International Regulation of Trade in the

Products of Biotechnology

Executive Summary

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INTRODUCTION

The products of modern biotechnology – such as genetically modified (GM) agricultural crops – are often commercialized on an international scale in order to cover high research and development costs. One complication of transboundary trade is that products approved under the regulatory approach at home may face a different regulatory approach in another jurisdiction. When the various regulatory approaches are in concert, both commercial and non-commercial benefits arise. These are likely to include increased certainty for exporters, predictability for investors and peace of mind for consumers. On the other hand, when the various regulatory approaches are in conflict, regulatory barriers to trade emerge and potential benefits can be lost.

Although it has not yet been ratified, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Biosafety Protocol or BSP)¹ has emerged as a blueprint for an international regulatory regime that has the potential to minimize the risks to environmental biodiversity from the transboundary movement of products of biotechnology. In attempting to standardize the application of the principles of risk analysis, the BSP could simultaneously create commercial and noncommercial benefits. From a commercial perspective, a standardized approach to regulating risk would eliminate the inconsistent application that currently prevails (most notably between the United States and the European Union) and, perhaps, eliminate subsequent regulatory barriers to trade. From a non-commercial perspective, the BSP has the potential to create a regulatory floor, ensuring that any transboundary movements of biotech products meet or exceed the standards set by the protocol even if the importing country does not have adequate domestic regulations of its own.

Despite this potential win-win scenario, adoption of the BSP as it stands would not be straightforward; the specific regulatory regime it proposes is in direct and significant conflict with the general principles of the regulatory regime for international trade in

¹ Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes (2000). Montreal Canada: The Secretariat of the Convention on Biological Diversity, (<u>http://www.biodiv.org</u>)

goods and services embodied in the World Trade Organization (WTO). In fact, at the WTO Ministerial Meeting in the autumn of 2001 in Doha, Qatar, the relationship between the international trading system and multilateral environmental agreements (such as the BSP) was identified as a key issue for the ninth round of multilateral trade liberalization negotiations.²

Examining the degrees of concert and conflict between the WTO and the BSP and considering the consequent legal and economic implications were the objectives of a major research project undertaken by the *Estey Centre for Law and Economics in International Trade*.

The purpose of this *Executive Summary* is to highlight the results of the major research project. The two international regimes were compared across a range of institutional dimensions, revealing substantial regulatory differences. These differences have significant legal and economic implications. Taken together, the institutional, legal and economic analyses suggest a particular direction for Canadian trade policy dealing with the regulation of products of modern biotechnology. Canada is uniquely positioned to take an important international role in devising a common regulatory regime for trade in the products of biotechnology.

² World Trade Organization (2001) *Draft Ministerial Declaration*. Ministerial Conference 4th Session, Doha, Qatar, 9-14 November 2001. Geneva: WTO WT/min(01)/DEC/W/1 14 November 2001. Article 31 Trade and Environment states:

With a view to enhancing the mutual supportiveness of trade and environment, we agree to negotiations, without prejudicing their outcome, on:

⁽i) the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements (MEAs). The negotiations shall be limited in scope to the applicability of such existing WTO rules as among parties to the MEA in question. The negotiations shall not prejudice the WTO rights of any Member that is not a party to the MEA in question.

INSTITUTIONAL DIFFERENCES

From an institutional perspective, the two regulatory regimes represented by the BSP and the WTO are significantly different (table 1). The WTO has, as its long-standing foundation, a narrow mandate of enhancing market access for traded products. This mandate is supported by a traditional range of interests, including exporting countries and firms engaged in export activities, and accepted by a wide range of policy makers who accept the proposition that trade liberalization is welfare enhancing. The enthusiasm policy makers have for a liberal trade regime is tempered, however, by the realization that domestic political realities require, at times, that the demands of protectionist interests be accommodated. The WTO represents a political compromise between these two forces. The fundamental aim of the WTO has been to develop rules that adhere to the baseline principle of non-discrimination (PND) and to identify legitimate violations of this principle given sufficient evidence.

