
Science on the tap, not on the top

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Abstract: Science plays an increasingly important role in trade policy and negotiations. A large number of trade agreements rely on scientific expertise for their work. Science is negotiated in setting environmental and health standards: trade disputes had highlighted the role of science as the legal test in the WTO.

Historically, it was the negotiations on agriculture that triggered interest in science as an alternative approach to regulating trade, with food safety emerging as a major concern. The recent extension of the *phytosanitary* domain to include *biosafety* represents the biggest challenge to the trade policy – a challenge of taking the WTO into the area of adjudicating on the appropriateness of domestic regulations.

Forming and managing the scientific consensus underlying trade-related rule-making, standard-setting and regulatory activities at the national, regional and international levels present formidable challenges. The notion of *science diplomacy* refers to activities of international cooperation and compromise on issues with a heavy scientific input. These activities and resulting networks offer excellent opportunities to share resources and hedge against diplomatic failures through exchanging experiences, opening countries up to better funding opportunities from international sources and sharing organisational capacity and expertise.

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“People are better off not knowing how sausages and laws are made.”
(Otto von Bismark)

1 Negotiating science

Science plays an ambiguous role in policy. Most risks implicit in policy making would be unknown, indeed unknowable without scientific research. Science is also widely perceived to be at the origin of many risks. Finally, no solutions are conceivable without resort to science. This ambiguity creates a unique and uneasy relationship between scientists and policy makers.

Science is not normally organised to provide information that can readily be used in policy making, therefore most countries have developed specialised procedures for scientific assessment. Scientific assessment is rooted in science but is not itself a scientific undertaking. It influences – and is influenced by – norms, standards, principles, institutions and procedures that serve the purposes of the society. They reflect culture and tradition, the society’s response to change and its reaction to risks, the status of various occupations, and the chosen economic system, to name a few factors. What make science particularly important from the trade policy perspective is that it operates as a regulatory anchor, i.e. forms the basis for national standards and technical regulations, which seek minimum necessary outcomes and assurances of quality and safety.

Since scientific assessments already incorporate certain aspects of the policy environment for which the assessments are being made, they are not readily transferable from one country or jurisdiction to another. This is a problem for the multilateral trading system as trade liberalisation inherently starts to require, rely upon and develop *positive* rules, i.e. it depends on common or shared standards and underlying perceptions, or at least, on mutual recognition of national (or regional) standards.

The GATT/WTO regime is predicated upon the concept of *national treatment*, as opposed to *mutual recognition*, of standards, subject to exceptions. However, the GATT/WTO effectively departs from this principle of *national treatment*, in favour of *mutual recognition*, when it comes to *process and production methods (PPMs)*. The concept of *national treatment* has been construed in such a way as to permit the application of domestic *product* standards to imported goods. However, the application of domestic *PPM* standards to imported goods would amount to less favourable treatment and hence derive no protection under *GATT (Article) III*. Products that are intrinsically comparable are considered as *like*, regardless of differences in the manner in which they have been produced or harvested. While *de jure* the principle of *national treatment* is preserved, because of the manner in which the term *like* is construed, *de facto* it has been undermined in the case of *PPMs*.

Capacity for harmonisation of standards is crucial in easing the path from *national treatment to mutual recognition*. However, the scope for harmonisation is limited to groups of homogeneous jurisdictions such as the European Union. An alternative to the harmonisation of international standards is *technical equivalence*¹. Technical equivalence addresses the legal and regulatory infrastructure and specific requirements – facilities, *PPMs*, tests etc. It is not as far reaching as *mutual recognition*, which rests on the *presumption* of equivalence.

Limited experience suggests that the negotiation of technical equivalence agreements is very difficult, partly because there are no formal structures to facilitate the process: no rules of procedure; no guidelines; no forum for discussion; no enabling framework at all.

A few years ago the same situation applied to conformity assessment procedures. Following the agreement on Technical Barriers to Trade (TBT), progress has been made in extending *national treatment* (and *non-discrimination*) to a wider range of conformity assessment. However, the Agreement provides only a limited basis to encourage acceptance of the results of tests or laboratory accreditation across national borders².

There are other complications. Article 6.3 of the TBT gives WTO members absolute freedom to enter into bilateral *mutual recognition agreements*. This is one area where discrimination can be done without any regard to MFN obligations. In this context, a question arises as to whether a linkage could be made with Article VII.2. of GATT, which has a conditional MFN clause and gives some negotiating rights to join a special agreement. This link is still missing in the 'judicial geometry' of the WTO and potentially could be a point to put on the books in future negotiations³.

The presumption of regulatory correctness that attaches to *international standards* makes the setting of these standards increasingly important. International standards in a sense constitute agreed or negotiated science. In fact, in the earlier days of GATT, it was common to refer to international *scientific*, rather than *standard setting*, organisations. International standards help countries move towards at least partial harmonisation and thereby remove potential barriers to the free flow of trade.

Both the TBT and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) urge the WTO Members to use international standards or resort to scientific justification whenever they chose a level of protection that would go beyond such standards⁴. The so-called 'three sisters' – WHO/FAO *Codex Alimentarius Commission (Codex)*, *International Plant Protection Convention (for plant health)*, and the *International Animal Health Organization/Office International des Epizooties* (for animal health) – have effectively become part of the WTO *aquis*. In spite of its voluntary nature, *Codex* is a particularly interesting organisation with regard to environment related food safety because it has been adopted by the SPS Agreement as its food safety standard. As a result it contains and addresses uncertainties both of science and rule making.

