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INTERNATIONAL CO-OPERATION AND CO-ORDINATION WITHIN THE
UNITED NATIONS SYSTEM

Exchange of information on banned hazardous chemicals
and unsafe pharmaceutical products

Report of the Secretary-General

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INTRODUCTION

1. Pursuant to General Assembly resolution 36/166 of 16 December 1981, a report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products (A/38/190-E/1983/67) was submitted to the Assembly at its thirty-eighth session, through the Economic and Social Council. That report summarized the experience of Member States in the exchange of information on banned hazardous chemicals and unsafe pharmaceuticals through existing information systems. It also contained information concerning the facilities available in the United Nations system for the international exchange of information, as well as a description of the work being undertaken by the organizations of the system involved in this area to develop sources of information on those substances, which might be of use to governmental authorities seeking international advice on specific problems. The report noted that one question which remained unanswered was whether countries had an adequate infrastructure to control the import of those substances and if they did, whether such infrastructures were put to use. Another of the difficulties confronted by countries regarding the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products was the lack of consistent product information on those products and the problem of misrepresented products.
2. The General Assembly, in resolution 38/149 of 19 December 1983, took note of the above-mentioned report and, in paragraph 8 of the resolution, requested the Secretary-General to submit to it at its thirty-ninth session, through the Economic and Social Council, a report on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products, identifying elements for possible further work in that area in regard to the needs and capabilities of developing countries to monitor and control those substances in the light of the relevant observations in the report of the Secretary-General (A/38/190-E/1983/67). In paragraph 7 of the same resolution, the Assembly requested the Secretary-General to submit to it at its thirty-ninth session a report on the implementation of Assembly resolution 37/137 of 17 December 1982, including the consolidated list of products whose consumption and/or sale had been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments.
3. The question of exchange of information on chemicals and pharmaceuticals is extremely complex, involving both the production and the handling and use of those products, nearly all of which have prescribed exposure limits. Governments have to assess the benefits to be gained from the use of potentially dangerous products under local conditions and also to consider the need for production controls and import regulations, as well as such factors as packaging and labelling. They need to exchange information, *inter alia*, on official regulatory measures taken with regard to specific products, the particular uses and conditions of use of specific products, and the administrative and legal frameworks established for dealing with those products.
4. A review of activities concerning different aspects of the exchange of information on those products undertaken by international organizations both within and outside the United Nations system reveals a great diversity in the types of

actions carried out. They can, none the less, be grouped according to their relationship to three principal functional categories: (a) the establishment and maintenance of mechanisms for the exchange of information; (b) the development of guiding instruments for the exchange of information; and (c) the preparation of technical information. Although any given activity may be related functionally to more than one category, it will normally be associated primarily with a single function. The first category, mechanisms for exchange of information, covers all those cases in which there is an established system for the exchange of information. Two subcategories are (a) systems for the exchange of information and (b) expert meetings (working groups, workshops, and panels and committees of experts, for example) which have been instrumental in the establishment of such systems or in their further development. The second category covers those elements which are the guiding instruments for the exchange of information, and includes (a) policy measures which have been approved by governing and legislative bodies of organizations and which establish, orient or guide the creation and evolution of an exchange of information (resolutions, recommendations, principles, agreements, system guidelines) and (b) specific, more detailed implementation measures (codes, standards, classifications, notification and certification schemes) of a technical nature which are used to carry out policy through normative (for example, codes) or procedural (for example, notification schemes) means. The last category comprises the basic technical information input which may be further subdivided as (a) reference documents (including product registers, lists and inventories, glossaries, directories and compendia) and (b) miscellaneous technical documents which deal more with the specific technical content of the information to be exchanged (technical data sheets and research reports, bulletins, technical guidelines on the manufacture, use and handling of the products, and manuals).

5. A considerable number of those activities have been initiated since the thirty-eighth session of the General Assembly. Moreover, there are currently various proposals aimed at promoting improvement in the exchange of information at the international level. Accordingly, it was felt that it would be useful to submit in the present report an overall review of the action being taken or proposed by the various organizations. 1/

6. Attention is particularly drawn to a number of recent developments of special interest in this context: the provisional notification scheme for banned and severely restricted chemicals proposed by the Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in Particular Pesticides) in International Trade of the United Nations Environment Programme (UNEP) (paras. 34-39 below), the draft guiding principles being developed in the Organisation for Economic Co-operation and Development (OECD) on the exchange of information related to export of banned or severely restricted chemicals (paras. 74-78 below); the work of the Council of Europe with regard to the sale of European pharmaceutical products in the countries of the third world (para. 83 below); and the work of the Organization of American States (OAS) with regard to the preparation of a list of substances banned or significantly restricted in the United States of America (paras. 94-96 below).

7. In addition to information collected from the organizations of the United Nations system, the present report draws on the "Survey of programmes and activities for the exchange of information on potentially harmful chemicals (in particular pesticides) in international trade", prepared by UNEP for the first meeting of the Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in Particular Pesticides) in International Trade (UNEP/WG.96/3). The information provided in the report on the activities of the regional intergovernmental and non-governmental organizations focuses on main relevant developments but is not intended to be exhaustive.

8. The information provided for the report has been presented according to organization, but it is supplemented, for the purpose of cross-organizational examination, by the table in the annex below, which groups organizations' activities according to the three functional categories described above and provides reference to the paragraphs in which the relevant text is located. The present report, together with the one being prepared pursuant to paragraph 7 of General Assembly resolution 38/149, is accordingly intended to provide Governments with a basis for considering what further action may be required.

II. ACTIVITIES OF THE UNITED NATIONS SYSTEM OF ORGANIZATIONS

A. United Nations

1. Department of International Economic and Social Affairs

9. Pursuant to General Assembly resolution 37/137, the Secretary-General of the United Nations, in co-operation with the organizations of the United Nations system concerned, has prepared a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments. A first issue of the consolidated list was completed on 20 December 1983 and it will be regularly updated. As mentioned above, pursuant to Assembly resolution 38/149, the Secretary-General will submit to the Assembly at its thirty-ninth session a report on the implementation of Assembly resolution 37/137, including the consolidated list.

2. United Nations Centre on Transnational Corporations

10. The work of the Commission on Transnational Corporations on the draft United Nations Code of Conduct on Transnational Corporations is relevant to the question of exchange of information on potentially harmful chemicals. The section of the draft Code concerning environmental protection specifies the information that transnational corporations should supply to the competent governmental authorities regarding products which may harm the environment. 2/

11. Paragraph 42 of the draft Code of Conduct states that:

"Transnational corporations shall/should, in respect of the products, processes and services they have introduced or propose to introduce in any country, supply to the competent authorities of that country on request or on a regular basis, as specified by these authorities, all relevant information concerning:

"Characteristics of these products, processes and other activities including experimental uses and related aspects which may harm the environment and the measures and costs necessary to avoid or at least to mitigate their harmful effects;

"Prohibitions, restrictions, warnings and other public regulatory measures imposed in other countries on grounds of protection of the environment on these products, processes and services."

12. In paragraph 43, the draft Code also states that:

"Transnational Corporations shall/should be responsive to requests from Governments of the countries in which they operate and be prepared where appropriate to co-operate with international organizations in their efforts to develop and promote national and international standards for the protection of the environment."

13. In 1982, the Ad Hoc Intergovernmental Working Group of Experts on International Standards of Accounting and Reporting made recommendations regarding disclosures to be made by individual member enterprises of transnational corporations regarding toxic or hazardous products which they manufactured, sold or licensed. The Working Group of Experts considered that, in the case of each such product of a transnational corporation, the individual member enterprise should disclose, among other things, company policies and standards adopted for the protection of health and the environment for the transport and storage of the product, and for safe waste disposal; known existing government restrictions and company sources for further information (see E/C.10/1982/8, annex III, paras. 304-305).

14. In addition, the United Nations Centre on Transnational Corporations provided information on names of manufacturers and trade names for inclusion in the consolidated list (see para. 9 above) and will continue to co-operate in providing information for future updates.

3. United Nations Conference on Trade and Development

15. The United Nations Conference on Trade and Development (UNCTAD) has organized regional workshops on trade and technology policies in the pharmaceutical sector, for the Caribbean and for French-speaking Africa. The action programme of the workshop held at Abidjan in 1981, in particular, stressed the urgency of drafting an international instrument that would take account of the interests and specific

needs of developing countries in all areas relating to the pharmaceutical sector (prices, advertising, procurement, distribution, research and development, industrial property rights, transfer and development of technology etc.). To that end, the participants invited international bodies, in particular the World Health Organization (WHO) and UNCTAD, to take the necessary steps for the formulation of a code of conduct in the pharmaceutical sector.