The BSP has emerged from a much different institutional setting. It holds a very wide mandate – consistent with the Convention on Biological Diversity – to promote conservation and sustainable development through mechanisms that minimize the risks biotech products may present to environmental biodiversity. Along with this wider mandate comes a broader set of interests than the narrow trade-liberalization interests underpinning the WTO.

From these different institutional backgrounds, divergent Risk Analysis Framework³ trajectories have emerged. The WTO deals with biotech products on a product basis. That is, the focus is on the *application* of the techniques and procedures of modern biotechnology (i.e., the outcomes) rather than on the *use* of biotechnology (i.e., the process) per se. According to such an approach, some applications may yield products that can be considered substantially equivalent to or "like" conventional products because the end use is the same, despite the fact that different production and processing methods

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may have been used in their creation. Further, in meeting the baseline PND or the criteria for its various permissible violations, the WTO trade rules adopt a commercial approval structure such that a biotech product, once approved, is approved everywhere and every time. This is in direct contrast to the regulatory approach under the BSP, which has adopted a process- or technology-based focus. For the BSP, it is the use of modern biotechnology per se that incurs regulatory oversight regardless of any determinations of substantial equivalence or like products. Essentially, this means that biotech products under the BSP are considered to be in a perpetual state of novelty and there is no granting of "like products" status. According to the Advance Informed Agreement (AIA)⁴ principle adopted in the BSP, the Partly of Import is entitled to perform a risk assessment on such novel biotech products, taking into account risks to environmental biodiversity, risks to human heath, and socio-economic outcomes. In this sense, the BSP approval approach is transaction-based, where each signatory is allowed to perform a risk assessment on a case-by-case basis. That is, there is no granting of "national treatment" or "most-favoured-nation" status under the BSP.

Further, within the divergent trajectories, the WTO and the BSP use the Risk Analysis Framework in different ways. According to the WTO approach and through its formal links to various international scientific organizations, the idea of scientific justification is limited to natural science determinations of hazard or risk. When the issue is environmental safety, only environmental biodiversity risks are considered, not human health risks. Further, socio-economic risks are not part of the risk assessment process. At the risk management stage, science essentially *makes* the regulatory decision and the goal is reduce and/or prevent actual risks only. In summary, the traditional trade approach attempts to disentangle trade barriers erected because of safety reasons from those erected for non-safety reasons. The former are subject to a scientific justification for the safety measure. In the event of such a justification, it is legitimate for a country to impose a

³ The Risk Analysis Framework, adopted by the U.S. National Academy of Sciences in 1983, attempts to bring science into public policy through a three step procedure: risk assessment, risk management and risk communication.

⁴ The AIA principle essentially makes the BSP a transaction-based regulatory approach whereby a Party of import may conduct its own risk analysis of the environmental and human health impacts of the first-time shipment of a living modified organism, subject to certain timelines.

unilateral safety barrier to particular imported products. The latter, non-safety measures, are subject to the traditional trade principle of non-discrimination. In the event that a country imposes a trade barrier against a certain product, this barrier must be enforced equally across similar or "like" products, both domestic and foreign.

In contrast, risk assessments under the BSP broaden the definition of science to include both natural science and social science. The result is to extend the idea of risk beyond environmental biodiversity risk and to include also risk to human health as well as socioeconomic risk. Accordingly, at the risk management stage, science *informs* but does not *decide* regulatory matters where the goal is not only to reduce and prevent actual risks but to also manage risk perceptions, regardless of the scientific justification for those perceptions. In short, the BSP regulatory regime may be characterized as blurring the distinction between science and other legitimate factors (socio-economic considerations) in the Risk Analysis Framework.

Beyond comparing the two distinct regulatory trajectories it is also useful to consider the potential for regulatory integration of the two regimes. The WTO is a multilateral trade organization with links to various international scientific organizations that deal with the issues of safety and science. It has a dispute settlement mechanism designed to deal with disagreements between Members over interpretations of the many trade provisions. Further, the Committee on Trade and the Environment (CTE) of the WTO recognizes potential conflicts between trade liberalization objectives and environmental protection objectives and aims to identify clearly the role of the WTO in such conflicts and, by default, those roles that the WTO cannot play. In contrast, the BSP is a multilateral environmental agreement (MEA) without links to a trade organization – despite its obvious implications for trade – and without a clear mechanism to settle a dispute in the event that a Party of export disagrees with a unilateral trade barrier imposed by the Party of import.

