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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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I. INTRODUCTION

1. During the last few years, considerable concern has been expressed over the export of banned hazardous chemicals and unsafe pharmaceutical products which may cause damage to the health of the population and the environment of the importing countries.

2. The General Assembly, in resolution 34/173, of 10 December 1979, urged Member States to exchange information on hazardous chemicals and unsafe pharmaceutical products and to discourage, in consultation with importing countries, the export of such products to other countries. The Assembly also requested the Secretary-General, in co-operation with the United Nations agencies and bodies concerned, especially the World Health Organization (WHO), to assist Governments in exchanging information and to submit a report to the Assembly at its thirty-fifth session, through the Economic and Social Council, about the experience of Member States and the United Nations agencies and bodies concerned.

3. The following year, the General Assembly, in resolution 35/186 of 15 December 1980, invited Member States to provide information on the measures they had taken to exchange information on hazardous chemicals and unsafe pharmaceutical products banned in their countries, and requested the Secretary-General to submit to the Assembly at its thirty-sixth session the report called for in Assembly resolution 34/173, since it had not been possible to prepare the report in time for the thirty-fifth session. In the same resolution, the Assembly also requested the Commission on Transnational Corporations to study, during its seventh session, ways and means within the information system on transnational corporations to improve the exchange of information on those products with a view to formulating appropriate recommendations.

4. In accordance with those two resolutions, the Secretary-General submitted to the General Assembly at its thirty-sixth session, through the Economic and Social Council, a report on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products (A/36/255).

5. The report was based on the relevant information received from countries and international organizations on banned hazardous chemicals and unsafe pharmaceuticals, and focused on those countries that had had practical, limited bans imposed on the domestic production and use of these substances while still making them available for export. It also covered the information systems available for the purpose of informing importing countries, before the arrival of shipments, about the restrictions of producing or exporting countries, so that they could take appropriate precautions. It was suggested in the report that progress in the development of these information systems should be reviewed after two or three years on the basis of information derived from specific questionnaires. The Centre on Transnational Corporations prepared a background paper (E/C.10/90) with a limited proposal for study by the Commission on Transnational Corporations at its seventh session.

6. The General Assembly, in resolution 36/166, took note of the Secretary-General's report and reiterated the need to intensify international co-operation in the search for a solution to problems arising from the production and export of banned or severely restricted substances. The Assembly also took note of the conclusions and recommendations in the report submitted to the Commission on Transnational Corporations. It urged Member States and other interested parties, including transnational corporations, to co-operate more fully in providing data on banned or severely restricted substances to the appropriate organs, organizations and bodies of the United Nations system with responsibility for information exchange in regard to such substances, and called on the United Nations organizations concerned to ensure that the documentation they prepared was adequately suited to the needs of and clearly understood by all those engaged in processing, handling, dispensing or using banned hazardous chemicals and unsafe pharmaceutical products. It requested the Secretary-General and United Nations organizations concerned to provide the necessary technical assistance to the developing countries, at their request, to help them establish an adequate system for monitoring the import of unsafe pharmaceutical products and banned hazardous chemicals, and to train scientific personnel to handle these problems; and invited Member States to deal with this subject through appropriate means, including possible legislation at the national level. Finally the Assembly again requested the Secretary-General to consult Member States on the existing information systems on banned hazardous chemicals and unsafe pharmaceutical products and to report to it at its thirty-eighth session through the Economic and Social Council.

7. The Secretary-General has accordingly consulted Member States on their experience in the exchange of information and on existing information systems on banned hazardous chemicals and unsafe pharmaceuticals. The present report contains a summary of the information obtained through these consultations and reaches certain tentative conclusions. The report also contains information concerning the facilities available in the United Nations system, 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 these substances, which may be of use to governmental authorities seeking international advice on specific problems.

8. The limits on the scope of the work in this area, as described in the earlier report (A/36/255), still apply. As in the earlier report, no reference is made in the present report to chemical wastes, as these are usually intractable mixtures of unwanted chemicals of no value. Those substances are still the subject of study by the United Nations Environment Programme (UNEP) as well as by other international organizations. Similarly, radioactive chemicals and wastes are not dealt with, since they present specific health hazards because of their radioactivity and not because of their chemical nature. The problems posed by these substances are being dealt with by agencies specialized in this field, such as the United Nations Scientific Committee on the Effects of Atomic Radiation and the International Atomic Energy Agency.