16. The Conference, at its sixth session, in resolution 143 (VI) of 2 July 1983, 3/ inter alia, noted the work carried out by UNCTAD in the field of pharmaceuticals and the proposed participation of UNCTAD, together with the United Nations Commission on Transnational Corporations, the United Nations Industrial Development Organization (UNIDO), the World Intellectual Property Organization (WIPO) and the Economic and Social Commission for Asia and the Pacific (ESCAP), in the project on the "Formulation of appropriate strategies for facilitating pharmaceutical supplies to the developing countries", for which WHO has been designated as the lead agency by the Administrative Committee on Co-ordination (ACC) Task Force on Science and Technology for Development, and requested the Secretary-General of UNCTAD to report to the Trade and Development Board at its twenty-eight session on the possible collaboration of UNCTAD with WHO in this sector, particularly in the area of transfer of technology (see TD/L.254). 4/ The Conference also requested the Secretary-General of UNCTAD to report to the Trade and Development Board, at its twenty-eighth session, on possible collaboration of UNCTAD with WHO in the pharmaceutical sector, particularly in the area of transfer of technology. The Secretary-General of UNCTAD presented a report (TD/B/982) to the Trade and Development Board in April 1984. The Board decided to remit that report and a draft resolution entitled "Towards the technological transformation of developing countries in the pharmaceutical sector" (TD/B/XXVIII/SC.1/L.2) to its twenty-ninth session for further consideration. In the draft resolution the Board would request the Secretary-General of UNCTAD to circulate to member States, for their comments, the International Federation of Pharmaceutical Manufacturers Associations' Code of Marketing Practices in the Pharmaceutical Sector, and Health Action International's draft proposal for an international code on pharmaceuticals.

4. United Nations Industrial Development Organization

17. The environmental work of UNIDO includes (a) investigation of water and air pollution by toxic chemicals stemming from industries, (b) recommendations on process changes or equipment required for the control of pollution from toxic chemicals, (c) preparation of guidelines which include toxic chemicals occurring in industrial processes, (d) preparation of studies which include preparedness for transport accidents involving hazardous chemicals and (e) implementation of training programmes on industrial pollution for officials from developing countries. In particular, UNIDO has thus issued guidelines on the formulation of pesticides in developing countries, in 1983, 5/ and related regional reports on pesticide use in Latin America, in 1980, and on a pesticide data collection system for Asia and the Pacific, in 1983. With regard to pharmaceuticals, good manufacturing practices, quality assurance and safety form an integral part of the pharmaceutical projects of UNIDO. UNIDO is also advocating that the control of imported pharmaceuticals should be exercised with the same strictness as is the case with local production of pharmaceuticals.

5. United Nations Environment Programme

18. The concern of UNEP with the world-wide environmental impact of chemical products dates back to the Action Plan for the Human Environment of the United Nations Conference on the Human Environment, held at Stockholm from 5 to 16 June 1972, especially recommendation 21 on international programmes for integrated pest control and reduction of the harmful effects of agro-chemicals, and recommendation 74 on an international registry of data on chemicals in the environment, which was to become the International Register of Potentially Toxic Chemicals (IRPTC). 6/

19. Since then, by decision 85 (V) of 25 May 1977, the Governing Council of UNEP urged Governments "to take steps to ensure that potentially harmful chemicals, in whatever form or commodity, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing country". 7/ By decision 6/4 of 24 May 1978, the Governing Council:

"1. Appeals to the countries exporting potentially harmful chemicals, in whatever form or commodity, to prevent the export of items which are restricted, or not registered for use, in the countries of origin until the exporting countries have ascertained that the results of tests and evaluations on the effects of these chemicals on the health of people and the environment (as well as detailed instructions in mutually agreed languages for the safe use of these products) have been provided to the designated authorities in the recipient countries, so as to make it possible for these authorities to make fully informed decisions on the import and utilization of the products;

"2. Further appeals to the Governments of recipient countries to take appropriate measures to strengthen the capabilities of the authorities designated to make the decisions referred to in paragraph 1 above;

"3. Calls upon the Governments of both exporting and recipient countries to institute adequate monitoring, evaluative and protective measures in this regard". 8/

20. In addition to the activities carried out under the IRPTC programme and those of the Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in Particular Pesticides) in International Trade, convened pursuant to UNEP Governing Council decisions 10/21 and 10/24 of 31 May 1982 and 11/7 of 24 May 1983, 9/ mention should be made of the IRPTC International Referral System (INFOTERRA) Directory of Information Sources on Chemical Safety and the reports and guidelines of the UNEP Industry and Environment Office, especially the 1982 guidelines on risk management and accident prevention in the chemical industry".

(a) UNEP/International Register of Potentially Toxic Chemicals

21. In subparagraph (e) of recommendation 74, the United Nations Conference on the Human Environment recommended that

"the Secretary-General, drawing on the resources of the entire United Nations system and with the active support of Governments and appropriate scientific and other international bodies ... develop plans for an International Registry of Data on Chemicals in the Environment based on a collection of available scientific data on the environmental behaviour of the most important man-made chemicals and containing production figures of the potentially most harmful chemicals, together with their pathways from factory via utilization to ultimate disposal or recirculation". 10/

22. The Governing Council of UNEP, in its decision 29 (III) of 2 May 1975, authorized the Executive Director of UNEP to establish a programme activity centre for the International Register of Potentially Toxic Chemicals, to serve as an essential tool in optimizing the use of chemicals for human well-being and at the same time to provide a global early warning system of undesirable environmental side effects. 11/

23. At its fourth session, in its decision 63 (IV) of 13 April 1976, the Governing Council decided that the Register should be a component of Earthwatch, the global environmental assessment programme of UNEP. 12/ Earthwatch consists of four components, namely, evaluation and review, research, monitoring, and information exchange. The Register, along with INFOTERRA for sources of environmental information, forms the information exchange component of Earthwatch. The Register has close links with all the agencies and bodies mentioned in the present report, as well as with information networks regionally and nationally, industry, and with non-governmental organizations dealing with environmental problems and groupings dealing with chemicals that are the cause of concern.

24. The Register's objectives are the following:

(a) To facilitate access to existing data on the effects of chemicals on man and his environment and thereby to contribute to a more efficient use of national and international resources available for the evaluation of effects of chemicals and their control;

(b) On the basis of information in the Register, to identify important gaps in the existing knowledge of the effects of chemicals and to call attention to the need for research to fill those gaps;

(c) To identify or help to identify potential hazards from chemicals and to improve the awareness of such hazards;

(d) To provide information on national, regional and global policies, regulatory measures and standards and recommendations for the control of potentially toxic chemicals.

25. The strategy to meet those objectives involves the following activities:

(a) Rendering the Programme Activity Centre of IRPTC capable of handling data and answering questions;

(b) Involving correspondents designated at the national, regional and sectoral levels in the operations of IRPTC;

(c) Building a network of participating data systems, which may make their files available to the Programme Activity Centre of IRPTC for incorporation in its central data files, or may respond directly to users' queries;

(d) Developing and continuously updating computerized central data files;

(e) Publishing selected information on chemicals.

26. In its decision 6/3 B of 24 May 1978, the Governing Council called upon the Executive Director of UNEP to ensure that IRPTC would facilitate access to available information; urged him to intensify his efforts to increase the number of national correspondents, to hold workshops to familiarize developing countries with the use of the Register; and requested him to give priority to providing countries with information on legal and administrative limitations, bans and regulations on potentially toxic chemicals. Member States were also requested to assist the Executive Director by appointing national correspondents of the Register and to improve their national mechanisms in terms of personnel, facilities and organization so as to enhance the capability of IRPTC to fulfil its task efficiently and effectively. 13/

27. The main operations of IRPTC involve the collection, validation, processing and storage of information on chemicals and its dissemination through a regularly published Bulletin, through data profiles for chemicals, and through the preparation of a query-response service and other means.

28. Those data profiles for chemicals provide the information necessary to evaluate the potential hazards posed by chemicals to the health of man and to his environment, or indicate the absence of such information in publicly available literature. They are prepared by IRPTC mainly for the use of those responsible for protecting human health and the environment from the noxious effects of chemicals. The data profiles contain information on, inter alia, production and use, pathways into the environment, concentrations and transformation in the environment, chemiokinetics, toxicity to mammals and man, effects on non-mammalian organisms and plants, treatment of poisoning, waste management, and national and international recommendations and regulations for the control of chemicals in the air, water, drinking water, wastes, soil, food and beverages, and consumer goods. So far, over 400 computerized data profiles on chemicals of international significance have been prepared and are available on request, while an additional 100 profiles are in an advance stage of operation.

29. Legal files for chemicals furnished by IRPTC in response to the request of the Governing Council of UNEP in its decision 6/3 B that priority should be given to providing countries with information on legal and administrative limitations, bans and regulations placed on potentially toxic chemicals in the producing countries, are of particular interest in the context of the present report. In 1983, IRPTC published a compendium of national and international recommendations and regulations for the control of chemicals in air, water, soil, food, beverages,

consumer goods, and wastes, which contains data on 450 chemicals from 12 countries and six international organizations. 14/

30. The International Register has been designed to operate on the basis of network arrangements for information exchange, and on the development of central files on chemicals. From the start of its activities, the identification of potential network partners and the implementation of effective collaboration has been a priority task for the Register. It has established contacts and working relationships with several United Nations agencies and bodies, information networks and governmental and non-governmental organizations dealing with the control of chemical hazards. IRPTC co-operates closely with the International Programme on Chemical Safety (IPCS) (see para. 66 below) and serves as a lead institution to the Programme for collection, storage and dissemination of data on chemicals which have been selected for risk evaluation.

