

GENERAL AGREEMENT ON TARIFFS AND TRADE

RESTRICTED

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Limited Distribution

Exports of domestically prohibited goods

ACTIVITIES OF OTHER ORGANIZATIONS IN RELATED FIELDS

Note by the Secretariat

Introduction

1. At their 40th session, the CONTRACTING PARTIES suggested that the secretariat prepare, by mid-1985, basic documentation designed to facilitate discussion of the question of export of domestically prohibited goods. Such documentation would also cover work being done in other organizations (GATT/AIR/2087). This note is a first attempt to give a picture of the activities of other international organizations in the field of information exchange concerning trade in domestically prohibited goods. The secretariat is following such activities closely and will update this note as necessary.

2. The organizations covered in the note are the United Nations, the OECD, the United Nations Environment Programme, the United Nations Food and Agriculture Organization and the World Health Organization. Reference is also made to work being undertaken in the International Labour Office and the United Nations Centre on Transnational Corporations. While the work done by the secretariat of the General Assembly is broadest in scope, that undertaken by OECD and UNEP/IRPTC covers very much the same groups of products (chemicals); moreover, the approach taken to the question by developed countries in the OECD has now also been very largely adopted in UNEP, as also in FAO in dealing with pesticides.

United Nations General Assembly

3. In response to the General Assembly resolution adopted in December 1982 on Protection Against Products Harmful to Health and the Environment (R37/137), a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or, in the case of pharmaceuticals, non-approved by the governments was circulated in December 1983. A revised version was circulated in July 1984.

4. In the revised version of the Consolidated List (document DIESA/WP/1 of July 1984), information included is based on replies from forty-five governments and the EC Commission, as well as information collected from other organizations (WHO, UNEP, ILO, UNCTC, OAS). The sum of such information covers sixty countries; however, the scope of the information provided varies greatly. Observations by a number of countries on the scope and utility of the list are contained in an Annex to the list. The UN secretariat has stressed that the list is supposed to be a complement to the information systems provided by other organizations which often provide more specific scientific and technical information on the potential benefits or hazards of specific products under particular conditions, and that it does not itself provide a sufficient basis for regulatory action, but constitutes an "alert mechanism" to warn governments that it may be necessary for them to take some type of regulatory action regarding these products.

5. Information on pesticides is confined to their use in agriculture; that on industrial chemicals to those which have been banned in the working environment for health or environmental reasons or which are only authorized for specific uses. Narcotic and psychotropic substances which are regulated under the Single Convention on Narcotic Drugs or the Convention on Psychotropic Substances are not included in the list. Information on consumer products is confined to products which are hazardous on account of their chemical composition.

6. In a discussion of the terms "banned", "severely restricted" and "not approved", it is recognized that some governments regulate products on the basis of lists of approved rather than banned products, and may therefore have assessed only a limited number of products directly related to their needs; that products may be banned or withdrawn for reasons other than safety or efficacy; that withdrawals may be made by manufacturers voluntarily for a variety of reasons; and that the term "banned" is often used in relation to combinations of products rather than specific substances. It is noted that "severely restricted" has no legal or scientific definition, although it is used in OECD and other intergovernmental bodies, and that governments therefore differ considerably as to the products which should be classed as such. Moreover, a given product often has a variety of uses and restrictions differ in each case; thus it is necessary to know to what uses and under what conditions the term "severely restricted" is being applied. It is also stressed, inter alia, that since certain products are banned or restricted only in certain specific uses or conditions of use, such bans or restrictions should not be interpreted as extending beyond such uses or conditions; moreover, it is recognized that different governments have differing views on the type of regulatory action considered necessary based on local conditions and their own evaluations of risks and benefits and that all severely restricted products are considered to be necessary for certain uses. In relation to "not approved" it is noted that the situation is complicated in relation to products for which appeals are pending and those for which approval has been denied for reasons other than efficacy or safety; 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. Overall, it is not to be assumed that a product which is not included in the list is not therefore potentially hazardous, since most chemicals and pharmaceutical products may be harmful if used outside their prescribed safety limits.