9. The problems posed by the transport of hazardous chemicals and dangerous substances also constitutes a separate problem, currently being dealt with by other organizations, including the Economic Commission for Europe (ECE) and the International Maritime Organization (IMO). IMO deals with the transport of

hazardous chemicals by sea, and ECE, through the work of the Group of Experts on the Transport of Dangerous Goods and the Committee of Experts on the Transport of Dangerous Goods, is developing a harmonized approach to the world-wide movement of hazardous substances by all means of transport, through the adoption of recommendations concerning the classification of dangerous substances, the packaging, labelling and marking of goods, the methods of testing etc.

10. Unlike other unsafe pharmaceutical products, narcotic drugs and psychotropic substances are already closely controlled under international treaties, namely, the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971. The Single Convention on Narcotic Drugs tries to exercise full import and export control of these substances through the mutual exchange of authorizations involving the International Narcotics Control Board as the monitor. Article 13 of the Convention on Psychotropic Substances is being used by a number of countries to keep out imports of unwanted products scheduled in this Convention.

11. It may also be noted that, under resolution 37/137 of 17 December 1982, entitled "Protection against products harmful to health and the environment", the General Assembly, after recalling resolution 36/166, inter alia, requested the Secretary-General to prepare a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceutical products, not approved by Governments. The implementation of that resolution is evidently closely related to the kind of concerns covered in the present report. In addition, the work being undertaken pursuant to Economic and Social Council resolution 1981/62 of 23 July 1981, which called for the elaboration of a set of draft guidelines for consumer protection is also relevant to the subject-matter of the present report, inasmuch as the guidelines provide recommendations to Governments concerning the export of banned hazardous products and international co-operation, including the sharing of information about these products.

II. SUMMARY OF REPLIES OF MEMBER STATES RELATING TO INFORMATION SYSTEMS AND EXCHANGE OF INFORMATION ON BANNED HAZARDOUS CHEMICALS AND UNSAFE PHARMACEUTICALS

12. In pursuance of General Assembly resolution 36/166, a note verbale with an attached questionnaire was sent to Member States on 30 August 1982 seeking information from them concerning the legislative means and the resources available in their countries to deal with banned hazardous chemicals and unsafe pharmaceutical products. The questionnaire made further inquiries about the use made by Governments of the international agencies involved in this field, and about the legislation and mechanisms existing at the regional, national and international levels to obtain and exchange information on imported chemicals and pharmaceutical products, on their potential hazards, and information on whether or not they are banned or proposed to be banned in the producing country or in any other country.

13. As at 15 May 1983, replies had been received from 38 countries, 1/ about half of which are significant producers and exporters of chemicals and pharmaceuticals.

14. Regarding the existence at the national level of regulatory machinery to keep out imports of banned hazardous chemicals and unsafe pharmaceutical products, almost all countries replying reported having legislation for the control of pharmaceutical imports, but only a little over half of the countries reported having legislation which can prohibit the entry of chemicals banned in another country. However, almost all of the countries that reported not having legislation which could prohibit the entry of banned hazardous chemicals, stated that they had a variety of legislative instruments which, with suitable modifications, could be used for this purpose, such as legislation in the field of customs, health, agriculture and the environment.

15. Most countries reported having institutions for reviewing and dealing with scientific and technological information on banned hazardous chemicals and unsafe pharmaceutical products. More than three quarters of the countries (31) reported having laboratories for independently controlling the quality of imported pharmaceutical products, and the same number of countries said they require the submission of documentation on the efficacy and safety of these substances, without which they were not permitted entry into the country.

16. Only two Governments reported incidents where chemicals which had been banned and/or severely restricted in another country had been shipped to their countries and used there in hazardous circumstances. One of the Governments gave details of two incidents in its country. One incident involved the use of sodium fluroacetate, which caused the deaths of several domestic animals, and the other concerned carbon tetrachloride, which caused a problem when used in fire extinguishers.

17. Regarding the use of the international information systems available to obtain data on banned hazardous chemicals, almost half of the countries (16) reported having used the facilities of the International Register of Potentially Toxic Chemicals (IRPTC) 2/ of the United Nations Environment Programme and/or the International Programme on Chemical Safety (IPCS), 3/ jointly sponsored by WHO, the ILO and UNEP at Geneva, to obtain information on imported chemicals and their potential hazards to the population and the environment, and to check if they are banned or proposed to be banned in the producing country or in any other country. Almost three quarters of those countries replying (25) reported having made formal or informal arrangements to gather information from international sources. More than half of the countries which said that they did not participate actively in IRPTC said they were willing to do so. Almost all countries having used IRPTC and/or IPCS considered those schemes adequate to meet the requirements of their legislation. One country having used these schemes considered them not to be fully adequate to meet the needs of its legislation.

