

Committee on Trade and Environment

ITEM 7: DOMESTICALLY PROHIBITED GOODS

ASSESSMENT OF THE PRODUCT COVERAGE IN SPECIFIC
INTERNATIONAL INSTRUMENTS

Note by the Secretariat

I. INTRODUCTION

This Note has been prepared in response to requests from delegations for additional information regarding existing international instruments relevant in the field of domestically prohibited goods (DPGs), with a view to facilitating identification of possible gaps in the product coverage.

The Note provides a survey of the product coverage and information exchange systems of the main international instruments relating to DPGs. The following international instruments are examined in this Note:

1. Amended London Guidelines for the Exchange of Information on Chemicals in International Trade, UNEP, adopted 1989.
2. International Code of Conduct on the Distribution and Use of Pesticides, FAO, adopted 1985.
3. International Register of Potentially Toxic Chemicals (IRPTC), UNEP, established 1976.
4. United Nations Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments, fifth issue, 1994.
5. Code of Ethics on International Trade in Chemicals, UNEP, adopted 1984.
6. Montreal Protocol on Substances That Deplete the Ozone Layer, UNEP, 1989¹.
7. Convention Concerning Safety in the Use of Chemicals at Work, ILO, 1990.
8. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, UNEP, 1992.
9. Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, WHO, adopted 1975.
10. 1988 Convention Against Illicit Traffics in Narcotic Drugs and Psychotropic Substances, UN, 1990.
11. 1971 Convention on Psychotropic Substances, UN, 1976.
12. 1961 Single Convention on Narcotics, UN, 1964, as amended by 1972 Protocol, 1975.
13. Codex Alimentarius, established 1962.
14. Agreement on Technical Barriers to Trade, WTO, 1995.
15. Agreement on Sanitary and Phytosanitary Measures, WTO, 1995.

¹Unless otherwise indicated, the date is that at which the agreement came into force.

Four broad categories of potential DPGs can be identified: chemicals (including pesticides and fertilizers), pharmaceutical products, consumer products and hazardous wastes. They are currently covered, to at least some extent, by international instruments operated by specialized UN agencies. Several of the most comprehensive of these instruments have come into force since the issue of DPGs was raised in the GATT in 1982. Work is continuing on some of the instruments listed above, including expansion and clarification of product coverage, exchange of information, and technical assistance.

The product coverage appears to be most extensive in the field of chemicals, pharmaceuticals and hazardous wastes. Although relative gaps may exist in terms of specific categories of products or wastes, identifying such gaps lies outside the technical competence and mandate of the WTO Secretariat. In meetings of the GATT Working Group on DPGs and of the CTE, certain delegations expressed the concern that in particular consumer products, certain pharmaceuticals, cosmetics and foodstuff, such as food additives, may represent gaps in coverage.

Residual gaps in the flows of information could stem from differences between membership of the WTO and those international instruments dealing with the products concerned. However, information and assistance are in principle made available upon request also to countries which are not signatories to or participants in those instruments.

Product coverage regarding consumer products appears to be less comprehensive. The UN Consolidated List provides relevant information in this regard, but is limited to the hazards embodied in some consumer products on account of their chemical composition. Consumer products may show other potentially dangerous characteristics which are the subject of government regulation, such as risk assessment of the hazards stemming from the use of a product. While some information can be drawn from TBT notifications, no established multilateral framework provides systematic information in this regard. This can be explained by the difficulty of defining and monitoring the required information in a field which is potentially unlimited. Whereas the hazards presented by a chemical on account of its composition, for instance, can in principle be objectively defined - and nearly universally recognized - the risk stemming, for instance, from the use of a potentially dangerous toy is more subjective. National sensitivities regarding the potential hazards of consumer products can vary from one country to another, as a result of differences in habits, lifestyle, culture, priorities, etc.

II. CHEMICALS AND PESTICIDES

- (a) The Amended London Guidelines for the Exchange of Information on Chemicals in International Trade and the International Code of Conduct on the Distribution and Use of Pesticides

The Amended London Guidelines for the Exchange of Information on Chemicals in International Trade² provide a voluntary instrument to assist governments in regulating trade in chemicals through the exchange of scientific, technical, economic and legal information on chemicals which are banned or severely restricted. This instrument is operated jointly with the FAO International Code of Conduct on the Distribution and Use of Pesticides³ which has the objective to establish voluntary standards of conduct and increase confidence between importing

²The London Guidelines were adopted in 1987 by the UNEP Governing Council, and amended in 1989.

