CHAPTER-V

BIOPIRACY AND SPECIFIC HEALTH ISSUES

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BIOPIRACY AND SPECIFIC HEALTH ISSUES

Geographical Indications and Biopiracy

What the world was not fully aware of was another danger, what has come to be termed bio-piracy, international companies while patenting traditional medicines or foods; it is not only that they seek to make money rightfully belongs to the developing countries, but in so doing, they squeeze domestic firms that have long provided the products. Protection of traditional knowledge and culture or the allowance of the patent holder’s right to exclusively work on the specialized area, has led to encroachment to the traditional knowledge by the patent holders of the developed countries. This led to biopiracy, Biopiracy refers to the use of intellectual property systems to legitimize the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialized cultures. There has been growing discontent amongst developing countries about the biopiracy i.e. unfair exploitation and monopolization of public domain knowledge and resources. The act of biopiracy is principled on western hegemonic biasness against other cultures. This fallacy of sociological and cultural displacement as an epistemological shift generating new knowledge is made possible as a result of colonial biases which have treated western knowledge systems

as exclusively scientific and non-western knowledge systems as unscientific. Indigenous systems of knowledge were defined as inferior, and in fact, unscientific.\(^4\) It includes the knowledge of ‘indigenous people’ or ‘tribal people’ but it is not limited to these specific categories. In fact, it is partly amorphous concept which covers all knowledge systems which are not based on the western system of scientific and technological development.\(^5\) Therefore, patenting of new drugs or new medical devices is driven by two opposing forces: one is that the inventor, either a private person or pharmaceutical giant, desires and needs profit, the other force is ethical, the interest of other people.\(^6\)

The western society is extremely atomized or based on individual liberalism. Whereas the non-western societies are alternatively established essentially on the principles of collectivity, plurality, diversity, heterogeneity. Therefore there is no concept of ‘private property’ in the community for common resources. The non western societies do not consider their heritage in relation with property in a very categorical manner, whereas western societies unequivocably prohets the conception of owner and economic benefit regarding traditional knowledge and heritage. For indigenous people, heritage is a bundle of relationships rather than a bundle of economic rights.\(^7\)

The traditional knowledge remains the part of public domain and remains freely accessible to the researchers or corporate giants for R & D, Thereby the patent holders apply basic knowledge freely accessible

\(^4\) Supra Note 2 pp. 51-52.
\(^7\) Supra Note 2 p.48.
to them and later after patenting restrict its public usage. In general, intellectual property rights over traditional knowledge related inventions thus foster a direct or indirect shift in property rights from traditional knowledge holders towards intellectual property rights holders. The IPR regime has again led to the ‘drainage’ on the part of traditional and community knowledge. The magnanimous corporate houses specially dealing in food products and pharmaceuticals or the highly sophisticated techno research institutes claim patent rights of exclusive functioning over the area, which makes the indigenous discriminated, relegated, exploited, excluded and alien to all the economic benefits extracted by the developed western society. Like the genes from the pattambi rice variety in Kerala in southern India were used to induce pest resistance in rice crop of south East Asia saving it from the brown leaf hopes attack during last decade. The Pattambi farmers are still poor but the seed companies flourished.

India is continuously becoming a victim of the biopiracy of its genetic resources at the hands of multinational agro business companies of the developed nations chiefly the US. Biopiracy is the illegal appropriation of life-microorganisms, plants and animals (including humans)- and the traditional cultural knowledge that accompanies it. Biopiracy is illegal, because it does not recognize, respect or adequately compensate the rightful owners of the life forms appropriated or the traditional knowledge related to their propagation, use and commercial benefit. The IPR regime provides tremendous incentive to indulge in

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biopiracy, by granting patent, on little innovation on genetic resources using existing indigenous and traditional knowledge.

There are patents on neem, turmeric (haldi), bitter gourd (karela), black cumin seeds (kalajira), brinjal, basmati, etc. The prominently important among them is the popular Indian variety of rice that is 'Basmati'. Rictec, a Texas based firm of the US collected specimens of basmati rice from the Indian subcontinent and cross bred them with other varieties and eventually patented them under names: such as ‘Texmati’, then ‘Kashmati’ and ultimately ‘Basmati’. The effect of the patent was that the Indian Basmati could be prevented from being exported to Middle East, Europe and US itself. Rictec claimed novelty because its Basmati, although identical in taste and aroma to the sought-after rice variety produced in India, has been produced by following a different method and in a different terrain. It is a blatant case of biopiracy of genetic resources of the developing countries, as no variety of Basmati could be developed without the original germplasm.

The US government’s decision to grant a patent for the prized Basmati rice violates the TRIPs Agreement. Basmati rice is traditionally grown in the Indian subcontinent and by granting a patent to it, the US violated the geographical indications provisions under the TRIPs Agreement. Article 22(1) of the TRIPs Agreement covers the protection of goods whose ‘quality, reputation or other characteristics’ are ‘essentially attributable’ to their geographical origin. Article 22(2)-(3) further provides that the Member-states shall ensure that geographical indications do not mislead the public about the origins of a produce or the quality of the product. They are under an obligation to refuse or invalidate any protection to such misleading trademarks.
As a result, it can be said that Basmati rice is as exclusively associated with the Indian subcontinent, as champagne is to France and Scotch whiskey is to Scotland. Just as the US cannot label their wine as champagne, they should not be given the right to label their rice Basmati. The Government of India challenged the claim through the Agricultural and Processed Food Products. Export Development Authority (APEDA). The authority produced clinching evidence for establishing the Indianness of the variety of rice which is popular all over the world for its large grains and appetite-building aroma.