18. In relation to the import of pharmaceutical products, almost half of the Governments that replied (17) reported having used the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce 4/ of WHO to ensure that the drugs being imported into their countries met the requirements of this Scheme, and half of them reported having used it for all their imports. Nineteen countries reported favourably with respect to its effectiveness in the control of imported pharmaceutical products. One country which had used this Scheme did not consider it to be effective.

19. Regarding the control of exports of banned hazardous chemicals and unsafe pharmaceutical products, very few of the countries that replied and that are exporters of chemicals, reported having legislation requiring that the authorities in the country to which the chemical is being shipped be notified if the chemical in question is banned or restricted in their territory. Among the countries that do not have this kind of legislative requirement, some reported having some sort of administrative rules or agreements with certain groups of countries or bilaterally, relating to such notifications.

20. Among the countries replying with legislation restricting exports, almost three quarters (20) reported having legislation restricting the export of pharmaceutical products whose use and distribution is banned or restricted in their own territories. Of those countries, nine reported having legislation which required informing the importing country that the pharmaceutical product being exported is banned or restricted in their territory, and 20 countries reported being party to bilateral, regional or other agreements by which they are bound to notify the importing country that certain pharmaceutical products being imported to that country are banned or restricted in their territories.

21. The conclusions which can be derived from this analysis must be of a very tentative nature, taking into account the limited number of countries that replied to the questionnaire. It appears that the majority of the countries that replied have some sort of regulatory machinery to keep out of their territories undesired imports of banned hazardous chemicals and unsafe pharmaceutical products. Little over half the countries (22) have legislation to control imports of chemicals, and of those that do not, almost all have alternative legislative means of control. Almost all countries (36) have legislation to control imports of pharmaceutical products. In addition, most countries that replied seem to have the institutional and technical instruments to deal with the information available on these substances.

22. The results of the questionnaire also indicate that the international information systems available are not being used to the fullest extent. Less than half the countries (16) reported having used IRPTC, IPCS and/or the Certification Scheme of WHO, and of those having used the latter system, not all have used it for all their imports of pharmaceutical products. However, the majority of the countries reported favourably on the effectiveness of these schemes, and most of them (26) reported having made agreements to gather information from international sources. In view of this situation, it may be desirable for countries to consider making more extensive use of these information systems.

23. With respect to the measures being taken by countries to restrict exports of pharmaceuticals and to notify importing countries about banned hazardous chemicals and unsafe pharmaceutical products, the majority of the countries that replied (20) restrict exports of pharmaceuticals which are banned or restricted in their territories; almost half of these (9) require that the importing countries be informed about such exports, and the majority (20) reported being party to agreements regarding such notifications. On the other hand, very few countries (3) require notification to the importing country regarding exports of banned or restricted chemicals. As pointed out above, these conclusions can only be tentative, given the small number of countries that replied to the questionnaire.

24. One question which remains unanswered is whether countries have an adequate infrastructure to control the import of these substances and if they do, whether such infrastructure is put to use. The effectiveness of the existing international information systems depends not only on their widespread use, but also on whether the importing country can effectively utilize the information to prevent unwanted products from being brought into the country. Although the results appear to indicate that most of the countries that replied to the questionnaire have legal, institutional and technical instruments to deal with the information provided by the international systems on banned hazardous chemicals and unsafe pharmaceutical products, it is not clear whether the expertise and resources available is adequate to control these substances. It is one thing to have adequate legislation to prevent unwanted imports from entering the country, and adequate access to international sources of information, and another to have the necessary infrastructure to implement that legislation and use the information which is available.

25. Another of the difficulties confronted by countries regarding the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products is the lack of consistent product information on these products and the problem of misrepresented products. Ambiguous or incomplete information, concerning the composition of a banned or hazardous product, may result in adverse effects on people and may complicate the search for an adequate antidote. In various developed countries, concern about labelling has resulted in strict labelling regulations and the availability of the formulations for various hazardous products to competent national authorities and poison control centres. This problem, however, could be solved at the international level by the elaboration of multilaterally accepted standards for the classification, packaging and labelling of dangerous substances moving in international trade, as has been done in the case of foods by the Codex Alimentarius Commission of the Joint Food and Agriculture Organization of the United Nations (FAO)/WHO Food Standards Programme.