The TBT Agreement does not refer to any particular standard-setting bodies⁵. However, the recent dispute on *Sardines* underlined the importance of international standards (*Codex* in this particular case) to the TBT Agreement. This is significant as *Sardines* is a first instance when dispute has gone to its ultimate stage with regard to the TBT Agreement.

To what extent international standards are a reflection of the situation in the world over rather than in the OECD countries is an open question. There is a clear relationship between technological and regulatory capacity, which accounts for the fact that the majority of developing countries are standard-takers rather than standard-makers. The uneven participation of countries in standard setting has proved an intractable problem. The mere notion of an international standard is still waiting an authoritative interpretation.

It is not uncommon for standards established in major markets to override international standards. They may be indirectly 'imported' into other jurisdictions; standard-complying goods may pass into standard-free territories, physically transferring 'nation-of-origin' regulatory results. Minor markets often have no choice but to rely on regulation imposed by other jurisdictions as assurance of public health and safety concerns in lieu of direct regulation.

The shift in trade rule making towards international regulatory convergence sets in motion a very complex dynamics that repeatedly tests national regulatory outcomes. Within certain categories of regulation, scientific justification and risk assessment pre-empt free-trade notions such as *least trade-restrictive*, *proportionality*, as the mark against which national measures are tested.

2 Science as the legal test

In so far as standards reflect the diversity of national values and technological capacity, they pose a formidable challenge to trade policy. Central to this challenge is the well-known fact that the capacity of states to regulate in a particular area is contingent, in practice, upon their capacity to demand compliance with these standards on the part of their trading partners.

The general rule under the GATT/WTO is that each country may determine for itself the level of risk it deems appropriate to embody in its product standards. This rule is qualified to ensure that these measures are not misused for protectionist purposes (*non-discrimination*). The evolution of this general rule has been propelled not by negotiation but by judicial interpretation.

Under the GATT, regulations were dealt with in the context of *Articles I, III (non-discrimination)* and the *Dispute Settlement Understanding (DSU, Annex 2 to the WTO Agreement)*. While there is no reference in these Articles to science, issues of science have repeatedly come up in disputes where these Articles were invoked, and the body of case law is very indicative in this regard. Regulations have also been treated through recourse to *Article XX (general exceptions)*, particularly *XX(b)(protection of human, animal or plant life or health)*, and *XX(g) (conservation of exhaustible natural resources)*. Technically speaking, an application of either exception generally comes in the form of a product standard⁶. However, some of these standards may be *related* to the process of production. As it is not the level of protection that is challenged, but the measure itself, scientific arguments have been crucial in determining whether a particular trade measure falls within the scope of this Article.

It was because *non-discrimination* had become an insufficient test that the WTO members have developed the SPS and the TBT Agreements. Indeed, what may be considered by some as product differentiation on quality of safety grounds, may be considered by others as a form of trade barrier. It is the function of the SPS and TBT Agreements to bring order and transparency in this regard. The SPS Agreement, in particular, marks an important step in the evolution of WTO rules. It takes WTO members beyond *non-discrimination*, and to a restrictive interpretation of the GATT *general exceptions* by elaborating the applicability of the GATT Article XX(b)⁷. This interpretation is rather 'closed' in its tendency to privilege scientific rationality. The SPS disciplines are greater than those in GATT Article III:1,4 and XX(b). Not only must there be no discrimination between supplying countries, but there must be no discrimination between the importing territory and that of others. This adds a national treatment note to the *chapeau* of Article XX.

While the SPS (*risk assessment*), the TBT (*necessity test*), GATT Article XX (*general exceptions*) and the Dispute Settlement (*right to seek information*) are the areas where scientific arguments really play out, there is a trend towards using science – again – in the context of provisions for *non-discrimination*, e.g. in cases that

have to do with *toxicity*. Increasingly, the Appellate Body leans towards the view that the environment and health do not always have to be treated as exceptions. For example, the standards of the International Agency for Research on Cancer and the ILO occupational health and safety standards were very much part of the proceedings in the *Asbestos* case. This trend – science ‘migrating back’ to the provisions for non-discrimination – is significant. Science has effectively become the legal test in the WTO with respect to trade measures that have to do with the environment, food safety and health⁸.

Increasing recourse to science in dispute settlement may lead to a new kind of international discourse, where certain moves are excluded. The WTO’s Dispute Settlement Mechanism is a quasi-judicial system that, strictly speaking, does not operate on precedent: panels and the Appellate Body are not bound by previous rulings so the pendulum can, at least in theory, easily swing the other way. However, while the Appellate Body and Panels do not legally bind members of the WTO, their acceptance of certain lines of scientific reasoning has important precedent-setting effect.

Part of the jurisprudence carried forward from the GATT has been to look at the notion of *like product* in *GATT Article III:4 (national treatment of like products)*. The ‘likeness’ of a given product depends upon intrinsic product quality and not upon a particular *PPM*. However, the two may be related, with production processes impinging upon product quality (*product-related PPMs*). The concept of *product-related PPMs* seems more relevant to the TBT than to the SPS where *PPMs* are a valid ground for distinction, or *GATT Article XX*, which is an exception to the entire GATT/WTO, and hence to the concept of *like product*, too. In the TBT, on the other hand, it is still not clear that *non-product related PPMs* can be considered relevant to technical regulations and this debate is at the root of the drawn out controversy on the applicability of the TBT disciplines to eco-labels in the TBT Committee as well as the Committee on Trade and Environment.