Previously, also the US had granted a patent to a US firm, on the use of ‘turmeric’ as a wound healing agent. The Counsel for Scientific and Industrial Research (CSIR) successfully challenged the patent for turmeric on the ground that the healing properties of turmeric had been ‘common knowledge’ in India for centuries. There is a clause in the US patent laws that will accept any information already available in published or written form anywhere in the world as ‘common knowledge’. As a result, India was able to furnish published evidence to support their case that the healing characteristics of turmeric are not a new invention and as such cannot be patented and the patent granted was cancelled.

The outcome in the Basmati case was not desirable in the still ongoing dispute at the US Patent and Trademark Office (USPTO) between Rictec and the Indian government. India lost its battle against the patenting of the world famous Basmati rice as the USPTO sustained the patents granted to three hybrid strains developed by the US firm, which according to the USPTO are ‘similar or superior’ to the Basmati
tradiitionally grown in the Indian subcontinent. Although USPTO's order does not allow the use of the word 'Basmati' as a trademark, Rictec can not sell its product as 'Bas 867' and label it as 'superior basmati rice'. As no variety of basmati rice can be developed without the original germplasm.

Besides pleading on the basis of 'geographical indications provisions, there is another strong line of argument. The patent granted to Rictec’s super Basmati was ‘product-patent’. For a product to acquire process/product-patent it is necessary that the product is the result of an ‘inventive’ step. In other words, the product must be ‘novel’ in characteristics. Rictec’s super basmati was the result of cross-breeding of the different varieties of basmati rice taken from the Indian subcontinent. However, the taste and aroma was identical to that of Indian basmati. If Rictec’s basmati is considered to be a ‘new’ product on the basis of its different genetic constituents, Indian basmati, which is distinct in genetic constituents from its Rictec counterpart, cannot be prevented from entering the US. On the contrary, If Indian basmati is sought to be denied entry for having identical taste and aroma to that of Rictec’s super basmati then Rictec’s basmati cannot be considered to have fulfilled the ‘novelty’ requirement over the Indian basmati, because grant of the product-patent, in that case would be illegal and violative of Article 27(1) of the TRIPs Agreement. Hence, the patent given under the name of ‘Basmati or otherwise i.e. ‘Super Basmati’/Bas

11 Ibid.
12 TRIPs Agreement, Article 27(1).
867, as long as that variety is substantially identical to 'Basmati' of the Indian subcontinent, is liable to the rejected.

1995, the US multinational company, WR Grace Co, patented neem-based bio-pesticides, Neemix, for use on food crops. Neemix suppresses insect feeding behavior and growth in more than 200 species of insects for which the European Patent Office (EPO) initially granted the patent to them. But the Indian government successfully argued that the medicinal neem tree is part of traditional Indian knowledge. Leading the campaign in the neem case was the EU Parliament's Green party, India-based Research Foundation for Science, Technology and Ecology (RFSTE) and the International Federation of Organic Agriculture Movements (IFOAM). In 2000, the challenge came out victorious, but the US multinational went in appeal. But on March 8, 2005, the appeal was lost.\(^{13}\) The main plank of RFSTE's challenge was that the fungicide qualities of the neem tree and its use had been known in India for over 2,000 years. The neem derivatives have also been used traditionally to make insect repellents, soaps, cosmetics, tooth cleaners and contraceptives. Under normal circumstances, a patent application is rejected for want of novelty or inventiveness, if there is prior existing knowledge about the product. Hence, the EPO agreed that the process for which the patent had been granted had actually been in use in India for many years.\(^{14}\)

In most countries to obtain a patent, an invention must be useful and novel (not publicly known or used by others), and must satisfy the standard of inventiveness denominated in the United States as 'non-obviousness'. It is sometimes said that mere discoveries are not


\(^{14}\) Ibid.
patentable. Patentable subject matter may include any useful process, machine, or composition of matter.

This is the reason that host communities have difficulty in proving the 'novelty' requirement for patenting an innovation, since their knowledge has often been in the community for generations. This extended time factor also works against the granting of IPRs, which grant exclusive property rights over knowledge for a much more limited time period. The main problem for the application of IPRs to a biodiversity information holder is the novelty requirement for patenting innovations. As specified by the TRIPs Agreement some degree of novelty, \(^{15}\) ingenuity and recognition of utility must be required for a system of 'discovering rights', to work.

The TRIPs Agreement does not provide any definition of invention. With the advent of biotechnology, the distinction between invention and discovery has become blurred. The US patent law does not differentiate between invention and discovery\(^{16}\) allows the granting of a patent in respect of the purified form of a natural product, if it is found in nature only in a non-purified form. Resultantly, a very thin line separates invention from discovery. Considering that the TRIPs agreement is modeled on the lines of the US patent law, seeking patents on mere discoveries might be considered the international norm, on patent laws under new IPR Regime. There are US patents drawn on the medicinal properties of Amla Jar Amla, Salai and other Indian plant species. Indian pharmaceutical companies too have a field for patents on the healing properties of some of the well-known herbal sources like

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\(^{15}\) 'Patents shall be available for any inventions, whether products of processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.' - TRIPs Agreement, Article 27(1).

\(^{16}\) D. Sharma, 'Patent India’s Biodiversity', in Hindustan Times, 16 December 1998.
Brahmi, Arjuna, Lodhara, Kantakari, Gokshoor, Chitrak and Vidang. This illustrates the growing trend even within the country, to seek monopolistic control over the process for the manufacture of an extract based on Ayurvedic medicinal plants. If discoveries could be patented under the TRIPs Agreement, India would be able to claim ownership over the country’s huge biological resources i.e., 45,000 plant species and 75,000 animal species.¹⁷

The two cases of turmeric and Neem explicitly and categorically articulate the hegemonic oppression of the IPR regime. The turmeric was patented in U.S. by two researchers based at the university of Mississippi Medical centre. Whereas turmeric has been inherently grown and used in India for healing purposes, for ages. The patent was challenged and later became invalid on 28th March 1999.