³Adopted in 1985.

and exporting countries in the availability, regulation, marketing and use of pesticides. Both instruments include mechanisms aimed at making existing information about hazardous chemicals more freely available, in order to permit competent authorities in countries to assess the risks associated with the use of these substances. The first mechanism is the prior informed consent (PIC) procedure, which was added in 1989 to help control imports of unwanted chemicals that have been banned or severely restricted. The PIC procedure is implemented through the FAO/UNEP Joint Programme on Operation of Prior Informed Consent⁴. The second mechanism concerns information exchange on chemicals in international trade.

As of March 1996, 145 countries were participating in the PIC and information exchange procedures.

(i) The PIC Procedure

The PIC procedure is voluntary and aims at assisting countries with limited resources to make decisions regarding the import of certain chemicals. The aim of the PIC procedure is to promote a shared responsibility between exporting and importing countries in protecting human health and the environment from the harmful effects of certain hazardous chemicals which are traded internationally. The PIC procedure is not meant to provide a legal framework for decision-making since the responsibility for making and enforcing the decisions required under the procedure remains with each country.

Chemicals eligible for the PIC procedure

The PIC procedure distinguishes three major use categories of chemicals, namely pesticides⁵, industrial chemicals and consumer chemicals⁶. Any chemical banned⁷ or severely restricted⁸ for health or environmental reasons in at least one country after 1 January 1992 is eligible for inclusion in the PIC procedure. In the case of chemicals banned or severely restricted prior to that date, those for which control actions have been taken in five or more countries are also eligible. The procedure applies to chemicals as such and not to products/articles which may contain residual elements of such chemicals.

⁴In UNEP, the International Register of Potentially Toxic Chemicals (IRPTC) is the lead office for industrial and consumer chemicals. In FAO, the Plant Production Division of the lead agency for pesticides.

⁵Article 2 of the FAO Code of Conduct defines a pesticides as "any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harms during or otherwise interfering with the production, processing, storage, transport, or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops whether before or after harvest to protect the commodity from deterioration during storage and transport".

⁶Article 1 of the London Guidelines defines a chemical as "a harmful substance whether by itself or in a mixture or preparation, whether manufactured or obtained from nature and includes such substances used as industrial chemicals and pesticides".

Industrial chemicals are chemicals used in industrial activities.

Consumer chemicals are chemicals which are customarily produced for private, non-occupational use.

⁷A "Banned chemical" means a chemical which has, for health or environmental reasons, been prohibited for all uses by final governmental regulatory action (Article 1(a) of the London Guidelines).

⁸A "severely restricted chemical" means a chemical for which, for health or environmental reasons, virtually all uses have been prohibited nationally by final government regulatory action, but for which certain specific uses remain authorized" /Article 1(b) of the London Guidelines).

In addition, acutely toxic pesticide formulations which have not been banned or severely restricted in any country for health and environmental reasons, but which are causing problems under conditions of use found in developing countries may also be included. An expert group is mandated to consider whether there exists a need for a list of such products to supplement the chemicals which are already subject to the PIC procedure. Consistent with the philosophy of informed consent, participating countries would be provided with information on these pesticide formulations to enable them to make informed decisions, based on an evaluation of the potential risks, concerning whether they wish to receive shipments. The FAO/UNEP Joint Expert Group of Experts on PIC is considering various criteria to identify pesticides which would fall under this category.

The amended London Guidelines do not apply to pharmaceuticals, including narcotics, drugs and psychotropic substances, radioactive materials, chemicals imported for the purposes of research or analysis in quantities not likely to affect the environment or human health, chemicals imported as personal or household effects, in quantities reasonable for these uses, food additives⁹. There is also an exclusion for small quantities of chemicals used for research purposes and some other small-volume uses.

As of December 1995, twelve pesticides and five industrial chemicals were subject to the PIC procedure. In March 1995, the FAO/UNEP Joint Group of Experts on PIC recommended the inclusion of a further seventeen chemicals into the PIC procedure, for which the DGDs¹⁰ will be circulated in 1996. Twelve were selected on the basis of control actions in countries and formulations of five pesticides were selected on the basis of potential problems under conditions of use in developing countries.