31. A network of 107 correspondents for IRPTC at the national level has been built up through appointment by 98 Governments. Those correspondents play an important role in the operation of IRPTC by providing information on new or planned legislation to control chemicals, newly prepared regulations and recommendations regarding chemicals, new additional studies on chemicals causing concern, and reports on accidents and incidents involving chemicals that have led to official inquiries. They also give advice on expertise relevant to IRPTC available in the country and distribute information processed and published by it. IRPTC assists in establishing national registers, in obtaining available information on chemicals, and in special training, where necessary, in order to provide a better understanding of IRPTC data presentation.

32. A regular Bulletin is published by IRPTC in English, French, Russian and Spanish and is widely disseminated through its global network. The Bulletin reports on new or proposed legislation and regulations on chemicals, newly discovered hazards or other news on chemicals, and on the work of IRPTC and other international and national organizations in the field of chemical safety. In addition, at the request of the Governing Council of UNEP, in its decision 9/6 of 25 May 1981, 15/ a list of environmentally dangerous chemical substances and processes of global significance was prepared, some of which are relevant to the present report, such as, for instance, pesticides.

33. Since its establishment in March 1976, IRPTC has responded to queries on chemicals using its own central files, and several other computerized bibliographic files, as well as handbooks and other reference works, criteria documents, reviews and regulations. Where necessary, it has sought the assistance of WHO, the International Occupational Safety and Health Information Centre of the International Labour Organisation (ILO) and national correspondents. Queries have been received from the United Nations, Governments, industry and individuals. They have ranged from questions on general toxicity information to questions on regulatory measures for specific chemicals in various environmental media from selected countries. At present an average of five queries a week are received in IRPTC, frequently covering more than one chemical at a time.

(b) Ad Hoc Working Group of Experts for the Exchange of Information on Potentially Harmful Chemicals (in Particular Pesticides) in International Trade

34. The first session of the Ad Hoc Working Group of Experts, convened pursuant to UNEP Governing Council decisions 10/21, 10/24 and 11/7, was held in the Netherlands from 26 to 30 March 1984. The participants considered draft guidelines for the exchange of information on trade and management of potentially harmful chemicals in particular pesticides (UNEP/WG.96/4). The meeting completed a first reading of the draft guidelines and recommended that further work be undertaken to revise the guidelines in the light of the comments made during the discussion and on the basis of those elements on which consensus has been reached. It was generally agreed that the guidelines should not apply to narcotic and psychotropic drugs and radioactive materials. However, no agreement was reached regarding other exemptions.

35. As a result of its deliberations, the Working Group recommended that the Executive Director of UNEP should submit to the Governing Council for possible adoption at its twelfth session in May 1984, a provisional notification scheme for banned and severely restricted chemicals. The stated purpose of the notification scheme is to provide experience with notifications which would assist the Ad Hoc Working Group in its future work.

36. The proposed scheme states that when the competent authorities in a country have taken control action to ban or severely restrict the use or handling of a chemical in order to protect human health or the environment domestically or to refuse a required authorization for proposed first-time use of the chemical domestically, based upon a decision that such use would endanger human health or the environment, they should notify directly or indirectly the designated national authorities in other countries of the action taken in order to give their competent authorities the opportunity to assess the risks associated with the chemicals and to make timely and informed decisions thereon, taking into account local environmental, public health, economic and administrative conditions. The minimum information to be provided for this purpose should be:

(a) The chemical identification/specification;

(b) 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;

(c) The fact that additional information is available, and the indication of the contact point in the country of export to which a request for further information should be addressed.

37. With regard to the export of a banned or severely restricted chemical, the proposed scheme states that the country of export should ensure that necessary steps are taken to provide the designated national authority of the importing country with relevant information. The scheme suggests that the minimum information to be provided for this purpose should be:

(a) A copy of, or reference to, the information provided at the time of the notification of control action;

(b) Indication that an export of the chemical concerned is expected or about to occur.

38. The proposed scheme further suggests that notifications regarding control action should be provided as soon as practicable after the control action is taken and should normally be addressed to the designated national authority in the importing country with a copy or summary to IRPTC. Alternatively, they could be addressed to IRPTC for transmission to designated national authorities. The information contained in such notifications is to be forwarded by IRPTC to the United Nations Secretariat. Information regarding exports should be provided by the country of export at the time of the first export following the control action and should recur in the case of any significant development of new information or conditions surrounding the control action. It is the intention that, in so far as possible, the information should be provided prior to export.

39. The Ad Hoc Working Group recommended continuous consultations and collaboration with other United Nations bodies and specialized agencies in the preparation and further elaboration of draft guidelines. Subject to authorization by the Governing Council, a second session of the Ad Hoc Working Group is scheduled early in 1985.

B. International Labour Organisation

40. The International Labour Organisation has a long history of activities and programmes on worker safety and industrial chemicals. The ILO Conference adopted, in 1919, recommendations on lead poisoning and white phosphorus and, in 1921, a convention on white lead. More recently, the Conference adopted a number of international instruments concerning the protection of workers against chemical hazards, namely, convention No. 136 and recommendation No. 144, in 1971, concerning the protection against hazards of poisoning arising from benzene; convention No. 139 and recommendation No. 147, in 1974, concerning the prevention and control of occupational hazards caused by carcinogenic substances and agents; convention No. 148 and recommendation No. 156, in 1977, concerning the protection of workers against occupational hazards in the working environment due to air pollution, noise and vibration. The ongoing ILO programme on toxic chemicals and exposure limits includes the negotiation of codes of practice such as, for instance, on occupational exposure to airborne toxic substances harmful to health. The ILO compendium of occupational exposure limits for airborne toxic substances will be updated at regular intervals, for which ILO has joined forces with IRPTC.

41. The International Occupational Safety and Health Hazard Alert System was established in 1978 as part of the ILO International Programme for the Improvement of Working Conditions and Environment. Its purpose is to disseminate rapidly, through a world-wide network of designated bodies in more than 100 countries, scientific and technical information on newly discovered or suspected occupational hazards and possibly on newly developed methods of prevention or protection. It

enables a country to issue an alert or request information on safety and health hazards that are found to be increasing. Three types of communications may thus be circulated in the system: alerts relating to hazards which are confirmed, described in detail and well documented; information concerning evidence of the existence of an occupational hazard that is not yet fully documented; and requests for information regarding a process or the use of a chemical substance suspected of presenting an occupational hazard on which more information is required.

42. Requests for published sources of information can be addressed to the ILO International Occupational Safety and Health Information Centre (CIS), a computerized data retrieval system established in 1959. The Centre provides abstracts in English and French from a data base currently containing more than 20,000 documents, including information regarding potential risks associated with specific chemicals and regulatory action taken on them in major industrialized countries.

C. Food and Agriculture Organization of the United Nations

43. The work of the Food and Agriculture Organization of the United Nations (FAO) in this field is especially related to the judicious use of pesticides in accordance with good agricultural practice and takes into account the potential hazards posed by the use of pesticides. FAO programmes and activities generally deal with a wide range of potentially harmful chemicals in international trade, including pesticides, fertilizers, veterinary products, food additives, food processing aids etc. The focus of attention since the early 1950s, from a point of view of transport, handling and use, has been on animal and plant protection products, as a key input for agricultural production.

44. Recognizing the possible hazards which might result from the widespread use of highly potent chemicals, the major objective of FAO in setting up its programme on pesticides was to ensure safety in both distribution and use. Over the past 20 years, as executing agency, FAO has many field development projects related to training in safe and efficient application practices and in monitoring of residues. Many of those projects have included support for the setting up of laboratories, for the provision of equipment and for the training of operatives and of laboratory technicians. The increasing emphasis on the study and management of pests in their natural environment, with consequently decreased reliance on chemical pesticides, has contributed to the overall objectives.

45. In addition to the policy guidance provided by the FAO Committee of Experts on Pest Control (formerly the Committee of Experts on Pesticides in Agriculture, established in 1962), the FAO Plant Protection Service provides secretariat services for four expert panels meeting on various aspects of pesticide usage, including their utilization in integrated pest control. The FAO Panel of Experts on Pesticide Residues in Food and the Environment meets jointly with the WHO Expert Committee on Pesticide Residues, providing the basis for the establishment of acceptable daily intakes and maximum residue limits in internationally traded food products as adopted by the Joint FAO/WHO Codex Alimentarius Commission.

46. The FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards (formerly the Working Party of Experts on Official Control of Pesticides, established in 1963) formulated guidelines for legislation concerning the registration for sale and marketing of pesticides, in 1969, jointly with WHO, and a model scheme for the establishment of national organizations for the official control of pesticides, in 1970 (revised guidelines are in preparation). The Panel of Experts also prepared a manual on the use of FAO specifications for plant protection products, in 1971 and, in co-operation with WHO, developed specifications for more than 200 technical grade pesticides and over 600 formulations thereof. The Panel also assisted in the organization of two Government Consultations on International Harmonization of Pesticide Registration Requirements, in 1977 and 1982, and Expert Consultations on Environmental Criteria for Registration of Pesticides, in 1979 and 1981.