**Case of the Turmeric Patent**

Suman K Das and Hari Har P Cohly, two researchers based at the University of Mississippi Medical Center in Jackson, Mississippi applied for a United States patent on the use of turmeric in wound healing. More specifically, the application related to the use of turmeric to augment the healing process of chronic and acute wounds. The inventors claimed to ‘have found that the use of turmeric at the site of an injury by topical application and/or oral intake of turmeric will promote healing of wounds.’ This was based on experimental evidence showing that turmeric cause endothelial cells to proliferate, indicating that this molecule can be used to augment wound healing. The patent application acknowledged that turmeric has been used for a long time in India as traditional medicine for the treatment of various sprains inflammatory

¹⁷ Ibid.
conditions. The specific claims of the inventors were (1) A method of promoting healing of a wound in a patient, which consists essentially of administering a wound healing agent consisting of an effective amount of turmeric powder to said patient; (2) The method according to claim, wherein said turmeric is orally administered to said patient; (3) The method according to claim, wherein said turmeric is topically administered to said patient; (4) The method according to claim, wherein said turmeric is both orally and topically administered to said patient; (5) The method according to claim, wherein said wound is a surgical wound; (6) The method according to claim, wherein wound is a body ulcer. The parent was granted in 1995 on the basis of limited searches for prior art which did not indicate the claims were part of the public domain. Subsequently, it came to the attention of some people that a patent had been granted on properties of turmeric which were widely known to India and in the public domain for long since the patent had been granted in the United States, the only possible way to object to the patent was to take legal action in the United States. As there was no specific individual or group affected by the patent, the Council of Scientific and Industrial Research Challenged the patent to have it revoked on the ground that the alleged invention was actually part of public domain knowledge in India. The patent was re-examined, all the claims were cancelled and the patent expired on 28 March 1999.  

Case of Neem Related Patents

Neem could be easily regarded as a second name for India. From centuries Indians have been using neem (Azadirachta Indica) for various

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purposes, owing to its medicinal properties. For Indians neem is considered as an integral and indispensable part of their personal and communitarian life. The neem is therefore referred as the ‘free tree’ of India.\(^\text{19}\) However a US timber importer Robert Larson was granted a patent on pesticidal neem extract from U.S. Environment Protection Agency (EPA) in 1985. W.R. Grace bought this patent from Larson three years later. Grace after several unsuccessful negotiations, set up a joint venture with a firm PS Margo Pvt. Ltd. By this mutual exchange, the Grace company would process several tones per day.

“The company’s demand for seed had three primary effects;

1) The price of neem seed had risen beyond the reach of the ordinary people; in fact, neem oil itself, used by local people to light lamps, practically became unavailable any more as local oil millers are not able to access seed.

2) Almost all seeds collected, which were freely available to the farmers and the indigenous health practitioners were purchased by the company because of its economic power.

3) Poor people had lost access to a resource vital for their survival, resource that was once widely and cheaply available to them.\(^\text{20}\)

Later the patent was challenged on the basis of process of extraction’ and ‘prior public use’. In 2005 the patent was declared invalid.

\(^{20}\) Ibid, p. 59.
The neem tree has various uses in households and in agriculture throughout India. Farmers have, for instance, used leaves from the neem to make effective, pesticides for a long time. In recent decades, properties of the neem tree have been the object of substantial attention and large-scale research has been carried out to turn some of the neem’s properties into commercially viable products.

Attention has focused specifically on uses of neem as a biopesticide because of the commercial potential in this area the challenge has generally been for manufacturers to extract the active properties of the neem and find way to increase the shelf life of the product. Indeed, one of the characteristics of the natural formulation is that the preparation only lasts a few days thus making commercialization of the leaf extract very difficult.

A number of neem-related patents have been granted in the US and Europe to Indian and foreign companies and inventors. Their common characteristic is that the patents generally claim novel process for making a neem processes or making a neem-based or neem derived pesticide and the resulting product.

Among the many patents applied for, WR Grace patent claiming a method for long term storage of the active pesticidal ingredient (azadirachtin) became the center of vigorous debates. In 1992, the United States Patent and Trademark Office issued a patent to WR Grace which covers a method of creating stabilized azadirachtin in solution and the stabilized azadirachtin solution itself. Subsequently, the US Environment Protection Agency registered Grace’s stabilized azadirachtin solution for use on food crops under the name for Neemix (Wolfgang.)
WR Grace, also filed for a patent for neem as an anti-fungal product with the EPO which was awarded in 1994. This patent claimed the invention of a novel insecticide and foliar fungicide derived from a neem seed extract and the processes to obtain the neem oil. This pesticide was alleged to have the ability to repel insects from plant surfaces, prevent fungal growth, and kill insect and fungal pests at various life stages.

This patent was challenged because the extraction process was not sufficiently different from traditional processes used. The Opposition Division of the EPO revoked the patent in 2000 after the opponents successfully argued that there was prior public use and the claims were therefore not novel.

An appeal was filed in April 2001 focusing on some procedural issues and claiming that the main affidavit on which the decision to revoke the patent was taken should not be taken into account. The appeal was upheld in March 2005.

The above cases make it amply clear that biopiracy is another outcome of the new patent regime which makes it difficult for the developing countries to protect and preserve their collective traditional knowledge.

**Specific Health issues and WTO Agreements**

The WTO Agreements explicitly allow governments to take measures to restrict trade in order to protect health. The emphasis in WTO rules is on how policies are carried out without hampering the underlying objectives of public health. It requires to look for the ways

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21 Source : Cullet Philippe, Intellectual property Protection and Sustainable Development, Butterworth's, New Delhi, 2005, pp 302-303
and means which are less restrictive in terms of trade and simultaneously do not compromise with the objectives of public health. Establishing synergy between health objectives and international trade policies is indeed a challenging task before the governments.