Procedure for including a chemical into the PIC system

In order to participate in the PIC procedure, each country must nominate a Designated National Authority (DNA) which will act as a national focal point. The DNA is responsible for collecting and providing national information on the substances concerned to FAO, UNEP and other countries, and ensuring that the information received is transmitted to all relevant authorities and organizations within the country.

The FAO and UNEP Secretariats are jointly responsible for the operation of the Joint Programme operated by the FAO/UNEP Joint Group of Experts on PIC. The FAO/UNEP Secretariat receives notifications of banned and severely restricted chemicals which are candidates for inclusion in the PIC procedure. On the basis of the notifications received, the FAO/UNEP Joint Group identifies the chemicals which will be included in the PIC procedure. For any such product, the FAO/UNEP Secretariat will establish a DGD. The DGDs will then be forwarded to all DNAs which will have to prepare, within 90 days, an Importing Country Response (ICR) on the basis of the information provided. In the ICR, countries report whether or not they accept future import, or allow import only under certain conditions. Import decisions must apply uniformly to imports from all exporting countries and to any domestic manufacture of the chemicals. These import decisions are compiled by FAO/UNEP Secretariat and distributed to all DNAs in participating countries every six months. Exporting countries should then ensure that PIC decisions made by participating importing countries are communicated to their exporter,

⁹It is left open to Governments to apply the guidelines to pharmaceuticals and food additives if they should wish to do so. So far, no Governments have provided information on regulatory actions on these types of chemicals.

¹⁰A Decision Guidance Document (DGD) sums up the most important characteristics of the product (its chemical and physical properties, the risks linked with its use, its effects on the environment, etc).

industry and any other relevant authorities, and that no export occurs contrary to the decision of participating importing countries. If the importing country has not provided an answer under the PIC procedure, the status quo should apply, i.e. export should not proceed without the consent of the importing country unless the chemical has been shipped for use in the country or has been officially requested by the country.

It is important to note that the export notification is not an obligation tied to the export of any chemical subject to the PIC procedure. The obligation to provide an export notification applies only to those countries which have actually banned or severely restricted a chemical, whether included in the PIC procedure or not. Therefore, any chemical, whether included in the PIC procedure or not, can be exported without the need for an export notification, from any country which has not taken regulatory action to ban or severely restrict that chemical.

Based on mandates from the FAO and UNEP Governing Bodies, two parallel processes have been initiated in 1995 which are monitored jointly by the two organizations. First, the Intergovernmental Negotiating Committee (INC) is currently working to develop an international legally binding instrument for the application of the PIC procedure for certain hazardous chemicals and pesticides in international trade; it is expected to complete its work by 1997. One part of its work is the identification of candidate chemicals for inclusion in the PIC procedure; the INC established a working group on this issue. Preliminary discussions have indicated that such chemicals should include chemicals notified as banned or severely restricted for health or environmental reasons by at least one party, as well as hazardous pesticides formulations which may be causing problems under conditions of use in developing countries. The second process is the Government Designated Expert Group whose mandate is to consider the need for additional measures to further reduce the risks of certain hazardous chemicals in international trade.

(ii) The Information Exchange Procedure for Chemicals in International Trade

The London Guidelines and the FAO Code of Conduct contain provisions which aim at facilitating the exchange of information between countries on chemicals moving in international trade, especially those chemicals which have been banned or severely restricted for health or environmental reasons. First, a government should notify UNEP and FAO as soon as possible of the action it takes to ban or severely restrict a chemical in order to protect health or the environment. This information is then compiled by FAO/UNEP Secretariat and sent to DNAs in participating countries. These notifications also represent the primary information for identifying chemicals and pesticides which may be included in the PIC procedure.

Secondly, the information exchange procedure foresees that the DNA of a country exporting a chemical which is banned or severely restricted for domestic use should ensure that the DNA of the importing country is aware that the export of such a chemical is to be expected or is about to occur. Exporting countries are encouraged to provide importing countries with information, advice and assistance, including appropriate precautionary information, regarding the chemicals they are exporting. The DNA in the importing country should also be informed by the DNA of the exporting country of the development of any significant new information relevant to the initial control action in the exporting country.

Information regarding classification, packaging and labelling of chemicals for exports is also provided for in the information exchange procedure. Exporting countries should ensure that exported chemicals are subject to the same stringent requirements for classification, packaging and labelling as comparable products intended for domestic use. In the absence of standards or requirements in the country of import, the exporting country should also ensure that the

classification, packaging and labelling of the chemical exported conform to recognized international standards.

