

Draft Working Paper No. 3

Implementing National Public Health Policies in the Framework of WTO Agreements

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April 2000¹

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¹ Paper prepared at the request of WHO. The author is thankful for the comments made on an earlier draft by N. Drager, R. Beaglehole, R. Kaukab, S. Zarrilli, D. Fidler and B.L. Das.

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Introduction

The primary purpose of the trade system developed under the GATT (1947) was to promote trade in goods through the reduction or elimination of protectionist policies. The Uruguay Round (UR) substantially broadened the trade system's scope by extending its rules into trade in services and intellectual property rights². As a result, the reach of the trade system has expanded under the WTO to cover a growing number of "beyond the border" policies that may affect trade (Tussie, 1994; Croome, 1995, Berger and Dore, 1996, p. 16).

At the same time, the number and scope of national regulations to protect public health significantly increased since the adoption of the GATT, as illustrated by the standards adopted for the commercialization of food, pharmaceuticals, agrochemicals and for the use of genetic engineering techniques. In general, greater societies' prosperity has been associated with increased demands for domestic policies on health and other public goods.

Public health does not only depend on medical care, but on many other factors of economic, cultural and political nature (Beaglehole and Bonita, 1999, p. 45; Mustard, 1999)³. It may be affected by the WTO agreements (i.e. the set of trade agreements adopted as a result of the Uruguay Round in 1994) in a variety of forms. The effects of such agreements on public health are likely to be both *indirect*, through the impact of WTO disciplines on trade and economic development and, particularly, on income generation and distribution, and *direct*, as a result of the application of particular

² The Uruguay Round also included negotiations on trade-related investment measures (TRIMs).

³ "Public health" is understood here to encompass not only medical care, but the satisfaction of basic requirements such as adequate food, safe water, shelter, clothing, warmth and safety.

provisions in various agreements that may limit the public health policy options at the national level.

Health standards improve in a country as income and education increase. The relationship between economic development and health, however, is complex (Cooper Weil, 1990; Carrin and Politi, 1996) and the indirect effects of the implementation of the WTO agreements on health are difficult to determine. If the optimistic estimates (Martin and Winters Editors, 1995; Perroni, 1998) made on occasion of the UR about the income increase that developing countries could obtain as a result of such Round were confirmed, such agreements may lead to a general, albeit uneven, improvement of the health situation in developing countries. Widespread environmental damage, declining salaries and growing inequalities seem, however, to characterize the impact of the current process of trade liberalization and globalization in many countries (UNRISD, 1995; UNDP, 1999, p. 36).

In a context of growing pressures for trade liberalization (Berger and Dore, 1996), clarifying the extent to which a State can impose restrictions on trade in response to public health considerations has become a critical issue. Though problems raised may substantially differ according to the levels of development of the countries concerned, understanding the direct effects of trade disciplines on public health policies is of particular importance in societies that have significantly improved their health standards and have become more sensitive and responsive to health issues, as well as in developing countries with high degree of poverty and unresolved health problems.

Thus, the Fifty-Second World Health Assembly expressed its concern about the fact that "one-third of the world's population has no guaranteed access to essential drugs", and noted that "there are trade issues which require a public health perspective". The Assembly urged the Member States "to ensure that public health interests are paramount in pharmaceutical and health policies" and "to explore and review their options under relevant international agreements, including trade agreements, to safeguard access to essential drugs"⁴.

⁴ WHA52.19, 24.5.99.

Some recent controversies, such as those involving trade in hormone treated beef and food produced with genetically modified organisms⁵, as well as the admissibility of measures to improve the access to antiretroviral drugs (Bond, 1999), illustrate the importance and complex nature of the issues that need to be considered from a public health perspective in the framework of multilateral trade disciplines.

This paper explores how the application of the WTO agreements may affect the sovereign rights of States to protect and promote public health, when the exercise of such rights requires the adoption of policies that may be inconsistent with trade liberalization obligations under those agreements. The paper examines, in particular, the room for maneuver left to WTO Members to adopt public health measures, and some possible strategies to safeguard public health interests within the WTO system.

Without ignoring the importance of better understanding the indirect effects of the WTO agreements on public health⁶, the purpose of this paper is to examine the provisions of the WTO agreements as they may directly affect the public health policy options at the national level. It considers, first, how issues relating to public interests have been dealt with under the GATT, particularly its Article XX. Second, the provisions and, where available, the GATT/WTO jurisprudence related to health and other public concerns in the WTO agreements are considered⁷. Third, an analysis is made on possible approaches and steps necessary to increase the sensitivity of the WTO system to health issues.

Trade obligations and public health under the GATT

The GATT, as adopted in 1947, does not contain provisions that directly restrict the WTO Members' freedom to adopt domestic policies and measures on environmental, health and safety issues. However, if they adopt such measures, Members need to observe, *inter alia*, Article III as it obliges Members to treat "like products" alike within the borders of the importing country. The Note to article III clarifies that "any of the measures listed in paragraph

⁵ See sub-section "Public health in the WTO Agreements" below.

⁶ For an annotated bibliography on trade liberalization and health, see Houriet, 1998.

⁷ Based on a review of the decisions published in the GATT-BISD (*Basic Instruments and Selected Documents*).

1 which applies to both an imported product and to the like domestic product is to be regarded as an international measure even if it is collected or enforced in the case of imports at the time or point of importation". This implies that an internal non-discriminatory regulation which prohibited the sale, for instance, of a product which may adversely affect health, would be consistent with GATT obligations notwithstanding that the regulation had the effect of an absolute ban on imports (Trebilcock and Howse, 1999, p. 139).

In other words, measures based on public health considerations that restrict trade do not necessarily contradict WTO general obligations. As exemplified by Jackson,

"Take, for example, a government regulation imposing a minimum standard of purity for certain drugs. If this regulation applies not less favorably to imported goods than to domestic goods, then no need exists to invoke Article XX: the national treatment standard is fulfilled (unless there is implicit or de facto discrimination...). On the other hand, it may be the case that, in order to achieve its objective of protecting consumers against impure drugs, a nation would find it necessary to impose some special regulations to take care of imports. Perhaps the manufacture of imported goods cannot be readily inspected because of the cost of sending inspectors to a foreign country. In such case it might be reasonable for the importing country to require that the drug imports be subjected to testing at or after importation. Article XX contemplates this possibility and allows it to occur without breaching GATT" (Jackson, 1999, p. 233).

Members may, hence, adopt measures grounded on health and other public interests, which violate their general obligations under the GATT. Article XX specifically provides for an exception to GATT rules, including national treatment, when necessary to protect health and other public goods. According to said Article,

"Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing

in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:

...

(b)necessary to protect human, animal or plant life or health;"

Article XX of the GATT thus recognizes "the importance of a sovereign nation being able to promote health interests, even if contrary to its general obligations under the WTO agreements" (Jackson, 1999, p. 233). The way in which this article was interpreted has defined the extent to which Member countries have been able to apply public health policies which could lead to trade-restrictions otherwise prohibited under the GATT rules. The following section examines relevant GATT/WTO jurisprudence on the matter. It should be noted, however, that with the adoption of the Agreement on Technical Barriers and, in particular, of the Agreement on the Application of Sanitary and Phytosanitary Measures⁸, most trade-restricting public health measures may be controlled under such agreements.

Jurisprudence on Article XX(b) of the GATT

The GATT/WTO system has attempted to ensure, as far as possible, a predictable application of its rules by limiting the scope for discretionary interpretation, and the effectiveness of the dispute settlement mechanism (Schott, 1994, p. 125; Hoekman and Kostecki, 1997, p. 44-50).

Not surprisingly, however, the understanding by different Member States of their obligations under the WTO agreements often diverge (Jackson, 1998, p. 64-72). Building upon the experience with the GATT system of dispute settlement, the WHO Dispute Settlement Understanding (DSU), as adopted as an outcome of the Uruguay Round, has established detailed procedures to settle conflicts arising from such divergences.

The application of the dispute settlement mechanism depends on actions by WTO Members. A dispute settlement procedure is initiated with a request for consultation by a Member, or group thereof, claiming that benefits under any of the covered WTO agreements are being nullified or impaired by the failure of another Member, or group thereof, to carry out obligations under any of the agreements. If

⁸ See a brief presentation of these agreements below.

consultations fail, the issue is submitted to a group of experts (panel) that assess the claims and issues a report. An Appellate Body (AB) may review, at the request of any of the parties to the dispute, the panels' reasoning and conclusions⁹. The final decision rests with the Dispute Settlement Body (DSB), composed of all the Member States. An AB report is adopted by the DSB unless the DSB decides by consensus not to approve it.

There is no "international" sanctionary mechanism in the WTO system but, if authorized by the DSB, the Member State that has successfully proven its case can apply retaliatory measures against the Member found as non-compliant. The decisions under the DSU only benefit or affect the Members to the dispute, and create precedents that can be reversed in subsequent decisions on the same matters (Jackson, 1998, p. 83)¹⁰.