Different countries have dealt with the health and trade policies according to their own requirements. In this regard there are several important health issues facing national policy makers, which relate to one or more of the WTO agreements. Some of the important health issues are food safety, infectious disease control, Tobacco control etc. Trade relevance and applicable WTO agreements as to these issues are illustrated in the succeeding part.

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1. Mention is made of only the most relevant agreements to the specific health issues.
Important Health Issues

- **Infectious Disease Control**

Cross-border movements of people as well as trade in goods and services are increasing the challenges for infectious disease control. The risk of infectious disease rises with increased mobility of people, growth in international trade in food and biological products, and social and environmental changes. These developments affect all elements in the infectious disease chain: hosts (people), agents (microbes causing disease), and vectors (means by which microbes come into contact with people).

The multiple transmission methods and the increase in volume of trade of all kinds means that to effectively control disease outbreaks in today’s world, public health officials need to collect and disseminate information quickly. Likewise, trade officials who negotiate and implement trade agreements need to be aware of health risks. In most cases, sound public health practice will focus on the mode of transmission for example, sexual behavior and drug use in the case of HIV/AIDS-rather than restrict the mobility of people or goods.

In exceptional circumstances, infectious disease control may require trade or travel restrictions. In the past, disease outbreak control concentrated on quarantines or trade embargoes. In recent years, a combination of sensitive early warning surveillance systems, rapid verification procedures and international response networks, epidemic

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22 In the past, as witnessed by Peru-cholera, 19914; India-plague, 1994. Most embargoes were avoided during the recent nipah virus and H5N5 outbreaks in Asia by destroying animals.
preparedness plans and stockpiles of essential medicines has reduced the need to employ trade embargoes or travel restrictions. To the extent trade restrictions are used, they should be time-limited and try to minimize disruption to international trade. This is one of the fundamental principles underlying WHO’s current revision of the IHR. The renewed International Health Regulation (IHR) will serve as the legal framework for WHO’s efforts to prevent disease epidemics from spreading globally. The historic purpose of the IHR is to “ensure the maximum security against the international spread of diseases, with a minimum interference with world traffic.” This purpose will continue in the new IHR.

Specific measures used to control infectious diseases, whether adopted by national governments, or recommended by WHO in the performance of its IHR duties, may be subject to WTO rules if they affect trade in goods or services. Which rules are relevant will depend on the circumstances of the particular case. For example, while sanitary measures to halt the spread of a food or animal borne infectious disease could have a substantial trade impact and would be covered by the SPS Agreement, it is unlikely that regulatory action aimed at mitigating such risks whatever the pathway or nature of the disease—would run contrary to WTO rules.

However, much depends on how this health objective is enforced in practice at the border. WTO rules require, for example, that the measure used should be properly balanced between the importance of the health interests protected, the efficacy of the measure and the impact of the law on imports and exports— to the extent that this is feasible without compromising the intended health objective. If it is possible to
enforce the health objective through checks or sampling rather than an outright ban, that would be preferable as it is the measure which would least interfere with trade while guaranteeing the level of health protection chosen by that Member. Since quarantines and trade embargoes are associated with substantial economic losses, these restrictions run the risk of being challenged unless they are unquestionably justified by the severity of the health risk. Likewise WTO rules on non-discrimination apply if a country's sanitary measure addresses a risk in products coming from one country but ignores similar risks in products originating from another country, the measure might be challenged as discriminatory. Such discriminatory action could flag, or serve as a warning signals that the objective behind the measure at issue may not solely be concerned with protecting health.\textsuperscript{23}

\textit{Case of Safety of imported fish during a cholera outbreak}

In early 1998, Tanzania complained in a SPS Committee meeting that the European Communities (EC) was unfairly blocking imports of fish from certain African countries. In response, the EC told the WTO SPS Committee that it had indeed banned imports of fruit, vegetables and fish products in light of a cholera outbreak in Tanzania, Kenya, Uganda and Mozambique. EC inspection procedures in these countries had uncovered deficiencies, and while, were trying to develop a joint cholera policy based on risk assessment.

A WHO investigator had told the EC that she did not consider the ban on fish imports necessary since fish products were not consumed in raw form in Europe. She cited the WHO Guidance on Formulation of

\textsuperscript{23} Joint Study Report of WHO and WTO 2002 P. 60.
National policy on the Control of Cholera: "Although there is a theoretical risk of cholera transmission associated with some food commodities moving in international trade, this has rarely proved significant and authorities should seek means of dealing with it other than by applying an embargo on importation".

In June 1998, Tanzania reported to the SPS Committee that the EC continued to prohibit the importation of fresh, frozen and processed fishery products from the four African countries, although tests had not found the bacteria concerned. Tanzania stressed that the EC ban was having severe effects on its economy. After a WHO official attested again this time to the SPS Committee that there was no proven risk of cholera transmission from the foods in question, and after an EU Scientific Committee reiterated this statement, the European Communities agreed to resume trade on 1 July 1998. The case underscores the importance of basing trade-restrictive public health measures on scientific evidence, rather than theoretical risk. It also demonstrates the usefulness to the SPS Committee of WHO recommendations based on the specific health risks of each situation.  

