

# GENERAL AGREEMENT ON

# TARIFFS AND TRADE

RESTRICTED

L/6459/Rev.1  
24 November 1989

Limited Distribution

## EXPORTS OF DOMESTICALLY PROHIBITED GOODS

### ACTIVITIES OF OTHER ORGANIZATIONS IN RELATED FIELDS

#### Note by the Secretariat

#### Revision

#### Introduction

1. The subject of Exports of Domestically Prohibited Goods has been included in the regular work programme of GATT (BISD 29S/19). The latest report on the subject was presented at the November 1988 Session of the CONTRACTING PARTIES (SR.44/2, pages 2-7). Subsequently, at the Ministerial meeting of the Trade Negotiations Committee held in Montreal in December 1988, some delegations emphasized the importance they attached "to the need for early action in GATT to bring under control trade in domestically prohibited goods and other hazardous substances". In the light of this, the Chairman of the TNC suggested in his statement at the conclusion of the meeting that the GATT Council "be requested to take an early appropriate decision for the examination of the complementary action that may be necessary in GATT, having regard to the work that is being done by other international organizations". At its meeting on 19 July 1989, the GATT Council agreed to establish a Working Group on the Export of Domestically Prohibited Goods and Other Hazardous Substances.

2. To assist further examination, this note updates the information contained in the note prepared by the secretariat in 1985 on the activities of other organizations in the fields covered by the subject (DPG/W/1). It will be revised, as necessary, to take into account any further information and comments that may be received from the relevant organizations.

3. The main organizations of which work has been covered include:

- I. United Nations Environmental Programme (UNEP);
- II. Food and Agricultural Organizations (FAO);
- III. World Health Organization (WHO);
- IV. United Nations General Assembly.

Reference has also been made to the work being undertaken in the International Labour Organization (ILO) and by the United Nations Centre on Transnational Corporations (UNCTC). The note also reviews briefly the work that is being done by the Organization for Economic Co-operation and Development (OECD), particularly as the approach to the issues taken by developed countries in co-operating among themselves, has provided a useful basis for the work in this area of other international organizations for promoting co-operation on a wider basis.

4. The information is presented in four parts. The first two parts describe the work of international organizations on products which are banned or severely restricted in countries where they are produced on grounds that they are dangerous to human health, and safety, and to the environment. In particular, Part I deals with dissemination and exchange of information on actions taken to control sale and distribution of such products, and on scientific reports prepared to explain the risks to human health and environment, involved in their use. Part II deals with the aspects of the work of these organizations, relating to specifically international trade in such products. It describes briefly the exchange network which has been developed for notification of exports of banned or severely restricted products and the work that is under progress for developing guidelines with a view to bringing under control exports of such products. The information contained in the two parts is closely related and its separate presentation has been attempted only with a view to bring out more clearly work which has a more direct bearing on international trade aspects.

5. Part III of the paper describes the work that is being done, mainly by the UNEP on "illegal traffic in toxic and dangerous products and wastes" and on "control of transboundary movement of hazardous wastes".

6. Part IV contains some concluding observations.

PART I

WORK ON EXCHANGE AND DISSEMINATION OF INFORMATION ON  
GOVERNMENTAL ACTIONS BANNING OR SEVERELY RESTRICTING  
SALE AND DISTRIBUTION OF PRODUCTS

A. UNEP - Work in the area of chemicals

(a) Exchange of information for evaluating hazards associated with particular chemicals

7. The main objective of the International Register of Potentially Toxic Chemicals (IRPTC) which was established in 1976, is to facilitate access to existing data on production, distribution, release and disposal of chemicals and their effects on human beings and their environment, and to provide basic data for evaluating the hazards associated with particular chemicals.

8. Towards this end, it has established a network of 119 national correspondents covering 111 governments. They provide information on new or planned legislation to control chemicals, as well as regulations, recommendations, studies and reports, and on accidents and incidents involving chemicals.

In particular the IRPTC:

- (i) has developed central files containing relevant information on health and environmental hazards posed by chemical substances. (Data profiles on over 800 chemicals of international significance, prepared by IRPTC staff assisted by consultants or network partners, are available for consultation by experts seeking information.);
- (ii) has built and is continuously updating a Legal File, containing information on legal and administrative limitations, prohibitions and restrictions placed on over 8,000 chemicals in countries. (This file is presently available on-line; a compendium of data on 550 chemicals supplied by twelve selected countries and six international organizations has been published in 1987.);
- (iii) publishes a Bulletin two times yearly, containing information on new or proposed legislation and regulations, risk evaluations, reports on toxicity and safe use instructions for chemicals, which is widely distributed with the aid of its national correspondents;
- (iv) provides a query response service on chemical products covered by the Register;

- (v) coordinates the reporting and information exchange under the London Guidelines for the Exchange of Information on Chemicals in International Trade among participating Governments and liaises with relevant intergovernmental and non-governmental organizations;
- (vi) assists with the strengthening of legal and institutional arrangements for the management of chemicals at the national level.