26. Finally, the attention of the General Assembly is drawn to the close interrelationship between the present report and the work being undertaken pursuant to General Assembly resolution 37/137 relating to the export of products harmful to health and the environment. The consolidated list of products which have been banned or severely restricted by countries, called for under that resolution, will supplement existing information mechanisms within the United Nations system and provide a further means for assisting importing countries to protect themselves from products, including banned hazardous chemicals and unsafe pharmaceuticals which may cause damage to health and the environment.

27. The Secretary-General accordingly wishes to recommend that the General Assembly should consider integrating the follow-up action to these two closely related questions, namely progress in relation to the use of the existing mechanisms for the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products, and the proposed review of the format of the consolidated list, as mentioned in paragraph 6 of Assembly resolution 37/137, so that they are dealt with in a unified manner.

Notes

1/ Argentina, Austria, Brazil, Bulgaria, Canada, Chile, Colombia, Costa Rica, Cyprus, Denmark, Dominican Republic, Egypt, France, Germany, Federal Republic of, Greece, Hungary, Iran, Israel, Italy, Kuwait, Madagascar, Malaysia, Mauritius, Mexico, Netherlands, New Zealand, Norway, Philippines, Portugal, Saint Vicente and the Grenadines, Spain, Sweden, Thailand, United Kingdom of Great Britain and Northern Ireland, United States of America, Vanuatu, Venezuela and Yemen.

2/ The International Register of Potentially Toxic Chemicals is a programme activity centre of UNEP in charge of collecting and disseminating information on chemicals. It provides importing countries with information on chemicals that have caused concern or have been banned in certain countries, and provides them with an opportunity to obtain information on request concerning the status of many potentially hazardous chemicals now being used. For more details, see the annex.

3/ The International Programme on Chemical Safety is a joint programme by WHO/ILO/UNEP charged with developing an international capacity for the integrated assessment of health risks due to multi-media exposure to environmental chemicals. It prepares and disseminates up-to-date reviews of research on the health effects of chemicals (including those suspected of giving rise to cancer, mutation of genes, changes in the human embryo and spontaneous abortion), guiding principles on exposure limits and on appropriate methods for exposure measurement and assessment, toxicity testing, epidemiological and clinical studies and risk assessment, information on methods for coping with chemical accidents, and information on the development of manpower in the field of chemical safety.

4/ The Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was adopted in 1975. Under this Scheme, the health authority of the exporting country is required to certify on request whether a specific product offered for export is available on the home market, and 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. For more details on the Scheme, see the annex below.

ANNEX

Relevant activities of the organizations of the United Nations system, including facilities for assisting Governments in exchange of information on banned hazardous chemicals and unsafe pharmaceutical products

A. World Health Organization

1. 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 these 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 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.

2. 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 verbatim to all member States, through its drug information circulars, decisions taken by national authorities to withdraw or restrict the availability of specific drugs on grounds of safety.

1. The international drug monitoring programme

3. 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.

4. The number of actively participating countries has increased from 10 to 22, 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 2,000 per month. Although the vast majority of these reports were received from countries with

highly evolved drug regulatory authorities, developing countries also demonstrated an active interest in the scheme. The operational activities take place at the Collaborating Centre for International Drug Monitoring of WHO, at Uppsala, Sweden. However, WHO retains full responsibility for co-ordination of the programme, participation of national and other centres and dissemination of information, including publications.

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

5. 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.

6. The Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce was adopted in 1975 in resolution WHA28.65, and 95 countries have now agreed to participate through designated national authorities. The health authority of the exporting country is required to certify on request whether a specific product offered for export is available on the home market, and 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 circulars and the Drug Information Bulletin

7. 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 decisions.

8. Many resolutions to reinforce this 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.

9. The drug information circulars of WHO and the quarterly WHO Drug Information Bulletin are now established as vehicles for the transfer of information on the safety and efficacy of drugs. The former service offers countries a mechanism to provide all member States with a rapid verbatim notice concerning any restrictive regulatory action taken in connection with an internationally available product,

while the Bulletin provides an edited commentary on such decisions, in which any differences in national viewpoints can be contrasted and discussed.