Scientific progress is pushing the limits and relevance of the concept of *like product*, which is fundamental to the principle of *non-discrimination* in the multilateral trading system. A question is sometimes posed as to whether the fact that any given *PPM* cannot be *detected* in the final good also means that it is not *related* to this product? There are those who argue that certain *PPMs* are not only *related* to the product but a quintessential part of it even though they cannot be *detected*. The argument aims at relaxing the concept of *product related PPMs* and making it more ‘elastic’ by including the notion of *related but not detectable PPMs*.

There is a growing list of *PPMs* which are not *related* to the product but which are nevertheless considered to be important for scientific (e.g. climate change, ozone depletion, deforestation) or social (e.g. consumer choice, societal preferences, animal welfare) reasons or sometimes both⁹. Controversy exists on whether Genetically Modified (GM) and non-GM products are *like products* in the context of the WTO¹⁰.

From the trade policy perspective, the definition of *like* is a matter of policy rather than a matter of fact. *Likeness* is construed to be contingent upon the aim and effect of the trade measure. Whether the measure is such as to afford protection to domestic product, and what is the overall legitimacy of the measure in terms of its regulatory purpose or protectionist aim or effect. This may explain the fact that when it comes to *PPMs* cases in the WTO disputes, there is consistency in terms of result though not in terms of reasoning.

Some argue that it may be to the advantage of the developing WTO Members if there were a shift in the WTO jurisprudence from the GATT to the TBT. This would open the door to more product differentiation and more precise rules. However, the jury is out on whether this change would actually make market access for developing countries easier. The use of *GATT Article III:4 (like products)* in *Asbestos* has promoted apprehensions that the concept of a *like* product has been reopened or nuanced leaving the door open to introducing non-trade concerns, including environment, labour and other human rights.

3 A special case: agriculture

Historically, it was the negotiations on agriculture that triggered interest in science as an alternative approach to regulating trade. Food safety emerged as a major concern, with a variety of factors such as consumer confidence, public health, culture, traditions and politics hanging in the balance.

A basic obligation of WTO Members is to ensure that SPS measures are based on *scientific principles*, a sanitary measure may not be maintained on a permanent basis unless there is *sufficient scientific evidence*, a food safety measure that affords a higher level of protection than the international standard can be introduced or maintained if there is a *scientific justification*.

Any sanitary measure must be based on *risk assessment*. In the first three cases (*Beef Hormones*, *Salmon*, *Varietals*) under the SPS regime, the parties to disputes and panels struggled to understand and apply correctly the rules regarding risk assessment. Although the SPS Agreement does not define the process for the risk assessment, it does refer to the risk assessment techniques developed by *Codex*, which must be taken into account it not necessarily followed. A risk assessment may set out both the mainstream of scientific opinion and the minority of divergent view.

In establishing broad principles for food safety measures, the SPS Agreement joins together two potentially contradictory concepts of sovereign discretion: trade liberalisation and scientific objectivity¹¹. It essentially protects with 'science' tariff concessions and reduces, almost eliminates, the ability of governments to respond to non-trade concerns in deciding whether a risk exists, leaving national values and preferences as well as their effects to be considered primarily with regard to measures taken under the TBT Agreement (e.g. labelling)¹².

While there is clear commercial logic to this approach, as *Beef Hormones* and the debate about GM foods illustrate, it can become problematic for consumers and their representative governments¹³. Trade measures based on science are equivalent to the 'race to the bottom' on the scales of consumer protection. One of the consequences is the potential for the a government to continue a policy that reflects tradition and (some) consumer's views, instead of adopting a policy that accords with the SPS regime¹⁴. The *Beef Hormones* case shows that there are regulatory issues that are so politically crucial that a major trading block is willing to remain in permanent contravention of a WTO decision.

Interestingly, the language of the SPS Agreement uses the word *scientific* rather than *science*. It is not entirely focused on laboratory, 'white coat' science but rather seeks to promote an approach or reasoning process that yields sound conclusions, an objective decision-making that considers all factors and views (Echols, 2001). Indeed, a key factor in the management of SPS issues in international trade is the integration of a broad range

of biological and natural sciences, economics, sociology, political science and other disciplines, and their systematic and integrated use in *risk analysis*¹⁵.

The development of consistent protocols, within and across countries, for using risk analysis and resolving SPS issues is an evolving process. Although the initial emphasis in disputes has been on *risk assessment*, decisions in those cases, as well as experience in bilateral and multilateral negotiations on technical equivalence, indicate that *risk management* and *communication* issues are also central to addressing SPS issues. The risk management decision must evolve with new information and establish the appropriate level of protection (policy). *Risk communication*, i.e. interactive communication with – and education of – all interested parties in all aspects of the process, is especially important when new technologies are brought to the market. As risk is ‘colonising’ many areas of life, an increasing attention is being paid to *risk perception* as an important ‘fourth factor’, besides risk assessment, management and communication.