(b) Exchange of information on banned or severely restricted chemicals

9. The UNEP Governing Council has also in May 1989 adopted the amended form of the London Guidelines for the Exchange of Information on Chemicals in International Trade to incorporate the principle of Prior Informed Consent (PIC) as had been requested by the Council in 1987. Under these Guidelines, States having taken a control action to ban or severely restrict a chemical should notify IRPTC. The IRPTC will disseminate these notifications to the designated national authorities in other participating countries in order to give these countries the opportunity to assess the risks associated with the chemical and to make timely and informed decisions. If an export of a chemical banned or severely restricted in the State of export occurs, the State of export should ensure that necessary steps are taken to provide the designated national authority of the state of import with relevant information. The PIC is a procedure which operates in addition to information exchange and export notification and gives those countries which elect to participate in it the opportunity to record their decisions regarding future imports of banned or severely restricted chemicals in a formal way.

10. As at 31 October 1989, seventy-five countries had designated their national authorities for the implementation of the London Guidelines. Countries are being invited to confirm their participation or their continued participation in the implementation of the Guidelines in their amended form.

B. FAO - Work in the area of pesticides

Exchange of information

11. FAO has established a system for exchange of information under the International Code of Conduct on the Distribution and Use of Pesticides which was adopted in 1985. (For further discussion of the Code, see page 13, paragraphs 44 and 45).

12. The Code which is voluntary in nature, lays down standards for all public and private entities engaged in the distribution and use of pesticides. It notes that there is an increasing concern about the propriety of supplying pesticides which are banned or severely restricted particularly to developing countries which have no system for registration and have not been able to develop their safe and effective use. A system of exchange of information has been established in order to enable the countries to decide whether imports of such pesticides should be allowed, taking into account their toxicological effects, the reasons for which they have been banned and the local public health, economic, environmental and administrative conditions.

## 13. Under this system:

- the government of any country that takes action to ban or severely restrict the use or handling of a pesticide in order to protect health or the environment should notify FAO as soon as possible of the action it has taken. FAO will notify the designated national authorities in other countries of the action of the notifying government. The purpose of this notification procedure is to give competent authorities in other countries the opportunity to assess the risks associated with the pesticide and to make timely and informed decisions as to their importation and use. The minimum information to be notified should indicate:
  - the identity (common name, distinguishing name and chemical name) of the pesticide;
  - a summary of the control action taken and of the reasons for it - if the control action bans or restricts certain uses but allows other uses, such information should be included;
  - the fact that additional information is available, and the name and address of the contact point in the country of export to which a request for further information should be addressed.
- if an export of a pesticide banned or severely restricted in the country of export occurs, the country of export should ensure that necessary steps are taken to provide the designated national authority of the country of import with relevant information. The purpose of this information regarding exports, which should be provided prior to export, is to remind the country of import of the original notification regarding control action and to alert it to the fact that an export is expected or is about to occur. The minimum information to be provided for this purpose should be:
  - a copy of, or reference to, the information provided at the time of the notification of control action;
  - indication that an export of the chemical concerned is expected or is about to occur.

C. WHO - Work in the area of chemicals and pharmaceutical products

14. The WHO work that may be considered as of direct relevance to the issues covered by the note, relates to:

- (i) that done by the Organization in collaboration with UNEP and ILO, under the International Programme on Chemical Safety (IPCS) to disseminate information and guidance on the safe use of chemicals; and

- (ii) that done by the Organization itself as a component of the WHO Pesticide Evaluation Scheme (WHOPES) related to pesticide safe use and the classification of pesticides by hazard;
- (iii) that done by it for dissemination and exchange of information on safety and efficacy of drugs;
- (iv) that done by the Organization in collaboration with FAO in the implementation of the Code of Conduct; and

(a) Work in the area of chemical safety

15. One of the main objectives of the IPCS is to carry out and disseminate scientific evaluations of the risks to human health and the environment from exposure to chemicals, mixture of chemicals or combination of chemicals and physical and biological agents. The evaluations carried out under the programmes provide scientific basis for countries in adopting their chemical safety regulations. In particular, the IPCS assists UNEP in the implementation of the Guidelines on Banned and Severely Restricted Chemicals by providing the scientific evaluation of the specific chemicals listed. The results of the evaluations are published in the following forms:

- (i) Environmental Health Criteria, which are, inter alia, designed to assist regulatory authorities in elaborating policies for the safe use of chemicals;
- (ii) Health and Safety Guides, which summarize for the benefit of administrators, managers and other interested members of the public in non-technical language the various aspects of using chemicals safely and avoiding health hazards;
- (iii) International Chemical Safety Cards, summarizing essential product identity data and health and safety information on chemicals for use at the "shop floor" level by workers.