7. A draft resolution on the consolidated list was adopted at the 1984 session of the General Assembly. The Assembly decided that an updated consolidated list should be issued annually, in alternating sets of three U.N. official languages each year, and that the data should be made available in a form which allows direct computer access; that the format of the list should be kept under review, and that this review should particularly cover the advantages and disadvantages of introducing to the list such information as the legal, public health and commercial context of the regulatory actions, as well as complementary information on safe uses of the products. All governments which had not yet provided information for inclusion in the updated versions of the list were invited to do so. A review of the information exchange schemes in operation within the United Nations system would be made for the 1987 General Assembly. (See document A/C.2/39/L.135.)

OECD

(a) Banned or severely restricted chemicals

8. In April 1984, the OECD Council adopted a Recommendation and Guiding Principles on Information Exchange Related to Export of Banned or Severely Restricted Chemicals. These were prepared by an expert group established under the OECD Special Programme on the Control of Chemicals. The principles underlying these documents have been incorporated into much of the work undertaken by UNEP. They also form a large element in the basis for the work done by FAO on pesticides.

9. The OECD recommendation and principles, while laying the primary responsibility for the protection of human beings and the environment from hazards associated with imported chemicals on importing countries, recommend that if any banned or severely restricted chemical is exported, information be provided from the exporting country to the importing country, including non-OECD members, to enable the latter to make "timely and informed decisions" concerning the chemical. "Banned or severely restricted" includes any chemical subject to a control action to ban, or severely restrict, the use of the chemical in order to protect human health or environment domestically: or to refuse required authorization for first time use on the grounds that such use would endanger human health or the environment. If such a product is exported, the importing country should be informed (if possible, before exportation takes place) that such an export is expected or imminent; informed of the identity or chemical specification of the chemical; given a succinct description of the control action taken by the exporting country; and given an indication that supplementary information is available and the contact point for such supplementary information. Such information would be on a one-time basis at the time of the first export following the control action.

10. The implementation of the Recommendation will be reviewed in 1987. Information exchange among member States is handled by contact points. It is not clear, at this stage, to whom information should be transmitted in non-members.

(b) Consumer products

11. The OECD Committee on Consumer Policy established an "Informal Notification Procedure concerning Product Safety" in 1973. The Council Recommendation concerning the Safety of Consumer Products of 1979 and Recall Procedures for Unsafe Products Sold to the Public of 1981, calls on governments of Member countries to ensure that those goods that are banned or withdrawn from sale within their territories because they are inherently so hazardous that they present a severe and direct danger to life, health or safety of any consumer of those goods are not exported to other countries and urges governments to consider the desirability of seeking powers to prohibit export of dangerous goods, where such powers do not yet exist. These questions are currently still under consideration in the Committee's Working Party on Safety of Consumer Products.

UNEP

(a) IRPTC

12. Under the auspices of UNEP, the International Register of Potentially Toxic Chemicals (IRPTC) was established in 1976. Its main objective is to facilitate access to existing data on the effects of chemicals on human beings and their environment, and to provide basic data for evaluating the hazards associated with particular chemicals. IRPTC operates on the basis of networks for information exchange and the development of central files for chemicals.

13. A network of 107 national correspondents has been established covering 98 governments. They provide information on new or planned legislation to control chemicals, as well as regulations, recommendations, studies and reports on incidents concerning chemicals.

14. The rôle of IRPTC in this regard is to ensure exchange of information and, as a priority, to develop central files containing relevant information on health and environmental hazards posed by chemical substances. Data profiles on over 400 chemicals of international significance, prepared by IRPTC staff assisted by consultants or network parties, are available for consultation by experts seeking information. Further profiles are under preparation. In addition, IRPTC issued a Legal File in 1983 containing information on legal and administrative limitations, bans and regulations placed on potentially toxic chemicals in the producing countries. This takes the form of a compendium of data on 450 chemicals supplied by 12 countries and 6 international organizations. In addition, IRPTC publishes a Bulletin three times yearly, containing information on new or proposed regulations, evaluations, reports and safe use instructions for chemicals, which is widely distributed with the aid of its national correspondents; and provides a query-response service on chemical products covered by the Register.