Panels and the Appellate Body are expressly prohibited from adding rights and obligations when adjudicating on disputes (article 3.2 of the DSU). However, "the line between interpretation and providing clearer parameters of the rights and obligations of Members under these agreements is often very fine" (Marceau and Pedersen, 1999, p. 33).

Article XX of the GATT has had a very limited application in connection with health issues. However, the interpretation given to said Article in a number of disputes related to health and to the environment¹¹, provides guidance on the extent to which public health interests may be actually protected where national measures lead to otherwise GATT-infringing restrictions.

⁹ The AB may only uphold, modify or reverse the *legal* findings and conclusions of panels and cannot enter into the determination of facts. The AB, however, has proceeded to *complete* the legal analysis of panels. On 13 of 15 occasions the AB found fault with the legal reasoning of panels (Vermulst, Mavroidis and Waer, 1999, p. 6).

¹⁰ The findings and recommendations of the panels and AB do not create precedents. Each panel process and each appeal is independent of any other such process. However, in actual practice the panels and AB go over the previous decisions and do get guided by them.

¹¹ Until the termination of the GATT 1947 at the end of 1995, seven panel reports on trade measures for environmental policy objectives had been submitted to the GATT Council. The first panel report under the WTO dispute settlement system, submitted in January 1996 to the WTO Dispute Settlement Body and subsequently appealed by the USA in February 1996, also focused on the GATT consistency of trade-related environmental measures (Petersman, 1998, p. 94).

In the *Thai Cigarette case*¹² (1990), the panel examined the application of Article XX(b) to an import ban of cigarettes imposed by the government of Thailand, grounded on public health considerations. Despite the evidence supplied, and the technical support given by WHO, the panel concluded that alternatives less trade restrictive¹³ than banning imported cigarettes would be available to achieve the intended public health objectives.

The panel dismissed the justification of the Thai government on the basis of Article XX(b) as a measure "necessary to protect human...life or health", notwithstanding the fact "that this provision clearly allowed contracting parties to give priority to human health over trade liberalization", because "the import restrictions imposed by Thailand could be considered to be 'necessary' in terms of Article XX(b) only if there were no alternative measure consistent with the General Agreement, or less inconsistent with it, which Thailand could reasonably be expected to employ to achieve its health policy objectives".

The Panel held that

"there were various measures consistent with the General Agreement which were reasonably available to Thailand to control the quality and quantity of cigarettes smoked and which, taken together, could achieve the health policy goals that the Thai government pursues by restricting the importation of cigarettes inconsistently with Article XI:1. The Panel found therefore that Thailand's practice of permitting the sale of domestic cigarettes while not permitting the importation of foreign cigarettes was an

¹² See BISD 37th. Supp. 200.

¹³ The panel applied the interpretation of "necessary" as developed in *United States-Section 337 case* (Doc. L/6439, para. 5.26, *BISD*, 36th. Supplement, 393) in relation to Article XX(d) of GATT, without elaborating whether such interpretation was suitable to address health-related cases. The Panel considered that there was no reason "why under Article XX the meaning of the term "necessary" under paragraph (d) should not be the same as in paragraph (b). In both paragraphs the same term was used and the same objective intended: to allow contracting parties to impose trade restrictive measures inconsistent with the General Agreement to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable. The fact that paragraph (d) applies to inconsistencies resulting from the enforcement of GATT consistent laws and regulations while paragraph (b) applies to those resulting from health-related policies therefore did not justify, in the panel's view, a different interpretation of the term "necessary".

inconsistency with the General Agreement not
"necessary" within the meaning of Article XX(b)".

The panel thus disregarded the various constraints, including institutional and fiscal, that the Thai government would have to face for the implementation of the less restrictive alternatives (Trebilcock and Howse, 1999, 165). In other words, the panel did not examine whether the less trade restrictive measures also were *reasonably available* to Thailand, as a developing country and given the particular problems faced by the government.

Equally illustrative of the approach taken on the room for maneuver left by Article XX, is the decision taken in the *Reformulated Gasoline Case*¹⁴, the first case to be considered by the AB under the new WTO rules, in which the application of the exception under Article XX(g)¹⁵ of GATT was considered.

The panel accepted that a policy to reduce air pollution was consistent with measures for the protection of human, animal or plants life or health. It did not accept, however, that the measures in question were "necessary", because there were measures -for instance a single statutory baseline covering both domestic and foreign refiners or a more detailed examination of the production of foreign refiners- which were consistent or less inconsistent with GATT, which were available to the US and which would have achieved the same objective.

In reviewing this decision, the AB stated that the GATT "should not be read in clinical isolation from public international law", and that "Article XX contains provisions designed to permit important State interests -including the protection of human health as well as the conservation of

¹⁴ The United States established gasoline programmes under the auspices of the Clean Air Act, which provided that in specific high pollution area as measured by ozone concentration, only "clean" reformulated gasoline could be sold, which meant that it had to be blended with ethanol. An interim standard was allowed over a five-year period, which was calculated using a formula that began with a 1990 baseline and would reduce the amount of olefines yearly on a percentage basis. Foreign producers, however, were not permitted to use their 1990 baseline, but a statutory baseline, which often imposed a stricter burden on them. Venezuela and Brazil filed a complaint claiming that the regulation violated Article III of the GATT (Trebilcock and Howse, 1999, p.154). See WT/DS 52 and WT/DS4.

¹⁵ Article XX (g) may justify measures "relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption".

exhaustible natural resources- to find expression". It added that the balance between affirmative commitments under Articles I, III and XI and the policies and interests embodied in the exceptions listed in Article XX "needed to be interpreted and judged on a case by case basis" (Cameron, 1998, p. 20).

The AB determined that any Article XX analysis is two-tiered. First, it must be analyzed whether the measures are provisionally justified under the concrete exception invoked; only if the answer to this question is positive, then the same measures must be further appraised under the introductory clauses or the chapeau of Article XX¹⁶. The AB accordingly stated that:

"The purpose and object of the introductory clauses of Article XX is generally the prevention of abuse of the exceptions of (what was later to become) Article (XX). This insight drawn from the drafting history of Article XX is a valuable one. The chapeau is animated by the principle that while the exceptions of Article XX may be invoked as a matter of legal right, they should not be so applied as to frustrate or defeat the legal obligations of the holder of the right under the substantive rules of the General Agreement".

The AB added that the burden of demonstrating that a measure within one of the concrete Article XX exceptions does not, in its application, constitute abuse under the chapeau, rests on the party invoking the exception (Vermuslt, Mavroidis and Waer, 1999, p.22).

The AB considered that the way in which USA standards were set affected exports of gasoline from Venezuela and Brazil to the US in a discriminatory manner, thus violating the right of National Treatment under Article III. The AB therefore recommended that the DSB request the United States to bring its gasoline regulations in conformity with its obligations under the GATT. However, the AB clarified that

"this does not mean, or imply, that the ability of any WTO Member to take measures to control air pollution or, more generally, to protect the environment, is at issue. That would be to ignore the fact that Article XX

¹⁶ The chapeau language had received little consideration in earlier GATT cases falling under Article XX. The new vigor conferred to such language may make it more difficult for a Member to justify a trade restrictive measure than under previous jurisprudence.

of the General Agreement contains provisions designed to permit important State interests -including the protection of human health, as well as the conservation of exhaustive natural resources- to find expression. The provisions of Article XX were not changed as a result of the Uruguay Round of Multilateral Trade Negotiations. Indeed, in the preamble to the WTO Agreement and in the Decision on Trade and Environment, there is specific acknowledge to be found about the importance of co-ordinating policies on trade and the environment. WTO Members have a large measure of autonomy to determine their own policies on the environment (including its relationship with trade), their environmental objectives and the environmental legislation they enact and implement. So far as concerns the WTO, that autonomy is circumscribed only by the need to respect the requirement of the General Agreement and the other covered agreements".

As noted by Jackson, the report on the *Reformulated Gasoline Case* has considerable importance, since in its approach to Article XX(g), the AB seems "to be enlarging the potential choices of a nation regarding the methods it wishes to pursue for environmental protection reasons" (Jackson, 1999, p. 234)¹⁷.

However, the exception under Article XX(g) (relating to the conservation of natural exhaustible resources) was interpreted in this case more broadly than the exception under Article XX (b) (relating to public health). The AB emphasized the differences in the terms used in such paragraphs, "relating to" in paragraph XX (g), and "necessary" under paragraph XX (b) (Petersman, 1998, p. 110), and in practice set for Article XX (g) a standard easier to meet than under Article XX (b) (Ranné, 1999, p.79). This, however, did not help the United States to prove its case, given the clearly discriminatory nature of the disputed measure.