47. The second Government Consultation, held in Rome from 11 to 15 October 1982, endorsed new FAO guidelines on good labelling practice for pesticides, proposed the further development of guidelines for the packaging and storage of pesticides and guidance on the disposal of surplus pesticides and pesticide containers, and recommended that the Director-General of FAO, in consultation with the appropriate United Nations organizations and bodies and international organizations outside the United Nations system, draft a code of conduct on the distribution and use of pesticides. Such a code is now in preparation and will be submitted to Governments for review in 1984. Article 10 of the draft code proposes the following provisions on information exchange:

"10.1 When a pesticide, the sale of which has been prohibited or severely restricted in the country of origin, is to be exported to another country, the trader involved should inform the authorities in that country of the prohibitions and restrictions imposed; and should fully inform such authorities, as well as handlers and users, as to the hazards posed by the product and ways of handling, transporting, using and disposing of the pesticide which will minimize health and environmental hazards.

"10.2 Where an exporting country has taken control action to ban or severely restrict the use or handling of a pesticide in order to protect health or the environment domestically, no export of such pesticide should take place:

"(a) without prior notification to the importing country government advising of the domestic regulatory status of the pesticide and the hazard which led to such restrictions;

"(b) without the explicit consent of the importing country.

"10.3 The exporting country should also take the necessary steps to provide to the importing country, at its request, additional available information which would assist the importing country in determining its need for carrying out an environmental impact assessment of such pesticides.

"10.4 The provision of such information by the exporting country must take into account protection of the confidentiality of data in the importing country.

"10.5 The importing country should establish internal procedures for the receipt and handling of information from the exporting country.

"10.6 The information received in the importing country, as described in this Article, should not be used in any manner which would be inconsistent with the provisions of the General Agreement on Tariffs and Trade (GATT)".

48. The Joint FAO/WHO Codex Alimentarius Commission also serves as the international food standard-setting body for the use of food additives and limits on chemical contaminants in food, on the basis of recommendations by the Joint FAO/WHO Expert Committee on Food Additives established in 1956. The Committee elaborates criteria (based on acceptable daily intake or, in the case of contaminants such as heavy metals, on the provisional tolerable weekly intake) for the acceptance of food additives in relation to specific food standards. The Food Policy and Nutrition Division of FAO provides technical assistance to developing countries for the implementation of those limits in the national food supply.

49. The Animal Production and Health Division of FAO, within the framework of the Programme for the Control of African Animal Trypanosomiasis and Related Development, published reviews on insecticides and application equipment for tsetse control and on the environmental impact of tsetse control operations, in 1977 and 1980, respectively. An Expert Consultation on the Environmental Impact of Tsetse Control was held in Rome from 9 to 12 June 1980. As part of the managerial structure of the programme, a Panel of Experts on the Ecological and Technical Aspects of Tsetse Control is convened every two years.

50. The concern for the impact on the environment of tsetse control is reflected in the high priority given to this subject in seminars, workshops and training courses. The impact on non-target organisms is routinely monitored in control programmes and research is supported to develop low-cost non-pollutant methods to be incorporated into integrated control systems. Funds for research are also provided to modify existing methods of insecticide application to decrease dosage and to apply the insecticide with greater selectivity to the tsetse habitat. A project has been implemented to study the fate and metabolism of trypanocidal drugs in order to use those compounds more effectively and economically and to determine the level of residues in livestock products.

51. The FAO Legislation Branch compiles and publishes the texts of national laws, including laws relating to the manufacture and use of agricultural chemicals, in its "Food and Agricultural Legislation" series, and provides related technical assistance to developing countries. In 1976 it published a study on international food standards and national laws, and it plans to prepare a comparative study on pesticide legislation for the biennium 1984-1985, which will concentrate on consumer protection aspects, pesticide hazards and international trade.

D. World Health Organization

52. The World Health Assembly has fully recognized the need for efficient channels of communication between member States on all issues bearing on the safety and

efficacy of drugs moving in international commerce, including the standards by which those criteria are determined. The basic fields of activity were identified in a resolution adopted by the World Health Assembly in 1962 (WHA15.41), in which the Director-General was requested to study means of:

(a) Establishing minimum basic requirements and recommending standard methods for the clinical and pharmacological evaluation of pharmaceutical preparations;

(b) Securing regular exchange of information on the safety and efficacy of pharmaceutical preparations;

(c) Securing prompt transmission to national health authorities of new information on serious side-effects of pharmaceutical preparations.

53. The World Health Organization has responded to this call and to a series of further resolutions adopted by its governing bodies by issuing reports of scientific groups on the general principles of toxicological testing of drugs and, specifically, on the assessment of bio-availability, mutagenicity and carcinogenicity; by developing an international scheme for monitoring adverse drug reactions; by devising a Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; and by transmitting to all member States decisions taken by national authorities to withdraw or restrict the availability of specific drugs on grounds of safety.

1. The international drug monitoring programme

54. For over a decade, WHO has fostered international collaboration in monitoring suspected adverse drug reactions. The primary objective was to identify at the earliest possible moment the liability of a drug to produce undesirable effects which were not detected during its clinical trials, and it was assumed that a population of international dimensions would facilitate and accelerate the detection of serious but relatively rare reactions.

55. The number of actively participating countries has increased from 10 to 25, and the number of adverse drug reactions in the international data base now exceeds 200,000; these are being added to at a rate of approximately 4,000 per month. Although the vast majority of those reports are received from countries with highly evolved drug regulatory authorities, developing countries also demonstrate an active interest in the scheme. The operational activities take place at the WHO Collaborating Centre for International Drug Monitoring at Uppsala, Sweden. However, WHO retains full responsibility for co-ordination of the programme, participation of national centres and dissemination of information, including publications.

2. WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

56. The World Health Organization has long expressed concern that drugs intended for export are not always subjected to the same quality control procedures as those produced for the home market. In this case, developing countries lacking adequate laboratory facilities for drug analysis are placed at a particular disadvantage. To redress this unsatisfactory situation, WHO has sought to extend and unify schemes already operated by the health authorities of some exporting countries, who issue a certificate on request to foreign importers in respect of drugs that have been subjected to statutory control.

57. The Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was adopted in 1975 in resolution WHA28.65, and 107 countries have now agreed to participate through designated national authorities. The health authority of the exporting country is required to certify on request whether the manufacturer has been found on inspection to comply with defined standards of practice in the manufacture and quality control of drugs. In the case of a product not authorized for sale or distribution in the exporting country, the reasons are explicitly stated and, when relevant, grounds for refusal of registration are disclosed.

3. Drug information

58. In 1963, the World Health Assembly, in its resolution WHA16.36, requested member States to communicate immediately to WHO any decision to prohibit or limit the availability of a drug already in use, any decision to refuse the approval of a new drug and any approval for general use of a new drug when accompanied by restrictive provisions. A number of resolutions to reinforce that request have been adopted subsequently, and the scope of WHO responsibility in this context was broadened in 1975 with the adoption of resolution WHA28.66 in which the Director-General was requested, inter alia, to disseminate to member States evaluated information on drugs.

59. As a result of Circular Letter CL.27.1981 dated 30 December 1981, member States were requested to nominate a senior official responsible for providing technical advice on the safety and efficacy of drugs, to whom information received by WHO on such matters could be sent. There are now some 114 national "information officers" who are the recipients of monthly mailings detailing restrictive drug regulatory decisions notified to the Organization, and who, in turn, furnish WHO directly with information on national regulatory action concerning pharmaceutical products. In this way, the WHO Drug Information Circular system has been extended as a vehicle for the transfer of information on the safety and efficacy of drugs. The WHO Drug Information Bulletin provides an edited commentary on such decisions, in which any differences in national viewpoints can be contrasted and discussed.

60. On 17 May 1984, the World Health Assembly adopted resolution WHA37.33 in which the Assembly:

"URGES Member States:

"(1) to support the development and dissemination of unbiased and complete drug information;

"(2) to collaborate in the exchange of information on the use and marketing of drugs through bilateral or multilateral programmes and WHO;

"(3) to strengthen the national capabilities of developing countries in the selection and proper use of drugs to meet their real needs and in local production and quality control, wherever feasible, of drugs;

"(4) to intensify action to introduce and implement comprehensive and rational drug policies;

"REQUESTS the Director-General:

"(1) to continue to develop activities at national, regional and global levels aiming at the improvement of use of drugs and of prescription practices and the provision of unbiased and complete information about drugs to the health profession and the public;

"(2) (a) to foster the exchange of information among Member States on drugs including registration and marketing practices;

"(b) to review the machinery within WHO concerning the dissemination of unbiased information relevant to the appropriate use of essential and other drugs; and to introduce appropriate improvements therein;

"(3) to arrange, in 1985, a meeting of experts of the concerned parties, including governments, pharmaceutical industries, patients' and consumers' organizations to discuss the means and methods to ensure rational use of drugs, in particular through improved knowledge and flow of information and to discuss the role of marketing practices in this respect, especially in developing countries;

"(4) to submit a report on the results of the meeting of experts and the implementation of this resolution to the Thirty-ninth World Health Assembly".

61. It should also be mentioned that the Third International Conference of Drug Regulatory Authorities, at which the question of exchange of information on drug safety will be discussed, is to be held at Stockholm from 11 to 14 June 1984.

4. The use of international non-proprietary names for pharmaceutical products

62. In accordance with the Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances, WHO also circulates lists of proposed international nonproprietary names (INN), requesting member States to recommend nonproprietary names and to prevent the acquisition of proprietary rights in the name.