To summarize, the WTO and the BSP regulatory regimes are much different and achieving convergence between them is a formidable task. The product-based WTO aims

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to establish a clear, consistent, predictable and stable regulatory approach. Commercial benefits include predictable market access opportunities, subject to the relevant requirements; non-commercial benefits include public confidence in the stability and stringency of the regulatory approach. The WTO is ever watchful that exemptions granted to the PND not be captured by or harnessed to protectionist interests. It is often argued, however, that in pursuit of its market access mandate the WTO places too much emphasis upon scientific rationality and not enough on social responsiveness. In contrast, it may be argued that the BSP offers mechanisms by which signatories can achieve social responsiveness. Yet the protocol is unclear and unpredictable; its many exemptions and provisional articles create an unstable regulatory approach. The BSP's deficiencies would not only have adverse effects on commercial opportunities but also could negatively affect public perceptions of the regulatory system.⁵

⁵ Public confidence may be negatively affected by a regulatory regime that appears to change frequently perhaps indicating that regulators lack control over the technology.

	WTO Regulatory Regime	BSP Regulatory Regime
Background	L	I
Mandate	Narrow: trade	Wide: MEA, sustainable
		development
Principle	Principle of non-discrimination	Advance Informed Agreement
	(PND)	(AIA)
Regulatory Trajectory		
Focus	Product focus:	Process focus:
	Substantial equivalence & novelty	Process- or technology-based
Approval	Commercial-based:	Transaction-based:
	PND or permissible violations	No PND
	Risks: scientifically justified	Risks: environmental, human
	environmental (IPPC) and human	health and socio-economic
	health (SPS Agreement)	
RAF	Science makes regulatory decision	Science only informs regulatory
		decision
	Science = natural science	Science = natural + social science
	Actual risks only	Actual and perceived risks
Regulatory Integration		
Links	Multi-multilateral:	Uni-multilateral:
	links with SPS, TBT Agreement	no links with scientific
	and IPPC	organizations
Dispute	WTO DSM	No DSM although compliance is
Settlement	IPPC DSM	provisional under Article 34;
		separate from CBD Article 27 on
		dispute settlement.

 Table 1: Institutional Comparison of the WTO and the BSP Regulatory Regimes

LEGAL IMPLICATIONS

Given the significant institutional differences between the WTO and the BSP and the potential for conflict, it is vital to understand the implications of these differences from the perspective of international law. Fundamental principles of the law of treaties do not provide an easy answer as to which regime would prevail in the event of a conflict. The BSP represents an example *par excellence* of the highly complex nature of the legal disputes occurring at the interface between free trade and environmental protection.

It is common knowledge that MEAs such as the Basel Convention on the Transboundary Movement of Hazardous Waste or the Montreal Protocol conflict with international trade rules. To date, none of these MEAs has been challenged at the WTO. It appears that the basis for tolerating this ongoing incompatibility stems from the popular support for the MEAs (the Basel Convention has been ratified by 148 countries and 180 countries have signed the Montreal Protocol) and from the unwillingness of countries to force a choice between trade and the environment under international law.

However, it may be unrealistic to expect Members of the WTO to tolerate the incompatibility of the BSP due to the significant institutional differences that exist. First, the BSP does not enjoy the popular support accorded to other incompatible MEAs. Second, the United States, the world's largest producer and consumer of products of modern biotechnology, has not ratified the Convention on Biological Diversity⁶ and, hence, is not a signatory to the BSP. Outside the NGO sphere, support within the United States for the BSP is virtually nonexistent. Furthermore, despite the public endorsement of the BSP by the European Union, no EU Member State has actually ratified the

⁶ The Convention on Biological Diversity (CBD) was concluded at the Earth Summit in Rio in 1992. Article 19 (3) of the Convention stated that the parties:

Shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism.