(b) The International Register of Potentially Toxic Chemicals (IRPTC)

The IRPTC was set up by UNEP in 1976, with the objective of identifying potential hazards associated with chemical use, assembling information on existing policies for control and regulation of hazardous chemicals at national and international levels, and making data on chemicals available. The information provided to governments is considered to be essential for developing and enhancing the chemical management capabilities of countries.

IRPTC includes information on all types of chemical substances, except pharmaceuticals and radioactive material. The data bank on chemicals contains a series of files on all aspects of some 100'000 chemical that are deemed important to conducting a hazard assessment (identity, properties, environmental behaviour and effects, toxicity of substances, etc). Belonging to this data bank, the IRPTC Legal File contains summary information on national regulations in 13 countries and international guidelines and recommendations of 6 international organizations related to control of substances in various media such as air, water, drinking water, wastes, soil, food and beverages, consumer goods (including cosmetics and toiletries), as well as their use and transport; it contains about 50'000 files. Finally, IRPTC keeps some 7000 Special files on substances of special international importance.

(c) The United Nations Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

The UN Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments is prepared jointly by the United Nations Secretariat, WHO and UNEP, and is periodically up-dated (the fifth and last issue was published in 1994). It presents information on regulatory action taken by governments on pharmaceuticals, agricultural and industrial chemicals, and consumer products. It is divided into two parts containing regulatory and commercial information respectively. The information provided is not considered to be exhaustive, neither in terms of products, nor in terms of regulatory measures, it covers nevertheless regulatory action taken by 93 governments on some 700 products. The List is meant to complement and consolidate the information produced within the UN system.

Regarding chemicals, the Consolidated List contains information on national control actions for about 370 agricultural and industrial chemicals. This information is based on notifications received by IRPTC from governments.

(d) Code of Ethics on International Trade in Chemicals

This instrument was implemented in 1994 under the auspices of UNEP and is intended to complement the Amended London Guidelines by setting forth voluntary standards of conduct for private sector industry.

The Code covers "the production and management of chemicals in international trade, taking into account their entire life cycle". The Code does not apply to pharmaceuticals, radioactive materials, small quantities of chemicals imported for research, chemicals imported as personal household or food additives.

By signing on to the Code, participants undertake to increase a sound production and safe management of chemicals by providing government authorities and interested private sector participants with relevant information regarding chemicals in domestic and international trade, and by complying with the relevant aspects of the PIC procedure carried out by UNEP and FAO. Producers are urged to provide sufficient information to importers, through labelling or other means, to ensure safe, environmentally sound management of wastes in trade.

(e) The Montreal Protocol on Substances That Deplete the Ozone Layer¹¹

The Montreal Protocol is a legally binding instrument aiming at the reduction and phase-out of consumption and production of specified substances that deplete the ozone layer. As of 31 December 1995, 151 countries had ratified it.

The substances controlled in Annex A of the original Protocol, whether existing alone or in a mixture, are 5 chlorofluorocarbons (CFCs) and 3 halons. Two subsequent amendments to the Protocol added more substances: the 1990 London Amendment covers carbon tetrachloride and methyl chloroform (Annex B) and the 1992 Copenhagen Amendment lists hydrobromofluorocarbons (HBFCs), hydrochlorofluorocarbons (HCFCs) and methyl bromide (Annex C).

The basic obligation is to progressively eliminate production and consumption of controlled substances. The Protocol lays down for each group of controlled substance a schedule for reduction and eventual phase-out of production and consumption. This implies a gradual reduction and elimination of trade among Parties, whose implementation is left to each Party to determine. The Protocol imposes a general obligation to ban exports of controlled substances to non-Parties. However, exports of controlled substances are allowed to non-Parties which fully comply with the Protocol control measures.

The London amendment introduced an obligation for the Parties to provide the Secretariat with statistical data on their annual production of controlled substances, as well as on their imports and exports to Parties and non-Parties respectively. Moreover, Decision VII/9 (Basic Domestic Needs) foresees that "(...) exporting Parties should report to the Ozone Secretariat by 30 September each year on the types, quantities and destinations of their exports of ozone-depleting substances during the previous year".¹²

(f) 1990 Convention Concerning Safety in the Use of Chemicals at Work

This Convention entered into force in 1993 and is implemented under the auspices of ILO¹³. It covers chemical elements and compounds, and mixtures thereof, whether natural or synthetic. "Use of chemicals at work" means any work activity which may expose a worker to a chemical, such as the production, handling, storage and transport of chemicals, the disposal and treatment of waste chemicals, the release of chemicals resulting from work activities, the maintenance, repair and cleaning of equipment and containers for chemicals.