Cholera is a long-standing endemic disease with well-known control measures. But the modern era has witnessed the emergence of new global health security threats, for which control measures are still evolving. HIV/AIDS was unknown until about 20 years ago and new pathogens have come to light, such as the Ebola and Marburg viruses. In addition, many "older" diseases (such as tuberculosis, malaria and

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24 Ibid.
sexually transmitted diseases) have become a greater threat because they have developed resistance to the drugs commonly used to treat them.\textsuperscript{25}

These developments persuaded WHO in 1995 to call for a revision of the IHR. It had become less useful as a tool to control the global spread of disease for several reasons. IHR covers only plague, cholera and yellow fever, while global health security can be threatened by a far wider set of diseases and infectious agents. In addition, the IHR “maximum measures” for control needed to be more flexible to design solutions to the particular circumstances surrounding each risk. Furthermore, IHR contains no enforcement provisions nor does it have any incentives to promote adherence to its recommendations and depends on the willingness of countries to make official notifications to WHO, which they have little incentive to do given the potential economic costs.

- \textit{Food Safety}

WHO estimates that world-wide almost 2 million children die every year from diarrhea, most of this caused by micro biologically contaminated food and water. Even in industrialized countries it is estimated that one third of the population suffers from food borne disease every year, and out of these may be up to 20 per million die. Considering that these figures only relate to microbiological problems, the addition of chemical contamination of food makes the situation extremely serious. The epidemic nature of outbreaks of food borne disease varies from localized and self-limiting out breaks- which would

\textsuperscript{25} There have been other recent outbreaks relevant to trade, such as the H5N5 outbreak in Hong Kong (poultry, fowl), nipah virus in Malaysia (pigs) rift valley fever (cattle) in Ethiopia. All of these diseases “crossed over” to humans.
not be relevant to international trade—- to rapidly spreading epidemics that can quickly cross international borders via trade.\(^{26}\)

Several new sources of food-borne diseases are of increasing relevance to international trade. In the past few years, chemical hazards in food-related products have been the source of several limited, but highly publicized health crises, for example the contamination of animal feed by dioxin in Belgium that affected food products throughout Europe. Changing patterns of farming and animal husbandry can also affect food safety, illustrated by the spread of mad cow disease and its onward transmission to people. The widespread use of antibiotics in animal husbandry has contributed to increased levels of antibiotic-resistant bacteria in humans. In addition, the safety for human consumption of certain genetically modified foods is a matter of concern to some.

Food safety concerns come into play in the context of international trade in foods, which has grown substantially over the past 10 years. Agriculture and food exports are essential to most developing countries as many have a comparative advantage in agricultural production. Furthermore, the trend towards the export of more and more processed food is increasing the importance of sanitary and phytosanitary measures and the SPS Agreement.\(^{27}\) Also, as tariffs and other classical barriers to trade are likely to fall further in the context of further agricultural reform— including support to agricultural production

\(^{26}\) A big burden of food-borne disease also lies in the sporadic cases, which are not linked to outbreaks, and therefore typically are not recognized or reported.

in the richer countries- the relative importance of non-tariff measures is likely to increase.

SPS and Codex

Need for uniform standards was felt a long back. In order to pursue this aim the Joint Food and Agriculture Organization/World Health organization (FAO/WHO) Codex Alimentarius Commission (Codex) was established in 1962 to establish standards for food safety. The Commission currently has 165 member governments who, with the advice of independent technical experts selected by FAO and WHO, develop food standards, guidelines and recommendations for the protection of consumer health. Codex recognizes the importance of minimizing the effect of such regulations on food trade. Member states formally endorse Codex standards, after thorough reviews of scientific papers based on widely accepted risk assessment procedures. While it remains voluntary for governments to apply Codex standards, there are strong incentives to do so, as food production that meets Codex standards can facilitate trade by creating greater export opportunities.

Several new ideas are being integrated into Codex recommendations and standards, Codex now recommends using a risk-based preventive approach in achieving food safety, and promotes the use of formalized Risk analysis. An example of a approach is the implementation of the Hazard Analysis and Critical Control point (HACCP) system. HACCP encourages the food industry and governments to target limited resources to the most critical steps of food production and distribution, rather than having to comply with a long list of product and procedure specifications as had been traditionally
prescribed. HACCP often requires reorientation of food safety authorities towards audit and training functions, rather than on physical inspection and laboratory analysis. Although HACCP does not completely eliminate the necessity for final product inspection, the concept of process controls is central to HACCP national food safety programs.

Codex is in the process of elaborating general standards covering food additives, contaminants and toxins to provide a wider basis for protecting consumers' health. Countries can better adapt themselves to this approach by implementing a generic regulation applicable to a wide range of products rather than maintaining an inventory of registered foods with specifications for each.

As opposed to some other "health issues", food safety has one WTO Agreement which is specifically relevant: the SPS Agreement. It applies to any trade-related measure taken to protect human life or health from risks arising from additives, contaminants, toxins, veterinary drugs and pesticide residues, or other disease-causing organisms in foods or beverages. The SPS Agreement clearly gives governments the right to restrict trade to achieve health objectives, but the measures applied must be based on scientific evidence.

The SPS Agreement formally recognizes the food safety standards, guidelines and recommendations established by the FAO/WHO Codex Alimentarius Commission (Codex). The recognition of Codex standards eliminates the need for each country individually to do its own risk assessment for any given hazard for which a standards,

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recommendation or guideline exists. If countries adopt national food safety standards that are not more stringent than the Codex standards, and have mechanisms for monitoring compliance among food producers and exporters with these standards, then their food safety measures are presumed to be consistent with SPS provisions. Recognizing that many global food safety issues lie beyond the reach of international trade agreements. WHO together with FAO and national governments are stepping up efforts to ensure that consumers across the globe are protected from threats to food safety from a wide range of sources.

After coming into the force of SPS Agreement in 1995, more than 100 specific trade concerns have been raised in the SPS Committee, of which about 30 are directly relevant to food safety. The remaining trade concerns have dealt with animal and plant health issues which are equally relevant to the SPS Agreement. The food safety issues range from discussions on restriction on imports of hard cheeses made from non pasteurized milk to labeling requirements on shelled eggs or shelf-life requirements for canned food products.