(b) Work in the area of pesticides

16. The main objective of the WHO Pesticide Evaluation Scheme is to test new pesticides on pests of public health importance; to reinforce the quality control of pesticides in developing countries; and to enable countries to purchase pesticides of known efficacy for operational use in vector (pest) control by developing specifications for pesticide use and publishing them in the periodic manual, Specifications for Pesticides Used in Public Health.

(c) Dissemination of information on safety and efficacy of drugs

17. Under the Drug Action Programme, the WHO brings out periodically Pharmaceutical News Letter, by which Health Ministers of member States are informed of decisions to prohibit or limit the availability of drugs already in use. In addition, evaluated information on drugs, is published for wider circulation in "WHO Drug Information"

D. United Nations Secretariat's Consolidated List of products banned, severely restricted and/or not approved by governments

18. The United Nations Secretariat plays a co-ordinating role by disseminating information collected from various international and other organizations by publishing, periodically, a Consolidated List of products "which are banned, withdrawn, severely restricted and/or not approved by governments". It is being prepared in pursuance of a Resolution adopted in 1982, which, inter alia, noted that continued exports of such products, was causing "damage to the health and environment" and suggested that publication of such a Consolidated List would assist "many developing countries (which) lack the necessary information and expertise to keep with the developments in the field".

19. The third version of the List, which was published in 1988 contains over 600 products relating to which some ninety-three countries have taken restrictive regulatory actions for health, safety and environmental reasons. The fourth issue, which will contain data current as of 1 March 1989, will mark an additional substantial increase. Under the collaboration arrangements which were formalized in 1985 the WHO collects, screens and processes the information relating to regulatory measures taken by governments on pharmaceutical products and on the reasons (health related and environmental) for which they were taken; the UNEP/IRPTC perform similar functions relating to chemical products. The United Nations secretariat co-ordinates these inputs, and ensures that the relevant information available in other organizations (e.g. FAO and ILO etc.) is utilized in preparing the List.

20. The Consolidated List is divided into two parts. In Part one, the information on restrictive regulatory decisions is presented separately for the following five product groups:

- (i) Pharmaceuticals (mono-competent products);
- (ii) Pharmaceuticals (combination products);
- (iii) Agricultural chemicals;
- (iv) Industrial chemicals;
- (v) Consumer products.

21. For each of the products listed under the group, the List contains information on:

- (i) product name;
- (ii) its scientific and common names and synonyms; and
- (iii) brief descriptions of the legislative or regulatory action taken.

22. The last heading indicates, in respect of each country taking regulatory action, effective date of the action, the grounds for the decision and an indication if action applies also to exports.

23. The Explanatory Notes to the List emphasize that:

"It should be noted that decisions taken by a limited number of Governments on a specific product may not be representative of other Governments' positions, particularly in view of differing risk-benefit considerations. It is also important to realize that all pharmaceutical and chemical products are potentially harmful if not correctly used. In addition, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country; it may mean that the relevant regulatory decision has not been communicated to the United Nations, WHO or UNEP, or that, in the case of pharmaceuticals and pesticides, for example, which are frequently subject to compulsory registration procedures, the product has not been submitted for registration. The efficacy of products listed is not addressed, but is an aspect that may be crucial when a Government is considering regulatory action."

24. The criteria on the basis of which products have been classified as (i) banned; (ii) severely restricted; (iii) withdrawn; and (iv) voluntarily withdrawn, have been developed in consultation with the governments (see Annex I). The Explanatory Notes to the List however state that even though the adoption of the criteria has significantly facilitated screening of the information, governments' interpretation of the criterion "severely restricted" in particular, continue to vary widely, leading to considerable unevenness in reporting on national restrictive regulatory measures.

25. The Explanatory Notes further clarify that:

- the list does not include many widely used industrial chemicals to which occupational exposure limits have been assigned by national authorities, and on which information is available in ILO and UNEP/IRPTC publications;
- food additives are also outside the scope of the List, since the FAO/WHO Codex Alimentarius deals with them;
- consumer products are only included when they are hazardous because of their chemical composition;
- psychotropic and narcotic substances scheduled under one of the international conventions are included only where a government is controlling a substance more rigorously than required under the relevant international convention;
- with regard to agricultural and industrial chemicals, it should be noted that regulations often refer to chemical groups, such as arsenic compounds, rather than to specific chemicals.



26. Part two of the Consolidated List presents commercial information, including data on trade names, relating to a large proportion of the products covered in Part one. It provides an easy method to cross-reference trade names with recognized common scientific names, under which the regulatory data are presented.