It may be argued, hence, that Member countries can devise the policies that better fit the interests of their populations, even if they contradict their general obligations under the WTO rules. Nevertheless, should those policies be challenged by another WTO Member, their

¹⁷ On the scope of application of Article XX (g) see also the panel decision in *Tuna-Dolphin case* (1994), which rejected the application of said Article to measures aiming to force other countries to change their policies on the methods of harvesting tuna (DS29/R of June 16, 1994).

necessity should have to be demonstrated¹⁸. As a result, despite the recognition of the States' autonomy in matters of public interest, public health-related measures that may impair trade obligations have been treated under a narrowly interpreted exception¹⁹.

As mentioned, "necessary" has been interpreted in the GATT/WTO system as "least GATT-inconsistent". Therefore, in order to determine whether a measure is "necessary" and whether other least trade-restrictive measures could have been adopted, panels and the AB have been required, in fact, to put themselves in the position of policy-makers. They had to second-guess domestic regulators without necessarily possessing the expertise and an adequate knowledge of the particular circumstances in which a measure has been adopted. In addition, the application of the "necessity" test has not involved a consideration of whether the alternative less-restrictive measures were reasonably available²⁰.

In sum, the exception under Article XX (b) of the GATT, as interpreted, has in practice left States with little room to design and implement public health measures. The main objective of the GATT/WTO jurisprudence has been to avoid possible abuses of the exceptions provided for in that Article, in the form of an "unjustifiable discrimination" or a "disguised restriction" on international trade. Consequently, though there is room for national autonomy in determining what the adequate public health measures are, the application of the "necessary" test limits the options available to the States. This may set a very high hurdle for public health policies, because measures that intrude less on trade are almost always conceivable and therefore in some sense "available"²¹.

Public health in the WTO agreements

Public health issues are dealt with in several WTO agreements. This is particularly the case of the Agreement

¹⁸ In principle, as examined below, the burden of proof would rest with the Member that invokes the exception (Trebilcock and Howse, 1999, p. 140)

¹⁹ See also the decision in *US-Import of Certain Shrimp and Shrimp Products* (WT/DS58), where the panel stated "that Article XX provides for an exception to obligations under the General Agreement. The long-standing practice of panels has accordingly been to interpret this provision narrowly, in a manner that preserves the basic objectives and principles of the General Agreement".

²⁰ *This kind of "feasibility test" may have led perhaps to a different result in the Thai Cigarette case, though not in the Gasoline case where the adoption of non-discriminatory baseline for clean air requirements was possibly feasible for the United States.*

²¹ See Esty, 1994, p. 48, who reaches this conclusion for environmental issues.

on Technical Barriers to Trade (TBT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the General Agreement on Trade in Services (GATS) and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The Agreement on Agriculture also deals with issues that may be relevant for public health²², but they are not addressed here²³.

It should be noted that according to a general interpretative note to Annex 1A of the WTO Agreement,

"in the event of a conflict between a provision of the General Agreement on Tariffs and Trade 1994 and a provision of another agreement in Annex 1A to the ...WTO Agreement, the provision of the other agreement shall prevail to the extent of the conflict".

This means that to the extent that an issue is specifically dealt with by any of the agreements included in said Annex (such as the TBT and SPS Agreements), their rules would prevail over the general provisions of the GATT. In particular, the SPS Agreement will supersede Article XX(b) for a large number of public health measures²⁴.

The case of the TRIPS Agreement is different, since it is contained in Annex C of the GATT. While the relationship between this Agreement and the GATT still needs to be worked out, a panel has held that the TRIPS Agreement has a "relatively self-contained, *sui generis* status within the WTO", though it is "an integral part of the WTO system, which itself builds upon the experience of over nearly half a century under the GATT 1947"²⁵.

Agreement on Sanitary and Phytosanitary Measures

²² In the Preamble and Article 20 of the Agreement on Agriculture, non-trade concerns in the agricultural sector are mentioned.

²³ The Agreement on Government Procurement may also be relevant in relation to the acquisition by government entities of health-related goods. This Agreement -which essentially prohibits preferences for domestic suppliers- is "plurilateral", that is, it only applies to its signatories. So far a small number of countries has adhered to this agreement.

²⁴ "Because SPS has more stringent disciplines than GATT, the health exception in GATT Article XX (b) is not available to a government as a defence in a SPS lawsuit"(Charnovitz, 1999, p. 174).

²⁵ See the Panel Report on USA- India - Patent Protection for Agricultural and Chemical Products, WT/DS50/R, adopted on 16 January 1998, para. 7.19.

The purpose of the SPS Agreement²⁶ is to minimize the restrictive effects on trade of SPS measures, by encouraging the harmonization of SPS measures on as a wide basis as possible, based on international standards, guidelines and recommendations where they exist (Article 3.1). A basic target of the Agreement is that such measures be, as far as possible, scientifically justified.

The SPS Agreement applies to measures -as defined in Annex A of the Agreement- to protect against exposures to pests (e.g. insects), to microorganisms, and to additives, contaminants and toxins in food for humans and feedstuffs for animals. It may not apply, however, to protection against the importation of genetically modified organisms, though the coverage of the SPS Agreement in this regard still is open to determination by future WTO decisions under the DSU (Charnovitz, 1999, p. 175). In addition, the SPS Agreement does not cover measures relating to the quality and other conditions for the approval and commercialization of pharmaceutical products.

The SPS explicitly recognizes the right of any Member to take SPS to protect human and animal life or health based on "scientific principles" (Article 2.2). It is presumed that SPS that conform to international standards are "necessary" to protect such goods, but Member may introduce SPS which result in higher levels of protection than would be achieved by the application of international standards, if there is scientific justification or it is determined to be appropriate based on risk assessment techniques (Articles 3 and 5). In the assessment of risks, the "relevant processes and production methods" shall be taken into account as part of the scientific evidence (article 5.2). In undertaking risk assessment, a minority scientific evidence may be taken into account.

Members have the right to take the SPS they deem appropriate to protect human, animal or plant life or health, but must ensure that they are "not more trade restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility" (Article 5.6).

²⁶ The negotiation of this Agreement has been considered a reaction of the trading system to certain cases of import restrictions under GATT, such as those applied by Japan on apples and by the European Community on beef treated with hormonal substances (Hoekman and Kostecki, 1997, p. 118). For an analysis of this Agreement and of the main issues for developing countries, see Zarrilli, 1999.

The SPS sets forth, in fact, two types of disciplines: a) science-based disciplines (e.g. Articles 2.2, 3.3, 5.1), and b) trade-related disciplines (e.g. Articles 5.5, 5.6). A SPS measure has to be justified under both types of disciplines; thus, even a SPS measure that is based in science might not be deemed as WTO consistent under the least trade restrictive test.

In cases where relevant scientific evidence is insufficient, a Member may "provisionally" adopt SPS measures on the basis of the available information, but only for a "reasonable period of time" until additional information for a more objective assessment of risk is obtained (article 5.7). This provision has been interpreted as restricting the use of the "precautionary principle", since potentially dangerous substances should be proven safe before they are put on the market (Wallach and Sforza, 1999, p. 54)²⁷.

In addition, the precautionary approach under the SPS Agreement can be applied when there is a probability (not simply a possibility of risk)²⁸ for a "reasonable period", while scientific analysis in some cases can require five, ten or even more years of monitoring and experimentation to yield statistically significant results, in particular in the case of products that are not inert, like biological materials that can reproduce, disperse and mutate (Parris, 1999, p. 149).

It is interesting to note that the Protocol on Biosafety developed in the framework of the Convention on Biological Diversity (Montreal, January 2.000) incorporated a precautionary approach broader than under the SPS Agreement. Article 11.8 of the Protocol states that

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or

²⁷ Said principle, as generally understood in environmental law, imposes the burden of proof on the party seeking to change the status quo. There should be proof of no harm prior to action, rather than proof of harm prior to halting action (Cameron, 1999, p. 245).

²⁸ See WTO Panel and AB Reports in *Australia-Measures affecting importation of salmon* (June 12, 1998 and November 6, 1998, respectively).

feed, or for processing in order to avoid or minimize such potential adverse effects".

According to the SPS Agreement, in the preparation and application of sanitary or phytosanitary measures, account will be taken of the special needs of developing countries, in particular, the least-developed ones. Where the appropriate level of sanitary or phytosanitary protection allows for the phased introduction of new measures, such Members would have a longer period in which to apply them to their products, so as to maintain their export opportunities (Article 10)²⁹.

In the case of food safety, the Agreement expressly stipulates that the reference standards will be those established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice (Kinnon, 1995, p. 26)³⁰.

The Codex Alimentarius standards long served as a reference for GATT with respect to technical barriers to trade and played an important role in procedures to settle food-related trade disputes. The Codex Commission, among other tasks, recommends to governments guidelines on good manufacturing practices, and has also prepared a code of ethics for international trade in food, covering such aspects as food hygiene, labeling, infant food, and nutritional value (Kinnon, 1995, p. 23).

