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Paper

International Legal and Policy Framework for WHO Framework Convention on Tobacco Control

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EXECUTIVE SUMMARY:

The international legal and policy framework for the development of a global tobacco control Convention is based on the need to curb the global tobacco epidemic. Tobacco continues to claim millions of human lives and developing countries will be hit harder in the next millennium. The basis of this effort stems from Article 19 of WHO Constitution which empowers WHO to initiate the development of Conventions to protect public health. Many provisions of WHO Constitution also support this process. The WHO Executive Board and World Health Assembly have in the past made various resolutions urging States to recognise and curb the tobacco problem. Of importance is Resolution 52.18 of the 52nd World Health Assembly in May 1999 which urged member States to prioritise tobacco control. It also laid framework for establishing a working group, an inter-governmental negotiating body and affirmed need for support for developing countries during this process.

The legal framework considers application of the World Trade Organisation (WTO) Trade law and policy, International human rights law, and drug law. These, expressly and implicitly have provisions to protect public health. Thus, under WTO law, article XX (b) of GATT 1994 permits trade restriction and control of a product in a country if it will harm public health. The qualification is that this must be necessary to protect health and shouldn’t be discriminatory. The need to curb the tobacco problem is already a necessity. The WTO trade law and policy also recognises the authoritative guidance of WHO in protection of public health. WTO trade decisions such as the Thai Cigarette case affirm this. It means the development of a global treaty on tobacco control poses no conflict with World trade rules. In addition to tobacco, other areas of interaction between WHOs public health work and WTO trade regime include the International Health Regulations, food safety, pharmaceuticals and vaccines and trade in health services. The WTO recognises the authoritative guidance of WHO in standard setting in these aspects of world trade. Various WTO agreements provide areas of synergy with these aspects of WHO work.

International Human Rights law offers a viable basis for tobacco control. The WHO Constitution provides the right to health as a fundamental human right. Many UN Instruments such as Convention on Economic, Social and Cultural Rights, the Convention on Elimination of Discrimination Against Women (CEDAW) and UN Convention on the Rights of the Child among others stress the need to ensure health for all. Committees of these Instruments have singled out tobacco as a major affront to health which requires curbing among vulnerable populations such as developing and least developed countries, women and children. Women and children are being increasingly targeted by tobacco countries in low income countries. Involvement of poorer countries in global tobacco control is not only crucial as protection of public health, but that of human right in developing and least developed countries.

Drug law provides a good example for global regulation of tobacco. Drug law in developing countries has been used to regulate harmful products such as poison, quality of drugs etc. It is now well established that there are over 1000 harmful products in tobacco. Drugs and food products and quality are regulated around the world. We shouldn’t continue to allow tobacco to escape regulation. Some countries are already using food or poison laws to regulate tobacco. Thus, the legal and policy aspects of drug regulation offers a good basis for the development of the WHO framework Convention on tobacco control.
Therefore, it is important that developing countries get involved in the global tobacco law making process. Existing WHO mechanisms need to be used to enhance technical support in legal and policy aspects for developing and least developed countries. The role of increased partnerships between the various UN agencies should be encouraged and existing legal structures in developing countries should be applied to further this law making process and future implementation.
I. INTRODUCTION.

Background

This paper is an attempt to expose the legal and policy basis for the development of a WHO Framework Convention on Tobacco control. It describes the state of the law that has enabled WHO to undertake this lawmaking. The core of the paper expounds other justifications that support the development of the Convention. This complements the increasing global burden of disease from tobacco as the central reason for developing the Convention. Indeed, the developing world will be hard hit due to absence of viable tobacco control infrastructure. The development of the Convention is a necessary vehicle for tobacco control in these countries.

I have considered the following areas of International law, the institutional law of WHO, the WTO law, Human rights law and Drug law. These are important for the following reasons. These areas of law justify the development of a legal instrument that seeks to protect Public Health via a tobacco control convention. These areas of law are a departure point for a Convention to protect public health. A convention to control tobacco will in fact strengthen and enhance the field of application of these laws. Finally, these laws can be the basis of dispelling any misunderstanding that may arise in the making and implementation of a tobacco control Convention. Thus, this paper aims to establish that the development of WHO framework Convention on tobacco control has a sound basis under existing international legal and policy framework.

The Case for an International Legal Instrument.

The tobacco problem requires multi-pronged strategy to fight it. While national programmes offer direct means of combating the epidemic, an international strategy becomes imperative. This is because tobacco industry tactics have been extremely elusive. Because the industry and the tobacco problem transcend national frontiers, international regulation offers a stronger tool to avert the tobacco problem. International action creates a vehicle for concerted action towards containing the ever rising statistics of tobacco related deaths today. Dr Brundtland, WHO Director General stated that tobacco control cannot succeed solely through the efforts of individual governments, national NGOs and media advocates. We need an international response to an international problem.

The making and implementation of the Convention, the central strategy in the fight against tobacco depends on continuous political and other support of national governments, global institutions and civil society. The special importance of Conventions in International law scarcely need emphasis. The multilateral treaty remains the best medium available at the moment for imposing binding rules of precision and details in the new areas into which international law and concerns is expanding, and for codifying, clarifying and supplementing the customary law already in familiar settings. Protection of public health by controlling tobacco is one where international law is crucial in addressing the multilateral nature of the problem.

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What is a Framework Convention:

Conventions are legally binding international agreements, concluded by States in written form, and governed by International law. A Framework Convention refers to a variety of legal agreements, which establish a general system of governance for a specific area such as tobacco control. The Framework Convention/Protocol approach allows States to proceed incrementally. The instrument that embodies these specific commitments is known as a Protocol. Examples are the 1976 Barcelona Convention for the Protection of the Mediterranean Sea against Pollution, which was negotiated under UNEP, and now has protocols concerning the dumping of hazardous wastes, land based sources of marine pollution, emergency response to oil spills, and specially protected areas. The 1979 Convention on Long range Transboundary Air Pollution which addresses the problem of acid rain in Europe and North America, has seven Protocols establishing specific obligations relating to the various sources of transboundary air pollution, including sulphur emissions, nitrogen oxides, volatile organic compounds, heavy metals and persistent organic pollutants. Other examples are the 1985 Vienna Convention for the Protection of the Ozone Layer and the 1987 Montreal Protocol on Substances that deplete the Ozone Layer.

This approach is the most feasible option for global tobacco control. It offers the advantage of dividing the negotiation of separate issues into individual agreements rather than trying to resolve all substantive issues in one document, is more politically acceptable than any other binding approach to global tobacco control, creates a forum for co-operation and negotiation for implementing detailed protocols, and offers a model for a continuous and dynamic process of law making.