4 A very special case: agricultural biotechnology

The more recent issues relating to the *protection and conservation of biodiversity* are certainly not making agricultural trade policy any easier. On the one hand, they have extended the *phytosanitary* domain to include *biosafety*, i.e. regulations that aim to protect plants – as well as human health – against potential threats from genetically modified seeds and crops. In a wider definition, animals, especially GM fish, are also included in the scope. On the other hand, there are growing attempts to ensure the conservation of biodiversity, sometimes referred to as *phylogenetic* conservation, through the imposition of conditionalities on the intellectual property rights. In fact, both these domains, represent two sides of the same coin, i.e. the management of agricultural plant biodiversity.

The CBD (*Cartagena Protocol on Biosafety, Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits*) and the FAO (*International Treaty on Plant Genetic Resources for Food and Agriculture*) provide the most important fora for these negotiations. However, the WTO Agreements (*SPS, TBT and TRIPS*) have always been at the centre of these negotiations, whether in the framework of the *Cartagena Protocol* or the *FAO International Treaty*. In the former case, it was the question of developing scientific risk assessment and management procedures in compliance with *SPS* and *TBT* provisions concerning crops that are destined not for planting but for consumption. In the latter, the implications of a potential review of *TRIPS Article 27.3(b)* – and its compatibility with the *FAO Treaty's* benefit sharing provisions – were at the core of the disagreements.

The *phytosanitary* negotiations, circumscribed by the *SPS, Codex, the Cartagena Protocol*, are of special interest as they follow an approach based on scientific methods of risk assessment, while the *phylogenetic* negotiations (*FAO International Treaty, the Bonn Guidelines* and *TRIPS*) are characterised by their more explicitly legal nature and emphasis on matters of finance. The recent agitation in negotiations around this highly dynamic interface of science and trade rules reflects both the large economic stakes involved and the rapid advancement of biotechnology research.

Risk assessment is one area where there is potential for conflict between the *SPS* and the *Biosafety Protocol*. Under the protocol, 'the party of import shall ensure that risk assessments are carried out, and it may require exporter to carry out the risk assessment' (*Article 15.2*). The importer can also require the exporter to bear the cost of risk assessment (*Article 15.3*). Under the SPS Agreement, measures have to be based either on risk assessment or on an international standard. The Agreement does not specify who carries out the risk assessment, but it is the importing country's obligation to base its measures on such an assessment. Of course, the importer may claim that the prohibition is temporary and therefore falls under the exception of *Article 5.7* of the SPS for provisional measures in the absence of sufficient scientific evidence. However, this in turn would mean that the importer has the obligation to seek additional information required for risk assessment, and to review the measure within a reasonable period of time. It is not clear how this difference in who bears the *burden of proof* might be resolved¹⁶.

In May 2003, the US, along with Argentina, Canada and Egypt moved for formal consultations in the WTO regarding the EU moratorium on the approval of GMOs, which has been in effect since 1998¹⁷. While the EU is the explicit target, an implicit target in the Cartagena Protocol on Biosafety (Isaac and Kerr, 2003), which entered into force in September 2003. The move is intended to seek a determination which of the two regulatory approaches - product-based (SPS/WTO) or processed based (CPB) - is trade compliant. And although the chances are the dispute will focus on procedural issues, it would represent the biggest challenge to the trade policy - a challenge of taking the WTO into the area of adjudicating on the appropriateness of domestic regulations.

This regulatory antagonism may spill over into other areas. For instance, it may make impossible any progress on agricultural policy reform, thus hindering the Doha Development Round. It would be ironic if the trade-environment issues, which found its way into the Doha Ministerial Declaration as a trade-off against agriculture negotiations were to become the main stumbling block for these negotiations.

5 Minority science: precaution

Given the non-commercial aspects of agriculture, food and food safety, there are often cross-overs and overlaps, which science alone cannot demarcate. A critical decision for regulators is whether to impose a measure when there is uncertainty or disagreement about whether a hazard/risk¹⁸ exists (GMOs), when there is inconclusive scientific evidence of a risk (the BSE/nv CJD link), the extent of the risk (dioxin), or in spite of a scientific finding that no risk exist (certain growth hormones). This is *precaution* as opposed to *prevention* and causes an intense unease and debate under any science-based agreement. *Precaution* suspends science as a necessary condition for policy measures and ushers in commitment to *risk avoidance*, which stands in stark contrast to the usual management protocols that pragmatically balance risks in one area with benefits in other areas.

Article 5:7 (*provisional measures*) of the SPS Agreement is an obvious expression of permitted *precaution*¹⁹. However, the goal, scope and references to the *precaution* permitted under the SPS Agreement are not yet fully understood. In particular, the views

differ greatly regarding as to when precaution is exercised. Some argue that *precaution* is an aspect of *risk management* – a process that takes into consideration non-scientific factors. Others assert that precaution is already factored into *risk assessment*, i.e. into the scientific analysis of risk, as well as *risk management*. For example, most risk assessment include a *dose-response assessment* and a *determinable acceptable limit*. An *average daily intake* is another example. The argument continues that, given the *precaution* imbedded in risk assessment, applying the principle during risk management is unnecessary and creates non-tariff barrier. In other words, if *precaution* is embedded in the food safety system, precautionary action during risk management is protectionism in disguise.

There have been proposals, admittedly drastic, to introduce the notion of precautionary principle into the TBT Agreement. However, a general feeling that the TBT is a complex and relatively untested agreement that has served the WTO membership well so far. The preference would be to leave it alone in the context of possible set of negotiations.

The *Cartagena Protocol*, which represents an elaborate system of consensus-based scientific information exchanges between exporting and importing countries, marks the first time that the *precautionary principle* has been embedded in the body of a treaty, effectively turning it into the international default setting²⁰. This means that, in the area of *biosafety*, at least, policies that *react* to adverse impacts are no longer the norm²¹.