In 1995 at the Second Conference of the Parties in Jakarta in November 1995, the Parties to the CBD took Decision II/5 to create an Open Ended Working Group on Biosafety. The end product of that work was the BSP.

protocol. In fact, only seven countries have ratified the BSP (Bulgaria, Czech Republic, Fiji, Lesotho, Norway, St. Kitts & Nevis, and Trinidad & Tobago) and none of these countries can be characterized as either a significant producer or consumer of products of modern biotechnology.

While recent WTO jurisprudence in the trade and environment field offers some evidence of an increased willingness on the part of the WTO Dispute Settlement Body to accept certain trade-distorting measures in limited circumstances, their preference is clearly for multilaterally agreed standards. Without widespread popular support for the BSP, it is unlikely that Members of the WTO can turn a blind eye to the degree of divergence between the two regulatory regimes. The glaring institutional differences become too great to ignore and, given the large number of non-parties to the BSP, a challenge to BSP-based trade rules at the WTO becomes a very real possibility. As discussed in the previous section, there are several grounds for such a challenge, including the processbased focus of the BSP, its case-by-case transaction basis under the AIA principle, and its focus on human health and socio-economic impacts beyond environmental biodiversity.

ECONOMIC IMPLICATIONS

In the previous two sections it was argued that institutional differences between the WTO and the BSP create subsequent legal uncertainties about the ability of WTO Members to tolerate the non-compliance of the BSP with the international trading system. In fact, it was argued that the potential for a trade challenge of an MEA is real. To be successful, a trade challenge would require a demonstration of the distortionary effects caused by the regulatory principles of the BSP, and the subsequent impacts on economic welfare. In this section, such impacts are assessed.

The WTO is underpinned by an economic model that produces the following results: consumers always win from a liberal trade regime, and trade barriers are welfare reducing.⁷ What follows from this conclusion is that it is only producer interests that will ask for protection from their government – never consumers (or other groups in society such as environmentalists). This is the heart of the WTO's narrow focus on applications – or end products – of biotechnology rather than on process or on the technology used. From the WTO perspective, if differences in processes could be used to justify an exemption to the PND, and thus to put trade barriers in place, the regulatory regime would be wide open to capture by protectionist interests. For example, if differences in technology were allowed as a justification for trade barriers, one would quickly find trade barriers put in place to protect mills that use computerized looms in developed countries against textiles produced on more cost-efficient hand looms in developing countries. The current resistance by developing countries to the inclusion of environmental and labour standards in the WTO stems from the same fear of capture by protectionist interests in developed countries.

It seems clear, however, that those asking their governments for protection from biotechnology are not traditional, producer-based protectionist interests. Rather, they are consumers and more broadly defined members of civil society such as environmentalists. If consumers (or society as a whole) could lose as a result of unfettered imports, then the

⁷ Leaving aside theoretical constructs such as "optimus tariffs", etc.

liberal trade regime results (i.e., consumers win and welfare is enhanced unambiguously) arising from the economic model underlying the WTO may not hold. In other words, a liberalized trade regime may or may not be good for consumers, and welfare results are ambiguous. If the imposition of trade barriers is not unambiguously welfare decreasing, governments may have a legitimate public policy reason for asking for an exemption that would allow trade barriers to be put in place. The European Union has, for example, asked that certain WTO sub-agreements be reopened for negotiation to take account of consumer concerns.

In the case of biotechnology, the concerns of consumers (and environmentalists) relate to the quantity and quality of the information available pertaining to biotechnology. In other words, information on the safety and desirability of the products of biotechnology is not costlessly available. As a result, some consumers value the products of biotechnology less than they value those produced with conventional methods and suffer a loss when GM products are introduced into their market.

The WTO tries to compensate for this "information problem" of consumers and environmentalists by recourse to science. In essence, the WTO assumes that a scientific consensus substitutes for costless information. If there is a scientific consensus on the safety of a product, then there can be no justification for the imposition of trade barriers. The problem with this approach is that there is a very large assumption that consumers or environmentalists trust the science upon which the consensus is based and believe that the scientists themselves are credible. Given recent problems with food safety systems (e.g., "mad cow" disease, dioxins in Belgian feedstuffs, etc.) this trust has been eroded, particularly in the European Union.