II: WHO LEGAL FRAMEWORK

WHO Constitution

WHO is legally empowered to develop Conventions. The development of a tobacco control Convention is well founded under WHO Constitution, which applies to all its members which includes all developing and least developing countries. However, this is the first time that WHO is activating its constitution to develop this treaty. Article 19 of the Constitution states that the Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall bind a member when accepted by it in accordance with its constitutional processes. It is important to note that Article 2 of the Constitution endows WHO with several functions that directly or indirectly require the application of legal principles. These include, to act as directing and co-ordinating authority on international health work, to propose conventions, agreements and regulations, and make recommendations with respect to international health matters and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective, and to develop, establish and promote international standards with respect to food, biological pharmaceutical and

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5 See Birnie and Boyle, Documents in International Environmental Law for these and other Conventions.
6 Taylor and Roomer, 1996
consumer products. Tobacco control is within this ambit. Articles 20, 61, 62, 63, 64 and 65 of the WHO Constitution are also relevant. They provide that members report annually to the Organization on its action taken to improve its peoples' health and on action taken with respect to recommendations, conventions, agreements and regulations by the Organization. Members shall communicate promptly to the Organization important laws; regulations, official reports and statistics pertaining to health which have been published in the State concerned. Thus, the development of a WHO convention on tobacco control is legally mandated and based on WHO Constitution. This constitution governs actions of the Organization and has a binding or persuasive effect on States who are members of WHO.

**Resolutions WHA49.17 and EB103.R11**

The idea to develop a global tobacco control treaty evolved since 1975. Gaining momentum in 1990s, was affirmed in 1995 by the Ninth World Conference on Tobacco or Health. The World Health Assembly in Resolution WHA49.17 requested the Director General of WHO, to initiate the development of a Framework Convention in accordance with Article 19 of the WHO Constitution.

In January 1999, the WHO Executive Board adopted Resolution EB 103.R11. This charted the course of pre-negotiation and negotiation phases for developing the Convention. The Resolution suggested 2 key decisions for the 52nd World Health Assembly to consider:

- To establish a Working Group on the Framework Convention on Tobacco Control, open to all member States.
- To establish an inter-governmental negotiating body open to all member States, to draft and negotiate the proposed WHO Framework Convention on Tobacco control. This body will prepare a draft text of the Convention.

The adoption by the World Health Assembly of the Resolution commenced the pre-negotiations phase for the convention. Formal negotiations of the Convention and its protocols commences with first meeting of the intergovernmental negotiating body expected in from May 2000. It is envisaged that the Framework Convention and its related protocols would be ready for adoption by the year 2003. The content, inertia and timing of the Convention and related protocols will depend upon the political will and sustained commitment of States determined to protect public health from the scourge of the tobacco pandemic. The interests of governments are paramount in treaty making and this should be reflected in the process of developing the content and implementation of the Convention and related protocols. States must perform these acts in good faith. As was stated by Judge Gros in the WHO Agreement Case “in the absence of a super State, each international organisation has only the competence which has been conferred on it by the States which founded it, and its powers are strictly limited to whatever is necessary to perform the functions which its constitutive Charter has defined. The WHO competence is thus that which is attributed to it by States. Specialised agencies of the UN have special competence which they have received from member States for well-defined tasks.” Treaty negotiation being a prerogative of States, key governmental ministries will be involved such as Foreign Affairs, Justice, Finance and Foreign Trade, Environment,

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7 Outline of projected activities as endorsed by WHO Executive Board in EB103.11, 1999.
8 See Article 26 of the Vienna Convention on the Law of Treaties. It provides that a treaty must be performed in good faith.
9 1980 ICJ Reports at page 103.
Education, Agriculture and Labour. The role of WHO Secretariat in this is pivotal and involves the following: Facilitating the activities of the Working Group with technical support and briefing sessions, assistance in the planning of inter-governmental consultations on the Framework Convention, promotion of the participation of the least developed countries in the treaty-making process and technical support to member States to advance the adoption of the convention. This conference fall within this role. Technical standards on tobacco control are being established and maintained by WHO, a primary specialised agency in the field of public health. The authoritative work of the WHO in this field has a binding effect derived from the WHO Constitution. In WHA Resolution WHA49.17, member States recognised the unique capacity of WHO to serve as a platform for the adoption of the Convention.

Resolution 52.18

The 52nd World Health Assembly of May 1999 is a landmark for the development of the WHO Framework Convention on Tobacco Control. The Resolution established an inter-governmental negotiating body for the Convention, which is open to all member States. The body’s role is to draft and negotiate the proposed WHO framework Convention on Tobacco Control and possible protocols. It also agreed to establish a Working Group on the Convention open to all member States in order to prepare the work of the Inter-governmental negotiating body. The working group will prepare proposed draft elements of the Convention. The Working Group will report on the progress to the Executive Board at its 105th session. It will complete its work and submit a report to the Fifty-third World Health Assembly.

The Resolution urged member States to give high priority to accelerating work on the development of the Convention and possible related protocols, to provide resources and co-operation necessary to accelerate the work, promote intergovernmental consultations to address specific issues, for example, public health matters and other technical matters relating to negotiation of the proposed Convention and possible related protocols, establish where appropriate, relevant structures such as national commissions and mechanisms to examine the implications of a Framework Convention on Tobacco Control within the context of health and economic issues, especially its effects on the economy of agriculturally dependent States, to facilitate and support the participation of non governmental organizations, recognising the need for multisectoral representation.

The Resolution urged the Director-General to do the following:

To promote support for the development of the Convention and possible related protocols among member States, organizations of the United Nations system, other inter-governmental, non-governmental and voluntary organizations and the media, to complete the technical work required to facilitate negotiations on the Convention and possible related protocols, to convene the working group on the Convention and the intergovernmental negotiating body on the basis of progress achieved by the working group, to provide the working group and the intergovernmental negotiating body with the necessary services and facilities to the performance of their work, to facilitate the participation of the least developed countries in the work of the working group, in intergovernmental technical consultations, and in the inter-governmental negotiating body.

It can be noted from this resolution that due consideration has been given to the role of developing countries in the negotiation and implementation of the Convention. The Resolution enjoins the international community to facilitate the participation of developing countries in the work of the Working Group and Intergovernmental negotiating Body of the Convention. It also calls for due attention to agriculturally dependent States which largely comprise the developing countries. The call for multisectoral approach to the process and involvement of NGOs is even more relevant in developing and least developed countries where the need for tobacco control is crucial. This conference is also covered under this resolution. This Resolution is thus a pivotal framework for the participation of developing countries in the development and implementation of the Framework Convention on Tobacco Control.

