Recommendation of the Council on Countering the Illegal Trade of Pesticides

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

For access to the official and up-to-date texts of OECD Legal Instruments, as well as other related information, please consult the Compendium of OECD Legal Instruments at http://legalinstruments.oecd.org.

Please cite this document as:
OECD, *Recommendation of the Council on Countering the Illegal Trade of Pesticides*, OECD/LEGAL/0446

Series: OECD Legal Instruments

Photo credit: © Ben Schonewille/Shutterstock.com

Date(s)

Adopted on 20/02/2019

Background Information

The Recommendation on Countering the Illegal Trade of Pesticide was adopted by the Council on 20 February 2019 on proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

Countering the illegal trade of pesticides

Pesticides are among the most regulated products in the world, but international shipments of illegal pesticides (e.g., counterfeit, unregistered, illicit or otherwise unauthorised active ingredients and finished products) can escape oversight by pesticide regulators and custom offices, which is a growing concern for governments.

The illegal international trade of pesticides undermines national registration and governments' risk reduction schemes, and public confidence in such schemes. It also distorts pesticide markets, e.g. constituting an estimated 13.8% of the regular EU market as reported by the European Union Intellectual Property Office (EUIPO), by replacing legitimate products with cheaper and possibly more hazardous products.

The illegal international trade of pesticides can also have significant impacts on human health, food chain safety, and the environment. The use of illegal pesticides may directly cause a number of problems associated with, for example, health and environmental hazards due to toxic residues in food or worker exposure during application, damages to crops or low/inadequate product performance and efficiency leading to a reduction in revenues for farmers.

Recommending increased cooperation and combined action

To address these concerns, this Recommendation has been developed to promote greater co-operation between countries and between custom authorities and regulatory and compliance/enforcement agencies in their efforts to identify and respond to illegal trade of pesticides. To that effect, the Council act recommends that Adherents establish or strengthen national procedures aimed at countering the illegal trade of pesticides, in line with the *Best Practice Guidance to Identify Illegal Trade of Pesticides* and taking into account national priorities, policies and programmes.

The Best Practice Guidance provides guidance for inspectors and regulatory authorities to identify and tackle illegal pesticides throughout the complete lifecycle of a pesticide, i.e. from manufacture, through formulation, trade and use to destruction. It provides practical advice, which inspectors and regulatory authorities can consider to strengthen national frameworks relevant to countering the illegal trade of pesticides.

OECD tools support Adherents

The implementation of the Recommendation and Best Practice Guidance will be supported by the OECD Network on Illegal Trade of Pesticides (ONIP). The initial aim of this network was to build a "global alliance" by bringing together experts knowledgable in countering illegal trade.

ONIP developed the OECD Rapid Alert System (RAS) for suspected illegal international trade of pesticides, which was launched in November 2012, and consists of a protected website only accesible to regulatory authorities for a rapid exchange of information about suspicious or rejected shipments of pesticides between experts and inspectors participating in the network.

To support the implementation of the Recommendation, the ONIP will continue to develop guidance and methodologies which will facilitate the identification of illegal pesticides and anticipate the modus operandi of illegal traders. ONIP will also serve as a forum for exchanging best practices, and continue to use the RAS for the rapid exchange of reports on suspicious or rejected shipments of pesticides. ONIP is keen on disseminating the accumulated expertise of its experienced experts and is developing a training course for inspectors and investigators to support countries in countering illegal trade of pesticides.

THE COUNCIL,

HAVING REGARD to Article 5b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the 1992 Rio Declaration on Environment and Development, adopted by the United Nations Conference on Environment and Development and endorsed by the United Nations General Assembly (A/RES/47/190, 16 March 1993);

HAVING REGARD to the 2002 Johannesburg Plan of Implementation of the World Summit on Sustainable Development which commits to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment;

HAVING REGARD to the Resolution of the Council on the Implementation of the Strategic Approach to International Chemicals Management (SAICM) [C(2008)32] and to the SAICM objectives concerning the prevention of illegal international traffic in toxic, hazardous, banned and severely restricted chemicals, including products incorporating these chemicals, mixtures and compounds and wastes and to promote information sharing and to strengthen the capacity of developing countries and countries with economies in transition at the national and regional levels for the prevention and control of illegal international traffic;

RECOGNISING that the illegal international trade of agricultural pesticides undermines national legislations on pesticide registration aimed at protecting health and the environment;

RECOGNISING that monitoring and responding to the illegal trade in pesticides can minimise the negative impact on trade, intellectual property rights, the sale of legitimate products and the protection of crops;

RECOGNISING that strengthened national and co-operative international efforts - including, in particular, the rapid exchange of information on suspicious or rejected shipments of pesticides - will substantially reduce the risks posed to health and the environment from the use of illegal pesticides;