In the case of non-safety concerns, the WTO only allows labelling restrictions on the basis of products being not alike. As explained above, the WTO does not allow the process used (e.g., biotechnology) to be the reason a product would be considered not "like" another product. It ignores the possibility that consumers may suffer a loss simply based on how a product is made. As a result, from the WTO perspective, the imposition

of a trade barrier will make the consumer a loser because it will raise the price and it will be welfare decreasing. If the BSP allows the imposition of trade barriers either in the face of a scientific consensus or on the basis of process then it will be considered distortionary at the WTO and the trade barriers could be struck down if challenged through the dispute settlement mechanism.

The BSP does not have a scientific basis for dealing with risk, and it explicitly requires labelling of imports on the basis of process in the case of biotechnology. To its credit, the WTO has never claimed competency in the area of environmental risk and has consistently suggested that these issues would be better handled by MEAs. Those that negotiated the compromise represented by the BSP, however, failed to clarify which agreement, the BSP or the WTO, would have primacy if the rules conflicted. Further, they did not endow the BSP with a dispute resolution mechanism. Hence, given that the WTO does have a dispute resolution mechanism, disputes relating to trade barriers imposed on the basis of the BSP will likely end up at the WTO despite its Members' preference for these matters to be handled through MEAs.

The focus of the BSP is to prevent a market failure from arising from an unanticipated environmental hazard that would negatively affect biodiversity. Beyond that focus, however, its mandate extends to the protection of human health and the consideration of adverse economic effects. It appears as if the framers of the BSP wanted to ensure that the possibility of such a market failure would never be underestimated – and so they allowed countries a bias towards precaution. This was accomplished by eschewing a strictly scientific criterion for managing risk in favour of a broader combination of scientific and social scientific criteria for decision making. In other words, a scientific (in the stict sense of the natural sciences) consensus is not sufficient to prevent the imposition of trade barriers. From the WTO perspective, the inclusion of non-scientific criteria as justification for the imposition of trade barriers leaves the process wide open for capture by producer-based protectionist interests – the antithesis of the WTO's focus. In particular, the economic-consequences criterion explicitly stated in the BSP flies in the face of the WTO's focus on welfare enhancement rather than on the losses to producers'

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vested interests that inevitably result from a technologically induced deterioration in terms of trade.

While the WTO has declared its preference that environmental matters be dealt with through MEAs, the inclusion in the BSP of risks to human health as a reason for the imposition of trade barriers leads to a direct conflict with the WTO's mandate to deal with human health risks in its Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). It is over this issue that BSP's non-strictly-scientific approach is in direct conflict with the WTO's scientific approach. In a dispute in this area, WTO panels would have to apply WTO principles.

It seems clear that the different economic models that underlie the BSP and the WTO lead to different emphases in trade policy design. Trade restrictions put in place under the BSP would lead to unjustified trade distortions according to WTO principles and, hence, a conflict seems inevitable. Given that the potential for the international exchange of the products of biotechnology is very large, removing the regulatory uncertainty created by incompatible but competing international regimes should be a priority.

CONCLUSIONS

From an institutional perspective there are significant differences between the regulatory regimes of the World Trade Organization and the Biosafety Protocol, differences that are more likely to produce conflict than lead to the emergence of an internationally consistent regulatory regime for biotech products. In fact, from a legal perspective, the divergence is significant enough to create the possibility of a trade challenge to a multilateral environmental agreement. From an economic perspective, the regulatory disequilibrium and regulatory regionalism created by the emergence of these two conflicting regimes create trade distortions and welfare losses. The objective of this final section is to consider the way forward for Canadian biotechnology trade policy.