The application of the SPS raises issues of interpretation similar to those discussed in relation to article XX of the GATT, as to the degree of autonomy that a Member enjoys to establish its own levels of protection on health grounds. Unlike the case of said Article XX, however, an SPS measure may be considered in violation of a Member's obligations even if it equally applies to domestic and imported products, to the extent that such measure is not grounded on scientific evidence (Wagner and Goldman, 1999, p. 14). Therefore, the room of maneuver for national

²⁹ Several developing countries made proposals for the WTO Ministerial Conference held in Seattle in December 1999 relating, *inter alia*, to the effective implementation of article 10 and the participation of developing countries in the international development standard process. See WTO document JOB(99)/4797/Rev.3, p. 26-28.

³⁰ The International Office of Epizootics and organizations operating under the International Plant Protection Convention are also standard setting bodies for animals and plants health, respectively.

policies under the SPS Agreement is more limited than under the GATT.

Said Agreement establishes (Article 3.3) the autonomous right of a Member to set a level of protection different from that implicit in the international standard and to implement or embody that level of protection in a measure not "based on" the international standard. The application of the SPS Agreement in these cases raises complex issues, since the determination of what constitutes a risk to health, food security or other central public interests are an essential element of a country's sovereignty. However, in all the cases so far decided³¹ under the DSU in which the SPS was invoked, no country's SPS measures were upheld as consistent with the WTO rules.

Though Members must apply international risk assessment methodologies and find a scientific justification, what constitutes an allowable risk will ultimately reflect the social values of a particular society at a particular stage of development. In many cases, it is unlikely to be a unique way to analyze empirical data. As noted by two commentators,

"Is an "appropriate risk" of a toxic substance one which allows cancer to develop in one out of a thousand, a hundred thousand or one million people? Or should it be zero? Article 5.3 of the SPS Agreement adds a further complication by injecting an economic "cost-benefit" test into the risk assessment process by taking into account relevant economic factors such as "the potential damage in terms of loss of production or sales... and the relative cost-effectiveness of alternative approaches to limiting risk". This seems to venture into an uncomfortable area of weighting the value of human health or the environment against more readily measurable economic concerns" (Trebilcock and Howse, 1999, p. 146).

The tensions between trade and sanitary/phytosanitary interests were addressed under the DSU in the *Beef Hormone Case*(WT/DS26), the first decision by a WTO panel on the SPS Agreement, in August 1997³².

³¹ As of November 11, 1999.

³² For an analysis of this case see, e.g. Wallach and Sforza, 1999; Cameron, 1999; Trebilcock and Howse, 1999; Pardo Quintillan, 1999.

The EU had banned the sale of hormone-fed beef based on the alleged risk for human health deriving from consumption of such product³³, and the United States requested a decision under the DSU. The panel upheld the US complaint in September 1997. It found that there were international standards for five of the six growth hormones in dispute, and for the sixth-one, for which an international standard did not exist, the panel held that the EU ban was not based on a scientific risk-assessment, that the EU had not conducted. The burden of proving that more stringent standards than those internationally established were necessary rested on the EU, which failed in the panel's view to produce such evidence. The Panel concluded that the EU measure violated the SPS Agreement.

The Appellate Body (AB) made extensive use of general principles of international law to determine the scope of the EU's discretion to apply its own health and environment standards even though they were higher than international standards. The AB overruled³⁴ the panel interpretation and distinguished the case of measures which "conform to" international standards, i.e. the international standard is completely embodied in the SPS measure, from the case in which an SPS measure is "based on" an international standard, meaning that such measure may adopt some, not necessarily all, elements of the international standard. While in the former case there is presumption -albeit rebuttable- of consistency with the GATT, in the latter there is no benefit of consistency presumption. Hence, if another Member questions a particular measure, the burden of proving consistency will rest with the Member relying on such measure.

However, the AB held that it does not appear that there is a any

"necessary (logical) or other connection between the undertaking of Members to ensure, for example, that SPS measures are 'applied only to the extent necessary to protect human, animal or plant life or health...' and the

³³ Exposure to the hormones in question has been linked to cancer in laboratory animals. See the AB Body Report in the referred case, para. 199, and Wagner and Goldman, 1999, p. 14.

³⁴ The AB also overruled the distinction made by the Panel between "risk assessment" (a "scientific" examination of data and factual studies) and "risk management" (a "policy" exercise involving social value judgments made by political bodies) and noted that the SPS Agreement only speaks of "risk assessment" thereby not providing a textual basis for such distinction.

allocation of burden of proof in a dispute settlement proceeding... A decision of a Member not to conform to a particular measure with an international standard does not authorize imposition of a special or generalized burden of proof upon that Member, which may, more often than not, amount to a penalty".

The AB also stated that harmonization only created a balance between the legitimate rights of states to maintain regulatory diversity and the need to reduce the trade-distorting impact of such diversity. In the AB's view, the language of the Agreement allows for a greater scope for diversity in the detailed measures themselves than the notion of "conformity" would seem to imply. An important element in the AB decision also was the opinion that risk assessment can include real world considerations, such as factors relating to the effectiveness in handling protective measures. The Appellate Body stated that,

"It is essential to bear in mind that the risk that is to be evaluated in risk assessment under article 5.1 is not only risk ascertainable in a science laboratory under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die".

The AB further clarified that there must be a rational relationship between the measure and the risk assessment, to be decided case-by-case³⁵. It also held that "the risk assessment must not necessarily embody only mainstream scientific opinion, but divergent opinions from qualified and respected sources may also be taken into account, especially when the risk involved is life-threatening".

The panel and the AB also had to address the issue of defining the limits, under WTO agreements, of States' autonomy to adopt measures in sensitive areas subject to national jurisdiction. In the *Salmon case*. The AB stated that:

³⁵ In analyzing such relationship in the *Japanese Agricultural Products case* (WT/DS76/R of 27. 10.98 and WT/DS76/AB/R of 22.2.99), the panel ruled that though there was a risk of introducing codling moths (which cause severe agricultural damage), Japan had not establish a rational link between that risk and the rigorous Japanese testing requirements .

"We do not believe that Article 11 of the DSU, or any other provision of the DSU or of the SPS Agreement, entitles the Panel or the Appellate Body...to substitute its own reasoning about the implied level of protection for that notion defined consistently by Australia. The determination of the appropriate level of protection, a notion defined in paragraph 5 of Annex A, as the "level of protection deemed appropriate by the Member establishing a sanitary...measure", is a prerogative of the Member concerned and not of a Panel or of the Appellate Body".

The ongoing opposition by the EU (despite the green light given to the United States to apply trade sanctions) to admit US beef treated with hormones³⁶, raises troubling questions about the extent to which the trade system may impose on the people living in a country or group thereof, a solution that is perceived as risky to public health. In the view of the European Commission,

"Judging what is an "acceptable" level of risk for society is an eminently *political* responsibility. Decision-makers faced with an unacceptable risk, scientific uncertainty and public concerns have a duty to find answers. Therefore, all these factors have to be taken into consideration" (European Commission, 2000, para. 5).

Some developing countries proposed (as part of the preparation for the WTO Ministerial Conference held in Seattle in 1999) to address the problems posed when scientific opinion is not acceptable to the public, who is skeptical or holds the opposite view³⁷.

Within the framework of the work on the Codex Alimentarius, some countries have also raised the possibility of including standards that are not uniquely science based and human health oriented. Certain countries emphasized the legitimacy of consumer concerns and the need to obtain a consumer consensus for the legitimacy of the international standards body (Blandford and Fulponi, 1999, p. 420). These proposals pose a difficult question about the

³⁶ Another possible controversial case may relate to the EU ban on the use of bovine somatotropin (BST), which is allowed in the USA and has a stimulating effect on milk secretion. No conclusive scientific evidence on the risks for health of such use is available (Cunningham, 1999, p.17).

³⁷ See WTO document JOB(99)/4797/Rev.3, p. 31.

extent to which public health measures which affect trade may rely on public perceptions and fears, rather on the available scientific evidence.

Finally, it is still uncertain, as mentioned before, whether the release of genetically modified organisms (GMOs), such as transgenic seeds, and the commercialization of products derived therefrom would fall within the coverage of the SPS Agreement. Some proposals for starting consideration of this issue within WTO have been made³⁸, in the context of quite divergent perceptions on the risks of GMOs for health and the environment.

There is currently no scientifically accepted evidence to suggest that the transgenic crops *per se* are any more or less toxic or allergenic than conventionally bred crops (Spillane, 1999, p.24). However, serious doubts remain, particularly in Europe, about possible risks and each country has the right to draw the biosafety measures it deems appropriate (UNDP, 1999, p. 75).