RECOGNISING that addressing illegal trade of pesticides is a responsibility of governments which may be shared between different levels of government, according to their legal and institutional frameworks;

RECOGNISING that, while there are differences in the domestic priorities, policies and programmes of Members and non-Members having adhered to this Recommendation (hereafter the "Adherents"), concerted international efforts to address the illegal trade in pesticides can produce more efficient utilisation of national and international resources;

CONSIDERING that the *Best Practice Guidance to Identify Illegal Trade of Pesticides* (hereafter the "Best Practice Guidance") [C(2019)13/ADD1], provides guidance for inspectors and regulatory authorities on best practices for identifying and tackling illegal pesticides throughout the complete lifecycle of a pesticide, from manufacture, through formulation, trade and use to destruction, and may be modified as appropriate by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology;

On the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology:

I. **AGREES** that, for the purposes of this Recommendation, the following definitions are used:

- **Agricultural pesticide** refers to a product which by its packaging, labelling or formulation, consists of or contains one or more active substance(s), co-formulants, safeners or synergists, and intended for one of the following uses: (i) protecting plants or plant products against harmful organisms or preventing the action of such organisms, unless the main purpose of the product is considered to be as a biocide; (ii) influencing the life processes of plants, such as influencing their growth, other than as a nutrient; (iii) preserving plant

products; (iv) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants; (v) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

- **Illegal trade of agricultural pesticides** refers to any form of trade of an agricultural pesticide that leads to a violation of domestic law, including counterfeiting, fraud and other forms of deception.
- **ONIP Rapid Alert System (RAS)** refers to a protected Internet website, hosted by the OECD, which allows the rapid exchange of information on suspicious or rejected shipments of pesticides between the government experts/inspectors who are directly involved in identifying and responding to the illegal international trade of pesticides.

II. **RECOMMENDS** that Adherents establish or strengthen national procedures aimed at countering the illegal trade of agricultural pesticides in line with the Best Practice Guidance, taking into account national priorities, policies and programmes. To that effect, Adherents should:

i) Ensure there is an appropriate regulatory framework for the management of agricultural pesticides;

ii) Ensure there are systems in place to detect and take regulatory action against illegal trade of pesticides;

iii) Co-operate on minimising the illegal trade of pesticides.

III. **INVITES** the Secretary-General to disseminate the Recommendation.

IV. **INVITES** Adherents to disseminate the Recommendation at all levels of government.

V. **INVITES** non-Adherents to take due account of and adhere to this Recommendation.

VI. **INSTRUCTS** the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, through the OECD Network of National Authorities Fighting Illegal International Trade of Pesticides (ONIP) to:

i) Develop guidance and methodologies which will facilitate the identification of illegal pesticides;

ii) Serve as a forum, using the RAS, for the rapid exchange of reports on suspicious or rejected shipments of pesticides, when such information is deemed relevant and urgent;

iii) Serve as a forum to exchange information on progress and experience with respect to the implementation of this Recommendation;

iv) Monitor the implementation of this Recommendation and report to the Council no later than five years following its adoption and every ten years thereafter.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

BEST PRACTICE GUIDANCE TO IDENTIFY ILLEGAL TRADE OF PESTICIDES[1]

***

FOREWORD

This document has been developed in the framework of the OECD Network on Illegal Trade of Pesticides (ONIP), a network of national governmental contact points in all questions related to the illegal international trade of pesticides and an OECD subsidiary body. The document was prepared in consultation with OECD Members and Partners and developed as part of the OECD's efforts to work with governments against the illegal international trade of pesticides.

This document is intended to provide guidance for inspectors and regulatory authorities on best practices for identifying and tackling illegal pesticides throughout the complete lifecycle of a pesticide, from manufacture, through formulation, trade and use to destruction.

It was developed with the aim both of providing best practices for tackling the issue of illegal pesticides, but also of raising awareness in Members and Partners of the issue of illegal pesticides at different parts of the chain; in turn facilitating regulatory authorities to take more effective action against illegal pesticides at different parts of the pesticides supply chain.

[1] This document has been approved by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology on 8 November 2018. It is published as: *Best Practice Guidance to Identify Illegal Trade of Pesticides*, Series on Pesticides, No. 99, ENV/JM/MONO(2018)35.

Contents

MANUFACTURE

Manufacturing and storage facilities

1. National competent regulatory authorities should maintain up-to-date lists of pesticides manufacturing and storage facilities (*e.g. National List of Active EPA-Registered Foreign and Domestic Pesticide and/or Device-Producing Establishments*) in order to enable inspections at all manufacturing and storage sites. To ensure that lists are current and complete, consideration may be given to authorisation requirements for manufacturing and storage facilities.