5. Chemical products other than pharmaceuticals

63. In 1973, the WHO Executive Board asked the Director-General to take steps to develop a tentative classification of pesticides that would distinguish between the more and the less hazardous forms of each pesticide. A recommended classification of pesticides by hazard was first adopted by the World Health Assembly in 1975, underwent several successive revisions and gained wide international acceptance, together with the guidelines to the use of the WHO recommended classification of pesticides by hazard. Revisions are prepared by the Expert Committee on Vector Biology and Control (Safe Use of Pesticides).

64. Jointly with FAO, WHO has also issued "pesticide data sheets" for over 50 compounds, providing detailed and updated instructions on safe application for workers and other persons exposed, to protect the environment and ensure proper use. The data sheets include general information, toxicology and risk assessment, recommendations for national authorities on regulation, prevention of poisoning in man, emergency aids, and information for medical and laboratory personnel on the diagnosis and treatment of cases of poisoning and on laboratory tests. Control technology guidelines for the safe formulation, storage and transport of pesticides are in preparation.

65. The WHO International Digest of Health Legislation regularly publishes texts or summaries of national laws, including texts on pesticides and other hazardous substances. Jointly with UNEP, the WHO Regional Office for Europe published, in 1982, a comparative study on legislative and administrative procedures for the control of chemicals, 16/ after review by the Working Group on Regulatory Schemes for Potentially Toxic Chemicals in Consumer Products, held at Varna, Bulgaria from 21 to 25 September 1981.

66. The increasing concern of WHO member States about all aspects of chemical safety was expressed in 1977 in resolution WHA30.47 on evaluation of the effects of chemicals on health. This in turn led to the establishment of the International Programme on Chemical Safety, which works jointly with UNEP and ILO, and in co-operation with FAO with regard to pesticide residues in food and food additives. One of its most important activities has been the joint WHO/UNEP Environmental Health Criteria Programme, with the purpose of evaluating all available information on the effects of specific chemicals or groups of chemicals that may influence human health and the environment, so as to provide a scientific basis for policy decisions aimed at protecting human health and the environment from adverse consequences of exposure to such chemicals. More than 50 Environmental Health Criteria documents have been published or are in preparation, covering a wide range of subjects, including heavy metals, air pollutants, pesticides, solvents and physical factors. The Programme on Chemical Safety has recently embarked on the production and publication of short-risk evaluation documents on chemicals of international significance and has established close working links with IRPTC for that purpose.

67. Other activities within the framework of the Programme include the UNEP/WHO/Scientific Committee on Problems of the Environment (SCOPE) of the International Council of Scientific Unions (ICSU) Scientific Group on Methodologies

for the Safety Evaluation of Chemicals; the monographs on the evaluation of the carcinogenic risk of chemicals to humans, published by the International Agency for Research on Cancer of WHO, with UNEP support; and the Programme's Working Group on Principles for Evaluating Health Risks to Progeny Associated with Exposure to Chemicals during Pregnancy.

E. World Bank

68. The World Bank, through its Office of Environmental Affairs, issued a series of guidelines for selection and use of agrochemicals in its projects, including occupational safety and health guidelines with regard to rodenticides, in 1980 and, in 1982, with regard to pesticides packaging and labelling, pesticides transportation and distribution and pesticides application. Those guidelines are continually undergoing revision and updating to reflect new information. The guidelines also contain information on pesticides which are banned or restricted under certain national regulations because of long-range effects and on equivalent acceptable substitutes for banned pesticides. The Bank is preparing educational materials for illiterate workers and their families on safe handling and use of pesticides, including a pamphlet on the recognition and early treatment of pesticide poisoning. As part of the handbook on the disposal of toxic and hazardous wastes, material is also being prepared on safe disposal of unused pesticides and pesticide containers.

F. General Agreement on Tariffs and Trade

69. The work of the General Agreement on Tariffs and Trade (GATT) in the area of banned hazardous chemicals and pharmaceutical products is basically related to the Agreement on Technical Barriers to Trade, the aim of which is to prevent unnecessary obstacles to trade that might result from technical regulations or standards adopted by Governments or other bodies for reasons of safety, health, consumer or environment protection or other purposes. The Committee on Technical Barriers to Trade, established under the Agreement, has instituted a notification procedure whereby Government signatories of the Agreement inform other signatories of proposed new technical regulations or certification systems and provide them with an opportunity to comment on such proposals. In this way, new regulations that may affect the domestic sale and importation of specific products are being brought to the attention of the Governments concerned. This does not, however, provide for the systematic notification of all measures that result in the banning for sale of hazardous or unsafe products. The Agreement on Technical Barriers to Trade also contains special provisions for technical assistance to developing countries in the area of standardization which cover some aspects of the issues dealt with in paragraph 6 of General Assembly resolution 36/166.

70. In addition, at their ministerial-level meeting held from 24 to 29 November 1982, the contracting parties to GATT adopted a decision on the export of domestically prohibited goods by which the contracting parties should, to the maximum extent feasible, notify GATT of any goods produced and exported by them but banned by their national authorities for sale on their domestic markets on grounds

of human health and safety. At their 1984 session, the contracting parties will consider, in the light of experience gained with this notification procedure, the need for the study of problems relevant to GATT in relation to exports of domestically prohibited goods and of any action that may be appropriate to deal with such problems.

71. So far, GATT has received 17 notifications from countries indicating that they do not produce or export any goods banned for sale on their domestic markets.

III. ACTIVITIES OF REGIONAL INTERGOVERNMENTAL ORGANIZATIONS

A. Organisation for Economic Co-operation and Development

72. In 1971, the Council of the Organisation for Economic Co-operation and Development (OECD) established a Procedure for Notification and Consultation on Measures for Control of Substances Affecting Man and his Environment (recommendation C(71)73 (Final)) to allow member countries to receive, as far as practicable, prior notification of measures pending, and early notification of measures taken in instances where such measures are likely to have significant effects on the economy and trade of other countries. To date, there have been 36 notifications and three consultations under the Procedure.

73. In 1977, the Chemicals Group of OECD established a Complementary Information Exchange Procedure to assist member countries in co-ordinating their activities as they implement new toxic substances laws or otherwise expand regulatory control of chemicals, and to keep each other and international organizations informed of such activities. Contact points were designated in member Governments and international organizations (ILO, FAO, WHO, Economic Commission for Europe (ECE), UNEP and European Economic Community (EEC)), and to date about 300 exchanges have been made.

74. As part of the OECD Special Programme on the Control of Chemicals, initiated in 1978, the Management Committee established an Expert Group on Information Exchange Related to Export of Hazardous Chemicals. In October 1983, the Second Joint Meeting of the Chemicals Group Management Committee endorsed guiding principles on information exchange related to export of banned or severely restricted chemicals, on the basis of the 1982 final report of the Expert Group. Following a final review by the Environment Committee, those principles were endorsed by the Second Joint Meeting of the Chemicals Group Management Committee, on 25 and 26 October 1983, and after review (requested by the Environment Committee) are to be forwarded to the OECD Council for adoption in 1984.

75. In recommendation C(84)37 (Final) adopted on 4 April 1984, the Council:

"1. RECOMMENDS that if a chemical is exported which is banned or severely restricted in the exporting Member country, information be provided from that country to the importing country to enable the latter to make timely and informed decisions concerning that chemical.

"2. RECOMMENDS that, in exchanging information related to export of chemicals which are banned or severely restricted in the country of export, Member countries take into account the Guiding Principles set out in the Appendix hereto, which is an integral part of this Recommendation.

"3. RECALLS that the Complementary Information Exchange Procedure established by the Chemicals Group in June 1977 calls for early and rapid exchange of information among Member countries on regulatory actions, planned or taken, concerning the control of chemicals.

"4. INVITES non-Member countries to take note of the provisions contained in this Recommendation and to consider applying them.

"5. INSTRUMENTS the Secretary-General to take the necessary steps to ensure the wide distribution of this Recommendation and to maintain communication with other international organisations working in this field.

"6. INSTRUMENTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries with a view to facilitating the practical implementation of this Recommendation, and to report thereon to Council no later than three years after its adoption".

76. In the context of the above Council recommendation, a banned or severely restricted chemical includes any chemical that is the subject of a control action taken by a competent authority in the exporting country:

- "i) to ban or severely restrict the use or handling of the chemical in order to protect human health or environment domestically; or
- "ii) to refuse a required authorisation for a proposed first time use of the chemical based upon a decision in the exporting Member country that such use would endanger human health or the environment".

77. The guiding principles annexed to the recommendation also state that the minimum information needed to alert the importing country would be:

- "i) The fact that an export is expected or about to occur;
- "ii) The chemical identification/specification;
- "iii) A summary of control action taken in the exporting Member country. If the control action bans or restricts certain uses but allows other uses, such information should be included. Information on the rationale for the control action may also be included;
- "iv) The fact that additional information is available and the indication of the contact point in the exporting Member country to which a request for additional information should be addressed".

