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REPORT OF THE ECONOMIC AND SOCIAL COUNCIL

Products harmful to health and the environment

Report of the Secretary-General

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* A/39/150.

I. INTRODUCTION

1. In resolution 37/137 of 17 December 1982, the General Assembly, inter alia, requested the Secretary-General, based upon the work already being done within the Food and Agriculture Organization of the United Nations, the World Health Organization, the International Labour Organisation, the United Nations Environment Programme, the General Agreement on Tariffs and Trade, the United Nations Centre on Transnational Corporations and other relevant intergovernmental organizations, to the maximum extent possible within existing resources, to prepare and regularly update a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, not approved by Governments, and to make the list available as early as possible and in any case not later than December 1983. It agreeed that the consolidated list should be easy to read and understand and should contain both generic/chemical and brand names in alphabetical order, as well as the names of all manufacturers and a short reference to the grounds and decisions taken by Governments that have led to the banning, withdrawal or severe restriction of such products. It also decided to keep under review the format of the consolidated list with a view to its possible improvement. In resolution 38/149 of 19 December 1983, the General Assembly, inter alia, requested the Secretary-General, for purposes of review by the Assembly at its thirty-ninth session, to submit a report on the implementation of resolution 37/137, including the consolidated list, taking into account the latest information and comments collected for possible improvement of the list, as envisaged in resolution 37/137.

2. The first issue of the consolidated list was transmitted to Governments in English on 31 December 1983. A revised issue is being published in English, French, Spanish and Arabic. The present report, prepared pursuant to General Assembly resolution 38/149, describes the role and content of the list and the steps taken by the Secretary-General in its preparation. It then discusses issues that have arisen in connection with the list and concludes with proposals regarding its future development.

3. Attention is also drawn to the report of the Secretary-General on exchange of information on banned hazardous chemicals and unsafe pharmaceutical products (A/39/290-E/1984/120) which was prepared pursuant to paragraph 8 of General Assembly resolution 38/149.

II. ROLE AND CONTENT OF THE CONSOLIDATED LIST

4. The consolidated list presents in a unified manner information on important restrictive regulatory decisions taken by Governments on pharmaceuticals, agricultural and industrial chemicals, and consumer products. It constitutes a tool which Governments can use to inform themselves of the regulatory decisions taken by other Governments on these products and of the possible need for regulatory action. It thus provides a means to assist them in establishing control of both the import and the manufacture and sale of products which may be harmful to health and the environment. It complements existing information mechanisms within

the United Nations system, including the WHO's Drug Information Bulletins and drug information circulars and the United Nations Environment Programme's International Register of Potentially Toxic Chemicals. 1/

5. The revised first issue of the list contains information on regulatory decisions taken by 60 Governments relating to nearly 500 pharmaceutical products, agricultural and industrial chemicals, and consumer products, although it does not constitute a full inventory of decisions taken by those Governments. In accordance with the resolution, the regulatory decisions involve bans, withdrawals, non-approvals and severe restrictions. In some cases, the list also includes restrictions which Governments do not regard as severe, in order to illustrate the range of views held by Governments which often have different opinions as to what regulatory decision is appropriate to their own particular situation.

6. The information on pharmaceutical products has been divided into a section on monocomponent products and a section on combination products. This is because combination pharmaceutical products are often banned or otherwise regulated because either several, or the combination, of their ingredients is considered to be unsafe, inefficacious or unnecessary; regulatory measures relating to monocomponent products, however, are concerned with a single active ingredient.

7. The information relating to industrial chemicals essentially refers to substances which have been banned in the working environment for health or environmental reasons, or are only authorized for specific uses. The list does not cover the large number of widely-used industrial chemicals to which significantly restricted occupational exposure limits, e.g. maximum allowable concentrations, have been assigned by national authorities. Such information is available in publications of the International Labour Organisation (ILO) and the International Register of Potentially Toxic Chemicals (IRPTC). 2/

8. Information relating to consumer products has been limited to products which are hazardous on account of their chemical composition. The list does not contain information concerning regulatory measures taken on food additives, as the question of international standards concerning such additives is being dealt with under the aegis of the FAO/WHO Codex Alementarius. Information on narcotic and psychotropic substances which was included in the first issue has been omitted from the revised first issue, since these substances are covered by the relevant United Nations conventions.