E. Work of other organizations

27. Other organizations active in this area of work include the International Labour Office (ILO) and the United Nations Centre on Transnational Corporations (UNCTC). ILO's work is concentrated on the International Occupational Safety and Health Hazard Alert System, intended to disseminate information on safety and health hazards found to be associated with the working environment, and on various aspects of the protection of workers against the effects of harmful or potentially harmful products. UNCTC contributed to the information provided by specialized agencies to the UN Secretariat, in drawing up the Consolidated List, by collecting such information as relevant trade names and transnational manufacturers of and distributors of particular chemicals identified by the secretariat as toxic and hazardous.

PART II

WORK DONE FOR DISSEMINATION OF INFORMATION ON EXPORTS OF PRODUCTS  
BANNED OR SEVERELY RESTRICTED AND FOR DEVELOPING GUIDELINES AND  
CERTIFICATION SCHEMES TO BRING UNDER CONTROL TRADE IN SUCH PRODUCTS

A. OECD

(a) Banned or severely restricted chemicals

28. In April 1984, the OECD Council adopted a recommendation and guiding principles on information exchange related to export of banned or severely restricted chemicals. These were prepared by an expert group established under the OECD Special Programme on the Control of Chemicals. The principles underlying these documents have been incorporated into much of the work undertaken by UNEP in the area of chemicals and by FAO in relation to pesticides, described later in this Part.

29. The OECD recommendation and principles, while laying the primary responsibility for the protection of human beings and the environment from hazards associated with imported chemicals on importing countries, recommend that if any banned or severely restricted chemical is exported, information be provided from the exporting country to the importing country, including non-OECD members, to enable the latter to make "timely and informed decisions" concerning the chemical.

30. "Banned or severely restricted" includes any chemical subject to a control action to ban, or severely restrict, the use of the chemical in order to protect human health or environment domestically; or to refuse required authorization for the first-time use on the grounds that such use would endanger human health or the environment. The guiding principles do not apply to hazardous substances.

31. If such a product is exported, the importing country should be informed (if possible, before exportation takes place):

- that such an export is expected or imminent;
- of the identity or chemical specification of the chemical;
- of the description of the control action taken by the exporting country; and
- if supplementary information is available and the contact point for such supplementary information.

32. Such information would be on a one-time basis at the time of the first export following the control action.

(b) Consumer products

33. The OECD Committee on Consumer Policy has been operating an informal notification system on safety measures concerning hazardous products since 1973. This procedure, which covers new product safety legislation, regulations and guidelines, product bans and recalls, and research projects, has generated more than 500 notifications since its creation. The Committee has recently undertaken an in-depth review of the system to strengthen the commitment for active participation by Member countries and to clarify certain procedures for the users of the system. This resulted in a proposed Draft Council Decision-Recommendation with Guiding Principles for implementation. Three points were discussed and have been confirmed by this review:

- that the system would cover consumer goods, excluding foods and drugs, automobiles and related transport equipment, which are monitored by specialised authorities or government agencies;
- that notifications, would be circulated only within the OECD area;
- that notifications to non-government bodies were risky and would be discouraged except if it is believed notifications are necessary and will be dealt with adequately.

The Guiding Principles require that Member countries notify the secretariat of their national contact points; describe the standard forms to be used for the presentation of information; recommend timings for notifications; and specify the degree of confidentiality involved in notification.

34. The Council Recommendation Concerning the Safety of Consumer Products of 1979 and Recall Procedures for Unsafe Products Sold to the Public of 1981, calls on governments of member countries to ensure that those goods that are banned or withdrawn from sale within their territories because they are inherently so hazardous that they present a severe and direct danger to life, health or safety of any consumer of those goods, are not exported to other countries and urges governments to consider the desirability of seeking powers to prohibit export of dangerous goods, where such powers do not yet exist. Following this Recommendation, several of the general product safety laws introduced in a number of countries also refer to the prohibition of the export of products banned on domestic markets. The Committee is expected to take a brief review of these developments in the near future.

B. UNEP

(a) Notification of exports of banned or severely restricted chemicals

35. The London Guidelines, which call upon countries to notify the designated authorities in other countries, the control actions taken by

them to ban or severely restrict a chemical, provide further that if an export of such a chemical takes place the exporting country should ensure that necessary steps are taken to provide the designated national authority of the importing country with the original notification regarding control action, and alert it to the fact that an export of the chemical concerned will occur, or is occurring. It is the intention that in so far as possible, the information should be provided prior to export.

(b) The Prior Informed Consent (PIC) Procedure

36. Prior Informed Consent (PIC) refers to the principle that the international shipment of a chemical that is banned or severely restricted in order to protect human health or the environment should not proceed without the agreement, where such agreement exists, or contrary to the decision, of the designated national authority in the importing country.