78. The guiding principles further state that

"The provision of such information to the importing country would be on a one-time basis when the first export following the control action in the exporting Member country occurs. It should recur in the case of any significant development of new information or condition surrounding the control action. For purposes of the Guiding Principles, where the use of a chemical has been banned or severely restricted before adoption of these Guiding Principles, 'the first export following the control action' shall be deemed to be the first export after adoption of these Guiding Principles, unless the exporting Member country has already provided such information".

79. The OECD Chemicals Group has also developed a series of related guidelines and principles concerning good laboratory practice in the testing of chemicals, a minimum pre-marketing set of data in the assessment of chemicals, test guidelines, and an international glossary of key terms for chemicals control legislation. In particular, on the basis of the Group's work, the OECD Council on 26 July 1983 adopted recommendations on the protection of proprietary rights to data submitted in notification of new chemicals, on the exchange of confidential data on chemicals, and on a list of non-confidential data on chemicals (recommendations C(83)96 (Final), C(83)97 (Final) and C(83)98 (Final)). Work is also being carried out with regard to an overview of international labelling practices for chemicals, with a view to discussing further harmonization in approaches to labelling practices. A recent proposal for an OECD code of conduct concerning the export of hazardous chemicals was referred back to the Chemicals Group for further study.

80. In 1973, the OECD Committee on Consumer Policy established an Informal Notification Procedure concerning Product Safety. In addition, on the basis of proposals by the Committee, the Council, in 1979, adopted a recommendation (C(79)202 (Final)) concerning the safety of consumer products and recall procedures. The recommendation called 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". It also urged Governments to consider the desirability of seeking powers to prohibit export of dangerous goods, where such powers did not yet exist.

B. Council of Europe

81. The European Agreement on the Restriction of the Use of Certain Detergents in Washing and Cleaning Products, signed under the auspices of the Council of Europe on 16 September 1968, prohibits the marketing of detergent products unless they are at least 80 per cent biodegradable. The Agreement is currently under revision, and an amending protocol is expected to be open for signature by the member States in 1984.

82. In 1971, the Council of Europe adopted resolution AP(71)4 on the classification of formulated pesticide products. This classification, which

is currently under review by the Council's Committee of Experts on Pesticides, followed earlier work, in 1969, for guidance on the safety labelling of formulated pesticides, published in a booklet on pesticides (fifth edition, 1981, sixth edition in preparation). Other work touching on the environmental and trade aspects of pesticides includes resolution AP(73)3 on the importation of raw edible nuts and oilseeds treated with pesticides and resolution AP(81)3 on the domestic use of pesticides. Two further resolutions (on wood preservation products and on contamination of animal products for human consumption owing to pesticides used on livestock and in livestock premises) are in preparation by the Committee of Experts on Pesticides. Other expert commissions exist for pharmaceutical questions, cosmetic products, health control of foodstuffs, flavouring substances, and materials coming into contact with food.

83. With regard to pharmaceutical products, the Parliamentary Assembly of the Council of Europe adopted in September 1983 recommendation 969(1983) on the sale of European pharmaceutical products in the countries of the third world. In paragraph 17, it is recommended that the Committee of Ministers:

- "(a) Invite the governments of the member States to give their full political support to the development of an effective code of marketing practices in the field of pharmaceuticals, which was already discussed in WHO in 1978;
- "(b) Invite the governments of the member States to participate more actively in the 'Certification Scheme on the quality of pharmaceutical products moving in international commerce' which is mainly an information scheme for the benefit of importing countries and is endorsed by the European industry;
- "(c) Invite the governments of the member States to give their full political support to the extension of the procedures and guidelines referred to in paragraph 12 [concerning the control of drugs] to pharmaceutical products intended exclusively for export to Third World countries;
- "(d) Instruct the competent expert committee of the Council of Europe to prepare guidelines for member governments taking into account the following principles:
 - "(i) The sale of pharmaceutical products cannot be considered as an ordinary trade since it involves human health and well-being. Member States, therefore, should revise, if necessary, their health aid programmes, in order to assist developing countries with drug evaluation and improved access to useful drug information;
 - "(ii) Companies which are willing to invest into research on tropical diseases and prepared to promote the transfer of essential drug technology on favourable terms to the least developed countries ought to be encouraged;

"(iii) Companies should be asked to respect more the purpose behind the WHO selection of essential drugs and not to push, by advertising campaigns and unethical pressures on public health professionals, expensive and irrational drugs;

"(iv) Big research-based companies, which until now mainly exported brand-named products, should be encouraged in their new trend to produce also generic drugs which no longer enjoy protection and are therefore cheaper for the consumer, rather than to leave this field to low quality imitators;

"(v) Plans by the governments of developing countries to rationalize their drug policies either by the creation of central purchasing agencies, the promotion of generic names or by other similar means should not be obstructed, provided that high standards of equality are observed".

C. European Economic Community

84. The European Economic Community (EEC) has adopted a series of directives requiring member States to bring their national legislation into conformity with common standards laid down for a wide range of potentially harmful chemical products, including industrial chemicals such as PCBs; agricultural chemicals such as pesticides, fertilizers and feedstuff additives; food additives and contaminants; cosmetics; detergents; solvents; paints, varnishes, adhesives etc. Other directives deal with workers' protection from harmful exposure to certain chemicals.

85. The most important general EEC enactment in this field is the so-called "sixth amendment" to the 1967 Directive on the Approximation of the Laws, Regulations and Administrative Provisions Relating to the Classification, Packaging and Labelling of Dangerous Substances. That amendment established detailed requirements for the notification of new substances marketed or imported in EEC member countries, if they fell within the given definitions of "dangerous substances" (explosive, oxidizing, flammable, toxic, harmful, corrosive, irritant, dangerous for the environment, carcinogenic). Annexed to the Directive are methods for the determination of physico-chemical properties; toxicity and eco-toxicity; classification and labelling requirements; a base set of technical information, additional information and text required. The uniform procedures of the sixth amendment are also followed in several non-member countries outside EEC.

86. In 1973, the EEC Council of Ministers adopted a data bank project, Environmental Chemicals Data and Information Network (ECDIN). ECDIN maintains chemical information, including information on manufacturers, gathered by itself or through the network established among the 10 Community countries. The basic principle of ECDIN is to store relevant information on chemicals, degradation products, metabolites and by-products, regardless of the form in which they are used, and to enable all people engaged in environmental management and research to obtain rapidly reliable information and data on chemicals. Although work is still

in a preparatory phase on an area-wide automatic information retrieval network, ECDIN made a major contribution in 1981 to the generation of the European Inventory of Existing Commercial Chemical Substances, within the context of the sixth amendment.

87. A common feature of most EEC directives for potentially harmful chemicals is the fact that they do not cover products exported to non-member countries. As a result, most products exported from EEC countries are not subject to the above-mentioned environmental safeguards and standards applicable to products marketed within EEC.

88. In order to remedy that situation, the European Parliament, on 14 October 1983, adopted a resolution on the export of various dangerous substances and preparations and the desirability of increasing the protection of workers and consumers in the importing countries and of the European consumers of exotic foodstuffs. In particular, the resolution called on the EEC Commission to amend the directives concerning pesticides "so that the pesticides can be exported under the following conditions:

- "(a) that the government of the importing country is informed of the particular nature of the product and of the restrictions to which it is subject in the exporting country and the reasons for such restrictions;
- "(b) that the government of the importing country, having received such notification, explicitly requests the purchase".

89. The resolution further requested that exports of pesticides destined for the developing countries be packaged and labelled under the same requirements as those marketed within EEC, and that the directions for use be "written in the most common language of the country of destination, preferably accompanied by diagrams, unless specified otherwise by the importing countries". It called furthermore on the EEC Commission "to include in development programmes:

- "(a) increased technical aid to developing countries to assist with their independent procedures for the registration and control of pesticides;
- "(b) greater attention to the techniques of integrated pest control so that yield does not depend exclusively on the use of chemical pesticides;
- "(c) more attentive studies on methods of protection for those who use pesticides, it being impossible to transfer the methods used in industrialized countries with a temperate climate;
- "(d) more decisive action on the training of instructors which should also provide for co-ordination with other international organizations in the use of the mass media and educational publications;
- "(e) closer contacts with the producing industry to study programmes for the training of instructors and methods of information on the dangers deriving from the uncontrolled use of pesticides".

D. Council for Mutual Economic Assistance

90. In 1972, the Council for Mutual Economic Assistance (CMEA) adopted Recommendations for the Protection of Plants and the Environment against Pollution by Pesticides. In 1979, the CMEA Standing Commission on Co-operation in Public Health initiated a programme on a toxicological passport for chemical compounds subject to introduction into the economy and domestic life of CMEA countries. Following the initiation of the programme, an expert meeting was convened at Leningrad in 1981, jointly with IRPTC, on the subject of basic principles of definition of toxicological and safety data for chemical substances in international trade. At the meeting, the participants stressed the importance of obtaining a broad range of information, especially for the developing countries, on chemical substances traded internationally. The meeting also proposed a draft set of toxicological and safety data for chemical substances in international trade, with a view to harmonizing international notification procedures.

91. The CMEA Standing Commission on Cooperation in Public Health held a further meeting on this subject in 1982 and participated in a UNEP-sponsored second expert meeting to review the revised draft, in Moscow from 5 to 9 December 1983. The meeting prepared a final draft document on the basic set of data for chemicals in international trade required for an assessment of hazards to man and the environment and conditions of safe use.