Agreement on Technical Barriers to Trade

The establishment of technical standards may create significant barriers to trade³⁹, by raising unit costs of production and/or transportation (Hoekman and Kostecki, 1997, p. 114). The TBT Agreement⁴⁰ encourages the use of internationally agreed standards as a basis for their technical regulations on trade. If a Member adopts an international standard, a presumption is established that, unless proof to the contrary, it does not create an unnecessary obstacle to trade. In the case that standards not in accordance with relevant international standards were adopted, the Member doing so must give notice thereof, and may be required to prove that such standards are necessary to protect human, animal or plant health or safety, or the environment. The burden of proof in this case will lie with the Member applying the standards.

³⁸ United States, Canada and Japan made proposals to establish a Working Group to examine the approval processes for GMOs. Other countries advocate for the treatment of this subject outside the WTO or in the framework of the Committee on Trade and Environment.

³⁹ According to the US Department of Commerce, in 1993 almost two thirds of the US merchandise exports were affected by technical standards and requirements in importing countries (Trebilcock and Howse, 1999, p. 137).

⁴⁰ For a general analysis of this Agreement, see Völlker 1995, p. 281-310.

If technical regulations were established by Members in the absence of international standards, such regulations should not be more trade restrictive than necessary to protect human, animal or plant health or safety, or the environment (article 2.2). Thus, the "necessity" test is under the TBT, like under the GATT, a key standard for evaluating national public health policies.

The Preamble of the TBT Agreement recognizes that "no country should be prevented from taking measures necessary ...for the protection of human, animal or plant life or health..." .Article 2.2 to some degree amplifies the limited nature of listed exceptions to Article XX, since it allows to consider, in assessing the risks referred to in that Article "...available scientific and technical information, related processing technology or intended end-uses of products"⁴¹. In order to address "urgent problems of ...health..." Members can omit the publication and notification requirements imposed by article 2.9 for the adoption of national regulations which may have a "significant effect on trade", where such regulations are not in conformity with international standards or such standards do not exist.

Developing countries enjoy a special and differential treatment in this area (article 12 of TBT). It is recognized that such countries may face special problems, including institutional and infrastructural problems, in the preparation and application of technical standards, regulations and conformity assessment procedures. Developing countries may, inter alia, adopt technical regulations or standards aimed at preserving indigenous technology and production methods, and are not expected to use international standards which are not appropriate to their development, financial or trade needs. If faced with difficulties, they may also request time-limited exceptions from their obligations. Members will take reasonable measures to ensure that, upon request of developing country Members, international standardizing bodies prepare norms for products of special interest to developing countries Members.

If internationally agreed standards are followed by national regulations, a *prima facie* presumption that the standards are not unduly trade-restricting will arise. If

⁴¹This represents a significant departure from the notion in the *Tuna case*, where it was determined that national treatment does not apply to the methods of production, as it may allow differentiation based on how a product is made, as opposed to the final product itself.

the international standards are not followed, the Agreement provides for some disciplines and procedures that the government should adopt. In this case, whether the national standards create unnecessary obstacles to international trade may give rise to a complex burden of proof. In the case of a dispute, the complaining country may have to give evidence of *prima facie* unnecessary obstacle to trade, and the defending country may have to give evidence that the adopted standard is not more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create (article 2 of the TBT Agreement).

It should be noted that while the SPS Agreement is intended to address food safety measures, along with those targeting plant and animal health risks, the TBT Agreement stresses the need to be aware of the negative trade impacts that can arise from differences in other forms of national-level standards that do not have direct health impacts. Clearly, "certain measures lie within the purview of both agreements. If a dispute cites both, separate dispute panels can be formed, with SPS matters assigned priority. Key initial disputes before the SPS and TBT Committees are still clarifying their spheres of influence" (Hooker, 1999, p.652).

An important difference between these agreements is that the SPS Agreement requires that SPS measures be scientifically justified, while under the TBT Agreement domestic measures may be based on various legitimate objectives, such as national security and the prevention of deceptive practices, and scientific information is only one of the relevant elements to be considered⁴².

WHO has an important role in the area of standards setting⁴³ for the quality, efficacy and safety of pharmaceutical, biological and similar products, inter alia, through the International Pharmacopoeia and the WHO Certification Scheme on the Quality of Pharmaceuticals Products moving in International Commerce.

General Agreement on Trade in Services (GATS)

⁴² See Article 2.2 of the TBT Agreement.

⁴³ WHO has been accorded observer status at WTO's Committee on Technical Barriers to Trade. For an analysis of WHO responsibilities and activities in this area, see Kinnon, 1995.

The adoption of the GATS was one of the major achievements of the Uruguay Round, insofar as it submitted for the first time international trade in services to multilateral disciplines (Hoekman, 1995, p. 327).

Such trade may take place in the health area through the different modalities identified under GATS⁴⁴:

- *across a border (e.g. telemedicine and diagnostic services);
- *through consumption abroad (for instance, a patient traveling to another country for treatment);
- *through commercial presence, i.e. establishment of a foreign subsidiary or branch;
- *through the displacement of people who are service suppliers (e.g. medical doctors).

Unlike the GATT, the principles under GATS, including national treatment, apply only to the sectors that Member countries have decided to open to foreign competition. Under this "positive list" approach, the "national schedules" include the services sectors and activities to which a Member will apply market access and national treatment obligations, on the basis of "horizontal" commitments, which apply to all sectors included in the schedule, and of specific commitments, which apply to a specified sector.

Despite the interest of developing countries in promoting free movement of labor (South Centre, 1998, p. 48), the GATS only obliges Member States to allow immigration in the case of those who are service suppliers or employed by a service supplier in accordance with the terms of a specific commitment.

The GATS contains provisions to promote the participation of developing countries in the international trade in services. Developed countries should, for this purpose, liberalize market access in sectors of export interests to developing countries and improve the efficiency of such countries' domestic services through access to technology on a commercial basis (Article IV).

⁴⁴ For an analysis of GATS as applied to health services, see Kinnon, 1995; Zarrilli and Kinnon (Editors), 1998.

Only 27% of WTO Members (developed and developing in equal numbers) made commitments to open up hospital services to foreign suppliers, and 35% (also roughly even among the two groups) did so for medical and dental services. Some 19%, mostly industrialized countries, scheduled the services of health personnel other than physicians. Out of the 21 developing countries involved, most place no limitation on foreign consumption of hospital or medical service. They often make no commitment on cross-border supply of services, usually because it is not technically feasible; and occasionally place a foreign-equity ceiling on commercial presence (Kinnon, 1995)⁴⁵.

Decisions on the liberalization of the trade in health services are likely to be based on a wide range of considerations, including developmental needs, domestic health policies and the competitiveness of the relevant sectors⁴⁶.

Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The very nature of patent rights is to exclude competitors in order to generate monopolistic rents to recover R&D costs and generate a profit⁴⁷. Given the implications of patent protection on the prices of medicines⁴⁸, concerns have been voiced from a public health perspective on the negative impact of patents on the affordability of medicines, specially for the poor. It is generally acknowledged, however, that given the characteristics of innovation in the pharmaceutical industry, this sector is particularly sensitive to the level and effectiveness of IPRs protection (Scherer, 1999).

Thus, the Fifty-Second World Health Assembly "took note of the concerns of many Member States about the impact of relevant international agreements, including trade agreements, on local manufacturing capacity and on access to and prices of pharmaceuticals in developing and least developed countries", but recognized that "the Agreement on

⁴⁵ In the case of NAFTA, all the member countries made a reservation dealing with "social services established or maintained for a public purpose", including "health" (Appleton, 1999, p. 95).

⁴⁶ See Zarrilli and Kinnon (editors), 1998.

⁴⁷ See, e.g. Scherer and Ross, 1990. For a review of economic literature on intellectual property, see Siebeck (Editor), 1990.

⁴⁸ See, e.g., UNCTAD, 1996, Annex 1 and References; Velasquez and Boulet, 1999 and annotated bibliography. See also Watal, 1996; Dumoulin, 1997; Lanjouw, 1997; Keayla, 1999.

Trade Related Aspects of Intellectual Property Rights (TRIPS) provides scope for the protection of public health"⁴⁹.

The TRIPS Agreement has partially addressed public health concerns. Article 8.2 states that

"1. Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

This provision incorporates the "necessity" test mentioned above, but seems to subject it to an additional "compatibility" test (not present in Article XX of the GATT) that, if broadly interpreted, may nullify a possible exception based on public health or other grounds⁵⁰.

In addition, as examined elsewhere⁵¹ the TRIPS Agreement leaves considerable room to establish, at the national level, certain exceptions aimed at improving the affordability of medicines, such as in relation to:

- * acts done privately and on a non-commercial scale, and for teaching;
- * use of the invention for research, including experimentation on the invention to test it or improve on it for commercial purposes (Cornish, 1998; NERA, 1998; Correa, 2000);
- * preparation of medicines under individual prescriptions;
- * prior use (use of the invention by a third party before the date of application for the patent).

⁴⁹ WHA52.19, 24.5.99.

⁵⁰ However, the "consistency" requirement may refer to ordinary or everyday public health measures, which could not undermine TRIPS obligations in a permanent way, as distinct from public health emergencies, which could trigger different criteria of "inconsistency" under Article 8.1 and allow for temporal derogations of obligations under the Agreement.