9. The list contains some information on trade names and on transnational manufacturers of some agricultural and industrial chemicals. In a few cases, there are also references to manufacturers and brand names of pharmaceuticals when these have been mentioned in regulatory decisions or voluntary withdrawals. The available data focus on the manufacturers of active ingredients, and do not cover the large number of formulators engaged in the final processing and packaging process.

III. PREPARATION OF THE CONSOLIDATED LIST

10. In preparing the list, the Secretary-General first collected the relevant information available within the United Nations system. The World Health Organization (WHO) provided information on decisions taken by national authorities to withdraw or restrict pharmaceutical products, either totally or in respect of specific uses. This information had already been disseminated to Member States in WHO's Drug Information Bulletins and drug information circulars. The United Nations Environment Programme's International Register of Potentially Toxic Chemicals (IRPTC) provided information on agricultural and other chemicals which had been obtained from Governments. This information had already been published in its Bulletins or was retrieved from its computerized central files on selected chemicals, or was available in its library. The ILO provided some information on chemicals. The information provided by both IRPTC and ILO relates to prohibitions regarding the production or use of agricultural and other chemicals. The United Nations Centre on Transnational Corporations (UNCTC) provided information concerning names of manufacturers and brand names of certain agricultural and industrial chemicals included in the list.

11. Following the collection of this information, the Secretary-General, after consulting with various groups of manufacturers and representatives of consumer interests, through non-governmental organizations, prepared a first tentative list of pharmaceuticals, chemicals, and narcotics and psychotropic substances which seemed appropriate for inclusion in the consolidated list. This first tentative listing, together with an explanatory note, was transmitted to Governments by the Secretary-General in a note verbale dated 10 May 1983. The Secretary-General requested Governments to indicate what regulatory measures they had taken in relation to the products on the tentative list and to provide information on any other products which they considered should be included in the list, as well as information on brand names and manufacturers, and also to state whether any of the substances specified in the tentative list did not, in their countries, meet the criteria set out in the resolution.

12. As at 30 November 1983, 35 countries had replied to the Secretary-General's note verbale, although not all these Governments provided information for inclusion in the list. 3/ The first issue of the consolidated list was prepared on the basis of this information and of the information provided by WHO, IRPTC and UNCTC. Information was also received from the Commission of the European Communities concerning directives on the use of agricultural chemicals and other chemical products.

13. Very limited information on names of manufacturers and brand names, particularly in the case of pharmaceutical products, was available. However, in an endeavour to comply with the request of the General Assembly, information on brand names and on transnational manufacturers of some agricultural and industrial chemicals was included. This information was provided by UNCTC in the context of its existing programmes, 4/ and by Governments in their replies to the Secretary-General's note verbale. 5/ As mentioned above, in a few cases, information on brand names or manufacturers of pharmaceuticals was also included.

14. In a note verbale dated 30 December 1983, the Secretary-General transmitted to Governments the first issue of the consolidated list, and invited them to provide further information with regard to:

(a) Regulatory action they had taken, indicating whether any corrections needed to be made to the first issue of the list in order to improve its accuracy;

(b) Products which were not included in the first issue but which in the Government's view should be included;

(c) Details of regulations as to specific conditions of use concerning products which were already included in the first issue or which should be included in it;

(d) Details as to the health or environmental reasons for the regulatory action taken with regard to products;

(e) Brand names and names of manufacturers of products reported for inclusion in the list.

15. The Secretary-General also requested that whenever Governments report the non-approval or non-registration of products they should specify whether approval or registration has been denied, or whether the product in question has not been submitted for approval or registration.

16. By 30 May 1984, 10 more Governments had responded to the Secretary-General's note verbale. 6/ A revised first issue of the list incorporating information provided by these Governments is now being issued. Additional information on pesticides taken from the "Preliminary List of Banned or Significantly Restricted Substances in the United States", prepared by the Organization of American States (OAS) and some information compiled from government gazettes and other statutory documents was included in the revised issue of the list. IRPTC also provided further technical data concerning trade and other non-proprietary names for inclusion in the revised first issue. Material submitted by non-governmental organizations (representing both producer and consumer interests) covering national regulatory measures, as well as corrections and clarifications to initial entries generated through information available in the United Nations system, was also utilized.

17. Throughout the process of preparation of the list there were close consultations with the United Nations organizations concerned, especially WHO, and UNEP and UNCTC. Useful consultations were also held with non-governmental organizations representing public interest groups and manufacturers.