10. In principle, those documents provide a reasonably comprehensive information service for interested administrative bodies and individuals, and particularly those in member States that lack highly evolved drug regulatory systems. In practice, however, the drug information circular system falls short of fulfilling its potential, since only a relatively small proportion of product withdrawals are reported to WHO. The system also suffers from inherent bias, for, whereas these decisions frequently devolve from controversial issues, only those countries persuaded of the need to take restrictive regulatory action provide a notification. The Drug Information Bulletin has the virtue of being able to place these decisions in a broader perspective but it cannot necessarily cover the omissions created within the drug circular system.

11. The roots of the deficiency of information provided by the drug information circulars are two:

(a) Drugs are most frequently removed from national markets by voluntary agreements with manufacturers rather than by enforcement of statutory controls;

(b) Drugs intended solely for export may not be subjected to regulations that apply to products destined for domestic markets. (Although this can be found out by the use of the clause in the Drug Certification Scheme, it requires a specific request from the importing country.)

12. An additional problem arises as a result of the inevitable and understandable reticence on the part of regulatory authorities to release information on a safety issue until a definitive position has been adopted on the implications of the available data and on the need for any restrictive action. Whereas this ensures that public concern is not aroused prematurely and perhaps unnecessarily on the basis of unrealized suspicions, it can frustrate or delay international discussion, and even international collaboration, as a problem develops. The need for confidentiality is thus counterbalanced by a need for each national authority to be fully and efficiently informed of any reservations about the safety of a product subject to its control, and by a need to establish international understanding on a given issue at the earliest opportunity. The Drug Information Bulletin of WHO, however, has had a discernible impact on regulatory decisions taken in many third world countries.

13. In the area of chemicals, WHO, jointly with FAO, publishes health risk evaluations on food additives and pesticide residues and other selected food contaminants. In addition the International Programme on Chemical Safety, a joint programme of the ILO, UNEP and WHO, involving the International Agency for Research on Cancer (IARC) and several other international organizations and national institutions, has published a series of criteria documents containing separate evaluations on chemicals. IPCS is also in the process of preparing short documents giving summaries of health data for important chemicals, which will appear in the data profiles provided by another participant in IPCS, namely IRPTC.

B. UNEP/International Register of Potentially Toxic Chemicals: summmary of relevant information

14. Recognizing the need for an international register, the United Nations Conference on the Human Environment, held at Stockholm in 1972, inter alia, 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:
>
> "...
>
> "(e) 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." a/

15. The Governing Council of UNEP, in its decision 29 (III) of 2 May 1975, b/ 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.

16. At its fourth session, in its decision 63 (IV) of 13 April 1976, c/ the Governing Council decided that IRPTC should be a component of Earthwatch, the global environmental assessment programme of UNEP. Earthwatch consists of four components, namely: evaluation and review, research, monitoring, and information exchange. The Register, along with the International Referral System (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.

17. 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 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.

18. 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.

19. In its decision 6/3 B of 24 May 1978, d/ the Governing Council requested the Executive Director of UNEP to ensure that IRPTC would facilitate access to available information, 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 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 positively by appointing national correspondents 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.

20. Without going into technical details, it may be said that IRPTC operations involve the collection and storage of information, filing of documents, inventorying of existing information systems on chemicals, dissemination of information through bulletins and other means, and the preparation and publication of data profiles for chemicals.

21. These 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, chemobiokinetics, 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.

22. The legal file for chemicals, furnished 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, is of particular interest. Legal data profiles containing data on recommendations/legal mechanisms, one of the 17 attribute fields covered by the Register, are therefore being developed as a priority, although they form part of the Data Profile series. National (eight selected countries) and international recommendations and regulations for the control of about 200 chemicals in the air, water, wastes, soil, food, beverages and consumer goods were collected and published. e/ The chemicals were selected from the Working List of Selected Chemical Substances of IRPTC, based on existing national and international lists. Since then IRPTC has added additional data profiles on chemicals to its list, which now covers about 450 chemicals but is open-ended, as more chemicals will be added to it according to the information needs of the countries concerned. The Governing Council of UNEP has repeatedly expressed its concern regarding the exchange of information on regulatory decisions placed on potentially toxic chemicals by various countries. The legal file of IRPTC, which contains data on approximately 450 chemicals from 12 countries and 6 international organizations, will be published in autumn 1983.