37. The PIC procedure is a procedure for formally obtaining and disseminating the decisions of importing countries as to whether they wish to receive future shipments of chemicals which have been banned or severely restricted. A country may elect at any time to participate or not participate in the PIC procedure by communicating its decision to IRPTC. All exporting countries are expected to participate in the PIC procedure by respecting the decision of importing countries.

(c) Identification of chemicals to which PIC procedures should apply

38. IRPTC will notify each participating country of each chemical that is the subject of a notification of a final government control action and that meets the definitions as being banned or severely restricted for environmental or human health reasons for a decision as to whether that country wishes to permit use and importation of the chemical.

39. IRPTC will send qualifying control actions, along with PIC "Decision Guidance Documents" (see paragraph 44), to the appropriate designated national authority or authorities in each participating country for a decision. A specific procedure was established for selecting chemicals for initial implementation of the PIC procedure. These include chemicals which have been previously banned or severely restricted by five or more countries as well as certain pesticide formulations which are acutely toxic.

40. Countries would then make a response within 90 days indicating a final decision to permit use and importation of these chemicals, to prohibit use and importation or to permit importation only under specified conditions; or an interim response to request information or assistance in evaluating chemicals or to permit or prohibit importation during the interim period until a final decision is made.

41. Importing countries participating in the PIC procedures would send their replies to IRPTC for further dissemination. Even if a country does not make a response, the chemical should not be exported without the explicit consent of the importing country, unless it is a pesticide which is registered in the importing country or is a chemical - the use or importation of which has been allowed by other governmental action of the importing country.

42. IRPTC will inform designated national authorities of decisions taken by participating importing countries in a timely fashion and should also make these available to industry and other interested parties on request, preferably through a computer data base. This information should also be included in the regular updates of the United Nations Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or not Approved by Governments. Semi-annually, IRPTC will notify all Governments in writing of the status of the decisions by importing countries.

43. For purposes of international communications, each State should designate a national governmental authority (or authorities) competent to perform the administrative functions related to the exchange of information and decisions regarding importation of chemicals included in the PIC procedure.

(i) With regard to imports of banned or severely restricted chemicals, the designated national authorities should ensure that decisions apply uniformly to all sources of import and to domestic production of chemicals for domestic use, and encourage that chemicals subject to PIC be purchased only from sources in exporting countries which are participants in that procedure.

(ii) With regard to exports of banned or severely restricted chemicals, the designated national authorities should communicate PIC decisions to their export industry, and implement appropriate procedures, within their authority, designated to ensure that exports do not occur contrary to the PIC decisions of participating importing countries.

(d) Institutional arrangements

44. UNEP will share with FAO the operational responsibility for the implementation of the PIC procedure and jointly manage and implement common elements including the selection of chemicals to be included in the procedure, preparation of decision guidance documents, mechanisms for information sharing and creation of data bases. UNEP and FAO will also collaborate in reviewing the implementation of the PIC procedure, including participation, responses and violations of importing country decisions.

C. FAO - Notification of export of banned or severely restricted chemicals

45. The 24th Session of the FAO Conference decided in 1987 that the principle of Prior Informed Consent should be incorporated in the International Code of Conduct on the Distribution and Use of pesticides. A working group was established to consider the issues involved and prepare a revised and amended text of the Code. This text was adopted by the 95th Session of the FAO Council which then agreed to request the 25th Session of the FAO Conference (11-13 November 1989) to approve the revisions and amendments to Articles 2 and 9 of the Code and the incorporation of the Guidelines on the Operation of Prior Informed Consent into the Code (see paragraphs 11-12), which would be operated in a joint programme with UNEP. As amended, the Code will provide that no pesticide which has been banned or severely restricted, as notified under the Information Exchange System, shall be exported to an importing country participating in the PIC procedure contrary to that country's decision made in accordance with information supplied to it through the Information Exchange System. The proposed text of the Prior Informed Consent Procedure requires FAO to:

- review notifications of control actions taken by countries to ensure that such action conforms with the Code's definitions of banned or severely restricted pesticides;
- develop PIC Decision Guidance Documents which will contain information on the reasons for the control actions taken by countries as well as some technical information on the pesticide. These documents will be transmitted to countries participating in the PIC procedure for their use in deciding what position they wish to take, with regard to importation of the pesticide;
- in cooperation with UNEP, develop and maintain a data base of control actions and decisions, taken by countries on individual pesticides;
- inform designated authorities and relevant international organizations of notifications of control actions, and any decisions communicated to FAO regarding the use and importation of a pesticide that has been included in the PIC procedure.