III: INTERNATIONAL TRADE AND TOBACCO : THE WORLD TRADE LAW

Article XX of GATT

The GATT was adopted in 1947 as the main international arrangement to encourage trade between States. It currently has 135 contracting parties and is designed to encourage trade between the parties to the agreement, by reducing tariffs and preventing trade barriers. The World Trade Organization, formed at the end of the Uruguay round of GATT in 1994 is the primary international institution governing international trade. GATT 1994 strengthened international trade regime by broadening WTO’s status, dispute resolution mechanism and jurisdiction. The 1994 agreements are a single package except the plurilateral agreements. The GATT has provisions for protecting human health. Relevant GATT agreements include Agreement on Trade in Goods and others such as the Agreement on the Application of Sanitary and Phytosanitary Measures, Agreement on Technical Barriers to Trade, Agreement on Agriculture, Agreement on import licensing Procedures, Agreement on Trade Related Aspects of Intellectual Property (TRIPS) and Agreement on Import Licensing procedures. The legal framework of the World Trade Organisation is relevant to the development of the Framework Convention on Tobacco Control. GATT Article III (1) prohibits the application to imported or domestic products of internal taxes and other internal charges, laws, regulations and requirements so as to afford protection to domestic products. Article III (2) prohibits the application, directly or indirectly, of internal taxes or other internal charges of any kind in excess of those applied directly or indirectly to like domestic products or in a manner contrary to Article III (1) which emphasises non-discrimination: Under Article XI, prohibitions or restrictions including quotas, import or export licences or other measures, on the import or export of any product from or another contracting party are prohibited. Article XX permits exceptions to these limitations. It provides interalia,

“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..., necessary to protect human, animal or plant life or health, relating to the conservation of
exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption.\textsuperscript{11}

By 1991, the GATT Secretariat had 17 agreements, which required certain products to be subject to import or export restrictions. The important agreements listed are the Convention on International Trade in Endangered Species of wild fauna and flora 1973, the Montreal Protocol on Substances that Deplete the Ozone layer, and the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal. \textsuperscript{12} WHO Framework Convention on Tobacco control will be one of many such conventions aforementioned. The GATT has always recognised that free international trade is not the only relevant policy goal for nations. In fact, it has many exceptions that give equal or greater weight to other policy goals. In consideration in these conventions is the exception under Article XX, that justifies among others trade controls for health reasons.

In addition to Article XX of GATT, there are other side agreements of the WTO relevant to the development of the Framework Convention on Tobacco Control.

**WTO Dispute Settlement Body Decisions on Article XX**

GATT Jurisprudence is scarce in the area of public health but decisions in the area of environmental law can be interpreted for International tobacco control since tobacco control is a means to protect health, the interpretation of provisos to Article XX can be applied to the exception relating to human health under the Article. The following are the four important GATT decisions relevant to the development of the Framework Convention on Tobacco Control.

**Thai Cigarette Case (1990)\textsuperscript{13}**

This case concerned prohibitions on import and export of tobacco and tobacco products by Thailand. Thailand sought to justify the trade prohibitions under Article XX (b) of the GATT, on the grounds that it had adopted measures to control smoking which could only be effective if cigarette imports were prohibited and because chemicals and other additives contained in US cigarettes might make them more harmful than Thai cigarettes.

The GATT panel held and accepted that “smoking constituted a serious risk to health and that measures designed to reduce the consumption of cigarettes fell within the scope of Article XX (b) of the GATT.” It meant that the measures to protect human health can be applied if necessary to achieve health policy objectives. On the basis of recommendations adopted in resolutions of the forty-third assembly of the World Health Organisation, the Panel held that other measures consistent with the GATT were reasonably available to Thailand to control the quality and quantity of cigarettes smoked, including nondiscriminatory regulations. These must be implemented on a national treatment basis (such as requiring disclosure of ingredients), a ban on unhealthy

\textsuperscript{11} See the World Trade Organisation; The Results of the Uruguay Round of Multilateral Trade Negotiations: The Legal Texts. 1994, page519.

\textsuperscript{12} Jackson and Davey, Legal Problems of International Economic Relations, 3\textsuperscript{rd} Edition, 1995, Pages 560-1

substances, and a ban on advertising and information campaigns. These could achieve Thailand’s health policy goals.

In fact GATT upheld the advertising ban, stating that various tobacco control measures could be adopted both to domestic and imported tobacco and still be consistent with GATT. The case implies that member States of GATT can adopt strong tobacco control legislation so long as the measures are aimed at protecting health and do not discriminate between domestic and imported tobacco. Thus, it would be possible to design stringent tobacco control measures to alleviate tobacco control deaths without violating GATT commitment. The Panel provided a general mechanism for tightening tobacco control without breaking WTO rules. For example, following the decision, Thailand maintained its advertising ban and has upheld other strict measures to control tobacco use. The future harmonization of tobacco control policies, including price increases, ad valorem taxes, advertising bans can be adopted as long as these policies do not discriminate between foreign and domestic products.

It can be concluded that the development of WHO Framework Convention on Tobacco Control is compatible with GATT law and policy. The Thai case demonstrates that measures to protect health by control of smoking comes within the ambit of exceptions laid under Article XX (b) of GATT Agreement. The panel moreover recognised the authoritative resolutions of a WHO body on the harmful effects of cigarette smoking. This means that inclusion of trade related measures in the Framework Convention should be seen as complementing the law and policy of the WTO especially regarding Article XX of the GATT. Many commentators have in fact concluded that the Thai Cigarettes case is a victory for public health. It implies the WTO recognition of the need to inculcate public health protection goals into international trade. Thailand’s response in adopting and enforcing strong multifaceted restrictive legislation is a model of what countries can do when faced with invasion by multinational companies and their advertising.14

The Tuna-Dolphin Case.15

This dispute arose over regulations adopted under the US 1972 Marine Mammal Protection Act. It regulates the harvesting of tuna by fishermen who are subject to the jurisdiction of the US. The law limited catch of dolphins to 20,500 per year in this part of the Ocean. It required the US Secretary of State “to ban the importation of commercial fish or fish products caught with commercial fishing technology resulting in incidental kill or serious injury of ocean mammals in excess of United States standards. The law meant US environmental standards should be applied to all countries in respect of their fishing activities. It obliged country of registry of vessels to satisfy that its regulatory regime was comparable to that of US. US also prohibited import into its customs territory of yellow-fin tuna products from Mexico, which were caught with purse seine nets with documentary evidence of this.

In January 1991, Mexico requested the GATT contracting parties to establish a panel to examine the compatibility of these US laws with the GATT. The panel examined the compatibility with GATT under among others Article XX

At the heart of the case was the question whether these import prohibitions were permitted under Article XX (b) and XX (g). The panel noted that US was

entitled to invoke Article XX, but noted that, “the practice of panels has been to interpret Article XX narrowly, to place the burden on the party invoking Article XX to justify its invocation. The main issue was whether it covered measures necessary to protect human, animal or plant life outside US jurisdiction. The Panel concluded that the drafters focused on the use of measures within the jurisdiction of the importing country. It also held that measures taken under Article XX (b) must be necessary and should not constitute a means of arbitrary or unjustifiable discrimination, and that Article XX (b) was intended to allow restrictions to pursue overriding public policy goals to the extent that such inconsistencies were unavoidable.

US had not shown that its measures were necessary, or that it had exhausted all other options reasonably available to it to pursue its dolphin protection objectives in a manner which was compatible with the GATT especially through the negotiation of international co-operative arrangements. The conditions adopted were too unpredictable to be regarded as necessary to protect the health or life of dolphins. However, the legislation regarding labelling was not discriminatory as it did not distinguish between products originating in Mexico and those originating in other countries.

This case supports the development of an international tobacco control convention because the measures can be argued as necessary (basing on the scale and evidence of the tobacco problem), is not discriminatory since the subject matter here is protection of health and national measures will emanate from international mutual arrangement and each nation will enforce the agreed measures within its boundaries and report to an international body.