E. European Free Trade Association

92. Under the auspices of the European Free Trade Association (EFTA), the Convention for the Mutual Recognition of Inspections in Respect of the Manufacture of Pharmaceutical Products was adopted at Geneva on 8 October 1970; among the member States there are also six non-EFTA countries. The Convention, commonly known as the Pharmaceutical Inspection Convention, provides for an exchange of information between competent authorities on quality standards for manufacturing practices and other information relevant to the quality control over pharmaceutical products upon the request of an importing country. According to article 5, if a competent authority discovers in the course of its inspection duties or otherwise particular circumstances which cause a pharmaceutical product to be of imminent and serious danger to the public, it shall immediately communicate its findings to the competent authorities of the other contracting States.

93. In 1979, the registration authorities of five EFTA countries (Austria, Finland, Norway, Sweden and Switzerland) signed a Scheme for the Mutual Recognition of Evaluation Reports on Pharmaceutical Products, as a voluntary understanding to facilitate the registration of foreign pharmaceuticals.

F. Organization of American States

94. In 1982, the Inter-American Economic and Social Council of the Organization of American States (OAS) adopted a resolution requesting the OAS secretariat, with the co-operation of other specialized international organizations, to prepare an

inventory of toxic products whose use had been restricted or prohibited in the United States of America or other countries and to disseminate this information to member States. Provision has also been made to keep the inventory up to date and to inform member States twice a year of modifications.

95. In September 1983, the Special Committee for Consultation and Negotiation of the Inter-American Economic and Social Council, after having seen the "Preliminary list of banned or significantly restricted substances in the United States" (CIES/CECON/463), resolved to instruct the General Secretariat to keep the report up to date and to prepare a list of alternatives that would enable the member States from Latin America and the Caribbean to have greater control and information on products imported from the United States that were banned or under investigation in that country, as well as the means aimed at achieving adequate identification of such substances and products with a view to controlling their marketing under other names. A report on this matter will be considered at the fourteenth regular meeting of the Special Committee for Consultation and Negotiation.

96. The OAS Inter-American Institute for Cooperation in Agriculture has sponsored several conferences on the harmonization of agrochemicals regulations in Latin America. As a result of a 1982 regional meeting at Cartagena, agreement was reached on common criteria for pesticide hazard categories (following the WHO classification), labelling and registration requirements.

IV. NON-GOVERNMENTAL ORGANIZATIONS

A. Industry and trade

97. The International Group of National Associations of Agrochemical Manufacturers (GIFAP), representing chemical industry associations in 25 countries, published in 1982, "Guidelines for the safe handling of pesticides during their formulation, packing, storage and transport", which also cover occupational health, industrial hygiene and environmental protection aspects in non-technical language. More recently, "Guidelines for the safe and effective use of pesticides" have been published. The GIFAP Bulletin informs members of current international developments in the field of trade controls for pesticides. A further set of guidelines on field emergency first aid is in preparation. In October 1983, one of the member associations of GIFAP, the United States National Agricultural Chemicals Association, after consultation with environmental organizations and church groups, accepted a set of guidelines for advertising practices in the promotion of pesticide products in developing areas of the world, as a voluntary code of standards for United States chemical companies exporting or marketing agricultural chemicals in developing countries. Further guidelines on labelling practices are under negotiation.

98. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA), representing pharmaceutical industry associations in 30 countries, plus 12 affiliated through the Latin American Association of the Pharmaceutical Industry, in 1981 adopted a Code of Marketing Practices in the Pharmaceutical Sector, as a voluntary model for its member associations, including provisions on the

obligations of industry, general principles of marketing practices, medical representatives, congresses, printed promotional materials and samples.

99. Information material on potentially harmful chemicals has been produced by the European Council of Chemical Manufacturers' Federations, in the form of transport emergency "TREM-CARDS"; and, in 1983, by the Oil Companies' International Study Group for Conservation of Clean Air and Water in Europe, in the form of health and safety data sheets for petroleum products, which include data on chemical composition, toxic properties and first aid, ecotoxicity, storage, spillage and disposal etc. The European Chemical Industry Ecology and Toxicology Centre, established in 1978 by the 40 major European chemical companies, has since 1983 produced critical reviews of the toxicology, including ecotoxicology, of selected industrial chemicals.

B. Environmental conservation

100. In addition to its joint work with UNEP and WHO in the International Programme on Chemical Safety, the Scientific Committee on Problems of the Environment (SCOPE) of the International Council of Scientific Unions carried out a study in 1983 for the appraisal of tests to predict the environmental behaviour of chemicals, and is considering proposals for further studies on prospective eco-epidemiology to determine long-term trends in the environment resulting from chronic exposure to chemicals. A report on methods for assessing the effects of chemicals on reproductive functions was published in 1983 (SCOPE Report No. 2).

101. The Commission on Ecology of the International Union for Conservation of Nature and Natural Resources (IUCN) established a working group on ecological aspects of environmental pollutants, which held a joint meeting with UNEP/IRPTC in 1981 to prepare a position statement on pesticide use, and a report on the assessment of future pesticide hazards to species and ecosystems. One of the IUCN member associations, the International Council for Bird Preservation, has expressed particular concern over the damage caused to bird populations in developing countries owing to the use of biocidal chemicals, many of which are banned or severely restricted in the countries of origin. The IUCN General Assembly, at its fifteenth session, held at Christchurch, New Zealand, in 1981, adopted resolution 15/15 on international trade in pesticides which

"calls upon all countries to prohibit the export of pesticides which are banned for domestic use in their country of origin, except (a) for specific purposes for which no alternate means of pest control are available; (b) at the explicit request of the government of the importing country; and (c) following appropriate notification by the exporter of the health and environmental consequences of the product".

102. The European Environmental Bureau publishes a "Toxic substances control newsletter" for the information of its affiliate environmental organizations. The Bureau organized a seminar on the export of pesticides to developing countries, at the North German Nature Protection Academy at Schneverdingen, Federal Republic of Germany, in May 1983. The seminar was followed by a co-ordination meeting at

Brussels in December 1983. The Schneverdingen seminar, which was attended by representatives of 35 non-governmental organizations from 15 countries, addressed resolutions to United Nations agencies and bodies and EEC, and called on national Governments of pesticide-exporting countries to

- "(i) enact immediately legislation to ensure that pesticide products banned, severely restricted, unregistered or voluntarily withdrawn from the market should not be exported without prior notification by the exporting country government to the competent authority of the importing country. This notification should contain all the relevant information on the products to enable the authority of the importing country to decide on its importation. After having received such notification the authority may ask for further detailed information on the product (or substitutes) in question;
- "(ii) ensure that this legislation prohibits the export of such banned, restricted, withdrawn and unregistered pesticides, unless specifically requested by the importing country subsequent to the information exchange process;
- "(iii) ensure that all pesticides for export are to be subject to the same registration procedures as pesticides for domestic use;
- "(iv) ensure that other relevant national and/or internationally agreed standards are being met and that notification and control procedures should be accessible to the public;
- "(v) work towards the provision of an annual notification of information on all other exported pesticides".

103. The Agricultural Chemicals Dialogue Group, convened since 1982 in the United States of America by the Conservation Foundation, with participation from other environmental organizations, church groups and industry, has also taken up the topic of guidelines for use in world-wide trade in agricultural chemicals, not intended to dictate decisions to importing countries, but rather to make certain that such countries have the proper quantity and quality of information to arrive at their own regulatory decisions.

104. The International Federation of Plantation, Agricultural and Allied Workers (IFPAAW) has long been concerned by the occupational health hazards caused by pesticides and other chemicals used in agriculture. IFPAAW held an International Seminar on Health and Safety in Agriculture at Geneva in 1982, with the participation of experts from international organizations and with regional reports presented by its affiliate rural workers' organizations. Through periodic circulars, IFPAAW keeps its affiliates informed of developments in the field of potentially harmful agrochemicals.

105. The International Organization of Consumer Unions (IOCU), established in 1960, has carried out a number of studies on the international trade in potentially harmful chemicals (for example, dangerous drugs, in 1979). The tenth World

Congress of IOCU, held at The Hague in 1981, adopted recommendations on the dumping of hazardous products, technologies and wastes into third world countries, and launched a "Consumer Interpol" project which co-ordinates the exchange of information on hazardous consumer products through a world-wide network of correspondents. In 1983, IOCU published a "consumer action and resource kit" on 44 hazardous chemical pesticides.

106. The International Organization of Consumer Unions was instrumental in a coalition of non-governmental organizations from 27 countries, Health Action International (HAI), established after a conference on pharmaceuticals held at Geneva in May 1981. The coalition initiated programmes for the exchange of information on the structure and practices of the multinational pharmaceutical industry, and for the co-ordination of consumer action campaigns in this field. Criticizing the IFPMA Code, it urged WHO and UNCTAD to develop a code of practice for the marketing of pharmaceuticals.