46. Governments of importing countries should establish internal procedures and designate an appropriate authority for the receipt and handling of information. It is envisaged that this authority will be the same for both FAO and UNEP purposes. In addition, governments of importing countries participating in the PIC procedure should:

- decide whether or not the pesticide in question will be accepted in their country and advise FAO as soon as that decision has been made;

- ensure that any actions taken with regard to an imported pesticide are not more restrictive than those applied to the same pesticide produced domestically or imported from a country other than the one that supplied the information;
- ensure that such a decision is not used inconsistently with the provisions of the GATT.

Governments of exporting countries should:

- advise their pesticide exporters and industry of the decisions of the participating importing countries;
- take appropriate measures within their authority and legislation to ensure that exports do not occur contrary to the decision of the participating importing country.

Both FAO and UNEP are presently discussing the details of the programme, to be launched sometime in early 1990.

D. WHO - Certification scheme on the quality of pharmaceutical products moving in international trade

47. A large number of countries permit domestic sales and imports of pharmaceutical products only after their drug authorities are satisfied on examination of the analytical data submitted by the company and the laboratory tests carried out by them, about their therapeutical and safety qualities. The manufacturers' plants at which such products are produced are also inspected periodically to ensure that adequate standards of cleanliness and quality control are maintained.

48. The drugs intended for exports are not always subjected to the same control procedures as is applicable to those produced for the home market. This places a number of developing countries, which have not been able to develop effective statutory control systems for prior registration of pharmaceutical products and laboratory facilities for drug analysis, in a disadvantageous situation, as drugs which have not been registered or have been refused registration as well as those which are substandard or spurious are exported to them.

49. To assist such countries WHO has evolved a certification scheme, under which an importing country may request the exporting country that pharmaceutical products exported to it should be accompanied by a certificate issued by a competent authority in the exporting country, which, inter alia, states that the exported pharmaceutical product:

- (a) is authorized for sale or distribution within the exporting member State (if not, the reasons therefore should be indicated);
- (b) the manufacturing plant in which it is produced is subject to inspection at suitable intervals and that the manufacturer conforms to requirements for good practices in the manufacture and quality control, as recommended by WHO.

50. At present, 118 countries participate in the scheme and have designated authorities which would be responsible for issuing the certificate or to make a request that products imported should be accompanied by such a certificate.

51. The scheme further calls on the designated authorities in the exporting country, to provide, if requested by the importing country's authority, additional information regarding the control exercised in the exporting country and on the implementation of the requirements relating to good manufacturing practices in the country.

52. The coverage of the scheme - which has been in operation since 1976 - was extended in 1988 to cover, apart from medicines intended for human use, veterinary products administered to food-producing animals presented in their finished dosage form, as well as "starting material" (basic drugs) used in their manufacture.

### PART III

#### WORK RELATING TO TOXIC AND OTHER HAZARDOUS WASTES

##### A. Illegal traffic in toxic and dangerous products and wastes

53. On 20 December 1988 the United Nations General Assembly adopted resolution 43/212 on the Responsibility of States for the Protection of the environment. This resolution contained obligations for the prevention of the illegal international traffic in, and the dumping and resulting accumulation of, toxic and dangerous products and wastes affecting the developing countries in particular. This resolution urged all States, to take the necessary legal and technical measures in order to halt and prevent the illegal international traffic in, and the dumping and resulting accumulation of, toxic and dangerous products and wastes; urged all States generating toxic and dangerous wastes to make every effort to treat and dispose of them in the country of origin to the maximum extent possible consistent with environmentally sound disposal. The resolution further requested the Ad Hoc Working Group of Legal and Technical Experts with a mandate to prepare a global convention on the control of transboundary movements of hazardous wastes established by the United Nations Environment Programme to give consideration to the present resolution and to the various views expressed during the forty-third session of the General Assembly. The General Assembly called upon the international community, in particular the developed countries, to strengthen its scientific and technical co-operation with the developing countries and to provide appropriate assistance to them in their efforts to eliminate the adverse consequences of toxic and dangerous products and wastes for human health and the environment.



54. The work of the United Nations Environment Programme (UNEP) in this field is on two fronts: first, in gathering information to assist the Secretary-General in the preparation of the report; and second, in developing mechanisms in the context of the Global Convention on Control of Transboundary Movements of Hazardous Wastes (see paragraphs 54-57 below), to address the question of control of illegal traffic in such wastes.

B. The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal

55. By Decision 14/30 of 17 June 1987, the Governing Council of UNEP approved the Cairo Guidelines and Principles for the Environmentally Sound-Management of Hazardous Wastes. By the same Decision, it authorized the Executive Director of UNEP to convene a working group of legal and technical experts with a mandate to prepare a Global Convention on Control of Transboundary Movements of Hazardous Wastes, to be ready for signature, if possible, by early 1989. UNEP was to base its work on the Cairo Guidelines and on work already undertaken by other international organizations and bodies in particular the OECD.