The objective of the Convention is to ensure that all chemicals are evaluated by a competent national authority to determine their hazards, provide information to employers and

¹¹UNEP, entered into force in 1989.

¹²See doc. WT/CTE/W/19 (23 January 1996).

¹³The provisions of this Convention are to be applied in conjunction with the Recommendation concerning Safety in the Use of Chemicals at Work, No. 177, ILO, 25 June 1990.

workers concerning chemicals used at work and to establish principles for programmes to ensure that these chemicals are used safely. For that purpose, all chemicals shall be classified. Hazardous chemicals shall be labelled and a chemical safety data sheet, containing detailed essential information regarding their identity, supplier, classification, hazards, safety precautions and emergency procedures shall be provided to employers. Requirements for marking and labelling chemicals, and for chemical safety data sheets, are established by the competent national authority, in accordance with national or international standards.

Pursuant to the Convention, exporting member States shall communicate to any importing country hazardous chemicals domestically prohibited for reasons of safety and health at work, as well as the grounds for such prohibition. Suppliers (manufacturers, importers or distributors) are to ensure that chemicals have been classified, marked or labelled as hazardous in accordance with the Convention, and that chemical safety data sheets are prepared for hazardous chemicals. Workers have a right to access to any information required to be kept pursuant to the Convention.

III. HAZARDOUS WASTES

(a) Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal

The Basel Convention was adopted in 1989 by 116 states, and entered into force in May 1992. As of January 1996, 97 countries had ratified it. The Convention aims at reducing the generation of hazardous wastes, and at minimizing their transboundary movement.

(i) Coverage

The Convention defines wastes as "substances or objects which are disposed of or are intended to be disposed of or are required to be disposed of by the provisions of national law"¹⁴. "Disposal" includes operations leading to final disposal (such as landfill, incineration on land or at sea, release onto continental waterbodies, release onto the ocean including sea-bed insertion), as well as those leading to recycling, resource recovery, reclamation, direct re-use or alternative uses. Wastes are considered as "hazardous" if they belong to any of the categories listed in Annex I and have any of the hazardous characteristics listed in Annex III¹⁵ of the Convention. In addition, wastes which are "defined as, or are considered to be, hazardous wastes by the domestic legislation of the Party of export, import or transit"¹⁶ also fall under the scope of the Convention; in this case, the relevant wastes shall be treated as hazardous wastes by other parties when dealing with the state in question. Household wastes as well as residues from their incineration (defines as "other wastes", Annex II) also fall under the scope of the Convention¹⁷.

The Basel Convention excludes radioactive wastes which are covered by pertinent international control system (namely those developed by the International Atomic Energy Agency), or wastes that result from normal operations of a ship, which are subject to 1973/1978 MARPOL Convention adopted under the auspices of the International Maritime Organization rules.

¹⁴Article 2.1.

¹⁵Annex I lists 45 categories of wastes to be controlled. Annex III enumerates a list of 9 hazardous characteristics.

¹⁶Article 1.1(b).

¹⁷Article 1.2.

(ii) Obligations

Under the original Convention, transboundary movements of hazardous wastes are allowed only if the exporting country does not have appropriate facilities for treating the wastes in an environmentally sound and efficient manner, or if the wastes are required as raw materials for recycling or recovery industries in the importing country. The Convention prohibits the export of wastes under certain circumstances, in particular when there is "reason to believe" that environmentally sound management or disposal options are not available in the importing country, if the importing country has prohibited such imports, or to countries that are not parties to the Convention.

The prior informed consent (PIC) principle applies when a transboundary movement of hazardous wastes takes place, namely the transboundary movement can take place only after the states of export and transit have given their express written consent to the state of export, on the basis of information provided by the latter. Under the Basel Convention, Parties must exchange information through the Secretariat on their waste-related activities. This information includes, inter alia, the changes in national definition of hazardous wastes, decisions related to the import or export of hazardous wastes.

