Volume 17 Number 2 2016/pp.91-95 www.usask.ca/esteyjournal

The Estey

Journal of International Law and Trade Policy

Regulatory Impacts on Trade in Products of Biotechnology – the Issues

Martin Phillipson
Dean, College of Law, University of Saskatchewan, Canada

The use of modern agricultural biotechnology is a contentious global issue. The absence of international regulatory harmonization or, even more fundamentally, agreement on approaches to the regulation of new technologies, inhibits international trade in products derived from the use of biotechnology at a time when global food security is projected to be a major challenge. The issues underlying the current regulatory disharmony are outlined and the articles that comprise the Special Issue of the Estey Journal of International Law and Trade Policy which follow are introduced.

Keywords: biotechnology, food, regulation, trade

Science and science-based regulations have been the cornerstone of regulatory frameworks in the industrial world for decades. The basic principles of science-based regulatory frameworks were advocated by international organizations such as the Organization for Economic Co-operation and Development, the Food and Agriculture Organization and the World Trade Organization. As developing countries sought to join international organizations that either promoted regulatory harmonization or improved international market access, efforts were made to assist these countries in following the lead of industrial countries. Over the latter half of the 20th century, a vast network of international agreements, agencies and organizations were birthed, developed and matured, resulting in a near global recognition and acceptance of science-based regulatory and trade mechanisms.

However, over the last 20 years this adherence to solely science-based mechanisms has been questioned and challenged. Nowhere is this more evident than in the regulation and trade of agri-food commodities and products. Numerous food safety failures in multiple countries contributed to a vocal questioning of the science involved in the production of food products and the regulation of those products and production processes. This movement was coupled with the rise of consumer dominated food retailing, resulting in supply chains seeking an increasingly diverse variety of food products to offer their customers. These initiatives, forces and regulatory failures have led many to question society's strict adherence to science-based governance. In essence, they argue that a purely science-based regulatory model does not address the wider ramifications of the growth of the global agri-food industry, the production methods it employs and the products it sells. The development and marketing of genetically-modified (GM) agri-food products has been of particular concern to those who question existing regulatory structures and the premises on which they are based.

These efforts culminated in the year 2000 with the development of the agreement that established the Cartagena Protocol on Biosafety (CPB) to the 1992 Convention on Biological Diversity (CBD). The impetus for the CPB was the unwillingness of the United States to reopen the Sanitary and Phytosanitary Agreement of the WTO to the inclusion of social attitudes to innovative agri-food products and technologies. The driving force behind efforts to have social attitudes reflected in international regulation and trade agreements was the European Union, where food safety failures had left a legacy of consumer mistrust and skepticism surrounding many food production processes and methods.

The CPB was opened for signature in 2000 and entered into force in 2003 with the objective of managing the regulation of, and trade in, living modified organisms. Globally, 170 countries have now ratified and adopted the CPB. While the initial intent of the CPB was to focus on the sustainable use of biological diversity, the resulting agreement has a wide remit, and the inclusion of socio-economic considerations as part of a member state's regulatory framework for the approval of GM crops is seen as a major factor in this extension of scope. This conscious attempt to move away from purely science-based regulation has resulted in impacts for the regulation and trade of products of biotechnology.

The December 2016 COP/MOP 8 meetings in Mexico will include considerable discussion about the role and relevance of socio-economic considerations (SECs) regarding biosafety and biotechnology regulations. While the CPB states that SECs are to be a voluntary part of regulatory decision-making, several parties to the CPB as

well as environmental non-governmental organizations (eNGOs) opposed to biotechnology and other agri-food innovations are lobbying for SECs to become a mandatory part of regulatory decision-making.

This special section delves into the impacts of the movement away from science-based regulation and trade for GM crops. Starting the analysis is an article by three academics from the University of Saskatchewan, Savannah Gleim, Stuart Smyth and Peter Phillips, who examine GM crop adoption in their article "Regulatory System Impacts on Global GM Crop Adoption Patterns". These authors draw on 20 years of GM crop adoption history to undertake an assessment of whether the expansion of socio-economic-based regulation is impacting adoption patterns for GM crops and for specific GM traits. Their analysis looks at technology diffusion in an effort to determine if there are correlations between the introduction of regulations and the adoption of new GM crop varieties and traits. The objective of the article is to determine whether the diffusion of knowledge regarding the scientific basis of GM crops, and their regulation in other jurisdictions, is impacting regulatory timelines and knowledge diffusion curves. This article sets the framing for the subsequent articles, which provide a more detailed assessment of the impact of including SECs in biosafety regulatory frameworks.