Specific trade concerns related to food safety are not limited to issues actually raised in the SPS Committee. Many concerns regarding food safety measures are solved bilaterally before they come to the WTO, or around the edges of the SPS Committee meetings without actually having been raised at the meeting itself. Whereas raising an issue in the SPS Committee is the most effective way to address the problem is for the government concerned to decide. Nevertheless, a key function of the SPS Committee is that of a forum where any country can raise any issue related to food safety and trade, and in the past a number of useful decisions have been adopted by the SPS Committee.
Only one issue relevant to human health, trade and foods safety has gone through the entire dispute settlement process. This is the so-called EC Hormones dispute between the United States, Canada and the European Union. Like the cholera case, the been hormone case underscores the importance of basing food safety regulations on scientific evidence and international food safety standards.

Case of “EC – Hormones” WTO panel on European Community-Measures concerning meat and meat products (hormones), Complaints by the United States and Canada

The case was a result of European consumers concern over the use of hormones for growth promotion purposes in livestock, a practice that grew steadily throughout the 1970s. The WHO-FAO Joint Expert Committee on Food Additives (JECFA) examined the use of these hormones and their health implications. On the basis of the JECFA recommendations, the Codex adopted standards for five of the growth-promoting hormones. The standards specified the maximum level of hormone residues in foods that are safe for human consumption. Despite these standards, several scandals concerning the use of illegal hormonal substances prompted the European Union in 1988 to completely ban the use of growth promoting hormones. In January 1996, the US, followed by Canada in June of the same year, challenged this EU decision as inconsistent with the SPS Agreement. In 1998, the Appellate Body ruled that the EC was in violation of SPS rules. As the International Codex standards existed for five of the six hormones at issue, the panel judged that the EC was required to justify its ban, and hence it’s non-application of the international standards, on the basis of its own assessment of the risks to human health. The scientific evidence
presented by the EU did not support the ban on hormones. The WTO Appellate Body affirmed the decision of the panel that the EC ban was in violation of the SPS Agreement because it was not based on a risk assessment.

But the Appellate Body also confirmed the rights of Members to have the level of health protection they want, even above international standards, and that it is for the Member challenging an SPS measure to bear the burden of proof. In May 1998, an arbitrator gave the EC until 13 May 1999 to implement the recommendation of the Dispute Settlement Body. As the EC was unable to act accordingly and failed to lift its import ban, on 12 July 1999, the WTO authorized the United States and Canada to impose compensatory measures in the form of the suspension of tariff concessions covering trade to a maximum amount of US $116.8 million per year for the United States and CDN $11.3 million per year for Canada. These measures are still in force.

What happens, however, when scientific evidence is inconclusive regarding possible risks to human health from certain types of foods? There may be cases where the lack of conclusive scientific evidence about risks to health and the environment do not justify regulatory inaction. According to Article 5.7 of the SPS Agreement, provisional measures are allowed in the absence of sufficient scientific evidence.

Article 5.7 of the SPS Agreement provides as under-

"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on

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the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.”

In the EC-Hormones case the EC did not specifically invoke Article 5.7 of the SPS Agreement unlike other articles. Rather, the EC attempted to justify its hormones ban by arguing that the “precautionary principle” was a general principle under international law. In other words, the EC invoked the “precautionary principle”. In general terms as an overriding principle, while never claiming that the ban on imports of hormone-treated meat was in any way “provisional”. The Appellate Body noted that the “precautionary principle”, other than as reflected in Article 5.7, did not override the obligation to base SPS measures on a risk assessment.

The most relevant case on Article 5.7 of the SPS Agreement is of the Japan Varietals case. In this case, the Panel found that the testing requirement imposed by Japan on certain fruit products could not be considered as a provision at phytosanitary measure in an area where scientific information was insufficient, since Japan had not sought to obtain the information necessary for a more objective assessment of risk and reviewed the measure accordingly within a reasonable period of

time. The Appellate Body (AB) upheld this finding, and interpreted the notion of "reasonable period of time":

Japan subsequently notified to the WTO that it had completed technical consultations regarding a new methodology on the products at issue in the dispute and currently subject to the import prohibition and expected shortly to notify the WTO of a "mutually satisfactory solution".31

Even after the harmonization and enforcement of the SPS Agreement and Codex standards to an important extent in area of safety of traded foods, there remain significant challenges. Many developing countries have found that for their exports to meet international food safety and quality standards, they need to invest substantially in both physical and institutional infrastructure. Article 9 of the SPS Agreement requires developing countries be provided with technical assistance to do this, but there is still a big gap between what is needed and what is provided. In addition, many of the least-developed countries lack the data as well as the capacity and technical expertise to fully participate in Codex standard-setting processes as well as other fora relevant to food safety and/or quality issues. The funding for developing countries participation in Codex work is also a problem. Both the WHO and FAO, among other groups, are providing more technical assistance to alleviate this problem, and more Codex meetings take place in each region to make it easier for developing to send representatives. Pursuant to a resolution passed by the World health Assembly in 2000, WHO is also

31 "Status Report by japan" notified to the DSB on 8 June 2001 (WT/DS76/11/Add.5)
stepping up efforts to support capacity-building in developing countries for critical food safety activities.

To address the problem of effective participation by developing countries in the standard-setting process, an inter agency cooperation and coordination mechanism, involving the WTO, the FAO, WHO, OIE (the world animal health organization) and the World Bank, was established to identify ways of facilitating developing country participation in standard-setting activities and addressing their technical assistance needs. In a joint statement delivered at the Doha Ministerial Conference, these organizations affirmed their commitment to "enhance developing countries capacity to participate effectively in the development and application of international standards and to take full advantage of trade opportunities". A workshop on the development of international standards was held at the WTO in March 2001 to provide information on their respective standard-setting processes with a focus on maximizing developing country involvement. Since the establishment of the inter agency mechanism, several meetings have taken place, and the cooperation of the WTO, the FAO, WHO, OIE and World Bank is ongoing.