The *precautionary principle* should be credited for putting the focus where it belongs – in preventing harm to human health and the environment. It can further be credited with recognising that decisions in predicting and preventing risks will always involve scientific uncertainty. Unfortunately, the principle does not provide a coherent answer to the question it rightly presents.

First, the principle is usually redefined *ad hoc* each time it is incorporated into an international agreement²². Second, any single version is itself ambiguous. Third, there is an ambiguity about the regulatory context, i.e. is the principle a replacement for risk analysis, or is it to be placed within the risk analysis, but limited to risk management and not risk assessment? Given these questions, the application of the precautionary principle may descend, much like peeling the layers of an onion, to the same core issues that confound current regulatory decisions.

It is important to note that the current regulatory system is generally precautionary in nature, proactively limiting or controlling many risks. For the *precautionary principle* to provide even more *precaution* would require a corresponding tightening in current regulatory premises. For example, that would require giving less or no consideration to the costs of regulatory measures, adopting more stringent thresholds for acceptable risks, perhaps approaching a zero-risk goal, or relaxing scientific norms for association and causation. Revealing such regulatory premises may undercut much of the support the principle enjoys now.

In any case, the application of the *precautionary principle* needs not be non-scientific. Rather, the principle can be used to promote more robust scientific practices that acknowledge complexity and uncertainty. Protection of the environment and public health is the primary goal of precaution, and scientific arguments can – and should – be used to clarify some of the core elements of this approach.

6 Majority science: substantial equivalence

In order to ensure consistency in the application of the *non-discrimination* principle, certain subsidiary rules have been developed, including the limits to which states can impose restrictions. Finding these limits reduces to answering a question of whether the particular product is *substantially equivalent* to other *like* products. To answer this question, the WTO defers to the *Codex*, which among other things is responsible for drawing up internationally agreed rules which establish the meaning of *substantial equivalence* in particular contexts. In matters other than food safety, substantial equivalence is intuitively the same concept as the principle of *like* products under the TBT Agreement.

The term *substantial equivalence* has been introduced into the concept of risk assessment of novel foods only recently, but the underlying strategy of comparing newly developed products or techniques to existing ones has been applied for a long time – not only in agriculture²³. Standards historically have had a significant role in addressing information needs for substantial equivalence determinations: conformity with a standard means a new or novel product is similar to previously marketed product in the areas covered by the standard.

Substantial equivalence is the current standard for risk assessment, but how ‘substantial’ is *substantial equivalence*? The weakness of *substantial equivalence*, when applied to GM foods, has been recognised by scientists, including at the international level. It ignores unpredictability of GM foods, overlooks unanticipated effects, only accounts for known allergens expected in analogous non-GM plants. On the other hand, substantial equivalence can serve as a practical reference point, provided there are no changes in the composition, nutritional value and intended use of the product in question. Besides, while testing alternatives exist, they are not currently feasible as they are more costly and time consuming²⁴.

Substantial equivalence is no substitute for risk assessment, and the adequacy of the concept as a contributor to the overall regulatory process is under continuing review. One thing is clear though, it can be a starting point for evaluation, but not a finishing point. Further, investigations of the full scope of the doctrine would better establish the degree to which novelty may be considered to be sufficiently related to current art to be substantially equivalent. Such an investigation could help determine what constitutes novelty of a degree which truly merits an application of the precautionary principle, a feature the principle sorely lacks in its current formulations.

The *precautionary approach* and *substantial equivalence* constitute an unexplored challenge to the science – some would say art – of risk assessment. They weigh in the risks of the incompletely-known *status quo* and the risks of the new in radically different ways. While the *precautionary approach* enables rejection of the notion that it is possible to ‘know enough’ about something to justify making use of it, the concept of *substantial equivalence* accepts the notion and is therefore central to interpreting the risks of the new in terms of the familiar risks of the *status quo*.

Both approaches fuel a debate that is crucial to the eventual meaning of a science-based system of trade rules. At some point the international community will have to square the circle either through a negotiated solution or by an imposed settlement. Advances in both the procedures and substantive rules of the international trading system could help alleviate some trade tensions. Science could help the trade community modernise these rules and procedures on the basis of greater analytic rigour.

7 Science diplomacy

Regulatory design and implementation is much more than a technical exercise; notwithstanding the movement to transform rulemaking into a scientific discipline, real world regulatory determinations remain political.

While the language of science is spoken in the WTO, when it comes to evaluating justifications for restricting trade, setting the qualitative threshold for establishing the existence of risk has proved difficult. This reflects not merely the uncertainty which characterises costs and benefits in a context of unknown or unknowable risk, but also the modern conceptions of science as capable of delivering merely a version of the ‘truth’, which has its roots in the premises, methodologies and values of the system within which it is articulated. Far from being fixed or universal, science is a highly contingent social construction whereby a plethora of non-scientific factors influence the methodologies and assumptions adopted by scientists with the result that ‘there is unlikely to be a single unique way to analyse even the purely scientific significance of such empirical data’ (Wirth, 1994).