The balance of the special issue is comprised of three articles by a trio of collaborators. José Falck-Zepeda is a research fellow with the International Food Policy Research Institute in Washington, DC; Karinne Ludlow is a law professor at Monash University in Melbourne, Australia; and Stuart Smyth is an assistant professor at the University of Saskatchewan in Canada. The members of this international collaborative team are world leaders for their research and insights into SECs and the impacts of their inclusion in biosafety regulatory systems.

The first article from this team is one led by Falck-Zepeda, titled "Zen and the Art of Attaining Conceptual and Implementation Clarity: Socio-economic Considerations, Biosafety and Decision-making". Designed to inform policy-makers in countries that have adopted SECs, or in countries that are contemplating inclusion of SECs, the article delves into crucial topics such as conceptual design and implementation issues. Drawing on real world examples of where SECs have been included in biosafety regulatory frameworks, the authors highlight the challenges of moving away from purely science-based regulatory frameworks.

The second article, led by Ludlow, focuses on a crucial aspect of SEC inclusion, that of continued compatibility with other international agreements and legal obligations. This article, "Consistency of Assessment of Socio-economic Considerations under the Cartagena Protocol on Biosafety with Other International

Obligations," highlights the concern that any state including an SEC in a biosafety regulatory framework must ensure that it continues to remain in compliance with existing international commitments. The authors stress that unless countries ensure that SEC related measures are compliant with existing obligations, the network of international agreements is undermined, as non-compliance would erode the functionality of these agreements. With a plethora of international agreements in existence, uncertainty exists as to which agreements the CPB would need to ensure compliance with; therefore, the authors undertake a detailed review of numerous key agreements that will, or would be expected to, have bearing on the inclusion of SECs into biosafety frameworks. This detailed review discusses the terms and commitments to be expected from SECs, clarifying the legal complexities that may arise.

The final contribution to the special issue is the article "The Costs of Regulatory Delays on Genetically Modified Crops". This article, led by Smyth, highlights the correlation between timely and efficient regulatory systems and private sector research and development investments. Drawing on examples of where private investment has been internationally reallocated due to "inefficient" regulatory systems, the authors investigate the costs of regulatory delays for the commercialization process and subsequent losses in societal benefits caused by the delayed introduction of innovation.

The articles in this special section demonstrate the challenge that initiatives for the inclusion of SECs pose for existing international agreements, their signatories and the organisations that run them. More explicitly, any regulatory analysis of the impact of agri-food innovations on socio-economic matters represents a significant philosophical challenge to the orthodoxy of purely science-based regulation that has dominated this area since the latter half of the 20th century. Arguably, this remarkably cohesive philosophy helped facilitate the growth of the agri-food industry and was instrumental in establishing globally significant trade in agricultural products. However, the inclusion of SECs in the CPB (and ongoing initiatives to make a consideration of them mandatory in the regulation and transboundary movement of GM agricultural products) represents a clear challenge to this orthodoxy. The research presented in this special section demonstrates that adding any examination of SECs (such as that contained in the CPB) to existing regulatory structures can and will have an impact on the diffusion of new agri-food innovations. Furthermore, the adoption of such measures will present significant legal problems for states that are signatories to many existing international agreements.

In conclusion, it is arguable that the research in this special section demonstrates a clear and fundamental incompatibility between measures to examine SECs and the

basic tenets and aims of long-standing agreements that govern and facilitate the global trade in food products. However, it is also clear that calls to include an examination of SECs in major international agreements are unlikely to dissipate. Furthermore, stating that addressing SEC's is difficult, or beyond the philosophical scope of existing agreements, does not mean that these enquiries are illegitimate. The question that subsequent research needs to address is whether SECs can be examined in other fora or in other ways that are minimally or negligibly disruptive to international trade and the diffusion of agri-food innovations. Much like the debates over agricultural co-existence, such an outcome would be highly desirable but may prove distressingly elusive. The research in this special section expertly highlights the challenges that future regulators face in this regard and makes a strong case for doing the hard work of designing *sui generis* mechanisms for such an analysis. Adding the consideration of SECs to existing agreements may only cause conceptual confusion and regulatory delays, which are well-established enemies of innovation.