From the face of it, the GATT panel adopted an approach, which seems to make it difficult to justify trade restrictions, which give effect to national health protection measures relating to activities emanating beyond the jurisdiction of parties adopting such measures. Under the GATT, trade restrictive provisions under WHO framework Convention will have to be proved to be necessary and must be non-discriminatory. The evidence base of the tobacco problem is so grave that it has become necessary to have its trade circumscribed. The measures shouldn’t be viewed as discriminatory. This case encourages use of international co-operative arrangements and the Framework Convention on Tobacco control is such arrangement. The decision of the GATT Panel seems motivated by policy considerations, including concern at the prospect of the adoption of unilateral measures and growing disparities in national environmental standards, and a desire to encourage an international regulatory response to trade problems posed by national environmental disparities.16

We can conclude that the Tuna-Dolphin decision was decided on the premises that nations were taking unilateral measures without a proper international regulatory framework. The decision encouraged adoption of such frameworks. Thus, the Framework Convention on Tobacco control will provide an international legal mechanism so that individual State actions towards tobacco control will be legitimate but not unilateral. Actions for tobacco control will emanate from an international arrangement. These are justifiable from this decision.

The Shrimp Turtle Case17

17 United States – Import Prohibition of Certain Shrimp and Shrimp Products.
The United States issued regulations in 1987 under the Endangered Species Act of 1973 requiring all United States shrimp trawl vessels to use approved Turtle Excluder devices or tow time restrictions in specified areas where there was a significant mortality of sea turtles in shrimp harvesting. These regulations were extended to areas with likelihood that shrimp trawling will interact with sea turtles with certain limited exceptions. Certification was granted to countries with a fishing environment, which does not pose a threat of incidental taking of sea turtles in the course of shrimp harvesting. It was also granted to nations that provide documentary evidence of the adoption of a regulatory program governing the incidental taking of sea turtles in the course of shrimp trawling that is comparable to the United States program. Under 1996 Guidelines, all shrimp imported into the United States must be accompanied by a Shrimp Exporter’s Declaration form attesting that the shrimp was harvested either in certified waters under Section 609 or under conditions that do not adversely affect sea turtles. The 1996 Guidelines extended Section 609 to shrimp harvested in all foreign countries from May 1996. The US justified the law under Article XX that among others provides for trade restrictions on health grounds. India, Thailand, Pakistan and Malaysia applied to the GATT Panel. On appeal, The Appellate Panel held that US import ban on shrimp and shrimp products cannot be justified under Article XX of GATT 1994.

This ruling is relevant to tobacco control. First, any trade regulation measures must not be applied in a manner, which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail or is a disguised restriction on international trade. The body also held that a wider interpretation be accorded to the exceptions from Article XX (a) to Article XX (g). For example, exhaustible natural resources were defined to mean both non-living and living resources. A wider interpretation is given to tobacco control if any party wishes to contest it as a discriminatory measure. The Panel recognised the recent acknowledgement by the international community of the importance of concerted bilateral or multilateral action to protect living natural resources and the explicit recognition by WTO members of the objective of sustainable development in the preamble to the WTO Agreement. This principle finds expression in protection of public health by global tobacco control. The protection of human health is arguable as sustainable development.

It further held that invoking of Article XX (g), if abused or misused, will to that extent erode the treaty rights of other members. However, because the GATT 1994 makes available the exceptions under Article XX, in recognition of the legitimate nature of the policies and interests embodied, the right to invoke one of those exceptions is possible. Article XX is a limited and conditional exception from the substantive obligations contained in other GATT provisions and the ultimate availability of the exception is subject to the compliance by the invoking member with requirements of the chapeau (opening statement). The chapeau is an expression of good faith. It’s a principle of law, especially in International law, which controls the exercise of rights by States. The principle prohibits the abusive exercise of a State’s rights and enjoins that whenever the assertion of a right impinges on the field covered by a treaty obligation, it must be exercised bonafide (reasonably). It is one, which is appropriate and necessary for the purpose of the right, in furthering the interests which it is intended to protect. It should be fair and equitable as between the parties and not one to procure unfair advantage for one or some of them.

The development of a global tobacco control convention would conform to all the requirements described above. It is an act been done in good faith. It is an evidence-
based action, stemming from the enormity of the global tobacco problem. Thus the convention will be compatible with the WTO law and policy and practice.

The Beef Hormones Case

This case relates to a complaint against the European Communities relating to an EC prohibition of imports of meat and meat products derived from cattle to which either the natural hormones: oestradiol-17, progesterone or testosterone, or the synthetic hormones: trenbolone acetate, zeranol or melengestrol acetate (MGA) had been administered for growth promotion purposes. The EEC law maintained the prohibition of the administration to farm animals of substances having hormonal or thyrostatic action. It prohibited marketing, or import from third countries, of meat and meat products from animals to which substances, including the six hormones at issue in this dispute were administered.

The Appellate Panel of the World Trade Organisation made a ruling relevant to protection of human health. Any future dispute between tobacco and trade can be resolved in reliance of this case since global tobacco control is protection of human health.

An SPS standard must derive from an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with relevant agreements. Any measures taken to protect human health must be based on the agreement. This does not relieve States of application of customary international law in interpreting the treaty. Precautionary principle of law though applicable shouldn’t override the Agreement.

The GATT Appellate Body also held that harmonisation by members of the SPS measures to international standards, guidelines and recommendations is not legally binding perse but as in international law, these need to be adhered to in good faith. The assessment of risks to prohibit trade under the agreement are not a closed list, i.e. **The risk to be evaluated in a risk assessment, is not only risk ascertainable in a science laboratory under strictly controlled conditions, but also risk in human societies as they actually exist, like “the actual potential for adverse effects on human health in the real world where people live, work and die”.** The body acknowledged that governments tend to base their legislative measures on mainstream scientific opinion. It is legitimate so long as it is done in good faith and signals a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening and is perceived to constitute a clear and imminent threat to public health and safety. Determination of this relationship can only be done on a case to case basis, after account is taken of all considerations rationally bearing upon the issue of potential adverse health effects. Moreover, without undertaking a risk assessment as a minimum procedural requirement, members States can still proceed to regulate products under the SPS

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18 EC Measures Concerning Meat and Meat Products (Hormones)
19 The core of the Precautionary Principle, still evolving, is reflected in Principle 15 of the Rio Declaration, which provides that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation. See among others, P. Sands, Principles of International Environmental Law, Vpl I (Manchester University Press 1995), page 212. And J. Cameron and T.O’Riordan (Eds), Interpreting the Precautionary Principle (1994), 262.
Agreement, provided the measures are not arbitrary, discriminatory or amount to disguised restriction on international trade.

For the development of the Framework Convention on Tobacco control, the use of evidence supplied by various scientific researches from WHO and member States is overwhelming. This will constitute a satisfactory and legitimate risk assessment of the harm tobacco causes to human health. Thus, the SPS Agreement is in fact a strong basis to assert that WTO law and policy considers the protection of public health as an important component of its International trade work. Moreover, this ruling has widened circumstances for the application of rules under the agreement. For example, the use of reasonableness as a standard, the dispensing with procedural requirements for a risk assessment, the acknowledgement of scientific evidence from International organisations such as WHO, the objective assessments of issues and the fact that States rely on mainstream scientific evidence to effect legislation to protect human health all support the development of a global tobacco control Convention.