Significant challenge on the international food safety agency concerns new foods derived from genetic modification. The application of biotechnology to food has made food production more efficient in some cases and contributed to increased harvest. Reflecting growing concern about the safety and nutritional aspects of foods derived from biotechnology, the Codex Alimentarius Commission decided in July

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32 A summary report of this workshop is contained in G/SPS/GEN/250, available on the WTO website (www.sto.org)
1999 to undertake “the consideration of standards, guidelines or other recommendations for foods derived from biotechnology or traits introduced into foods by biotechnology.” The same session also established an Intergovernmental Task Force on Foods Derived from Biotechnology, with a three-year mandate, to help formulate a global consensus on the safety and nutritional aspects of foods derived from biotechnology. At its March 2002 meeting, the Task Force reached agreement on a final draft of “Principles for the risk analysis of foods derived from biotechnology,” which will provide the necessary framework for evaluating the safety and nutritional aspects of GM foods. The task force also adopted detailed requirements for assessing the safety of GM plants including tests for allergenicity. In April 2001, FAO and WHO published new recommendations to strengthen the process used to protect consumers from the risk that some GMOs could pose for a small percentage of people with food allergies.\(^{33}\)

Besides above, the challenges include the need to develop global standards for pre-market approval systems of genetically modified food to ensure that these new products are not only safe, but also beneficial for consumers. On the trade side, arguments are surfacing over the feasibility of regulations that would place “traceability” and labellings requirements on bio-engineered foods and their consistency with WTO trade rules.

• **Tobacco Control**

Since about 1950, more than 70,000 scientific studies have proven that smoking causes disease, disability and death. About one in every two long-term smokers die from their habit. Tobacco use is a major cause of cardiovascular disease, while 90 per cent of all lung cancers and 75 per cent of all cases of chronic bronchitis and emphysema are due to tobacco. WHO estimates that tobacco products currently kill 4.2 million people each year. By the year 2030 this annual toll will rise to nearly ten million deaths, about 70 per cent of which will occur in developing countries. In other words, tobacco will cause 150 million deaths in the first quarter of the century, and 300 million in the second quarter- if current trends continue. In developed countries, about half of these deaths will occur in people in their most economically productive years. Exposure to cigarette smoke causes higher risk of lung cancer and several other children’s health problems – sudden infant death syndrome, low birth weight, and respiratory disease.

A global public health threat has manifested in the form of Tobacco promotion and trade. While tobacco consumption fell in many high-income countries in the 1980s and 1990s, it rose in developing countries. That is largely due to the inroads made by transnational tobacco companies (TTCs) into the markets of poor and middle income nations in the last decade. TTCs have been strong proponents of tariff reduction and open markets to enable them to compete with domestically manufactured tobacco products in high growth markets in

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Latin America, Eastern Europe, and Asia. Eliminating or reducing tariffs and other barriers to imported tobacco products enables foreign companies to compete more fairly with locally produced ones. The increase in competition associated with opening the market to foreign producers may also lead to more intensive promotion and marketing of tobacco products.

Evidence collected from empirical studies confirms that trade openness leads to increased tobacco consumption. Aggressive marketing efforts by TTCs undertaken in the wake of bilateral agreements negotiated between the USA and several Asian countries in the 1980s stimulated demand for tobacco in an initial period. The evidence also indicates that the effect of TTC marketing on increasing tobacco consumption is greater in the poorer and more vulnerable countries.

There exists the economic rationale for intervention in the tobacco market. Economic theory suggests that if consumers know all the risks and bear all the costs of their choices, governments have no reason on efficiency grounds to intervene in a market. But the tobacco market is characterized by several market failures and inefficiencies which necessitate government intervention. These include (i) inadequate information about the health risks of tobacco; (ii) inadequate information about the risks of addiction; and (iii) the physical and financial costs imposed on non-smokers.

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37 Ibid.
Studies have documented a range of effective tobacco control policies and interventions that substantially reduce tobacco prevalence and consumption. Studies of the individual and combined effects of various policies showed that increasing the price of tobacco products through excise taxes or duty tariffs constitutes by far the most important policy tool available. Tobacco tax raising the price of cigarettes by at least 10 per cent have been very effective in lowering tobacco use, particularly in developing countries. Non-discriminatory taxation is consistent with WTO rules.

Higher tariffs on tobacco may, among other factors (such as taxes), contribute to a rise in consumer price, which leads to lower levels of consumption and lower prevalence of smoking among youth. Raising tariffs however, runs counter to the general goal of trade liberalization, which is to reduce, or eliminate tariffs and non-tariff barriers to international trade. Commitments to reduce tariffs on tobacco products are now part of existing multilateral regional and bilateral trade agreements. But one of the key objectives of the WTO agreements-reducing tariffs and eliminating non-tariff barriers to trade-does not prevent governments applying non-discriminatory internal taxes and certain other measures which they may consider appropriate to safeguard public health.

The health and tobacco trade debate dates back to the late 1980s. At that time, the US government began a series of actions to get Thailand and some other Asian countries to open their markets to US tobacco products. In each case, tobacco manufacture and sales were

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controlled by state monopolies. The US government succeeded in negotiating bilateral agreements that removed excise taxes and distribution practices that discriminated against US tobacco products—except in Thailand.