Canada is in a unique position with respect to the two regulatory regimes. It is a Member of the WTO and not only a signatory of the BSP but also host to the Secretariat of the Convention on Biological Diversity.⁸ Of course, as a WTO Member, Canada must continue to respect the rights and obligations outlined under the various WTO agreements. Yet as a signatory to the BSP Canada must also - according to the Vienna Convention – comply with the "object and purpose" of the protocol even though it has not yet been ratified. As Canada tries to meet its obligations under both regimes, several problems emerge. How can Canada comply simultaneously with the product-based focus of the WTO and the process-based focus of the BSP? An important constraint is associated with regulatory resources. Pursuing both regulatory trajectories at the same time would require a significant amount of resources, and the level of resources dedicated to the traditional product-based focus in Canada is already under criticism.⁹ Strictly from a government resource perspective, it seems prudent for Canada to work towards a reconciliation – if possible – between the two regimes. This need would be exacerbated in the event of a conflict between the two regimes. In such a case, Canada would have to choose which organization and which approach is more beneficial to follow: either the science-based, product focus of the WTO or the process- or technology-based focus of

⁸ Located at the World Trade Centre, Montreal, Quebec, Canada

the BSP, which relies less on scientific justifications. A conflict like this would have symbolic repercussions: the international trade regime v. Mother Earth. Perhaps the most prudent approach for Canadian trade policy is to work to prevent such a conflict in the first place.

As the champion of the BSP, Canada has a unique opportunity to pursue the following:

(1) Work toward limiting the protocol to the protection of conservation and sustainable development from the risks posed by living modified organisms only. This is entirely consistent with the overall objective of the protocol to develop an international regulatory floor for biotech products.¹⁰ Limiting the protocol in this way would mean that references to human health and socio-economic risks would be abandoned. The full weight of influence of the protocol must be brought to bear on the risks to environmental biodiversity and not be obfuscated by secondary concerns such as human health risks, which may in fact be better addressed elsewhere. Further, other issues such as socio-economic impacts, labelling and liability must be considered only in the context of environmental protection. For instance, labelling would be only an instrument used by those in the Party of export to alert those in the Party of import of the potential risk from the transboundary movement of a living modified organism (LMO); it would not be a consumer tool used to meet the consumers' right to know, as this issue has nothing to do with the protection of environmental biodiversity. Similarly, liability would refer only to the unintended release of an LMO in the Party of import and not to the unintended presence of GMO material (adventitious contamination) in products destined for the market in the Party of import. The latter is, again, an issue that has nothing to do with protecting environmental biodiversity.

Once the BSP has been refocused on environmental protection only,

⁹ See Royal Society of Canada's Expert Panel on the Future of Foods from Biotechnology (http://www.rsc.ca/foodbiotechnology/GMreportEN.pdf)

¹⁰ BSP Preamble: "*Recalling* also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the sustainable use of biological diversity"

(2) Work toward having the Advance Informed Agreement (AIA) procedure more clearly specified to reduce any ambiguity embedded in the decision criteria and to inject certainty and predictability into the procedure.

This is not to suggest that the regulatory hurdles under the AIA procedure should be set low. In fact, to protect environmental biodiversity the regulatory floor may be set quite high, as long as it is operational and stable. Further, the regulations must focus on *actual* risk to environmental biodiversity and resist the pressures to regulate based on domestic risk perceptions. Actual environmental risks may be identified in two ways. One, the International Plant Protection Convention may have developed a phytosanitary standard for the particular LMO intended for environmental release. If no such standard exists, then the risk assessment conducted by the Party of import as a step in the AIA procedure must be congruent with the scientific standards-setting approach supported by the IPPC. If the Party of import could demonstrate an actual risk from the environmental release of a particular LMO, then the Party of import would be free to take unilateral action to ban the importation of the LMO. Such a ban would be completely trade compliant under Article XX(b) of the WTO. That is, through the regulatory regime of the BSP, a Party of import could establish a fully trade-compliant environmental protection measure.

This is an entirely desirable result with a win-win trade and environment outcome. The environmental benefit would be the establishment of a first-best regulatory floor, ensuring that biodiversity protection is the primary objective of a well-supported international protocol. The trade benefit would be the establishment of an agreement much like the SPS Agreement that identifies when countries may unilaterally impose trade barriers provided they have a scientific justification to do so. Furthermore, the Committee on Trade and the Environment of the WTO has recently argued that it would support such revisions to the BSP because it believes that an MEA is, in fact, the best place to establish first-best policies for environmental protection.¹¹

¹¹ World Trade Organization (1999) Trade and the Environment: Special Studies 4. Geneva. The Appellate Body and the CTE have also made numerous such pronouncements of a more general nature. See, for example, the comments of the Appellate Body in Shrimp–Turtle Implementation, supra, note 206 at Paragraph 5.88 :

Additionally, this approach avoids having the WTO decide which environmental protection regulatory approaches are the most trade compliant, as this task would reside with the more credible BSP.

