POST-MORATORIUM EU REGULATION OF GENERICALLY MODIFIED PRODUCTS: TRADE CONCERNS

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Crina Viju
Institute of European, Russian and Eurasian Studies
Carleton University

May T. Yeung
Estey Centre for Law and Economics in International Trade

William A. Kerr
Department of Bioresource Policy, Business and Economics
University of Saskatchewan

http://www.catrade.org

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International trade in agricultural products produced using biotechnology is a very divisive trade policy issue. In some countries, and particularly the European Union (EU), politicians have been faced with vociferous opposition from segments of civil society to the presence of genetically modified (GM) organisms and products in their natural environments and markets. This has made policy-making for these products very difficult. In other countries such as the US and Canada, biotechnology has proved less contentious and the approval of new GM products, while rigorous, has proceeded in an orderly fashion. Thus, GM-crops have been grown extensively in Canada, the US and a number of other countries, while in the EU, approval of GM-crops stalled for more than a decade. Without EU approval, GM products cannot enter the EU customs territory. The lack of EU approvals has been a *de facto* ban on imports of biotechnology products and is seen as a major impediment to agricultural trade by countries having GM products available for export.

The current set of multilateral trade rules were negotiated in the Uruguay Round which ended in 1994, prior to the commercialization of GM-crops and, hence, preceding their becoming a major political issue in the EU. The rules of trade covering the types of barriers used by the EU to exclude GM products are embedded in the World Trade Organization's (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). In the SPS, all Member States of the WTO, including the EU, agreed that such barriers could only be justified on a scientific basis. Given the subsequent domestic political difficulties over the issue of biotechnology, the EU has chafed over the use of science as a decision criterion and has put forth its own interpretation of the roles of science in trade commitments. These interpretations differ in significant ways from that of GM producing countries and the issue became one for a WTO disputes Panel to sort out.

In 2003 Canada and the US initiated a case at the WTO against a 1999 EU temporary moratorium on imports of GM products. Meanwhile, a new EU regulatory framework for GM approvals was put in place in 2003. The WTO dispute pertaining only to the moratorium continued, with the Panel's decision coming down in September 2006. The WTO Panel supported the complainants. The EU said it would comply with the WTO Panel but requested extended time to do so. The new EU regulatory regime of 2003 is now in place and accepting applications for the approval of GM-products. The first product to successfully work its way through the revised EU-level approval process – BASF's Amylopectin ('Amflora') potato – received its approval on March 15, 2010 based on an application made in February 2005. Thus, only now can the EU's GM regulatory regime be assessed. Canada and other countries have a clear interest in whether the new EU GM regulatory regime is compliant with the SPS and with the Panel ruling of 2006. Based on the procedures outlined in EU Commission Directives, the new decision criteria appear not to comply with the EU's WTO commitments and are sufficiently cumbersome that they may not be the 'least trade restricting' means of achieving the official policy objectives.

The SPS Agreement recognizes that countries have an inalienable right to protect human, animal and plant life or health (Isaac, 2007). Hence, if a legitimate justification exists, WTO Member States may put trade barriers in place. The question that the SPS attempts to establish is what constitutes a *legitimate justification*. According to the SPS, unilateral (i.e. those not having

been developed by an international scientific organization[1]) SPS measures must be 'based on scientific principles' and cannot be maintained 'without sufficient scientific evidence' unless it is a temporary measure put in place until sufficient evidence is acquired (SPS Agreement, Article 2.2). According to Isaac (2007, p. 385), "The science-based measures adopted must be proportional to the risk that is being targeted."

The EU's 2003 domestic regulatory regime is extremely complex comprising at least 3 Directives and 9 Regulations as well as Recommendations. The procedures set out have not been fully clarified because only a limited number of the potential approval/rejection paths have been called upon. Further, the regulatory regime now used by the European Commission remains contentious among some EU countries and it appears that final approval for the use of GM organisms may devolve to the individual countries. Given that the European Commission, not individual countries, represents the EU at the WTO a number of potential trade law issues are raised.

Cutting through the complexity of EU decision making, the approval procedures at the EU level do not make science the final arbitrator in decisions. There is a scientific body that reviews GM applications. The European Food Safety Authority (EFSA) has jurisdiction over the scientific assessment of GMO authorization applications. Its GMO Panel reviews each GMO authorization application on a case by case basis as no GMO is presumed to be safe. The GMO Panel consists of 21 independent experts supported by a number of specialized Working Groups drawing on a pool of more than 40 external experts in fields such as allergenicity, ecology, microbiology, toxicology, plant physiology and molecular genetics. The EFSA can refuse to approve an application to allow a new GM product on a scientific basis.

The problem arises, however, in the instance where the EFSA recommends approval on the basis of its scientific assessment. At this point, the approval moves into the political arena and a scientifically acceptable GM product can be denied approval for non-scientific reasons. This runs directly counter to the interpretation of the SPS rules that is taken by Canada and the US and suggests that the EU may also not be in compliance with the Panel ruling in 2006. Thus, the "new" EU regulatory regime would seem open to a WTO disputes challenge. Of course, the political consequences of such a challenge would have to be carefully weighed.

References

Isaac, G.E. 2007. "Sanitary and Phytosanitary Issues." In W.A. Kerr and J.D. Gaisford, eds. *Handbook on International Trade Policy.* Cheltenham: Edward Elgar. 383-393.

[1] There are three organizations that establish international SPS standards that are recognized by the WTO; the Codex Alimentarius Commission for human health, the World Organization for Animal Health (OIE) for animal health and the International Plant Protection Convention (IPPC) for plants health (SPS Agreement, Article 5.1).