Sceptics could argue that WTO Members have practically unfettered discretion to justify whatever trade (environmental or SPS) measures accord with their policy goals. This flexibility suggests that a defendant will almost inevitably be able to select, or even commission, a scientific opinion that accords with its policy goals. In other words, in situations where national interests are at stake, one can anticipate many cases where scientific consensus is split along national lines (Atik, 1996). The history of trade disputes has already demonstrated the possibility of rival scientific positions arguing contrary regulatory stances.

Cross-border flows of scientific consensus will play an increasingly important role in mediating tensions between national regulatory concerns and the demands of international community. Scientific consensus is geographically distributed and flows from centres of influence. These centres of scientific authority correspond, not accidentally, to the major players in the world trading system. Countries commanding resources for the establishment of scientific consensus are in a position to exert important influence on national regulations around the world. It is not clear to what extent nations removed from the scientific centres of authority can obtain the science they need to support desired regulatory outcomes.

The notion of *science diplomacy* refers to activities of international cooperation and compromise on issues with a heavy scientific input. It places an emphasis on incorporating scientific knowledge into the process of formulating and implementing policy – ‘science for policy’. These activities and resulting networks offer excellent opportunities to share resources and hedge against diplomatic failures through exchanging experiences, opening countries up to better funding opportunities from international sources and sharing organisational capacity and expertise.

Science diplomacy still presents challenges, particularly in its relative lack of formal procedures and systematisation. First, the right people to ‘cross over’ and serve in advisory roles need to be identified. Brokering relationship on both formal and informal levels is an important step for improved institutional coordination. The most important task is ensuring a meaningful participation of developing countries in rule making and standard setting.

Different countries have adopted differing models of science diplomacy. For instance, the US Government assigns carefully selected Science Counsellors to embassies in countries where S&T related activities are of major interest to the US and to missions to international and regional organisations of considerable foreign and trade policy significance. Since it is in US embassies and missions to international organisations that much of the melding of the requirements of diplomacy and the contributions of experts takes place, greater importance is given to the assignment of specialised personnel. In some cases, a specialist who is already assigned overseas to represent the interests of another department or agency will serve in a 'dual-hatted' capacity as a science officer. A number of other steps are being implemented, including the establishment of science and technology advisory committees, increasing the resources available to meet the science and technology requirements, increasing the use of specialists from various departments and agencies as rotating employees assigned to positions in Washington and abroad, as participants in trade negotiations, and as advisers on topics in their areas of expertise; streamlining interagency reviews of existing and proposed international and bilateral agreements.

Switzerland has taken a very innovative approach to science diplomacy – the establishment of scientific consulates. The Swiss Consulate in Boston (Swiss House for Advance Research and Education) is a pilot project, arguably unique in the world. It is an official Swiss representation, operated jointly by the Swiss Federal Science Agency and Department of Foreign Affairs. According to its hybrid character, the Consulate-Share reports to the State Secretary for Science and Research, the Director of the Swiss Federal Science Agency (parent organisation) for all matters of operations and finance, and to the Ambassador of Switzerland to the US in Washington DC on behalf of the Federal Department of Foreign Affairs for all official and diplomatic matters. There is an advanced plan for setting up similar consulates in other countries.

United Nations agencies have a wide range of activities relating to science and technology. The work of UNCTAD in this area is particularly relevant to trade policy and negotiations. It seeks close correlation with discussions and negotiations in and around the WTO and targets a number of areas of current diplomatic attention, including the management of environmental and SPS risks in international trade, standard-setting activity, and the impacts and applications of new and emerging technologies, most notably biotechnology. The objective of these activities is to upgrade the knowledge base surrounding trade policy and negotiations; alert trade officials and negotiators to complex or newly emerging issues; provide focused support to trade ministries and missions during international negotiations, major international conferences and implementation of technical assistance programmes.

8 Science diplomacy and trade policy

There are two key features of the scientific knowledge that are central to trade policy and negotiations. First, science is becoming increasingly specialised and therefore demands greater expert input. Second, the application of science to trade policy requires the ability to integrate the divergent disciplines that are needed to address specific problems. Trade diplomacy now demands that government negotiators deal with both specialisation and integration. This is not to say that trade diplomats need to acquire extensive scientific competence, but they do need to learn to identify and tap the best available expertise.

Examples of trade-related issues with significant scientific component are: adequate food supply; food safety and contamination of food exports; biotechnology for pharmaceuticals; health and environmental implications of trade in GM food products; dual-use technologies, including environmental technologies; fishing activities; harmonisation of approaches to TRIPs; technical equivalence and conformity assessments; promoting links between risk assessment and risk management in the context of the SPS Agreement; the use of science in dispute settlement. Discussions and negotiations on these issues need to be infused with scientific and technical knowledge that reflects high technical standards. On the other hand, experts need to understand the governance structures that may impinge on the conduct or reporting of their research.

Trade and trade-related measures for non-trade purposes such as environmental protection or food safety are one area where the benefits of science diplomacy may turn out to be particularly important. Scientific familiarity will be crucial for assessing trade measures based on the *precautionary principle* as well as in setting standards that may make such measures unnecessary.

Getting redress through the WTO dispute settlement mechanism is often dependent on the quality of underlying technical dossier. Trade disputes tend to be of a highly technical nature, involving complicated scientific fact-finding and assessments. Cases increasingly show patterns of high complexity, both in terms of law and facts, and can no longer be successfully handled by a single lawyer, supported by one or two assistants and inter-agency coordination. They require well-structured and well-led task forces. Putting together the relevant facts requires specialist expertise that developing countries often do not have, nor do they possess sufficient funds to hire such expertise on an *ad hoc* basis.

