

Novelty as a regulatory trigger for new bio-products and crops



Event

The regulation of plant varieties in Canada as plants with novel traits (PNTs) is unique. This divergence from the regulatory systems of Canada's trading partners creates challenges both for researchers seeking to introduce new crop varieties and for regulators attempting to harmonize regulations at the international level.

Significance

The application of biotechnology and the 'omic' sciences underlies Canadian research into new crop varieties. On average, between 1 and 30 new varieties in each key commercial species may be introduced every year to sustain competitive competitiveness. The PNT rules often makes the Canadian regulatory approval process more costly and time consuming than elsewhere, and impedes needed technological change.

Analysis

In Canada, new plant varieties are regulated as PNTs, based upon the presence of a newly expressed trait that is either entirely foreign to Canada or exists at significantly different levels in the Canadian environment and food system than elsewhere. Determination of novelty is entirely based upon the trait in question and does not consider the method of introduction. That is, it is based on 'products' not 'processes.' The regulatory system thus captures all forms of plant modification, including living modified organisms (LMOs) produced through direct genetic modification and non-LMOs developed via mutagenesis, mutation breeding and conventional breeding.

In the 1970s and 1980s the concept of novelty and risk assessment were introduced to set laboratory safety standards for rDNA technologies. The concept of novelty was found to be useful in multilateral policy development surrounding the approval of bio-products for environmental release. The FAO and the OECD subsequently reached consensus that risk assessment, as applied to biotechnology, should not be exclusively product-based, but should also include safety reviews triggered by the use of rDNA technology, integrated into existing food and agricultural safety protocols. Most national regulatory systems followed that lead and use the presence of rDNA as the trigger for regulatory review of new products. In Canada, the regulatory system institutionalized a 'novelty trigger' in its risk assessment procedures for PNTs, reflecting a strict product-based approach. All PNTs are subject to the same regulatory standards regardless of method of modification.

There is a debate about its merits. One perceived drawback to the novelty trigger is that the Canadian Food Inspection Agency's conditions for PNTs status are broad, requiring intensive regulatory evaluations of more and different products than in other agri-food producing and exporting countries. The PNT assessment process can take up to a decade to complete and requires substantial financial resources, which is perceived as a barrier to innovation by some firms and researchers and an obstacle to international regulatory harmonization. Regulatory scientists, in response, argue the novelty approach has long-term value. The PNT rule captures all new products regardless of the method of modification. Given what has been and promises to be substantial innovation in methods for developing new crops, rDNA-based systems may miss new risks.

Conclusion

While the novelty trigger for PNTs is viewed by many regulatory scientists as the safest regulatory method, its unique character presents challenges to investment and trade in bio-products for Canada. One option some have suggested is to revise the PNT system to introduce a tiered regulatory approach that takes into account variable levels of risk arising from breeding methods and the regulatory schemes of major trading partners.