Relevant GATT Agreements

These agreements attest to the fact that GATT 1994 is not only an arrangement solely for trade objectives but does have health protection goals in the provisions of the various agreements.

Technical Barriers to Trade

The Agreement on Technical Barriers to Trade (1979 TBT Agreement) was negotiated during the 1973 to 1979 Tokyo Round and adopted in 1979. The agreement ensures that technical regulations and standards, including packaging, labelling and marketing requirements and methods of certifying conformity with technical regulations and standards, are not adopted or applied so as to create unnecessary obstacles to trade. All products are subject to the agreement. It provides for use of labels on products such as tobacco. The Agreement allows restrictive technical regulations, as an exception necessary to fulfil a legitimate objective. One of these is the protection of human health. In assessing such risks, relevant factors of consideration comprise scientific and technical information, related processing technology or intended end use products. The scientific evidence on the harm caused by tobacco is well established. The escape clauses such as “where necessary”, “except when” and “wherever appropriate” provide good arguments as tobacco Control is now a public health necessity for the international community. The Agreement further states that where urgent problems of health arise, members may omit procedural requirements for the adoption of the technical regulation. This expedites global tobacco control by restricting tobacco advertising, packaging, labels and regulation of nicotine levels in cigarettes. The provision that such actions be based on scientific evidence is relevant. WHO as the most authoritative world body

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on health matters has a wealth of scientific evidence on the lethal nature of tobacco products and trade.22

The Agreement seems cumbersome in application of the health exception but it is possible for a global tobacco convention to provide the impetus to enable States fulfil conditions for enforcement of technical regulations relating to health. Thus, the TBT Agreement is compatible with the development of the Framework Convention on Tobacco Control.

**Agreement on Sanitary and Phytosanitary Measures.**23

The Agreement provides that WTO members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health. These measures are to be based on scientific principles and shouldn’t be maintained without sufficient scientific evidence. Evidence from International organisations is recognised. Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between members States. These measures shall not be applied in a manner to restrict international trade. They should conform to the agreement and GATT 1994 measures relating to sanitary and phytosanitary measures especially Article XX (b) of GATT.

Member States shall harmonise these measures based on international standards, guidelines or recommendations, where they exist. However, members may introduce or maintain measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or if appropriate for a State. Further, sanitary or phytosanitary measures shall be based on assessment of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by relevant international organisations. In this, account shall be taken of available scientific evidence, testing methods, ecological and environmental conditions and or treatment.

On the relevance to tobacco control, the Agreement allows restrictions to protect human health. Tobacco control is protection of human health. The agreement enjoins international organisations to provide information as a basis for sanitary or phytosanitary measures. WHO is such organisation and the fatality of tobacco trade is well documented by the organisation. WHO provides global guidance in the field of public health. It promotes technical co-operation in this area and carries out programmes to control and eradicate disease. The International Health Regulations ensure maximum security against the international spread of diseases. The work of FAO in setting food standards in the Codex Alimentarius is also another acceptable standard. WHO effort to develop the Framework Convention on Tobacco Control is thus legitimate, compatible with WTO law, policy and practice.

**Agreement on Trade related Aspects of Intellectual Property Rights (TRIPS)**

The TRIPS agreement provides minimum standards for governing the use of intellectual property, including medical technologies and pharmaceuticals. It guarantees product and process patent protection. All WTO members are given a year

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22 Article 2 of the WHO Constitution grants these powers.
to fulfil obligations under the agreement, excepting developing nations have a 4 or 5 year grace period. Least developed countries have a 10-year transitional period. TRIPS like GATT, contains an exception for measures necessary to protect public health. Australian and South African health warnings of 25% of the packet fall under this category and these have not been challenged under TRIPS.

In the WTO Dispute Settlement Panel Decision on India-Patent Protection for Pharmaceutical and Agricultural Chemical Products, the United States complained that India was in breach of its obligations under the TRIPS Agreement. The Panel concurred with the US that India had failed to ensure adequate mechanisms for ensuring product patents for pharmaceutical and agricultural chemical products and processes. This decision and TRIP calls for harmonisation of intellectual property standards could help curb counterfeit unregulated cigarettes that flood developing country markets and increase the risks of the tobacco problem. This could help control smuggling of these products.

**Agreement on Import Licensing Procedures**

This provides for licensing of controlled goods such as tobacco and certain dutiable commodities, such as liquors and methyl alcohol. Hence restriction of tobacco using licensing poses no conflict with WTO rules provided the procedures laid are followed.

**International Convention on the Simplification and Harmonization of Customs Procedures, Kyoto 1974**

This has provisions relating to duty free sales in its Annex. The procedures to take to trade in duty free sales is laid down and this is compatible with the public health objective of controlling duty free sale of tobacco around the world which has increased tobacco use.

**World Trade Rules and Health: Concurrence or Conflict.**

There may be various views on the impact of International trade on the quality of health. A theory is that increase in per capita income does not necessarily damage health. A country with a stagnant economy will be under pressure to improve its health. The opportunity for countries to trade in world markets for goods and technology facilitates the implementation of needed health programmes at home. Paradoxically, an expansion of trade can produce negative health effects so large that they outweigh the conventional benefits from open markets, resulting in an overall decline in national welfare. The trade in tobacco is a typical example of this phenomenon. In case of tobacco, its no longer possible for developing nations to create appropriate tobacco control policy entirely on their own. Unilateral tobacco control policies may lead to friction with trading partners. What are thus needed are multilateral rules to guide countries in formulating tobacco controls. When a health problem involves a transborder physical spill-over, the only alternative to unilateral actions based on economic and political power is for countries to co-operate in the design, implementation and enforcement of an appropriate multilateral agreement for dealing with the problem at hand. The contribution of multilateral co-operation is to

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25 See World Bank: Curbing the Epidemic: Governments and the Economics of Tobacco Control, 1999, Pages 67-78.
reduce the possibility that solutions to the tobacco problem are affected by differences in the economic and political strengths of the parties involved. Given the justifiable basis for a diversity of tobacco control standards among countries, it is important to minimize the risk of solutions being imposed by larger or richer countries. Thus, this conference is timely and will involve the developing countries in seeking solutions to the tobacco problem.

Protection of health through tobacco control has promised to be important for the benefit of future generations. International tobacco control will involve rules of international co-operation, sanction or both, so that government actions to protect health of its population is not undermined by actions of other governments, for example smuggling of cigarettes. Such rules may involve trade-restricting measures.

Secondly, free trade is important for enhancing world economic welfare and trade restrictions may decrease achievement of this goal. These two theories of free trade and trade restrictions may seem conflicting. Indeed, there is evidence that health policy and trade policy are complementary in that increasing world welfare can lead to citizen demands and governmental actions to improve protection of health. The poor developing nations may not have effectual citizen demands for tobacco control. Hence forth, a framework Convention of this nature becomes imperative.