Against this background, the Technical Expertise Trust Fund, created at the Advisory Centre on WTO Law (ACWL), is a very important development²⁵. Now, in addition to the Centre's subsidised legal services, developing countries, economies in transition and least-developed countries may have access to the Fund to help finance the technical expertise needed to engage in WTO dispute settlement proceedings²⁶. The ACWL's experience with the Fund will be valuable to developing countries in terms of promoting practical approaches to using science in dispute settlement.

Putting together the technical and scientific facts may be necessary to see if there is a WTO case worth pursuing. However, having a well-researched technical dossier does not always have to result in a WTO panel. Such a dossier could be instrumental in settling a dispute already at the consultations stage, i.e. through mediation rather than arbitration. In fact, timely access to scientific advice during in trade discussions and negotiations can go along way towards avoiding the onset of trade disputes.

Access to scientific and technical expertise is necessary for developing country exporters to be able to understand the reason a particular environmental or SPS measure is being put in place, and what is the best way for them to comply with the measure. The inability to evaluate trade measures based on risk assessment and make a judgement on how scientific a particular assessment is, will make developing country exporters increasingly vulnerable as they try to diversify into sectors with higher technological sophistication and value-added, where the proliferation of standards and technical regulations may effectively create non-tariff barriers.

The impact of new standards is often felt in precisely the areas into which many developing countries are moving. In the SPS area, they have become particular disincentives by hitting developing countries where they are most vulnerable – the need

to diversify production. With only limited scanning capabilities and resources, most developing countries do not perceive changing standards in time, cannot evaluate their likely impact or plan a strategy to deal with them. Over time, as producers who have taken the risk of investing in diversification for export face the sudden impact of new standards and an absence of support mechanisms to assist in meeting them, the downward spiral is reinforced.

The unexpected closure of major external markets, adds to the vulnerability of developing countries and creates a disincentive to diversification. The emphasis here is on the difficulties that developing countries have in monitoring approaching changes in standards, evaluating their likely impact and knowing where to go for help in building the capacity to respond in a timely and appropriate fashion.

Concerns relating to technical assistance²⁷ have certainly been front and centre stage on the agenda of TBT and SPS Committees for some time now, driven in part by the triennial reviews of the TBT²⁸ as well as by larger discussions on 'implementation issues' in the WTO. Proposals have been made in the context of these discussions to introduce binding commitments with respect to technical assistance. Some useful work has been done by the WTO with the various international standardising bodies. However, for such assistance to pay off, it is also necessary to improve coordination at the national level.

Pre-standard harmonisation, i.e. coordination between regulatory systems, common data collection processes, testing protocols, scientific methodologies, and risk assessment procedures might go a long way toward alleviating the problem. It makes sense for both regulators and regulated entities, offers one of the most promising avenues for responding to market access pressures associated with changes in standards.

There is a bigger point. Concealed in the narrower debates about the environment and human health are wider concerns about market dislocations, product displacement and concomitant socio-economic changes. While technical assistance in the form of advice and training – as well as credits, donations and grants for the purpose of seeking advice and training – is important for easing the developing countries' adjustments to and compliance with measures necessary to achieve the appropriate level of quality and SPS protection in their export markets, it does not address these bigger problems. Generally, product displacement and similar adjustments are considered to be part of the evolution of markets. However, the pace and scale at which they occur may threaten the export prospects for developing WTO Members (UNCTAD, 2002).

These problems underline the need for such technical assistance as will permit the developing country Members to maintain and expand its market access opportunities for the product involved. However, this type of assistance, also agreed to by WTO Members as per Article 9:2 of the SPS Agreement, is rare²⁹.

Science diplomacy may help refocus technical assistance on the dynamics of innovation and international trade and exploit the potential for scientific and technological cooperation in trade relations. It may also help trade diplomats address of broad range of questions such as:

- What are the contours of new and emerging technology applications?
- Are there any environmental or health risks – actual or potential – associated with the use of particular technologies, old or new?
- How can these risk be managed in the context of trade policy and multilateral trade negotiations?

- What are the main trends in international standards setting activity?
- What are the possible shifts in competitive advantage and potential market gains and losses?
- Which countries – or companies – may become new – or major – players?
- Is there risk of major frictions between the old and new players? In which sectors?
- How big are the risks of product displacement? Is there a danger of worsening terms of trade in particular sectors, i.e. commodities?
- How prospective standards, environmental, health, etc., may affect trade flows and market access?
- What is the scope for the harmonisation of regulatory regimes?

The list goes on. The ultimate objective is to help countries avert the risks of market exclusion and capture the ‘public goods’ nature of international trade.

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Notes

- 1 *Technical equivalence* essentially means that Members accept that technical regulations different from their own fulfil the same policy objectives even if through different means. This approach, based on the European Community's 1985 'new approach' to standardisation, is contained in Article 2.7 of the WTO Agreement on Technical Barriers to Trade.
- 2 Article 6 of the TBT code exhorts signatories to move toward harmonisation of conformity assessment through mutual recognition of one another's procedure. Article 4 is the corresponding statute in the SPS Agreement.
- 3 The observation was made by Thomas Cottier at the international workshop entitled: Negotiating Agenda for Market Access: Cases of SPS and TBT, Geneva, April 24–25, 2001.
- 4 Under the TBT, Members are allowed to deviate from international standards because of fundamental climatic or geographical factors, or fundamental technological problems. Moreover, the developing Members are not expected to use international standards that are not appropriate to their developmental, financial or commercial needs.
- 5 Governments can add to the WTO *acquis* other international organisations or agreements whose membership is open to all WTO members.
- 6 E.g. the amount of pesticide residue or the presence of unwanted insects in imported foods.
- 7 Before the entry into force of the SPS Agreement, health regulations only had to be justified once a prior violation of one of the GATT principles had been found. Article XX(b) of GATT (human, animal or plant life or health) is, indeed, activated only once a violation of, say, the non-discrimination. Provisions (in Articles I or III of GATT) has been established. Under the SPS Agreement, all disciplines apply even if no prior discrimination has been found.