Thailand argued that its import restrictions were part of a comprehensive policy to control tobacco use. In response, the United States filed a complaint with the General Agreement on Trade and Tariffs (GATT), the predecessor to the WTO, against Thailand. In brief, as a result of this case Thailand had to lift its import ban and reduce the excise duty on tobacco because these could not be justified on health grounds so long as the sale of domestic cigarettes was allowed. But Thailand was allowed to continue with its advertising ban since this applied to all products without discrimination. In line with the GATT ruling, the Thai government lifted the import ban in 1990 and legal exports of cigarettes commenced to Thailand in 1991. Thailand was, of course, still free to charge duty on imports. It was also free to set its excise duty at any level so long as it did not discriminate between local and imported products.

The opening of the domestic market to foreign producers initially led to an increase in cigarette consumption, but it is also served to strengthen national tobacco control efforts. After the GATT ruling, support grew for national tobacco control measures and in 1992 the Thai parliament passed two important tobacco control acts designed to restrict tobacco sales. The measures included increased sales taxes, smoking bans in public buildings, disclosure of ingredients, and
requirements for prominent health warnings on cigarette packages. As a result, smoking prevalence declined in the mid and late 1990s\(^{39}\).

Most countries, however, face strong challenges to implementing effective, comprehensive tobacco control measures. There is often fierce political opposition from domestic producers, who may be fully or partly owned by the government. Meanwhile, foreign producers continue to seek market access. These challenges are further compounded by international tobacco smuggling.

**Case of Thailand-Cigarettes**

Under the 1966 Tobacco Act, Thailand prohibited the importation of cigarettes and other tobacco preparations, but authorized the sale of domestic cigarettes. Cigarettes were also made subject to an excise tax, a business tax and a municipal tax. In 1989, The United States complained that the import restrictions were inconsistent with GATT Article XI (on the “General Elimination of Quantitative Restrictions”), and considered that they could not be justified by either (i) some of the exceptions to the elimination of quantitative restrictions allowed for under that same Article, or (ii) Article XX(b) (on “General Exceptions” pertaining to measures necessary for the protection of human life or health). It also argued that the internal taxes were inconsistent with GATT Article III:2 (on “national Treatment on Internal Taxation and Regulation”).

Thailand responded by arguing, inter alia, that the import restrictions were justified under Article XX(b) because the government

\(^{39}\) Supra note 24.
had adopted measures which could only be effective if cigarette imports were prohibited, and because chemicals and other additives contained in United States cigarettes might make them more harmful to human health than Thai cigarettes.

WHO submission to the GATT dispute panel confirmed differences between cigarettes manufactured in developing countries like Thailand and those in developed countries, which contained more additives and flavoring to make them easier to smoke, especially by women and adolescents. However, WHO did not find any scientific evidence to show that one type of cigarette was more harmful to health than the other.

Thai Panel found that the import restrictions were inconsistent with Article XI and not justified under the exceptions which that Article allows. It further concluded that the import restrictions were not "necessary" within the meaning of Article XX(b) (i.e. not necessary for the protection of human life or health). The internal taxes, on the other hand, were found to be consistent with Article III:2 Import restrictions were found not to be necessary because other methods could be used to protect public health, including various tobacco-control measures, without favoring domestic production. Two of these were bans on advertising and point of sale promotion, which applied to cigarettes of all sources. For this reason, the panel rejected the United States call for the advertising ban to be lifted. Thai health and trade officials welcomed this last decision.
A growing number of countries have comprehensive tobacco control programs. In addition to tax increases and other price measures, these programs include policies to ban or severely restrict tobacco advertising, expand public health information campaigns, restrict sales through vending machines, ban smoking in public places and encourage cessation of tobacco use, and support for tobacco control coalitions.

Depending on how governments choose to manage trade in tobacco and tobacco products, a number of WTO rules could come into play. The US Thai tobacco case illustrated the relevance of the General Agreement on Tariffs and Trade (GATT), as it affected taxes, prohibitions and human-health related exceptions to GATT Rules. Other WTO agreements that may be applicable, but which have not yet been involved in tobacco-related controversy among WTO Members, include:

(a) the Technical Barriers to Trade (TBT) Agreement in relation to product requirements such as packaging and labellings;

(b) the Agreement on Agriculture in relation to government support for tobacco production.

(c) the General Agreement on Trade in Services (GATS) in relation to restrictions on cigarette advertising; and

(d) the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in relation to trademark protection and the disclosure of product information considered by producers to be confidential.
The challenges to comprehensive tobacco control policies that the outside national borders, led WHO in 1996 to propose the development of a Framework Convention on Tobacco Control (FCTC). Its purpose is to facilitate multilateral cooperation and action at the global level to address transnational tobacco control strategies, the effectiveness of which in reducing demand for tobacco, is substantiated by overwhelming empirical evidence. These include tobacco taxes and prices, restrictions on advertising and promotion, use of mass media and counter-advertising, design of warning labels and packaging, clean indoor air policies, and treatment of tobacco dependence.

The Framework Convention calls for cooperation amongst countries in achieving broadly stated goals, and establishes the general norms and institutions of a multilateral legal structure. An accompanying set of protocols will elaborate additional and more specific commitments and institutional arrangements to achieve the goals, WHO member States began the FCTC negotiation process in October 2000 at the first session of the Intergovernmental Negotiating Body. A second session was held in early May 2001 and the third in November 2001.

In the past, several of the potential inconsistencies between Multilateral Environmental Agreements (MEAs) and WTO rules may have arisen as a result of the lack of proper coordination between trade and environment officials both at the national and international levels. In this sense, it is noteworthy that the draft FCTC has been modeled on a number of multilateral agreements, several of which are MEAs. As the relationship between WTO rules and those of other international treaties can offer lessons for the FCTC, WHO intends to monitor the
deliberations of the WTO Committee on Trade and Environment where such issues are discussed\(^{40}\).

A conclusion that can be drawn is that proper coordination between trade and health officials at the national and international levels is crucial in order to ensure the free trade, high standards of public health and also the preservation of interest of developing countries.

\(^{40}\) Ibid.