**Conclusion**

A stronger case exists for the development of the Framework Convention on Tobacco control. The fact that various WTO Agreements and Panel Cases have recognised the protection of human health and regulation of products give credence to the conclusion that a WHO global WHO Tobacco control convention is consistent to WTO law, policy and practice. What is needed is further elaboration by WTO of these rules relating to protection of human health. Any future disputes between trade law and protection of public health using the framework convention may be referred to the WTO dispute settlement mechanism. As can be seen from the decisions above, the WTO Dispute panel strongly bases its arguments on general International law. The WTO Rules on Dispute Settlement provides that member states recognise it as central to the multilateral trading system. Any provisions of the agreements are to be interpreted in accordance with customary rules of interpretation of public international law. Indeed the WTO Appellate Body affirmed this position in the case of United States – Standards for Reformulated and Conventional Gasoline.

Thus, if there is a conflict between WTO obligations and the implementation of a global tobacco control convention, the later Framework Convention on Tobacco Control can override GATT 1994 provisions if a state is party to both treaties. Under Article 30 of the Vienna Convention on the Law of Treaties, “when all the parties to an earlier treaty are parties also to the later treaty…, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty. If the provisions of two treaties are in conflict, the later in time prevails, as between the parties to both, unless one treaty specifies otherwise. Under Article 30 (4) (b), if a State is a party to only one of the parties to both, only that treaty governs. It’s a different matter if both States are parties to GATT and only one, a party to a global tobacco control convention.

Finally, it must be stressed that international law develops with pace of global changes, concerns and issues. The WTO trade regime is not averse to changing global concerns. Since 1970s and increasingly in 1980s, the fast
deterioration of environment led to global concern on protection of the environment. This hastened GATT formation of a Body on the environment in 1991. In 1994, WTO adopted a Decision which established a Committee on Trade and environment to raise and recommend to the WTO issues relating to the environment. Therefore, while environment issues have become an aspect of WTO trade regime due to global concern for the environment, so has increasingly become public health concerns which WTO needs to enhance its work. Tobacco is a major aspect of this global public health concern. There should be no conflict between WTO trade regime and the development of a global tobacco control convention.

IV. INTERNATIONAL HUMAN RIGHTS LAW AND PUBLIC HEALTH.

Overview

Global control of tobacco is an important facet of protection of public health. Public health is the science and art of preventing disease through organised community efforts for the sanitation of the environment, the control of community infections, the education of the individual in principles of personal hygiene, the organization of medical and nursing service for the early diagnosis and preventive treatment of disease, the development of the social machinery which will ensure to every individual a standard of living adequate for the maintenance of health, and organising these benefits in such fashion as to enable every citizen to realise his birthright of health and longevity. Grad, a leading United States expert in health law, has noted that “the reach of public health law is as broad as the reach of public health itself. Public health and public health law expand to meet the needs of our society” (Grad 1986). Thus, we can assert that international public health law is as broad as the reach of international public health itself as both expand to meet the needs of society.

The development of the Framework Convention on Tobacco Control is a mechanism to attain public health as defined. According to Jonathan Mann 26, “The goal of linking health and human rights is to contribute to advancing human well-being beyond what could be achieved through an isolated health or human rights based approach…. The health and human rights perspective offers new avenues for understanding and advancing human well-being in the modern world.”

A strong link exists between human rights and the tobacco problem. The increasing deaths resulting from tobacco consumption is a denial of human rights. The personal freedom of individuals to smoke (which too affects their health) must be balanced against the freedom of others to live in a smoke-free environment, and the responsibility of the State to protect public health of citizens and the expenses incurred by the State arising from tobacco use and problem. The argument by the tobacco industry that legislation to curtail the industry restricts the right to freedom cannot be accepted. In the US in 1989, Philip Morris launched a US$ 30 million campaign associating the company with the 200th anniversary of the Bill of Rights. Commenting on this effort to convey the image of the tobacco company as a great defender of the peoples liberties, John F. Banzhaf III, Professor of Law at George Washington University and Executive Director of Action on Smoking and Health (ASH) in the United States, said “It’s ironic that the manufacturer of the only legal product that enslaves most of its users is associating itself with freedom.

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26 Jonathan Mann and others, Health and Human Rights in Health and Human Rights, Fall 1994.
A powerful argument is advanced against this scheme by the industry to portray itself as defenders of human rights. In all countries, the government has the responsibility to protect the health of the people, particularly of the youth, to preserve the quality of the environment, to regulate trade and commerce, and to promote the public health, safety and welfare of its citizens. Government action for the welfare of society as a whole is generally upheld as valid even if it runs counter to the interests of some individuals, especially when there is compelling necessity for such action. Thus, the right of States to protect the health of its people by controlling the tobacco industry through the development of tobacco Control instrument takes precedence over the freedom of the tobacco industry to promote its harmful product. The lethal nature and deaths arising from the industry activities need not be overstated.27

Health is not simply the absence of disease. It is something positive, a joyful attitude to life, and a cheerful acceptance of responsibilities that life puts upon the individual. According to Stampar, President of the First World Health Assembly, the goal of medicine is social. It is not only the care of disease, the restoration of an organism. This became the notion of social responsibility for health as a whole, and the corresponding duty of individuals to care for their health.

According to Theo Van Boven, formerly Director General of UN Human Rights Office,

*Three aspects of the right to health have been enshrined in the International human rights instruments. These include, the declaration of the right to health as a basic human right, the prescription of standards aimed at meeting the health needs of specific groups of persons, and the prescription of ways and means for implementing the right to health.*

It is important to note that the global human rights movement and Human Rights Instruments stress the protection of vulnerable groups. These includes women, children, populations of developed and less developed countries and less educated segments of the population. The negative health effects of tobacco among these populations is well documented and the development of a global tobacco convention will conceptualise the realm of international human rights law.

**Applicable International and Regional Human Rights Instruments.**

There are various provisions for health in international human rights law. Foremost, the language of the Constitution of the World Health Organization endows the right to health. It states that:

*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions.*

The Universal Declaration of Human Rights(1948) provisions on health is fundamental. Paragraph 1 of Article 25 provides that, everyone has the right to a

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standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. Motherhood and childhood are entitled to special care and assistance. The WHO efforts to protect health of persons especially those of women and children from the scourge of the tobacco epidemic finds support here.

Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) provides that, the States parties to this Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties to the present covenant to achieve the full realisation of this right shall include those necessary for: the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child, the improvement of all aspects of environmental and industrial hygiene, the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Human Rights law has increasingly placed responsibility on States to control non-State actors. Thus, a State’s obligation to protect and promote economic and social rights includes the obligation to prevent non-state actors such as tobacco companies, advertising agencies and sports activities from promoting tobacco products which kill. The UN has already developed a code of conduct for multinationals violating environmental and labour standards especially in poorer countries. Holding tobacco companies for misleading advertisements targeting minors and fraud is now based on existing international practice. A global tobacco control law will further these aspects.