If Canada does not champion the BSP and refocus the protocol to reflect these changes the potential benefits will be lost, conflicts between the two regimes will arise and the demise of the BSP is sure to follow.

At the WTO, Canada should:

(3) Work toward having "consumers' right to know" issues dealt with directly at the WTO.

Even if changes are made to build a more effective BSP that is focused on minimizing the risks to environmental biodiversity from the transboundary movement of living modified organisms and more congruent with the international trade regime, an important trade policy issue remains: the consumers' right to know about the process by which a product was produced. In the case discussed in this research project, this refers to the right to know about the use of modern biotechnology techniques. However, this trade policy issue is in fact much broader than biotechnology and would also encompass the consumers' right to know about animal welfare (e.g., leg-hold traps, free-range chickens, etc.) or labour practices (e.g., child labour).

This trade policy issue emerges because in its attempts to encourage stable and predictable market access rules the WTO has essentially drawn a line between safetyrelated measures (for which there are opportunities for Members to unilaterally ban trade in violation of the principle of non-discrimination) and non-safety-related measures (for which there are no legitimate grounds for a trade ban in violation of the PND). The problem is that according to this division, trade barriers that meet consumer demands for protectionism but are not supported with a scientific

In a context such as this, a multilateral agreement is clearly to be preferred.

justification are non-compliant with the WTO even though they may be politically necessary in the domestic market.

The WTO has gone to great lengths to avoid dealing with the problems of social protectionism, but all that has happened is that the "social protectionists" have sought to attain the right to ban on non-safety, process grounds through other regulatory regimes. The result has been the emergence of regimes that are in conflict with the international trading system – such as the BSP! In this sense, it is time for the WTO to deal with such issues head-on.

The standard response from the Committee on Trade and the Environment and from recent dispute settlement panels at the WTO is that while such issues are relevant, they are perfect candidates for a market-oriented, voluntary labelling program such as an eco-label or a humane-label. The rationale is as follows. If consumer demand for the ability to avoid a certain process or production method in favour of alternative methods is truly strong, then the first-best policy is to encourage those firms employing the alternative methods to use a voluntary label to identify their products in the marketplace and capture this demand. Of course, there would have to be considerable research concerning which is the best labelling mechanism to use (first-party, second-party or third-party);¹² however, the CTE argues that shifting the solution of this trade policy problem from a regulatory measure (a mandatory labelling strategy) to a voluntary, market-oriented measure is the most effective method for dealing with the non-safety process concerns that consumers may have in a manner congruent with the international trading system.¹³

Recent research that is worth further consideration suggests that the issue of process concerns unsubstantiated by scientific risk assessments should be dealt with through a separate agreement in the WTO that would defer to a new international expert

¹² For a discussion on eco-labels see Isaac, G.E. and Woolcock, S.B. (1999) Green Labels: Consumer Interests and Transatlantic Trade Tensions in Eco-labelling. Research Project for the Consumers International project "Support to Consumer Organisations in Promoting Sustainable Consumption."

¹³ World Trade Organization (1999) Trade and the Environment: Special Studies 4. Geneva.

organization.¹⁴ Successful negotiations to create such an agreement and corresponding organization would essentially internalize the problem of non-safety process concerns in the international trading system. Any new agreement and organization would have to be carefully constituted to prevent their capture by traditional protectionist interests.

By clearly identifying the regulatory failure and working to remove it, Canada can take the opportunity to play an important leadership role in the international arena while at the same time both ensuring that the potential domestic benefits of biotechnology are not stifled by badly designed trade rules and providing a means of including the concerns of civil society in the rules governing international trade in the products of biotechnology.

¹⁴ Perdikis, N., W.A. Kerr and J.E. Hobbs (2001) Reforming the WTO to Defuse Potential Trade Conflicts in Genetically Modified Goods, *World Economy*, 24 (3), 379-398.