⁵¹ See UNCTAD, 1996; Correa and Yusuf, 1998; Correa, 2.000.

- * imports of a legitimate product⁵² which was put on the market in a foreign country by the patent owner or with his consent (Verma, 1998; Bronckers, 1998).
- * experiments made for the purposes of seeking regulatory approval for marketing of a product after the expiration of a patent ("early working" or "Bolar" exception)⁵³;

The last exception is of particular importance to the health sector. Its purpose is to help generic drug producers to place their products on the market as soon as the respective patent expires. The U.S. Drug Price Competition and Patent Term Restoration Act (1984), for instance, has permitted to carry out testing to obtain approval of generic products before the expiration of the relevant patent. Similar provisions were established in other countries, such as Canada, Israel and Argentina. The WTO dispute settlement mechanism was put in motion in 1999 by the EU against Canada, in relation to an exception in Canadian law that authorized not only to undertake registration procedures before patent expiration but also to start production and stockpiling six months before that date⁵⁴. The panel decision confirmed that an early working exception is *consistent* with the TRIPS Agreement, even in the absence of an extended period of protection for the patent. However, the panel considered that the right to manufacture and stockpile before the expiration of the patent was not consistent with said Agreement⁵⁵.

Article 31 of the TRIPS Agreement on "Other use without the authorization of the right holder" permits to grant compulsory licenses on grounds to be determined by national laws, including in order to satisfy health needs. Such licenses have been extensively used in the United States to remedy anti-competitive practices and for governmental use; in some countries provisions for the specific case of health-related inventions have been established (Correa, 1999a).

⁵² This are generally called "parallel imports" and admissible under the principle of international exhaustion of rights (article 6 of the TRIPS Agreement).

⁵³ See NERA, 1998.

⁵⁴ In addition, unlike the US law, the Canadian legislation did not provide for an extension of the patent term in order to compensate for the time consumed for the first approval of the drug by the health authority.

⁵⁵ [See WT/DS114/R, 17 March, 2.000](#)

Despite the legitimacy of these pro-competitive measures, some Member countries that applied one or more of them have faced the threat of unilateral retaliations, or the suspension of aid, by some developed countries⁵⁶. Of particular interest was the dispute between the USA and South Africa in relation to South African legislation aimed at allowing parallel imports and compulsory licenses for medicines. Despite the legality of such measures under the TRIPS Agreement, the US government and pharmaceutical industry put enormous pressure on the South African government to eliminate such measures⁵⁷. Supported by a number of active NGOs (particularly those concerned with the dramatic rise of HIV-related infection in South Africa), the South African government resisted such pressures and eventually obtained the suspension of the judicial case brought by US companies as well as the withdrawal of South Africa -in December 1999- from the "Super 301" list.

The relationship between the TRIPs Agreement and public health has been the subject of considerable debate. The introduction of product patent protection for pharmaceuticals in developing countries, is likely -as demonstrated by several studies⁵⁸ to increase prices and worsen the problems related to access to drugs, particularly by the poor. Possible options for the design of national patent laws with provisions that may mitigate such problems have been proposed (Velazquez and Boulet, 1999; Correa, 2.000), but many issues (such as parallel imports) remain highly controversial. The panel's decision in the EU-Canada case on the early working exception -which, as mentioned, held the legality of such exception- illustrates, however, that there is some room under the Agreement to adopt measures aimed at the protection of public-health.

Developing a public health-sensitive approach to WTO agreements

The protection and promotion of health is one of the basic State's obligations. The counterpart to such an obligation is the right of citizens to health⁵⁹, the

⁵⁶ See the US Trade Representative Press Release, April 30, 1999, listing the countries that may be subject to trade sanctions under Section 301 of the US Trade Act.

⁵⁷ See Bond, 1999.

⁵⁸ See a summary of such studies in Unctad, 1996; Correa, 2.000.

⁵⁹ See the declaration of the WHO/UNICEF International Conference on Primary Health Care, Alma Ata, 1978.

achievement of which is grounded on ethical as well as economic considerations.

As evidenced by the previous analysis, tension often exists between the trade interests reflected in the WTO agreements and health and other public goods. The GATT/WTO jurisprudence indicates that the WTO system recognizes the need to protect such goods, but via exceptions which have been construed rather narrowly. The nature of the exceptions under Article XX of the GATT and under other WTO agreements, puts the State arguing public health interests on the defensive, since it must justify "deviations" from its general obligations.

A crucial issue from a public health perspective is, hence, to ensure that national policies on the matter are not subordinated to the priorities of the trading system.

The basic question that may be posed is, in other words, how to achieve a well informed, objective and balanced consideration of possibly competing trade and health interests, in a manner that prevents that trade perspectives dominate the interpretation of the WTO agreements, while ensuring that health and other public interest grounds are not used to masquerading rules that unfairly restrict trade.

It may be argued that the development of a "health-sensitive" trading system may be the outcome of the progressive application and interpretation of WTO rules through the evolution of the WTO jurisprudence, on a case-by-case basis. The resolution of possible conflicts between public health and trade interests may be left, thus, to the decisions to be taken by existing bodies and procedures under the existing rules.

However, the outcome of such process is uncertain. Other possible ways to ensure that health policy elements are better taken into account in the application of the WTO agreements are considered below.

A constitutional role for WTO?

It is generally recognized that the main aim of the GATT/WTO system is to liberalize trade by combating trade protectionism, while such system does not aim to exclude legitimate governmental policies in areas other than trade liberalization (Cottier, 1998, p. 57).

The need to reconcile trade commitments with national policies, including on public health, has been recognized as one of the tasks that WTO must face. According to the former Director General of the WTO,

"(One) should not underestimate the growing pressure on the multilateral trading system to give answers to issues which are very real public concerns, but ones whose solution cannot rely on the trading system alone. Whenever people talk about trade now, other issues come up immediately: financial instability, development, marginalization, protection of the environment, social conditions, employment, public health, or cultural diversity. It would be wrong for the international trading system to ignore such issues, or not make the contribution that it is possible for it to make. We have to improve our ability to respond within our own rules and institutions to the interrelationships which undoubtedly exist, showing that the different policies required can be mutually supportive rather than contradictory".⁶⁰

The methods and criteria applied to solve the tensions between the satisfaction of national public interests, and the compliance with the general WTO obligations, will determine the scope that sovereign nations retain to pursue legitimate national objectives. Solving such tensions is not, however, an easy task since it may be difficult to distinguish between legitimate measures and those adopted with a purely protectionist intent⁶¹. Different approaches have been suggested to address the referred to tension.

According to one approach, given that there exist diverging societal perceptions and attitudes towards health-related and other public policy issues, the sovereign rights of States to deal with such issues should be affirmed (Whalley, 1996, p. 94). The primacy of nationally-defined policies in relation to health, the environment and safety, has been asserted, for instance, in the US Uruguay Round Agreements Act" (1994) which provides that

⁶⁰ Statement given on occasion of the second WTO Ministerial Conference (May 18 & 20, 1998).

⁶¹ The efforts by national governments to protect citizens from health and other hazards "has become a virtual minefield for trade policy-makers.. Even when there is no protectionism intent on the part of lawmakers, through a lack of coordination, mere differences in regulatory or standard-setting regimes can function to impede trade" (Trebilcock and Howse, 1999, p. 135).

"Nothing in this Act shall be construed
(A)to amend or modify any law of the United States,
including any law relative to

- (i)the protection of human, animal, or plant life
or health,
- (ii)the protection of the environment, or
- (iii)worker safety..."

The President of the USA has also stated that

"...international trade rules must permit sovereign
nations to exercise their right to set protective
standards for health, safety and the environment and
biodiversity. Nations have a right to pursue those
protections -even when they are stronger than
international norms".⁶²

Under this view, national health and other public
policies and rules should prevail over multilateral
disciplines when a conflict arises. In particular, a
"sovereignty school" has developed in the area of
environmental policies, according to which environmental
policymaking should be left entirely to national politicians
and the GATT should be stripped of all authority to
challenge nationally determined policies. While some
supporters of the sovereignty school would accept the review
of environmental policies by the GATT to determine if they
are really disguised protectionism, others would permit no
international oversight whatsoever (Esty, 1994, p. 56). Thus,
measures used with clear environmental intent should
override any restrictions on them implied by existing
GATT/WTO rules, and trade provisions of environmental
treaties should be given precedence over such rules
(Whalley, 1996, p. 86).