Article 24 of the Convention on the Rights of the Child (1989) provides that States Parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States parties shall strive to ensure that no child is deprived of his or her right of access to such healthcare services. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures: to diminish infant and child mortality, to ensure the provision of necessary medical assistance and healthcare to all children with emphasis on the development of primary healthcare, to combat disease and malnutrition, including within the framework of primary, through, inter alia, the application of readily available technology, and through the provision of adequate nutritious foods and clean drinking water, taking into consideration the dangers and risks of environmental pollution, to ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breast-feeding, hygiene and environmental sanitation and the prevention of accidents, to develop preventive health care and guidance for parents. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realisation of the right recognised in the present article. In this regard, particular account shall be taken of the needs of developing countries.

Although the Convention on the Rights of the Child does not contain any explicit right to protection of harms of tobacco, interpretation of the Convention by

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the Committee on the Rights of the Child and state practice demonstrates that tobacco is a human rights issue. The Committee has thus identified the issue of tobacco consumption as within the scope of the Convention. Under the State Party Reporting Guidelines established by the Committee, States are requested to,”...provide information on legislative and other measures taken to prevent the use by children of alcohol, tobacco and other substances which may be prejudicial to their health and available with or without restrictions to adults, and on any evaluation made of the effectiveness of such measures, with the data on use of such substances by children. The Plan of Action from the 1990 World Summit for Children also identified tobacco use as a problem requiring action, especially preventive measures and education among young people. Carol Bellamy, UNICEF Director has stated, “Children have a right to be protected from tobacco’s collateral effects—they have a right to health and development and their use of tobacco is frequently a consequence of denial of those rights. The main violators of children’s rights are the easily obtained legal substances, tobacco and alcohol”.

The Convention on the Elimination of All Forms of Discrimination against Women also makes provisions for protection of health of Women. Article 10(h) makes a provision for health education and information for women and their families. Article 11 provides for the right to protection of health and to safety in working conditions. It further provides that protective legislation relating to matters covered in this article shall be reviewed periodically in the light of scientific and technological knowledge and shall be revised or extended as necessary. Article 12 provides that States shall take all appropriate measures to eliminate discrimination against women in the field of healthcare in order to ensure access to healthcare services. Drug addiction and tobacco fall in this area. This is relevant for a global tobacco control law. Recent research in many parts of Africa and Asia has shown the tobacco industry is increasingly targeting women. A 1992 WHO Publication on Women and Tobacco showed 10% of women in Africa smoke and the figure is rising. Smoking and involvement of women in tobacco production all harm their health. The scientific evidence of the lethal nature of tobacco products justifies the development of the Convention to protect health of women and this finds support in CEDAW. Indeed the UN Committee on the Elimination of Discrimination Against Women in its General Recommendation 24 was on Article 12 covering women’s health throughout their life cycle. It has stressed increased expenditure for women’s health services.

Article 16 of the African Charter of Human and Peoples Rights provides that every individual, shall have the right to enjoy the best attainable state of physical and mental health. States parties to the present Charter shall take the necessary measures to protect the health of their people. A Protocol to the American Convention on Human Rights (1969), the Additional Protocol in the Area of Economic, Social and Cultural Rights (1988) makes a provision on the right to health. Article 10 provides that everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well being. In order to ensure the exercise of the right to health, the States Parties agree to recognise health as a public good and, particularly to adopt the following measures to ensure; primary healthcare is made available to individuals and family in the community, extension of the benefits of health services to all individuals subject to the State’s jurisdiction, universal immunisation against the principal infectious diseases, prevention and treatment of endemic, occupational and other diseases, education of the population on the prevention and treatment of health problems and satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.
Of importance is that many of these international human rights standards can be found in various constitutions and legislation in various States.29

The ICESCR, CEDAW and Convention on the Rights of the child are usually grouped as Economic and Social rights. Developing countries usually complain they are unable to implement these rights due to lack of funds. Recognising the need for some financial support, the prohibition of advertisement, increased taxes on tobacco sales and mass education on the dangers of tobacco will be less costly to implement.

These international human rights instruments can only be effective in enhancing the health of individuals, families, nations and communities if further implemented through national legislation. However, in case of tobacco, national legislation has not been effective due to the nature of the tobacco epidemic whose tenets are transnational. For example, internet advertisement, standard setting in tobacco products, smuggling and taxation issues and the fact that the industry is multinational have undertaken years of calculated deceit, national legislation is essential but insufficient. Thus, the development of the Framework Convention will help realise aspects of human rights law. Most of the instruments emphasise protection of health of the youth, mothers, massive health information and education. They provide for preventive/primary healthcare and also treatment of disease. These provisions are an ample legal basis for the development of the WHO Framework Convention on Tobacco Control. This is because its objectives will help realise health goals provided in the various human rights instruments.

In conclusion, quoting Dr Jonathan Mann of Harvard University, “The recent discovery of inextricable linkages between human rights and health is one of the great advances in the history of health and society…the major causes of preventable illness, disability and premature death around the world are caused as much by societal discrimination, inequity and injustice as by viruses or parasites….How many preventable cancers result from marketing of tobacco in the third world while violating the right to information about its dangerous consequences.”

V. DRUG LAW AND GLOBAL TOBACCO LAW.

World Health Organisation has been instrumental in guidance in the development of standards and regulations relating to drugs at country level. These include special reference to the Ethical Criteria for Medicinal Drug Promotion, endorsed by the World Health Assembly in a Resolution in 1988. Recently, WHO has prepared Guidelines for Good Clinical Practice for trials on pharmaceutical products. WHO has been actively involved in the so called ICH process, the convening of a series of International Conferences on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use which provides a forum for regulatory authorities and experts from the pharmaceutical industry of the EU, Japan and the US to discuss scientific and technical aspects of the marketing authorisation of pharmaceutical products. WHO has also being able to play a major role in the Organization of a series of international conferences of drug regulatory authorities, the recent one in Berlin in June 1999.

29 See for example, articles 39(e) (f), 42 and 47 in part IV of the Constitution of India which all provide for protection of health of men, women and youth. Chapter III of Constitution of Uganda makes a similar provision.
The UN Drug Conventions are relevant to global tobacco control. Article 2 of the Single Convention on Narcotic Drugs, 1961 as amended in 1971 provides that drugs specified in its schedules are subject to control and regulation. Under Article 3, where States or World Health Organisation in its opinion requires amendment of the schedules, it may recommend adding of such substance to be controlled either under schedule I or II. This means WHO has an international mandate under the Drug Conventions to opine that tobacco is a drug subject to regulation. WHO action to develop a global tobacco control Convention is thus a furtherance of existing international drug law. Article 32 (1) of the 1988 UN Convention against illicit traffic in Narcotic Drugs and Psychotropic Substances provides for dispute settlement among others by way of conciliation, negotiation, inquiry, mediation, conciliation, judicial process or other peaceful means of their own choice. Oversight monitoring functions have been granted to the International Narcotics Control Board. This can be applied for the monitoring of a global tobacco control Convention.30

The European Union has adopted instruments that make provisions related to drugs. Article 129 contained in Title X of the Treaty on European Union provides that the community shall contribute towards ensuring a high level of human health protection by encouraging co-operation between the member States and if, necessary, lending support to their action. Community action shall be directed towards the prevention of diseases, in particular the major health scourges, including drug dependence, by promoting research into their causes and their transmission as well as health information and education.