56. Pursuant to that Decision, the Ad Hoc Working Group of Legal and Technical Experts has met six times between October 1987 and March 1989. At the same time a number of informal negotiation meetings were convened by the Executive Director of UNEP with representatives of Governments, non-governmental organizations and industry. Experts from 96 States participated in the sessions of the Working Group and representatives of over 50 organizations attended as observers.

57. As the result of these negotiations, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the 116 States participating in the Conference of Plenipotentiaries on the Global Convention on the Control of Transboundary Movements of Hazardous Wastes, which was convened by the Executive Director of the United Nations Environment Programme (UNEP) and held in Basel at the invitation of the Government of Switzerland. The Final Act of the Basel Conference was signed by 104 States and the European Economic Community (EEC). As of 1 September 1989, 37 States and EEC have signed the Convention which shall remain open for signature up to 22 March 1990 and shall enter into force upon ratification by 20 State signatories. As of the same date one State has ratified it.

58. A summary of the basic principles and major provisions of the Basel Convention include:

- (i) The generation of hazardous wastes and other wastes listed in Annexes to the Convention must be reduced to a minimum in terms of quantity as well as hazard potential. Where the generation of hazardous wastes or other wastes is unavoidable, they must be disposed of as close as possible to their source of generation, and the environmentally sound management of the wastes must be guaranteed, whatever the place of their disposal.

- (ii) Hazardous wastes shall only be exported if the State of export does not have the technical capacity and facilities to dispose of them in an environmentally sound manner; the export of hazardous wastes and other wastes is prohibited if the exporting State has reason to believe that their environmentally sound management and disposal would not be guaranteed in the prospective state of import.
- (iii) Every State has the sovereign right to ban the import of hazardous wastes or other wastes and shall inform the other States, through the Secretariat of the Convention, of its decision. No State shall allow any transboundary movement of hazardous wastes or other wastes to a State which has prohibited their import.
- (iv) The States shall also prohibit export of hazardous wastes to a group of States belonging to an economic and/or political integration organization if the national legislation of these States prohibits such import. The export of hazardous wastes to a State which is not a party to the Convention, as well as the import of hazardous wastes from a non-party State is prohibited. Parties have the right, however to enter into multilateral, bilateral or regional agreements with other parties or with non-parties, provided that such agreements are no less environmentally sound than the provisions of the Convention and that these provisions are not less stringent.
- (v) Hazardous wastes or other wastes subject to transboundary movement must be packaged, labelled and transported in conformity with generally recognized international rules and standards and due account must be taken of relevant internationally recommended practices.

Furthermore, the control measures of the Convention stipulate that where transboundary movements are generally permissible, the Convention provides for an elaborate control system which is based on the principle of Prior Informed Consent (PIC):

- (i) The State of export must inform the competent authority of the State of import of any intended transboundary movement of hazardous wastes or other wastes. The information required must be sufficiently detailed to enable the authorities of the State of import to assess the nature and the risks of the intended movement. Among other things, it must specify the reason for the export, the exporter, the generator, the site of generation and the process by which the waste is generated, the nature of the wastes and their packaging as well as the intended itinerary, the site of disposal, the disposer and the method of disposal.

- (ii) The State of import must respond to the notifier in writing, consenting to the movement with or without conditions, denying permission for the movement or requesting further information. The State of export may not allow the movement to commence until written consent has been given and confirmation of the existence of a contract between the exporter and the disposer, specifying environmentally sound management of the wastes imported has been received.
- (iii) A transboundary movement of hazardous wastes or other wastes can take place through one or more States other than the State where the wastes are finally disposed. Unlike the States of export and import, a transit State can be a State which is not a party to the Convention and must be given prior notification containing the same information as is given to the State of import.
- (iv) Every State which considers the wastes to be hazardous is accorded the rights pertaining to its position in the transaction, even if other States concerned do not define the wastes as hazardous.
- (v) If a transboundary movement of hazardous wastes or other wastes which is otherwise carried out in accordance with the provisions of the Convention cannot be completed according to the contractual agreement, the State of export has a duty to ensure the re-importation of the wastes if alternative arrangements for environmentally sound disposal cannot be made within 90 days from the time the export State and secretariat have been informed.

The Convention provides for international cooperation, technical assistance and transmission of information in the following manner:

- (i) The Convention calls for international cooperation between parties in areas related to environmentally sound management such as development of low-waste technologies and environmentally sound waste management systems, transfer of technology and know-how, training of technicians, harmonization of technical standards and guidelines, and monitoring of the effects of waste management on human health and the environment. Special consideration is to be given to assisting developing countries, which are parties, in these areas.
- (ii) The Convention calls for transmission of information related to the control system, such as national definitions of hazardous wastes, authorities responsible for giving and receiving notifications of transboundary movements, decisions made by parties to ban the import and/or export of hazardous and other wastes, decisions by transit States not to require prior written consent, and bilateral, multilateral or regional agreements entered into by parties. The parties shall also inform each other on particulars of transboundary movements in which they have been involved, accidents occurring during transboundary movements, and measures adopted by them in implementation of the Convention.