23. The Data Register of IRPTC, providing the information for strengthening the data profiles, is designed as a system which allows for data collection and exchange through network arrangements with world-wide partners. The computerized Register will eventually contain data for many chemicals in the various attribute fields. At present, IRPTC is striving to complete data profiles for 450 chemicals of its Working List through systematic searches for relevant data for all attribute fields. Profiles on many of these chemicals will become available during late 1983.

24. A regular Bulletin, which is widely disseminated through its global network, is published by IRPTC in English, French, Russian and Spanish. 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 (decision 9/6, of 1981), a short list of environmentally dangerous chemical substances and processes with global impact was prepared, some of which are relevant to the present report, such as, for instance, pesticides. In the field of environmental law, UNEP will be calling a meeting of governmental experts, in March 1984, to "consider guidelines or principles on ... the exchange of information relating to trade in and use and handling of potentially harmful chemicals in particular pesticides" (UNEP/GC.10/14, decision 10/24). Progress towards the establishment of formal explicit international arrangements for the notification of exports of banned hazardous chemicals will be dependent upon the success of these activities.

1. Query-response service and national correspondents

25. Since its establishment in March 1976, IRPTC has responded to queries on chemicals using several computerized bibliographic files, 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 ILO and national correspondents (see paras. 26 and 27). Queries have been received from United Nations bodies, 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.

26. To facilitate information exchange with countries, Governments have been invited to nominate national correspondents to act as national co-ordinating centres for interaction with IRPTC and to provide them with the necessary resources. The functions of the national correspondent are the following:

(a) To provide information on relevant expertise, criteria documents, reviews and monographs, data banks and information systems, legislation and regulations on chemicals, accidents involving chemicals and chemicals causing concern in his country;

(b) To assist in the development of the query-response service;

(c) To distribute IRPTC publications (Bulletin, etc.) and information about IRPTC and its services in his country.

27. So far, 96 countries have appointed national correspondents. Regional workshops are being organized to familiarize the national correspondents with the use of the Register and to encourage active participation in its operation. Plans are being implemented to assist national correspondents establish national registers compatible with IRPTC.

C. International Labour Organisation

28. The work of the ILO in this field concerns mainly the operation of the International Occupational Safety and Health Hazard Alert System, and the protection of workers against harmful or potentially harmful products.

1. The International Occupational Safety and Health Hazard Alert System

29. This system has the capability to disseminate rapidly, through a world-wide network of designated bodies, scientific and technical information on newly discovered or suspected occupational hazards. It enables a country to issue an alert or request information on the safety and health hazards that are found to be increasing. It is part of the ILO International Programme for the Improvement of Working Conditions and Environment (PIACT).

30. The system is linked with the relevant programmes of other international organizations, particularly with the International Programme on Chemical Safety, a

joint WHO/ILO/UNEP venture, the International Register of Potentially Toxic Chemicals of the United Nations Environment Programme, the Complementary Information Exchange Procedure of the Organisation for Economic Co-operation and Development, and the activities of the commissions of the European Communities.

31. The Hazard Alert System is intended to convey, in a coherent and co-ordinated manner, original scientific or technical information concerning the safety or health of workers which warrants attention and is considered sufficiently important to require action at the national level. It deals with all aspects of safety and health in the working environment. Thus it covers not only chemical risks but also physical and biological ones. It is designed to assist countries in the exchange of information on occupational safety and health hazards and their prevention. It is not, however, intended to satisfy requests for information on published material; these can be addressed to the International Occupational Safety and Health Information Centre (CIS) of the ILO under its established procedures.

32. Three types of communications may be circulated in the system:

(a) Alerts relating to hazards which are confirmed, described in detail and well documented;

(b) Information concerning evidence of the existence of an occupational hazard that is not yet fully documented;

(c) 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.

33. The Hazard Alert System is a dynamic system designed to promote preventive action at the national level. Such action may consist in the setting up of an enquiry, a research project, a safety compaign, an alert at the national level, and/or the preparation of guidelines, laws or regulations.

2. Protection of workers against harmful or potentially harmful products

34. The ongoing programme on toxic chemicals and exposure limits of the ILO includes:

(a) The drawing up of conventions and recommendations, for instance, on benzene, occupational cancer, air pollution, noise and vibration etc.;

(b) Negotiation of codes of practice, such as for instance, on the occupational exposure to airborne toxic substances harmful to health;

(c) Dissemination of information, inter alia, through: the International Occupational Safety and Health Information System of ILO; the International Occupational Safety and Health Hazard Alert System; international symposia: control of air pollution in the working environment (Stockholm, 1977), prevention of occupational hazards (Helsinki, 1981);

(d) Co-sponsorship of IPCS;

(e) Co-operation with WHO concerning exposure limits.