IV. ISSUES ARISING IN CONNECTION WITH THE CONSOLIDATED LIST

18. The information collected so far is quite substantial but still needs to be expanded, both in terms of the number of countries included and the number of products reported. While there are cases in which the information covers a range

of measures taken by a number of countries on a given product, it often only reflects the positions of a small number of Governments, which may not be indicative of those of other Governments.

19. The usefulness of the list also depends largely on the level of detail provided regarding such matters as the uses in respect of which products are regulated, the regulatory context within which the measures are taken, and the health and environmental reasons for them. Governments need to be aware of the limits of jurisdiction of the regulatory agency involved in order to understand the nature of a particular regulation, and also to know whether the regulation has been made for specific health or environmental reasons or on account of unrelated economic or other reasons.

20. A further issue is that of definitions. The wording used in General Assembly resolution 37/137, specifying that the list should cover products whose consumption and/or sale has been "banned, withdrawn, severely restricted, or in the case of pharmaceuticals, not approved by Governments" raises a number of problems, particularly regarding the application of the term "severely restricted". The meaning of the term "banned" clearly involves prohibition, but its application to the list has given rise to certain questions. First, it should be noted that many Governments prefer to regulate products on the basis of positive rather than negative lists, i.e. lists of approved products. They may, therefore, have assessed only a limited number of products directly related to their needs, so that it is not possible for them to provide information on products that have not been submitted for registration. Secondly, products may be banned for reasons other than safety or efficacy, for example economic reasons, which are not related to the purposes of the list. Products may also be withdrawn - sometimes voluntarily by the manufacturer - for reasons other than health or efficacy. Withdrawals may take effect immediately or allow for the phasing out of the product. When products are banned or withdrawn for safety reasons, it is because the regulatory agency concerned considers that the risks associated with their use under local conditions outweigh their potential benefits. Such evaluations can obviously vary according to different local circumstances, or because of different assessments of technical data.

21. The term "severely restricted" has not been defined either in a legal or scientific context although it is being used in certain international instruments. 7/ Governments may differ considerably as to the potential hazards of particular products and may therefore impose different levels of restriction to them. It is therefore a question of judgement as to the degree of restriction which warrants the inclusion of a particular product in the consolidated list. When a product is severely restricted, this means that while it is potentially harmful the risk/benefit ratio justifies its use for certain purposes, and it may even be essential for such purposes. With regard to chemicals, in particular, it is important to recognize that a given product often has a variety of uses and that different types of restrictions apply in each case. Thus, it is necessary to know to what use or uses and under what conditions of use the term "severely restricted" is being applied.

22. The term "not approved" refers to products which require regulation or approval by regulatory agencies and for which Governments have denied approval on health or environmental grounds after a review of the technical data. The situation is complicated, however, in the case of products for which appeals are pending, and products for which approval has been denied for reasons other than efficacy or safety. A product may also be "not approved" as a result of a lack of agreement between a national regulatory agency and a manufacturer or distributor concerning restrictions to be imposed on the manufacture, sale and use of a product, such as indications and counter indications, rather than a completely negative risk/benefit assessment. In addition, it is not usually necessary for products which are destined exclusively for export to be submitted for approval in the country of origin. As a general rule, information concerning non-approval of products is considered to be privileged information.

23. These problems of definition, however, have not been a major hindrance for the preparation of the list and it has proved possible to use the terms specified in the resolution for the collection of information. Similar problems have been faced in connection with other international schemes for information exchange, none of which have developed clear-cut definitions, and it appears that, unless an internationally agreed set of harmful chemical and pharmaceutical products is established, there is no alternative to the use of such terms as "banned", "withdrawn", "severely restricted" and "non-approved".

24. The issue of trade names and names of manufacturers also needs to be considered. Limited information has been included in the list on this question and there are various problems involved in collecting it. First, products with the same brand name may have different compositions in different countries; secondly, it is extremely difficult to identify the large number of producers engaged in particular in the formulation, packaging and sale of products; thirdly, not all countries have legal requirements for registration of the chemical composition of a product with a certain brand name and it is therefore not possible for them to provide meaningful information for inclusion in the list. Fourthly, the composition of products with given brand names is often subject to change without widespread notification, and brand names often survive when products are withdrawn, so that it is virtually impossible to keep this type of information up to date.