A second approach suggests to reinforcing the role of
the WTO to deal more systematically with trade-related
issues, under an expanded "constitutional role" (Cottier,
1998, p. 58). This would permit WTO to address the
restrictions on market access which derive from diverging
attitudes towards new technologies and risks, as well as to
address the protection of global goods and of interests of
common concern. Under this "constitutional role" the WTO
could not longer be based on a negative integration scheme
(i.e., prohibiting restrictions) as its sole task in

⁶² Statement by the President of the USA on occasion of the second WTO
Ministerial Conference (May 18 & 20, 1998).

construing trade-related rules. Thus, while the purpose of GATT was almost exclusively the reduction of trade barriers,

"the WTO increasingly assumes constitutional functions in a globalizing economy. The goal of dismantling trade barriers is increasingly accompanied by the inclusion of trade-related issues. The environment has been one of them. Intellectual property, competition (antitrust) and, possibly, links of trade and labour standards, are yet other ones. The system becomes multifunctional. It increasingly has to deal with a number of partly competing, but equally legitimate policies. It becomes a matter of balancing interests" (Cottier, 1998, p. 58).

This view may find some support in the growing nature of health as a "global public good". Recent analyses have emphasized that while health include both public and private properties, globalization may be shifting the balance of health to a global public good⁶³.

The implications of an expanded "constitutional" role of WTO⁶⁴ in relation to public health and other public interests may be far-reaching. Such a role would imply that the protection of global commons and of interests of common concern, such as health or the environment, should not be longer approached under traditional doctrines of exclusive national sovereignty and jurisdiction (Cottier, 1998, p. 59).

However, given the difficulties that the GATT/WTO system has faced to deal with major public concerns, such as

⁶³ "Globalization is blurring the traditional line between public and private in health. Some have observed that we are witnessing the emergence of an unprecedented "third wave" of health threats -emerging infections, new environmental threats and behavioral pathologies. This blend of new as well as resurgent older diseases is planetary in scope and threatens all countries, rich and poor. As a result the traditional categorization of diseases demands serious reconsideration. Most of these threats characteristics of a global public bad, and their ultimate resolution will require global cooperation beyond the capability of any single actor or nation state" (Chen, Evans and Cash, 1999, p. 285-286).

⁶⁴ In fact, the WTO has already assumed an "international oversight" through the the TBT and SPS Agreements. This would amount to a "policed decentralization" which means that national authorities are largely free to pursue their own policy objectives but must do so subject to a set of broadly applicable legal constraints (Trebilcock and Howse, 1999, p. 161).

those related to public health and the environment⁶⁵, and the heavy burden put on many developing countries (UNCTAD, 1999; Khor, 1999, p. 37), an expanded competence of WTO is unlikely to positively change that situation, particularly in relation to specific public health issues.

Interpreting the WTO rules

The focus of the GATT/TWO principles and procedures on trade concerns, may fail to provide an adequate forum for addressing the vast range of problems posed by a growingly globalized economy and, in particular, for reconciling trade with other public interests.

The WTO dispute settlement bodies have faced the complex task of distinguishing the limits of what is a disguised restriction to trade from legitimate measures adopted to protect public interests. Though panels and the AB have recognized the need to reach a balance and ensure room for national action, they have not upheld so far national measures based on public-health reasons. How to secure that the exercise of the sovereign rights of States to adopt public health and other policies is not unduly limited by the application of trade disciplines, is still an open issue that is central to future deliberations within WTO.

A possible strategy for safeguarding public health interests in the WTO system, would be to develop agreed interpretations through General Council decisions on critical issues, such as Article XX(b) of the GATT as far as it applies to matters not covered by the SPS Agreement, the exceptions and precautionary approach under the latter and article 8.1 of the TRIPS Agreement. An agreed interpretation requires, unless otherwise provided, a three-fourths majority (Article IX of the Marrakesh Agreement Establishing the WTO)⁶⁶.

⁶⁵ For an analysis of GATT/WTO jurisprudence relating to environmental issues, see Petersman, 1998 and Easty, 1994.

⁶⁶ An alternative would also be to propose amendments to existing rules, as contained in the GATT and the relevant WTO agreements. Amendments require consensus or a two thirds majority, but if they alter the rights and obligations of the Members, amendments shall take effect only for the Members that accepted them. The Ministerial Conference may decide by a three-fourths majority that an amendment is of such nature that a Member not accepting it may withdraw from the WTO or remain a with the consent of the Conference (Article X.1 and Article X.3 of the Marrakesh Agreement Establishing the WTO).

Increasing participation

So far, the development and application of GATT/WTO rules have been strongly influenced by specific industries and commercial interests, as illustrated by the deep involvement of multinational firms and various of their industry coalitions in the process leading to the adoption of the TRIPS Agreement (Ryan, 1998).

Panels and AB may become more sensitive to broader public policy concerns, such as public health, through the increasing and effective participation of other international organizations, such as WHO, in the decision making process. Of course, this will require agreement by the membership of such organizations -which in some cases may be difficult to reach- as well as the building up of capacity within them to deal with trade disciplines and their interaction with public health issues.

Consideration should be given, in particular, to the ways in which WHO may actively supply opinion and technical advice in disputes where public health matters are involved. This may be one important aspect in the implementation of the WHO Revised Strategy on Essential Drugs⁶⁷. Such participation should encompass scientific evidence, as well as other supportive elements that may contribute to incorporate a public-health perspective in decisions by panels and the AB.

Though the implementation of various WTO agreements, as mentioned above, significantly relies on standardizing activities undertaken by WHO, there has been so far little substantive interaction and cooperation between WHO and WTO. An important step to this effect may be the participation of WHO as an observer in the WTO Councils⁶⁸ and other bodies, as appropriate, and a growing involvement of WHO in the decision making process. Panels and the AB may benefit from opinion and advice from WHO, when the consideration of public health-related issues is at stake.

One precedent in which WHO advice was requested is offered by the already mentioned *Thai Cigarettes* case, where on the basis of an understanding between the parties and in pursuance of Thailand's request, the panel asked the World Health Organization (WHO) to present its conclusions

⁶⁷ See WHA52.19, of 24.5.99.

⁶⁸ Currently the WTO has observer status in the TBT and SPS Councils.

on technical aspects of the case, such as the health effects of cigarette consumption, and on related issues for which the WHO was competent.

The WHO indicated in its submission to the panel, that the sharp differences between the cigarettes manufactured in Thailand and in developed countries were of public health concern, because they made smoking western cigarettes very easy for groups who might not otherwise smoke, such as women and adolescents, and create the false illusion among many smokers that these brands were safer than the native ones which consumers were quitting. In Thailand the market was dominated by a state-owned monopoly which promoted smoking minimally, in the absence of competition. Locally grown tobacco leaf was harsher and smoked with less facility than the American blended tobacco used in international brands. According to the WHO, another major difference was that manufacturers of American cigarettes designed special brands aimed at the female market, which was not the case for Thai cigarettes. The WHO also argued that the demand for cigarettes, in particular the initial demand for cigarettes by the young, was influenced by cigarette advertisements and that bans on advertisement could therefore curb such demand.

The United States considered that the WHO was not "specially competent to address the health consequences of the opening of the market for cigarettes" as requested by Thailand, and urged the Panel to limit the issues presented to the WHO to health effects of cigarette use and consumption.

The panel noted that the WHO resolutions on smoking recommended non-discriminatory health measures concerning all not only imported cigarettes, but did not took into account other considerations made by WHO based on empirical work (Trebilcock and Howse, 1999, p. 165). In fact, the WHO argumentation against the importation of U.S cigarettes was disregarded by the panel.

Transparency

The need to improve the transparency in the WTO operation, has been stressed by developing and developed countries alike⁶⁹. The dispute resolution process relies on close-doors reviews by panels of trade experts (generally

⁶⁹ See Third World Network, 1999. See also the Statement by the President of the United States at the Second WTO Ministerial Meeting, Geneva, 1998.

lawyers or diplomats) without expertise on technical aspects such as those involved in public health issues. It is questionable, hence, the extent to which the WTO procedures and, in particular, the dispute settlement mechanism, are adequate to duly take into account broad public interests (Esty, 1994, p. 217). The shortcomings of a secretive process of decision-making has been observed by some WTO Members⁷⁰, though very little has been actually done to improving transparency for the marginalized WTO Members.

It should be noted that the formal participation of non-Members in the dispute settlement process is limited. Only Members can initiate dispute settlement procedures. Article 13 of the DSU states, however, that panels are authorized to obtain information from any sources:

"1. Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate...

2. Panels may seek information from any relevant source and may consult experts to obtain their opinion on certain aspects of the matter. With respect to a factual issue concerning a scientific or other technical matter raised by a party to a dispute, a panel may request an advisory report in writing from an expert review group..."