35. In addition, regarding the protection of workers against harmful or potentially harmful products, the ILO published the Occupational Safety and Health Series No. 37, entitled "Occupational Exposure Limits for Airborne Toxic Substances", which is a compendium of exposure limits from a score of countries published in a tabular form for the guidance of those concerned with the improvement of the working environment. It was revised for the second time in 1981. It is now proposed to store the data in a computer, in collaboration with the International Register of Potentially Toxic Substances, for updating the exposure limits with a view to publishing revised editions at regular intervals.

D. Food and Agriculture Organization of the United Nations

36. The work of FAO in this field is related to the potential hazards posed by the use of pesticides. Since the early 1950s, FAO has been concerned with these substances as a key input for agricultural production.

37. 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.

38. Over the past 20 years, as executing agency, FAO has managed many field development projects related to training in safe and efficient application practices and in monitoring of residues. Many of these 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 of the study and management of pests in their natural environment, with consequently decreased reliance on chemical pesticides, has contributed to the overall objectives.

39. Under the guidance of panels of experts, assistance has been provided to member Governments through the issuance of quality control standards for pesticides, of maximum residue limits and through provision of advice in setting up and operating of official and legal-based procedures for pesticide registration and control.

40. Government consultations have been convened by FAO in 1977 and 1982 whose basic objective was to assist member countries in initiating and operating or improving their own pesticide registration and control schemes, while at the same time introducing a certain degree of uniformity in registration requirements and control procedures. Such procedures include guidelines on labelling practices, on packaging and storage and on the safe disposal of surplus pesticides and pesticide containers. The gradual introduction of these guidelines should prove instrumental in overcoming many of the problems currently encountered in many parts of the world.

41. It is the intention of the organization to continue to support and pursue such activities in the future.

42. In addition to the work on registration schemes, FAO, in consultation with other concerned agencies and industry, through the International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP), is preparing a code of conduct on the distribution and use of pesticides. Its objectives are to identify the potential hazards, define the precautionary measures needed and clarify the responsibilities of the various interested parties. These include Governments, manufacturers, dealers, users etc. The code should be particularly valuable in countries which do not yet have official control procedures. The preparation and implementation of the code is being actively pursued by FAO.

E. United Nations Centre on Transnational Corporations

43. The General Assembly, in resolution 35/186, requested the Commission on Transnational Corporations to study the ways and means within the information system on transnational corporations to improve the exchange of information on banned hazardous chemicals and unsafe pharmaceuticals with a view to formulating appropriate recommendations. To assist the Commission on Transnational Corporations in its review, the Centre prepared a background report (E/C.10/90) with a limited proposal for action. In the report it was stressed that the lead agencies in the United Nations system in prescribing guidelines for the establishment of standards of safety for human life and health and for the environment in the chemical and pharmaceutical sectors are WHO, UNEP, the ILO and FAO. The Centre's contribution would be supplementary to the role of those lead agencies. The Commission on Transnational Corporations requested that the Centre co-ordinate its work with the agencies in this regard.

44. The Centre's contribution to the information provided by the specialized agencies will principally relate to providing the names of transnational manufacturers and distributors and their product trade names for the chemical and pharmaceutical products identified by the specialized agencies as toxic or hazardous. A working list of toxic or hazardous chemicals is being drawn up in consultation with the specialized agencies concerned. Similar efforts are being made in respect of pharmaceuticals. In respect of the products identified as being toxic or hazardous on the basis of the above procedure, the Centre would collect information on transnational corporations manufacturing and distributing such products. The information would include (a) identification data, (b) a summary paragraph on the hazards involved, (c) the trade names, and (d) transnational manufacturers and distributors and principal markets where the products are sold. Preliminary work in this regard has been undertaken. The data collected and analysed will be verified with individual transnational corporations.

F. General Agreement on Tariffs and Trade

45. The work of 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 Governments 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 might 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.

46. 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.

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

Notes

a/ 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, recommendation 74, subpara. (e).

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

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

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

e/ IRPTC, Data Profile Series No. 2, Legal Data Profile for Selected Chemicals, 1980.