107. In 1982, HAI published a "Draft proposal for an international code on pharmaceuticals: discussion document". The draft contained a preamble and the following 14 main sections: (a) aims, (b) scope, (c) definition, (d) drug registration, (e) registration of new drugs, (f) pre-registration of clinical trials, (g) information, (h) labelling, package inserts and promotional material, (i) sales and promotion of pharmaceutical products, (j) pricing, sales and distribution, (k) pharmaceutical technology, (l) research and development, (m) implementation and (n) monitoring and review procedures.

108. In the preamble to the draft, HAI invited comments from experts and stated that the adoption of a code would require the expertise of various agencies, most importantly of WHO and UNCTAD.

109. A Pesticide Action Network (PAN) was founded at a meeting at Penang, Malaysia, in May 1982, by non-governmental organizations from 16 countries, followed by the establishment of regional focal points for Asia and the Pacific (IOCU), Europe (OXFAM) and North America (Friends of the Earth). The Environment Liaison Centre (ELC) based at Nairobi serves as the African focal point, distributes a regular PAN Pesticide Digest as part of its own "Ecoforum" journal, and in November 1983 hosted an African Seminar on the Use and Handling of Agricultural and Other Pest Control Chemicals, at Nairobi. That seminar was attended by representatives of national agencies and non-governmental organizations from African countries and adopted a series of resolutions calling, inter alia, for the harmonization of international notification and regulation systems for banned and severely restricted pesticides, and specifically requiring the explicit consent of the importing country before the product was exported.

V. CONCLUDING OBSERVATIONS

110. There is an increasing awareness on the part of the importing and exporting countries alike of the need for exchange of information on internal control measures taken by the Governments of exporting countries with respect to the manufacture, handling and use of chemical and pharmaceutical products. The

principle of notification to importing countries of measures designed to ban or severely restrict specific products in the country of manufacture has gained wide acceptance in many forums. As to responsibilities for the exportation of those products, both notification to the projected user country of the measures banning or restricting the product and official control of exports to that country may be involved. The more restrictive position taken in this regard is that export can occur only after notification is given, followed by a request from the competent authorities of the importing country and the issue of an export license. Both adequate notification and official control over each export are explicit in this position. In the less restrictive case, the minimum requirement on the exporting country is only that of notification at the time of the first export of any ban or restriction on the product. Under those conditions any actual controls over that export or future exports are the responsibility of the importing country and no further constraint is imposed on the exporter regarding further shipments, provided that the importing country imposes no further restrictions. In cases where the use of the product is officially permitted in the importing country, only notification is involved.

111. Further negotiations will obviously be needed in order to reconcile those positions. The proposed provisional notification scheme for banned and severely restricted chemicals, being developed by the UNEP Ad Hoc Working Group of Experts, represents an important step towards the harmonization of positions in this regard. In addition, improved use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce will enhance the quality and safety of imported pharmaceuticals (see paras. 56-57 above).

112. Although the focus of discussions may vary in different forums with regard to principles relating to the exchange of information on chemicals (in particular pesticides) and on pharmaceutical products, the general nature of the principles that are evolving is sufficiently wide to embrace both those types of products. Considerable work is being carried out on guidelines relating to various aspects of pesticides, such as in the case of the draft code sponsored by FAO (see para. 47 above), which would provide comprehensive coverage on all aspects of this category of chemical agents. Those guidelines would contain provisions for the disclosure of information, including labelling and packaging, as well as advertising and promotion. As indicated above, those efforts are being undertaken at various levels of activity, both within the United Nations system of organizations and elsewhere, including dialogues between manufacturers' associations and consumer groups. A continued dialogue will thus be needed in order to harmonize positions taken on the various instruments.

113. With regard to the legislative and administrative capability of developing countries to control the manufacture, import, sale and use of chemical and pharmaceutical products, recent information indicates that progress appears to have been made in recent years. In addition to the technical co-operation assistance provided by various organizations, developing countries can benefit from the exchange of information at the international, regional or bilateral levels on administrative and legislative models followed by other countries. In this regard, the activities of FAO and WHO should be noted.

114. The reference framework provided by the table in the annex below illustrates the areas of activity in which each organization has been engaged and provides a basis for an examination of the nature of actions taken or proposed within each category of activity by referral to the text.

Notes

1/ As in previous reports of the Secretary-General on this subject, work being undertaken on the transport of dangerous goods, radioactive materials, and on the control of narcotic and psychotropic substances has not been included in the present report.

2/ Official Records of the Economic and Social Council, 1983, Supplement No. 7 (E/1983/17/Rev.1-E/C.10/1983/S/5/Rev.1), annex II, paras. 41-43.

3/ TD/325 and Add.1. To be issued as Proceedings of the United Nations Conference on Trade and Development, Sixth Session, vol. I, Report and Annexes (United Nations publication, Sales No. E.83.II.D.6), part one, sect. A.

4/ Following the thirty-seventh session of the World Health Assembly, WHO indicated at the sixth session of the Intergovernmental Committee on Science and Technology for Development that, because of progress made at the country level by the WHO Action Programme on Essential Drugs and Vaccines and because of recent decisions by WHO intergovernmental bodies which reaffirmed the overriding emphasis to be placed by WHO and member Governments on national programmes, it was now most unlikely that WHO could continue participating in the joint activity proposal.

5/ Formulation of Pesticides in Developing Countries (United Nations publication Sales No. E.83.II.B.3).

6/ See Report of the United Nations Conference on the Human Environment, Stockholm, 5-16 June 1972 (United Nations publication, Sales No. E.73.II.A.14), chap. II.

7/ See Official Records of the General Assembly, Thirty-second Session, Supplement No. 25 (A/32/25), annex I.

8/ Ibid., Thirty-third Session, Supplement No. 25 (A/33/25), annex I.

9/ Ibid., Thirty-seventh Session, Supplement No. 25 (A/37/25), part two, annex; Thirty-eighth Session, Supplement No. 25 (A/38/25), annex.

10/ See Report of the United Nations Conference on the Human Environment ..., chap. II.B.

11/ See Official Records of the General Assembly, Thirtieth Session, Supplement No. 25 (A/10025), annex I.

12/ Ibid., Thirty-first Session, Supplement No. 25 (A/31/25), annex I.

Notes (continued)

13/ Ibid., Thirty-third Session, Supplement No. 25 (A/33/25), annex I.

14/ IRPTC Legal File 1983, IRPTC Data Profile Series No. 4 (United Nations publication, Sales No. E.83-0-1).

15/ See Official Records of the General Assembly, Thirty-sixth Session, Supplement No. 25 (A/36/25), annex I.

16/ Legislative and Administrative Procedures for the Control of Chemicals, European Cooperation on Environmental Health Aspects of the Control of Chemicals, Interim Document 5 (Copenhagen, WHO Regional Office for Europe, 1982).

ANNEX

Functional guide to the activities of the organizations

(Matrix numbers refer to the relevant paragraphs of the present report in which the activities of the organizations, grouped here by functional categories, are described.)

Organization	Institutional structure for exchange of information		Primary guiding instruments for the exchange of information		Basic technical information input	
	(1)	(2)	(3)	(4)	(5)	(6)
	System	Experts meetings <u>a/</u>	Policy instruments <u>b/</u>	Implementation measures <u>c/</u>	Basic ref. docs. <u>d/</u>	Misc. tech. docs. <u>e/</u>
I. UNITED NATIONS SYSTEM						
A. United Nations						
1. DIESA					9	
2. UNCTC		13	13	10-12	14	
3. UNCTAD		15	15-16			
4. UNIDO						17
5. UNEP	22-27, 30-31, 33 (IRPTC)	34	18-19, 21-23, 26, 34-35, 39	35-39	20-21, 29	20, 27-28, 32
B. ILO	41-42 (CIS)		41	40	40	
C. FAO		45-46, 48-50	47	47	51	46-47, 49
D. WHO	54-56, 59, 63, 66 (CCIDM) (ICPS)		52, 58, 60, 66	57-63	62-65	53-59, 64, 66- 67
E. WORLD BANK						68
F. GATT	69		69-70	69-71		

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Organization	Institutional structure for exchange of information		Primary guiding instruments for the exchange of information		Basic technical information input	
	(1)	(2)	(3)	(4)	(5)	(6)
	System	Experts meetings <u>a/</u>	Policy instruments <u>b/</u>	Implementation measures <u>c/</u>	Basic ref. docs. <u>d/</u>	Misc. tech. docs. <u>e/</u>
II. REGIONAL INTERGOVERNMENTAL ORGANIZATIONS						
A. OECD		74	74-79	72-73, 80	79	79
B. Council of Europe		82	81-83	82-83		
C. EEC	86 (ECDIN)		84-85, 87-89	85	86	85
D. CMEA		90-91	90		91	
E. EFTA			92-93	92		
F. OAS			94		95-96	
III. NON-GOVERNMENTAL ORGANIZATIONS						
A. Industry and Trade				97-98		97-98
B. Environmental conservation	105-106, 109	101-104	101-102, 105	107-108		100-109

a/ Expert meetings: working groups, workshops, panels and committees of experts.

b/ Policy instruments: resolutions, recommendations, principles, system guidelines, agreements.

c/ Implementation measures: codes, standards, classifications, notification and certification schemes.

d/ Basic reference documents: product registers, lists and inventories; glossaries; directories; and compendia.

e/ Miscellaneous technical documents: technical data sheets and reports, bulletins, technical guidelines and manuals.