According to one interpretation, Article 13 is broad and appears to give full discretion to panels to decide whether and what type of information or technical advice it needs or desires from any source (Marceau and Pedersen, 1999, p.34). This provision, however, is addressed only to panels and not to the Appellate Body. Consequently, the faculty to obtain outside information would be limited to evidence, as opposed to legal arguments. Unlike the procedures before other courts (such as the European Court of Justice) the DSU procedures do not explicitly envisage the possibility for the panels or AB to invite "*amicus*

⁷⁰The US government, for instance, offered to open up every panel it is party to: "Today, when one nation challenges the trade practices of another, the proceeding takes place behind closed doors. I propose that all hearings by the WTO be open to the public, and all briefs by the parties be made publicly available. To achieve this end, we must change the rules of this organization. But each of us can do our part -now. The United States today formally offers to open up every panel that we are a party to -and I challenge every other nation to join us in making this happen (US President submission at the 2nd. WTO Ministerial Conference).

briefs" from NGOs and other organizations (Marceau and Pedersen, 1999, p.34).

In the *US-Import of Certain Shrimp and Shrimp Products* case, the panel received two "amicus briefs" submitted by NGOs. In considering these submissions, the AB reached "a ground-breaking conclusion" (Marceau and Pedersen, 1999, p. 35). It held that since panels are masters of the panel process, a panel is authorized (albeit not obliged) to accept and consider submissions from NGOs even if that panel did not requested them. This means that even if the panel ultimately decides not to accept the submissions by a NGO, the latter is given the opportunity to present arguments that may be considered (or not) by the panel. The Appellate Body stated that:

"We consider that a panel also has the authority to accept or reject any information or advice which it may have sought and received, or to make some other appropriate disposition thereof. It is particularly within the providence and the authority of a panel to determine the need for information and advice in a specific case, to ascertain the acceptability and relevancy of information or advice received, and to decide what weight to ascribe to that information or advice or to conclude that no weight at all should be given to what has been received".

In the present context, authority to seek information is not properly equated with a prohibition on accepting information which has been submitted without having been requested by a panel. A panel has the discretionary authority either to accept and consider or to reject information and advice submitted to it, whether requested or not. The fact that a panel may *motu proprio* have initiated the request for information does not, by itself, bind the panel to accept and consider the information which is actually submitted. The amplitude of the authority vested in panels to shape the processes of fact-finding and legal interpretation makes clear that a panel will not be deluged, as it were, with non-requested material, unless that panel allows itself to be so deluged".

This would mean that while the DSU does not give Members which are not parties to the dispute the right to be

heard, even where broad public interests are at stake⁷¹, it would allow panels to request, at their discretion, information from third parties, including NGOs and international organizations⁷², and to consider the information provided by such third parties, even if unsolicited. The interpretation given in the *US-Import of Certain Shrimp and Shrimp Products* case to article 13 of the DSU appears to be beyond the competencies of the AB (Vermulst, Mavroidis and Waer, 1999, p. 32), and it is a precedent that may undermine the exclusive authority of the Ministerial Conference and the General Council to interpret the GATT/WTO rules (South Centre, 1999, p. 17).

Developing countries, in particular, fear that the opening up of the dispute settlement process to NGOs could offer a golden opportunity for NGOs from the North (including business associations and trade unions) to get their interests reflected in panel decisions, against the fundamental interests of developing countries in development-related issues. In fact, firms and other private interest groups have been very active and influential in policy-making and dispute settlement procedures within WTO (Dunoff, 1998).

Reforming the system

The interpretation of the WTO agreements through the General Council and case law under the Dispute Settlement Understanding will be limited, in any case, by existing rules and by the competence of the bodies in charge of the settlement of disputes⁷³.

Careful consideration should be given to the ways in which public health objectives may be reconciled with trade disciplines under the WTO system, including possible reforms of procedural or substantive aspects thereof.

⁷¹ In order to address this problem, the substitution of a "trade" interest, by a "systemic" interest as the condition to joining consultations has been proposed (South Centre, 1999, p. 27).

⁷² The panel sought and took into account the expert advice of several renowned scientists in the *Beef Hormones* case; in *India- Quantitative restrictions on imports of agricultural, textile and industrial products*, the panel asked for input from the International Monetary Fund (Steger, 1999, p. 47).

⁷³ As mentioned before, the "recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements" (Article 3.2 of the DSU).

A higher sensitivity of the WTO system to health and other public concerns may be sought, for instance, through improvements relating to the burden of proof. Though, as indicated above, the SPS Agreement has already changed the burden of proof -as compared to the situation under Article XX(b)- when a Member is complying with accepted standards, several pending issues remain in this area⁷⁴. Thus, it has been proposed in relation to Article XX(b) that

“a complainant should bear the burden of proving that a domestic policy measure of another country has a disparate and substantial impact on international trade. If this can be proven... the burden of proof should then shift to the respondent country to demonstrate that notwithstanding this, the policy measure both genuinely engages a legitimate policy objective... and that no less trade restrictive policy instrument is reasonably available...” (Trebilcock and Howse, 1999, p. 164).

Moreover, a “patently unreasonable” standard may be considered. The country whose domestic policies are under challenge would simply be required to produce evidence sufficient to suggest that the policy choice is not patently unreasonable or a grossly disproportionate adaptation of means to ends, or put otherwise, is a plausible means of attempting to achieve the legitimate policy objective in question, even if the reviewing body could itself imagine superior instruments. This approach would be more respectful of domestic political sovereignty and policy autonomy than the present approach, which invites panels or the AB to second-guess the domestic policy choices of national governments (Trebilcock and Howse, 1999, p. 164-165).

Some proposals for the review of the TBT and SPS agreements have been submitted by several developing countries as part of the implementation problems agenda, particularly aiming at ensuring the participation of such countries in the standards setting process⁷⁵. There are also suggestions relating to the review of the TRIPS Agreement (Correa, 1999b), such as to amend article 27.1 in order to allow developing countries to exclude the patentability of “essential medicines” listed by WHO⁷⁶.

⁷⁴ See Koivusalo, 1999, p. 32.

⁷⁵ See WTO document JOB(99)4797, p. 19-20.

⁷⁶ See the Submission of Venezuela for a possible review of the TRIPS Agreement (WT/GC/W/282). An alternative to the non-patentability may be to subject such medicines to automatic compulsory licensing. It should be noted, in any case, that most of the products in the WHO list of “essential drugs” are off-patent, and that it does not contain medicines which are too expensive (such as antiretroviral drugs for HIV patients). Therefore, the list does not cover all basic therapeutical needs of the population.

Likewise, possible improvements of the Dispute Settlement Understanding as part of its mandated review have been submitted, such as to increase the transparency of the procedures by requiring Members to make public their Panel and AB submissions⁷⁷. More substantive reforms to ensure that decision making under the DSU take into consideration, in a balanced manner, the interests of developing countries also deserve consideration⁷⁸.

Conclusions

The GATT, as adopted in 1947, recognized that conflicts may arise between specific trade objectives and those emerging from other public concerns, such as health, safety and the environment. Given the basic objective of the trade system, however, these concerns have been dealt with as limited exceptions, only allowable under narrowly defined conditions.

Though health and other public concerns have been taken into account in several of the agreements adopted in Marrakesh in 1994, these agreements have not substantially altered the dominance of trade interests in cases where such concerns are at stake.

The GATT/WTO jurisprudence has admitted, notably in cases related to the protection of the environment, that Member States enjoy a large measure of autonomy to deal with public concerns. Such autonomy, however, is circumscribed by the nature, scope and interpretation of the applicable provisions. The defendant Member State has not only had the burden of proof that the measures it has adopted did not violate its obligations, but the WTO panels and the AB may always second-guess the defending government and find that "least-GATT inconsistent" measures are available. In fact, no Member has been able so far to make successful use of the GATT and SPS Agreement provisions allowing Members to depart from trade rules in order to protect public health.

The tensions between trade and health interests are likely to increase as the globalization of the economy proceeds and public health growingly becomes a global public good. The coverage of public health regulations has substantially increased since the inception of the GATT

⁷⁷ See, e.g., WTO document JOB(99)/497/rev.3, p. 119 and 185.

⁷⁸ See, e.g. South Centre, 1999; Raghavan, 2000.

system, while trade liberalization has aggravated in many countries inequalities in income distribution, and has worsened the opportunities for access to medicines, particularly by the poor.

A crucial aspect is, therefore, how such tensions may be faced and solved within the WTO system in a manner that fully recognizes public health concerns, as determined by each Member State. WTO Members may define and demand for a health-agenda in possible future negotiations in WTO aimed at ensuring that national public health interests, as determined by national authorities, are not unduly subordinated to the currently dominant trade perceptions.

The appropriate route should not be to expand the role of the WTO to accommodate public health concerns. The WTO, as it is, is proving quite burdensome for the developing countries; any expansion of its role by having additions to obligations of nations would be against the interest of the weaker countries.

A possible strategy for better integrating public health interests in the trade system may include, among other steps, a more active involvement of WHO, the international specialized organization in health, in the day-to-day-activities of WTO Councils and other bodies, to develop a health-sensitive framework for the interpretation of public health exceptions under GATT and the relevant multilateral trade agreements, to increase the transparency of the decision-making process and to review the rules on burden of proof in cases involving domestic public health measures in possible conflict with WTO rules.

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