In addition, Decision II/12¹⁸ prohibits the exports of hazardous wastes (i) from OECD member states to non-OECD member states for the purpose of final disposal, and (ii) as of 31 December 1997, from OECD member states to non-OECD member states for the purpose of recycling or resource recovery. At the third meeting of the Conference of the Parties in September 1995, Parties decided by consensus to include Decision II/12 as an amendment to the Basel Convention¹⁹. This amendment will enter into force between the Parties having accepted it once at least three-fourths of the Parties have ratified it.

In Decision III/1, Parties further requested the Technical Working Group (TWG) to accelerate its current work on the definition of hazardous wastes characteristics. The TWG is developing a list of wastes which are hazardous and thus fall within the scope of the Convention (list A), and a list of non-hazardous wastes which normally would not be subject to the Convention (list B). The TWG is also developing a list C containing wastes for which further clarification is needed. The purpose of those lists is to provide guidance to Parties in determining if a waste is hazardous or not within the framework of the Basel Convention considering the fact that some categories of wastes listed in the Convention may contain specific wastes which are always hazardous and wastes which may be sometimes hazardous. It should be noted that at present the classification of wastes in the Convention is particularly difficult for wastes which possess hazardous constituents and where there is a need to determine at what level such constituents will cause that waste to exhibit hazardous characteristics. The TWG is expected to present its recommendation to the Conference of the Parties at its fourth meeting in 1997 for decision-making.

¹⁸Adopted by consensus at the Second Meeting of the Conference of the Parties, in March 1994.

¹⁹Decision III/1, Amendment to the Basel Convention, see doc. WT/CTE/W/12, 10 October 1995.

IV. PHARMACEUTICALS, INCLUDING NARCOTIC AND PSYCHOTROPIC SUBSTANCES

(a) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

This instrument was adopted in 1975 under the auspices of the WHO. As of March 1996, 139 countries participated in the Certification Scheme.

For the purpose of the Certification Scheme, "pharmaceutical products" means any medicine intended for human use, or a veterinary product administered to food-producing animals, presented in its finished dosage or as a starting material for use in such a dosage form, when it is subject to control by legislation in the exporting Member country and in the importing Member country.

The Certification Scheme is linked to the WHO standards on Good Manufacturing Practice (GMP)²⁰ and provides a simple administrative mechanism which allows an importing country to gain important information about the regulatory status of a specific product in the exporting country.

Countries participating in the Scheme must communicate to the Director General of WHO information concerning the competent authority responsible for the certification of their exports of pharmaceutical products. At the request of a commercially interested party, the competent authority shall certify that the pharmaceutical product is authorized for sale or distribution within the jurisdiction of the exporting country, or, if it is not authorized, the reason why that authorization has not been accorded. The competent authority of the exporting country must also submit information relating to the plant in which its exported pharmaceutical products are manufactured and must attest that all product information, including labelling, is currently authorized in the certifying country. The competent authority of the importing country must decide upon receipt of the certificate whether to grant or refuse the authorization for sale or distribution of the pharmaceutical product or to make authorization conditional on the submission of supplementary data. A country may opt to participate solely to control the import of pharmaceutical products and active substances. In the case imported products show quality defects that are considered to be of a serious nature by the importing country, the competent authority of that country should notify the competent authority of the exporting country with a request to institute enquiries. Conversely, if the competent authority of the exporting country ascertains serious quality defects, that competent authority should notify the competent authority of the importing country.

In addition to the Scheme, WHO monitors various instruments providing information about pharmaceuticals. Among them, the WHO Drug Monitoring Programme focuses on the exchange of information about safety and efficacy of pharmaceutical preparations, as well as new information regarding their serious side-effects. This programme provides a channel through which countries are informed of decisions to prohibit or limit the availability of drugs already in use. WHO makes available evaluated information regarding safety and efficacy of drugs in two widely disseminated publications, the monthly *WHO pharmaceutical Newsletter* and the quarterly *WHO Drug Information*, which cover in particular general policy topics, reports in individual drugs and recent regulatory decisions, lists of newly approved pharmaceutical products.

²⁰The GMP text provides comprehensive guidance to governments and manufacturers on important aspects of drug manufacturer, including personnel, premises, equipment, sanitation, starting materials, manufacturing operations, labelling and packaging, quality control system, self-inspection, distribution records, complaints and reports of adverse reactions, expiry dates.