(b) Exchange of information relating to exports and imports of potentially harmful chemicals (in particular pesticides).

(i) Provisional notification scheme for banned and severely restricted chemicals.

15. A Working Group of experts first met in March 1984 to initiate work on the establishment of guidelines on the exchange of information relating to exports and imports of potentially harmful chemicals (in particular pesticides).

16. Pursuant to this meeting, the Governing Council of UNEP adopted a decision in July 1984 on a Provisional Notification Scheme for banned and severely restricted chemicals. "Banned and severely restricted chemicals" are defined as any chemical that is the subject of a control action taken by a competent authority in the country of export, either to ban or severely restrict the use or handling of the chemical in order to protect human health or the environment domestically, or to refuse a required authorization for a proposed first-time use of the chemical based upon a decision in the country of export that such use would endanger human health or the environment. The scheme is modelled very largely on the guiding principles adopted by OECD in April 1984.

17. Under the scheme, when a country has taken control action to ban or severely restrict a chemical, it should notify directly or indirectly (i.e. by letter to other participating national authorities with copy to IRPTC, or to IRPTC for transmission to other national authorities) the designated national authorities in other countries, of the action it has taken, with the purpose of giving authorities in other countries the opportunity to assess the risks associated with the chemical and to make timely and informed decisions thereon taking into account local environmental, public health, economic and administrative conditions. Minimum information to be provided is specified, including an indication of the contact point for further information in the producing country. The notification of the control action should be made as soon as practicable after it is taken; for chemicals banned or severely restricted before the scheme took effect, an inventory of prior control actions should be provided to IRPTC.

18. If an export of a banned or severely restricted chemical takes place, the exporting country should ensure that necessary steps are taken to provide the designated national authority of the importing country with the original notification regarding control action and to alert it to the fact that an export of the chemical concerned is expected or about to occur. Such information should be provided 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 condition surrounding the control action.

19. As at 1 April 1985, 55 countries had designated their national authorities for the implementation of the provisional scheme.

20. The operation of the scheme was reviewed at a second meeting of the expert group in January 1985. For most of the countries involved, implementation was at an early stage. This was reflected in the scope of the information which had by then been transmitted to or through IRPTC. Only four designated national authorities (Bangladesh, Chile, Federal Republic of Germany and New Zealand) had provided IRPTC with information on chemicals whose use or handling had been banned or severely restricted before the adoption of the scheme, with detailed information on the types of control action provided only by New Zealand. Two further authorities (United States and Finland) had notified new actions taken on particular products.

21. The actions notified by the countries which have so far replied to the UNEP scheme range from complete prohibitions, through restrictions of products for use in specified circumstances or by specified users, suspensions of registration, listing of particular products as poisons implying a permit for use, to voluntary withdrawal of products from the market.

22. Some countries have so far encountered legal or procedural difficulties in bringing the scheme into operation, including in some cases the need to adapt legislation or regulations to the provisions of the scheme.

23. A review of the operation of the scheme will be undertaken by the expert group in 1987, before the annual meeting of the UNEP Governing Council.

(ii) Draft guidelines for the exchange of information on potentially harmful chemicals in international trade.

24. Guidelines in this field were initially discussed at the first meeting of the expert group, and revised for the second meeting in January 1985. They cover definitions, general principles, designated national authorities and their functions in relation to imports and exports, classification, packaging and labelling, information on chemicals either not registered for use or banned or severely restricted in exporting countries. They attempt to extend the broad principles underlying the provisional notification scheme to a wider range of chemical products.

25. At the second meeting of the expert group, it was agreed that prior to the 1987 session of the UNEP Governing Council, the working group should meet again in order to review the implementation of the Provisional Notification Scheme and, at the same time, "to complete work on the draft guidelines to the extent possible and to take all appropriate measures to expedite their preparation with a view to their early adoption by the Governing Council".