V. PROPOSALS FOR IMPROVING THE CONSOLIDATED LIST

A. Coverage and content

25. One of the main ways in which the list can be improved is to expand its coverage in terms of the countries and decisions on products included in it. Governments need to provide further information on legislative measures they have taken to ban, withdraw, severely restrict or not approve the manufacture, import, sale or use of products. It should be noted in this connection that additional information should become available as a result of the recent adoption by UNEP's Governing Council (at its twelfth session in May 1984) of the Provisional Notification Scheme for Banned and Severely Restricted Chemicals under which Governments are called upon to exchange notifications of regulatory actions for chemicals, to be compiled and/or disseminated by IRPTC.

26. Fuller information is also needed regarding the regulatory context in which measures are taken by Governments, the nature of the limitations imposed regarding the manufacture, import, sale and use of products, and the health or environmental reasons for which regulatory measures are taken. The manner in which this information would be included in the list would need to be considered from technical and legal points of view. In this context, greater use could be made of official documents in order to collect additional information of relevance to the consolidated list, and to verify and seek additional details concerning existing information.

27. Additional issues involve the categories of consumer products covered by the list, and the question of the information to be included on trade names and names of manufacturers. With regard to consumer products, the consolidated list has so far only included products that are considered unsafe to health and the environment because of their chemical composition. The General Assembly may wish to decide whether this information is adequate.

28. The task of collecting reliable and up-to-date information on trade names and names of manufacturers of all the products included in the list is especially difficult. As indicated above, little information is available in the United Nations system and hardly any information has been received so far from Governments. If the General Assembly wishes to pursue further this aspect of the consolidated list, it is suggested that information should be limited to products still under patent.

B. Method of dissemination

29. The first issue of the consolidated list and its first revision have been published as documents, and distributed to all Member States. As the volume of data can be expected to grow steadily, other means of dissemination, such as computer tapes, should be considered. Eventually the list could, perhaps, become part of a computerized data base covering information on products that may be hazardous to health and the environment.

C. Periodicity

30. In its resolution 37/137 the General Assembly requested that the list should be regularly updated. It will be necessary to decide whether this updating should take place on an annual basis, or more frequently.

D. Resource implications

31. Since the amount of resources required for future work on the list will depend on the decisions taken by the General Assembly regarding the scope of the list, no specific proposals are being made at this stage. It will be recalled that an appropriation of $90,000 was authorized by the General Assembly for the preparation of the first issue of the list, to cover the hiring of consultants, the provision

of computer services and translation. These resources have been utilized for the preparation of the first issue. In addition, one P-5 staff member was deployed, on a nearly full-time basis, from the programme planning and co-ordination programme which has suffered a lower implementation rate as a consequence. Substantial staff support for the preparation of the list was also provided by UNCTC, UNEP and WHO. Further work on the list will require continued redeployment of staff from existing programmes or the provision of additional resources.

Notes

1/ See also the report of the Secretary-General on the exchange of information on banned hazardous chemicals and unsafe pharmaceutical products (A/39/290-E/1984/120).

2/ International Labour Office, Geneva. Occupational Safety and Health Series No. 37. Occupational Exposure Limits for Airborne Toxic Substances, 2nd edition, 1980. International Register of Potentially Toxic Chemicals. United Nations Environment Programme. Geneva. Data Profile Series No. 4 IAPTC Legal File 1983, vols. 1 and 2, 1983.

3/ Bangladesh, Bolivia, Canada, Colombia, Denmark, Dominican Republic, Finland, Germany, Federal Republic of, Greece, Guatemala, Hungary, India, Italy, Japan, Kuwait, Malaysia, Netherlands, New Zealand, Norway, Peru, Philippines, Romania, Saudi Arabia, Sri Lanka, Singapore, Spain, Sweden, Switzerland, Thailand, Tunisia, Turkey, Union of Soviet Socialist Republics, United Kingdom of Great Britain and Northern Ireland, United States of America and Venezuela.

4/ See E/C.10/90.

5/ Data on trade names were provided by a number of countries, but only five countries (Colombia, Greece, Hungary, Sweden and Turkey) provided data on national manufacturers. In the initial edition of the consolidated list, data on national manufacturers was excluded so as not to prejudice the small sample of respondents.

6/ Bulgaria, Cyprus, Israel, Malta, Mauritius, Mexico, Nigeria, Pakistan, South Africa and Tunisia.

7/ These include the OECD Council recommendation on information exchange related to export of hazardous chemicals, the FAO Draft Code of Conduct on the Distribution and Use of Agricultural Chemicals, and the UNEP Provisional Notification Scheme for Banned and Severely Restricted Chemicals.