- 8 This observation derives from the presentation by Doaa Abdel Motaal made at the Expert Meeting on Environmental Requirements and Trade, UNCTAD, Geneva, October 2002.
- 9 Indeed, there are several instances where the importance of non-product related *PPMs* has already been recognised by the international community. For example, the signatories to the Montreal Protocol on Ozone Depleting Substances (ODS) have agreed to impose trade restrictions on goods made with (but not containing) ODS; and the importance of how a good is made is recognised in GATT Article XX (e) regarding the products of prison labour.
- 10 While this controversy may be resolved only after a panel or Appellate Body decides in future. However, GM products can, in principle, be considered to have different product characteristic from non-GM products as the new gene changes the character of the product, resulting in their being considered as product-related *PPMs* and hence covered under the disciplines of the TBT.
- 11 Article 2 of the SPS Agreement.
- 12 The difference between a sanitary measure and a measure that falls under the TBT Agreement is not always clear. The difficulty of determining how to categorise a measure has, in a few instances, led governments to notify their measure under the wrong WTO Agreement or under both agreements.
- 13 When the SPS Agreement was negotiated, consumer concerns were very much on the table, particularly on the part of the EU. However, when the Agreement had been concluded, these concerns were kept out, and the current approach to risk assessment is biased towards producers' interests.
- 14 For instance, in *Beef Hormones*, delays in and disagreements regarding implementation have created a 'second tier' of conflicts over the use of arbitration and the imposition of sanctions.
- 15 It is important to bear in mind what the SPS Agreement does not do or is not designed to do. The SPS Agreement does not formally use the full language of risk analysis currently employed in international regulatory circles. That language breaks the risk analysis process into three steps: risk assessment, risk management, and risk communication. The SPS Agreement does not use the term risk management, but instead refers to a country's choice of an appropriate level of protection.
- 16 For the moment, there is no certainty on what rules might eventually apply to GMOs, or on whether they are covered by the SPS Agreement. The notification of the proposed labelling requirements by the EU, first in the TBT, and then, at the insistence of some members, in the SPS, is indicative of this uncertainty.
- 17 With the new bylaw on GM food and feed and their traceability, enacted in July 2003, the EU announced an end to the moratorium. However, the request for consultations at the WTO has not been withdrawn and a trade dispute remains very likely.
- 18 A hazard (scientific parlance, also used in Codex) is a factor or condition with the potential to cause harm. After a hazard has been identified and characterised, the regulators determine the risk from that hazard. The risk (WTO parlance) is a probability of an adverse effect and the severity of that effect.
- 19 Other probable bases for precaution exist in paragraph six of its Preamble (appropriate level of protection) Articles 2:1 and 3:3 and Annex C (Control, Inspection and Approval Procedures). Finally, an emergency situation may trigger the exercise of precaution.
- 20 The protocol employs risk assessment as a primary decision making framework, but grants parties a right to invoke the precautionary principle (Articles 10.6, 11.8).
- 21 Shortly after the Cartagena Protocol, the Stockholm Convention on Persistent Organic Pollutants (POPs) incorporated the precautionary principle into both the treaty preamble and its operational provisions. Moreover, courts in several nations have started applying the principle as a legal rule.
- 22 There are at least twenty different versions of the precautionary principle, with substantial variations. The Appellate Body's note on the status of the precautionary principle in international law is of special interest: 'it is regarded by some as having crystallised into a

general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear ... We note that ... the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation’.

- 23 The concept of ‘substantial equivalence’ was first introduced in 1993 by the OECD ‘Safety Evaluation of Foods Derived by Modern Biotechnology’, and was subsequently endorsed in 1996 by the FAO and WHO.
- 24 E.g. long-term animal testing, human testing, screening for unexpected allergens, toxicity screens.
- 25 The ACWL has been recently set up to provide subsidised legal assistance in WTO dispute settlement proceedings, as well as free legal advice and training, to developing countries, economies in transition and least-developed countries. See www.acwl.ch.
- 26 As of 3 February 2003, Denmark, Norway, the Netherlands and United Kingdom have contributed over CHF 700,000 to the Technical Expertise Trust Fund.
- 27 SPS Article 9 (Technical Assistance), TBT Articles 12 (Special and Differential Treatment of Developing Country Members) and 11 (Technical Assistance to Other Members).
- 28 The SPS Committee is on the verge of adopting a similar practice of triennial reviews.
- 29 According to Article 9:2 of the SPS Agreement, ‘Where substantial investments are required in order for an exporting developing country Member to fulfil the sanitary or phytosanitary requirements of an importing Member, the latter shall consider providing such technical assistance as will permit the developing country Member to maintain and expand its market access opportunities for the product involved’.