- (b) 1988 Convention Against Illicit Traffics in Narcotic Drugs and Psychotropic Substances²¹, 1971 Convention on Psychotropic Substances²² and 1961 Single Convention on Narcotics²³

The 1961 and 1971 Conventions were primarily designed for the control of licit supply of narcotic drugs and psychotropic substances respectively. Narcotic drugs include opium and its derivatives (morphine, codeine and heroine), other narcotic drugs of man-made origin (such as methadone and pethidine), as well as cannabis and cocaine. Psychotropic substances include mainly hallucinogens, stimulants and depressants. Based on WHO recommendations, the UN Commission on Narcotic Drugs determines which substances should be subject to control: as of August 1995, the 1961 Convention covered some 115 substances and some 105 substances were included in the 1971 Convention. The Conventions categorizes drugs according to their addictive properties, their therapeutic value and the risks arising from their abuse in schedules annexed to the respective instruments. For example, the provisions governing Schedule IV substances, which are the least stringent, include *inter alia*, the requirement to issue licenses for manufacture, trade, distribution, import and export, and the right for countries, Parties to the Convention, to notify other Parties that they intend to prohibit or restrict the import of specified substances, which obliges then other Parties to ban or control exports to that country, accordingly.

The 1988 Convention complements the two previous instruments. Its objective is to prevent and combat drug abuse through controlling the illicit supply of narcotic drugs and psychotropic substances and to prevent trade in and the diversion of materials and equipment for their illicit production or manufacture.

- (c) UN Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

The drug section of the Consolidated List is the result of a collaboration between WHO and UNEP/IRPTC. The last issue, published in 1994, contains information on more than 300 products by notified 99 governments. In order to put the national decision into an international perspective, WHO has prepared a comment which appears at the end of each product entry; this comment is cleared by all national regulatory authorities whose decisions have been reported.

V. CONSUMER PRODUCTS

- (a) UN Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments

In collaboration with IRPTC, the UN Consolidated List provides information on regulatory measures taken by governments in relation with consumer products, including a description of and the grounds for the action taken. The information covers only consumer products which are hazardous on account of their chemical composition. The List contains information regarding action taken on some 106 substances which are prohibited or restricted in

²¹Adopted in 1988, entered into force in 1990.

²²Adopted in 1971, entered into force in 1976.

²³Adopted in 1961, entered into force in 1964, amended by 1972 Protocol which entered into force in 1975.

consumer products, such as children's articles, household products, automotive, cosmetics, cleaning fluids, paints, personal products, textiles and clothing.

(b) Codex Alimentarius²⁴

The Codex Alimentarius is a collection of international food standards adopted by the Codex Alimentarius Commission, which is the international body responsible for the execution of the Joint FAO/WHO Food Standards Programme. More than 150 countries currently participate in the Programme, which was created in 1962 with the purpose of protecting the health of consumers and facilitating international trade in foods. The Codex Alimentarius includes standards for all the principal foods, whether processed or semi-processed or raw. It includes provisions in respect of the hygienic and nutritional quality of food, including microbiological norms, provisions for food additives²⁵, pesticides residues, contaminants²⁶, labelling and presentations, and methods of analysis and sampling.

The standards and maximum limits for pesticides residues are established by the Codex Alimentarius Commission. Governments must then notify the Codex Secretariat whether they accept the new or amended standards. When a government cannot accept a standard, or when it accepts the standard conditionally, it must also notify the reasons therefor. This notification system ensures that Codex Alimentarius can be used as a reference for governments and traders.

Regarding food additives, for instance, the Codex Alimentarius contains General Principles for the Use of Food Additives, and an International Numbering System for Food Additives (INS) whose purpose is to facilitate the identification of food additives in ingredient lists. Further provisions relate to the carry-over of food additives into foods, the labelling of food additives when sold as such, etc.

VI. WTO INSTRUMENTS RELATED TO DPGs

(a) The Agreement on Technical Barriers to Trade

The TBT Agreement recognizes the right of Members to adopt measures such as technical regulations, standards, testing and certification procedures to the extent they consider appropriate for the protection of human, animal or plant life or health, or the environment, or to meet other consumer interests. A technical regulation amounts also to a ban on the domestic sale or use of the product concerned which does not meet the standard set in that regulation.

The Agreement increases transparency by requiring prior notification, affording other Members opportunities for comments, and establishing enquiry points to answer enquiries from

²⁴Latin expression, meaning Food Law or Code.