The European Free Trade Association (EFTA) has been active in the field of pharmaceuticals, having been responsible for the development of the Convention for the Mutual Recognition of Inspections in respect of the Manufacture of Pharmaceutical Products (Pharmaceutical Inspection Convention (PIC) and for the Scheme for the Mutual Recognition of Evaluation Reports on Pharmaceutical Products (PER Scheme). This Convention, originally signed in October 1970, has been joined by many countries that are not members of EFTA, while a number of additional countries have shown an interest in accession.

Currently, the deadly forms of nicotine delivery-tobacco products, are the most widely available and least stringently regulated, while the safest forms of nicotine delivery-medicines designed to help those addicted to tobacco to quit smoking are strongly regulated. This amounts to preferential treatment of tobacco products over treatment products. This state of affairs even in the developing world has led to calls for levelling of the playing field between the regulation of medications for treating tobacco dependence and the regulation of tobacco products.

It should be noted that tobacco products are the only dangerous products that are not regulated. Many products including medicinal drugs, food and toxic chemicals are often regulated. During the Ninth International Conference of Drug Regulatory Authorities (ICDRA), the Director of the WHO, Dr Gro Harlem Brundtland had this to say. “Cigarettes are inherently dangerous products. One of the largest transnational tobacco companies opposes tobacco content regulation. Yet this company has a food products division whose contents are regulated. How can we justify that the contents

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30 See Jimmy Gurule, The 1988 U.N. Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances – A Ten Year Perspective: Is International Cooperation merely Illusory? 22 Fordham International Law Journal, 1988; David P Stewart, Internationalizing the War on Drugs: The UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 18 Denver Journal of International Law and Policy, 387/8, Spring 1990. These have further discussed the implementation of the UN Drug Conventions.
of food products, made by a company are regulated but that the contents of cigarettes, another of its products, are not.

It needs to be noted that in order to protect health of consumers; governments have the general responsibility of restricting distribution of dangerous products. This usually covers pharmaceutical products as well as toxic chemicals and addictive drugs, usually given to drug regulatory authorities. Drug and food regulation usually exist to protect health. Marketing of pharmaceutical products should be regulated so as to ensure not only the safety but also the efficacy of the product.

Many developing countries have been slow to recognise that legislation constitutes an important input in the health sector and that the formulation of policies must be followed by an appropriate legislation to give effect to such policies. There are other reasons to develop global regulation of contents of tobacco especially nicotine. Recent research has shown that there are about 4000 other dangerous substances found in cigarettes.

In many countries including developing nations, many legal systems are structured on the premise that what is not prohibited by law is permissible. By sanctioning certain activities, subject to various rules and conditions, and by prohibiting other activities, a law clarifies what individuals or corporate bodies may and may not do. Laws on regulation of cigarette content may for example proscribe dangerous products in cigarettes. To permit control policies to be implemented, there is need to have an authority whose powers and duties are laid down by legislation. For example, they can have the power to cancel, modify and suspend a licence. Legislation in developing world has also helped to ensure that the pharmaceutical products are of acceptable quality, safety and efficacy. These applicable standards must be laid down in a legal instrument or other document having the force of law, and non-conformity with such standards must entail appropriate penalties. Some of these standards are enforced through registration, certification and information dissemination. These lay strategies for the assurance of drug quality, safety and efficacy.31

Registration is usually based on information, which comprises administrative data, toxicological, pharmacological, pharmaceutical, and therapeutic and clinical data. Developing countries have prescribed varied grounds for which registration of drugs may be denied. For example, in Kenya, a certificate may be suspended or revoked if new information has been discovered by the Pharmacy and Poison Board indicating that the drug is unsafe or dangerous. Other conditions may include: procurement of the registration by fraud or misrepresentation, violation of the conditions subject to which the drug was registered, public interest, misleading advertisement etc. Tobacco products fall in this category and could be regulated.

Thus, there is an imperative justification to regulate tobacco products and contents like by legislation. The Framework Convention on Tobacco control will lay threshold standards and different States can then enact national legislation to implement this to attain the objectives of national tobacco law. Regulation of tobacco would be a two pronged approach. First is the regulation of tobacco products especially nicotine and other many harmful contents of tobacco. Second aspect is the regulation of products that reduce tobacco dependence. This will involve for example fast track requirements aimed at hastening the approval and use of cessation products. Existing legal framework in developing countries for regulation of drugs or pharmaceuticals could be amended to cater for regulation of tobacco products. For

31 See D.C Jayasuriya; Regulation of Pharmaceuticals in Developing Countries, Legal Issues and Approaches, WHO Geneva, 1985.
example in New Zealand, the Poison Act has been utilised to regulate tobacco products. The second option is to develop entirely new Statute law to specifically address regulation of tobacco products. In this way, the role of the Framework Convention on Tobacco Control will be instrumental in setting basic framework and setting the problem clearly in a trans-national context.

VI. CONCLUDING REMARKS AND RECOMMENDATIONS

The International legal framework for the development of WHO Framework Convention on Tobacco Control is well established. WHO Constitution provides an adequate legal basis. There is concurrence between international trade law and international human rights law on protection of health, from tobacco epidemic. The intensity of the tobacco problem on developing countries calls for their full participation in this international law making and implementation process if tobacco related deaths are to be controlled. Salient recommendations in the legal, policy and institutional area should include the following:

   Developing countries should establish national institutions to support the development of the WHO Framework Convention on Tobacco Control. This can help establish a national framework for tobacco control within the States. These could utilise international legal standards relating to health and support the development of the Convention.

   Developing Countries and the International Community should work with WTO and its member States to establish a Committee on Trade and Health. This could be similar to the one established by GATT on the Environment in 1971 and strengthened in 1994. It could examine upon request any specific matters relevant to the trade policy aspects of measures to protect health with regard to the application of the provisions of GATT taking into account the particular problems of developing countries. The current negotiations in Seattle could be a starting point for this.

   Developing countries should harmonise their strategies for tobacco control and use the Framework Convention on Tobacco Control as a vehicle for tobacco control. Technical consultation such as this could serve to develop a solid base for the participation and implementation of the Framework convention in Developing States.

   The International community especially WHO should use the Convention to address the specific problems of developing countries on tobacco control. WHO should increase technical support to developing countries for the negotiation and implementation of the WHO Framework Convention on Tobacco Control.

   WHO should enhance collaboration with the larger international and regional Human rights machinery. The joint study by WHO and UNICEF on tobacco and children’s right and a WHO study on CEDAW is a good start. WHO focus on the tobacco problem should involve the human rights community concerned with the right to health. This would enable for example, the ECOSOC to emphasise dialogue with representatives of ratifying States on the right to health and the necessity for governmental action to curb tobacco use and problem. The chairing by WHO of the Adhoc UN Task Force on Tobacco control is a positive step in that direction which needs to be strategically used for this purpose.