breeding in the development of the PNT definition. Despite assurances from CFIA and the recommendation of CARC, we do not have a product based regulatory system. We now have a system in which both product (novelty) and process (GMO) is regulated. In the Procedures for the Registration of Crop Varieties in Canada published by the CFIA the pedigree of the proposed variety is required such that:

In the case of varieties resulting from recombinant gene technology, information on the gene(s) inserted, its source and gene products must be provided. Exact DNA sequence information must be provided to facilitate the generation of gene probes for variety verification purposes. http://www.inspection.gc.ca/english/plaveg/variet/proced/regproe.shtml

In the Variety Registration Application Form, the developer is specifically asked: *does this variety contain traits that are novel to its species?,* is referred back to Regulatory Directive 94-08.

Examples of the effect of PNT regulation

The "Flor de Mayo" bean is a particular market class of *Phaseolus vulgaris* L. that has a pink, marbled seed coat color and is not unlike the pinto or cranberry classes grown in Canada. It is a popular market class in Mexico, which has export potential for Canada. However, there is no variety of "Flor de Mayo" bean registered for production in Canada. The Crop Development Center (CDC) at the University of Saskatchewan developed a variety of "Flor de Mayo" and applied for a Canadian registration of the variety in April of 2002. After considering the application, the CFIA asked the CDC to prove that it wasn't a PNT since this "type" had never been grown in Canada. Since the market potential for Saskatchewan grown "Flor de Mayo" beans was judged to be too small, the CDC determined that the costs associated with demonstrating the "safety" of this market class were not worth it. Consequently, the application to register the variety was withdrawn.

The experience of the CDC in the registration of the low phytate barley, HB379, is an example of other difficulties that the PNT definition has produced. The low phytate character is one that was often referred to at this conference, as it is an example of mutant genes being used for improving the nutritional and environmental quality of some crop plants. The CDC had developed a low phytate barley, HB379, and applied to CFIA for registration in May 2006. There was no indication from CFIA that this was a PNT but there was a concern that it was a "novel feed." The concept of a novel feed was one that arose out of the novel plant concept and is administered by the CFIA. It took 17 months and hundreds of man-hours before HB379 was finally registered for production in Canada.

Conclusion

The concept of PNTs as developed and applied in Canada is time-consuming, expensive and an innovation barrier for Canadian plant breeding. It is a threat to the constructive use of plant mutations for crop improvement and it is to be hoped that other countries will not follow Canada's example.

BIBLIOGRAPHY

1. CANADIAN AGRICULTURAL RESEARCH COUNCIL, Proceedings of a Workshop Regulation of Agricultural Products of Biotechnology. Ottawa, Canada (1988).