²⁵According to the Codex, food additive means "any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result, (directly or indirectly) in it or its by-products becoming a component of or otherwise affecting the characteristics of such foods. The term does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities.

²⁶According to the Codex, contaminant means "any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. (...).

other Members. Notifications under the TBT Agreement contain information on technical regulations administered at the national level which is of relevance to the discussions on DPGs. For example, under the category of wastes and chemicals, TBT notifications included in 1995 information on a ban on export of mercury and mercury compounds (G/TBT/Notif.95.300); and a ban on the import and export of the chemicals methylene chloride and trichloroethylene. Although notifications dealing with food and food additive and other requirements are primarily addressed under the SPS Agreement, some 49 TBT notifications dealt with a range of technical regulations related to food in 1995. These included labelling requirements for expiration dates of food (G/TBT/Notif. 95.152); regulations related to foodstuffs (G/TBT/95.113); and regulations related to the allowable use of certain food additives (for example, the allowable use of sweeteners (G/TBT/Notif. 95.117) and maximum allowable use of erythosine in fish and other food products (G/TBT/Notif. 95.187). Notifications have also been received under the TBT Agreement on regulations related to the import and handling of radioactive wastes (G/TBT/Notif. 95.185).

(b) The Agreement on Sanitary and Phytosanitary Measures

Before the entry into force of the WTO, regulations regarding sanitary and phytosanitary measures, including food safety standards, were subject to the TBT Agreement for those countries which were signatories.

The Sanitary and Phytosanitary (SPS) Agreement²⁷ recognizes the right of Members to adopt and enforce "measures necessary to protect human, animal or plant life or health" but requires that these measures are not applied in a discriminatory or arbitrary manner nor represent a disguised restriction on international trade. The SPS Agreement encourages countries to harmonize their SPS requirements by basing them, whenever possible, on international standards²⁸. Countries can take more stringent SPS measures if they have a scientific justification, or if they can demonstrate that the international standard would not provide what they consider to be the acceptable level of risk.

Transparency procedures contained in the SPS Agreement are similar to those of the TBT Agreement. Members shall also establish enquiry points responsible for answering questions relating to SPS measures. When a SPS measure differs from international standard, guideline or recommendation, Members shall additionally notify them to other Members through the WTO Secretariat. Some 277 SPS regulations have been notified since the entry into force of the Agreement. They address requirements regarding, *inter alia*, food quality standards (limits for pesticides, antibiotics, preservatives and other residues in food), food additives, labelling requirements for food.

Thus, the SPS Agreement, through its notification and enquiry point system, provides a valuable source of information regarding food safety and food additive regulations implemented in WTO Member countries. Moreover, any question relating to the implementation of the SPS Agreement can be raised in the SPS Committee.

²⁷Sanitary and Phytosanitary measures are "[A]ny measure applied (...) to protect human, or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;" (emphasis added). For a complete definition, see Annex A of the Agreement.

²⁸The international standards referred to in the SPS Agreement are the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention.

VII. GATT WORKING GROUP ON DOMESTICALLY PROHIBITED GOODS

Under the GATT Working Group on Domestically Prohibited Goods, select Contracting Parties submitted DPG notifications which provided specific information related to product coverage. Between 1989 and 1990, 6 DPG notifications were received by the Contracting Parties. Product coverage was broad, and notifications also contained information on related export notification procedures, compulsory licensing, inspection procedures and other measures related to products withdrawn or restricted from domestic marketing. DPG/Notif.89.1 provided information on national export certification schemes related to pharmaceutical products which had been withdrawn or restricted from domestic marketing. Under the same DPG notification, information was provided on export licensing and export permit schemes covering hazardous wastes and ozone depleting substances. In DPG/Notif. 90.1, information was provided concerning mandatory export licensing procedures covering the following products: foodstuffs, consumer goods, agricultural products, medicines, chemicals, wastes, woods preservatives, medicines and pharmaceutical, pesticides. Under DPG/Notif. 90.4, notification was provided of export permits, export bans or export notification systems covering the following products: animals and animal products subject to mandatory inspection procedures; foodstuffs; atomic energy and related equipment; toxic chemicals (PCBs) and CFCs; hazardous wastes; PCB waste; fish and fish containers; meat products; illegal drugs; fertilizers.