FAO

International Code of Conduct on the Distribution and the Use of Pesticides

26. It was agreed in 1982 within the FAO (Second Governmental Consultation on International Harmonization of Pesticide Registration Requirements) that an international code of conduct on the distribution and use of pesticides should be drawn up. A draft of such a code was circulated in June 1984. In relation to information exchange on exports on pesticides, the draft Code states that "Governments of pesticide exporting countries which take action to ban or severely restrict the use or handling of a pesticide ... should take appropriate measures to ensure that ... no export takes place 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; without the explicit consent of the importing country;" and that supplementary information is available on request which can assist the importing country in determining its need for carrying out an environmental impact of such pesticides, and which also takes into account protection of the confidentiality of data in the importing country. A revised draft is to be circulated in the spring of 1985. In drawing up the redraft, FAO intends to make use of the concepts incorporated in the UNEP Provisional Notification Scheme and Guidelines mentioned above.

WHO

27. The World Health Organization undertakes a variety of programmes related to quality, efficacy and safety of drugs. From the point of view of international trade, the two most significant programmes are as follows:

(a) Certification scheme on the quality of pharmaceutical products moving in international commerce

28. The WHO Certification Scheme was first proposed in 1969 and revised in 1975. 108 countries participate in the scheme. The aim is to provide a simple administrative mechanism whereby importing countries can obtain assurance that a product has been authorized to be placed on the market in

the exporting country and, if applicable, obtain information on the reasons for a product not so being authorized; obtain assurances as to the standards of manufacture and quality control of drugs as recommended by WHO; and exchange information on the implementation of inspection and controls exercised by the authorities in the exporting country.

29. Unlike the OECD and UNEP schemes for chemicals, certificates are issued by exporting countries' competent authorities not on their own initiative but only at the request of importing countries.

30. The scheme covers any medicine in its finished dosage form, intended for human use, that is subject to control by legislation in the exporting and importing Member States. While it has been suggested, and appears technically possible, to extend the scheme to active raw materials for the production of drugs, this has not so far been undertaken.

(b) Information on safety and efficacy of drugs

31. The Drug Action Programme of WHO provides a channel by which, through circular letters, health ministries of member states are informed of decisions to prohibit or limit the availability of drugs already in use. In addition, evaluated information on drugs is issued twice yearly in the Drug Information Bulletin.

Other organizations

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

Conclusions

33. It appears from the above that there is a large volume of international activity in the field of information exchange on chemicals and pesticides, but relatively little in other areas. Some of the work done in different organizations overlaps and a considerable effort is being made to ensure that provisions of different schemes co-ordinate.

34. The work being done in UNEP and FAO draws very heavily on the code of conduct drawn up by the industrialized countries in OECD. Under these schemes, a working definition of banned or severely restricted products has been evolved which can, it appears, chime with the practices used in most industrialized countries, many of which involve positive approval of products for use on domestic markets, often for particular restricted uses under specified conditions, rather than a negative concept of ban. All these

schemes, while admitting that it is up to the importing country to take measures aimed at protecting human health and the environment, seek to ensure the provision of information from authorities or firms in exporting countries to enable importing countries to make informed judgements on the products entering into trade. However, the notion of "prior informed consent", included in the early draft of the FAO Pesticide code, and to which consumer groups have attached importance, is not included in the OECD/UNEP principles.

35. The work done in WHO in the field of certification of pharmaceuticals (drugs), is longer established, but depends on the initiative of authorities in importing countries to seek information on particular products, rather than information being provided by authorities in exporting countries. WHO also disseminates information through circular letters and published bulletins.

36. The United Nations' Consolidated List is still at a preliminary stage and a number of proposals have been made for its modification and improvement.

37. The operation of many of the programmes being undertaken by international agencies is due to be reviewed in 1987: this is the case for the UN Consolidated List, the UNEP programmes, and the OECD Recommendation and Guiding Principles. Any work to be done under the aegis of GATT might bear this in mind.