59. The Basel Convention furthermore regulates the following matters:

- (i) the definition of hazardous wastes and other wastes to be covered by it;
- (ii) illegal traffic in hazardous wastes;
- (iii) liability and compensation for damage;
- (iv) action in case of emergencies;
- (v) establishment of the Conference of Parties;
- (vi) establishment of a Secretariat to ensure application of the Convention;

The Convention contains a series of annexes dealing with categories of wastes to be controlled and requiring special consideration: a list of hazardous characteristics; disposal operations; and information to be provided on notification.

60. The diplomatic conference held in Basel on 20-22 March 1989 also adopted several resolutions concerning the establishment of mechanisms for the implementation of the Convention; the relationship of the Convention with the London Dumping Convention; the review of existing rules, regulations and practices with respect to transport of hazardous wastes at sea; the protocol on liability and compensation for damage resulting from transboundary movement and disposal of hazardous wastes and other wastes; the harmonization of procedures of the Convention and the code of practice for international transactions involving nuclear wastes; and the development of technical guidelines for the environmentally sound management of wastes controlled by the Convention.

#### PART IV

##### CONCLUDING OBSERVATIONS

61. It would appear from the above description of the work done by other international organizations that considerable emphasis has been placed on development and improvement in systems for exchange of information on products which are banned, severely restricted or withdrawn from sale, in the markets of the exporting countries on the grounds that they are dangerous to public health, safety and the environment. All these systems, while admitting that it is to the importing country to adopt measures aimed at protection of human health and the environment, seek to ensure the provision of information from authorities or firms in exporting countries to enable importing countries to make informed judgments on banned or severely restricted products, that are entering trade. Such systems for exchange of information seem to have been relatively well developed in relation to three important product groups (viz. chemicals, pesticides and pharmaceuticals). For other product groups, particularly for consumer products, even though the UN Consolidated List contains some information, the work is at a relatively preliminary stage.

62. In addition to developing systems for exchange of information, effort has been made by some of these organizations to elaborate principles and guidelines which both exporting and importing countries might wish to adopt to bring trade in such products under control. These include, inter alia:

- (i) prior notification to the designated authorities in the importing countries that chemicals, pesticides or pharmaceuticals which are being exported are banned or severely restricted in the exporting country to enable them to decide whether the products should be imported or not;
- (ii) the elaboration of a concept of "prior informed consent" (PIC) under which an exporting country would permit exports of certain chemicals, pesticides, etc. which are subject to national control actions to ban or severely restrict their use, in accordance with relevant definitions of banned or severely restricted, only if the importing country consents to such imports being made; and
- (iii) the prohibition, where feasible and appropriate, of exports of goods which are considered to be inherently so hazardous that they present a severe and direct danger to human life, or health and safety of consumers.



ANNEX I

Criteria for the Inclusion of Pharmaceutical and  
Chemical Products in the Consolidated List

A. Pharmaceutical products<sup>1</sup>

(i) "Banned product"

A product that has been withdrawn from use and/or sale nationally in one or more countries by order of the competent national authority, having regard to its safety in relation to its intended use.

(ii) "Voluntary withdrawal"

A product that has been withdrawn from use and/or sale nationally in one or more countries by voluntary action of the manufacturer, having regard to its safety in relation to its intended use.

(iii) "Severely restricted"

A product containing:

(a) a substance that is controlled more rigorously than is provided for under the 1981 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances or that is subjected to analogous control at the national level before it has been considered for international scheduling;

(b) a substance that may be incorporated in pharmaceutical dosage forms only within specific limits determined by statute;

(c) a substance that is approved by a competent national authority and is subsequently subjected to restrictions that exclude its use in a substantial proportion of the potential target population of patients, having regard to its safety. A substance which from the outset has been severely restricted in its indications having regard to the known balance of safety and efficacy is excluded.

(iv) "Non-approved"

A product that has been formally submitted for registration by a manufacturer to a national competent authority and which has been rejected on grounds of safety.

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<sup>1</sup>Products which are in illicit trade only would not be considered.

B. Chemical products

(i) "Banned"

A product that has been prohibited for all uses nationally in one or more countries by final government regulatory action because of health or environmental reasons.

(ii) "Withdrawn"

A product formerly in commerce that has been withdrawn for all uses nationally in one or more countries by final voluntary action of the manufacturer because of health or environmental reasons.

(iii) "Severely restricted"

A product for which virtually all uses have been prohibited nationally in one or more countries by final government regulatory action because of health or environmental reasons, but for which certain specific uses remain authorized.