2. This list should include the details of any identified previous cases of the manufacturing or storage of illegal pesticides by the facility.

3. Pesticides that are being manufactured or stored within a country with the intention of being sold in that country, should have a valid registration/authorisation for the country and a valid label.

4. Pesticides that are being manufactured or stored within a country and that are destined for another country should have a valid registration/authorisation for the destination country.

5. Manufacturers should be required to record the details of manufactured and stored pesticides and to keep these records for a period of at least 5 years. Such records should include: pesticide name; destination country; pesticide composition (distinguishing the active substance and co-formulants); date of manufacture; name and address of manufacturer(s) of active substance; date(s) of acquisition of active substance; name and address of manufacturer(s) of co-formulant(s); date(s) of acquisition of co-formulant(s); date of manufacture of pesticide; batch number; type of packaging used; name and address of purchaser; date of sale / goods out.

6. In order to facilitate the aforementioned record-keeping by manufacturers, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities. As a minimum, the details indicated above in point 5 should be included in such a template or form.

7. In order to facilitate the international exchange of information on pesticide manufacture, it is recommended that the template or form be transmissible electronically, and that in addition to the national language of the manufacturing country, the information be recorded in English.

8. In order to ensure traceability during manufacturing, batch numbers should be printed indelibly on the packaging (e.g. bottle or the bag) that is in direct contact with the pesticides.

Inspectors

9. Inspectors should have knowledge of: (1) the storing and packaging requirements of pesticides, and; (2) key elements to assist in the identification of illegal pesticides at manufacturing and storage facilities. To this end, inspectors should be provided with suitable training and/or guidance.

10. Suitable legal provisions should exist to ensure that inspectors have access to all documents, records and information, including confidential information that is relevant for the confirmation of the legality of a manufactured or stored pesticide; and to all relevant areas of a facility where an illegal or suspected illegal pesticide is manufactured or stored.

11. In order to facilitate inspections of manufacturing and storage facilities, inspectors should have: access to listings of equivalent sources; access to pesticide registration databases to enable the confirmation of the existence of a registration/authorisation in the destination country, and; simple and suitable sampling and analysis methods.

12. Targeted inspections for illegal pesticides should take place based on (1) historical information (point 2), and (2) intelligence indicating the possible manufacture or storage of illegal pesticides at a facility.

13. Company and/or personnel under investigation in relation to the suspected manufacture or storage of illegal pesticides should be obliged to co-operate with inspectors and to facilitate inspections. This may be enabled by the existence of suitable legal provisions to this effect.

14. In the case of the identification of illegally manufactured or stored pesticides, clear follow-up actions by inspectors should be foreseen. This may include: administrative seizures; pesticide recalls, and; destruction. For counterfeit pesticides, destruction of the pesticide should always be the ultimate goal of the national competent authorities. As certain of these actions may be high-cost, consideration should be given to clarifying the party responsible for the costs of any such actions (see point 105).

15. In the case of the identification of illegally manufactured or stored pesticides, the need and possibility for prosecution should be considered, taking into account the details of the case. The procedure for the pursuit of prosecution should be clear.

16. Co-operation with other countries should be sought if evidence supports this. There should be clear contact points in the authorities of each country for the co-operation in such cases, and the procedures for contacting and sharing relevant information with the authorities of other countries in such cases should be clear.

FORMULATION

17. Routes for the entry of potentially illegal ingredients for the formulation of illegal pesticides should be investigated. This analysis can be performed as part of the broader strategic analysis (point 58).

18. National competent regulatory authorities should maintain up-to-date lists of toll manufacturers/formulators and companies producing packaging for pesticides in order to facilitate their inclusion, if necessary, in investigations by regulatory authorities.

19. Toll manufacturers/formulators should be required to record the details of toll manufacturing/formulation and to keep these records for a period of at least 5 years. These records should include: name of base materials used; name and address of provider of base materials; composition/recipe; and name of country where the pesticide will be placed on the market (destination country). Furthermore, the following should also be kept for each manufactured/formulated batch: safety data sheets (SDS) of base materials; samples of the formulated pesticides; and test results.

20. Pesticides manufactured/formulated by toll manufacturers/formulators should have an authorisation/registration for the country of destination.

21. In order to ensure traceability during manufacturing/formulation, batch numbers should be printed indelibly on the packaging (e.g. bottle or the bag) that is in direct contact with the pesticides.

EXPORT

List of exporters

22. National competent regulatory authorities should maintain up-to-date lists of operators exporting pesticides from their territory in order to facilitate the identification of pesticide exports and further inspection of exporters. The list of exporters should be set up in a way that ensures individual consignments can be linked to exporters by national competent regulatory authorities.

23. To ensure that lists are current and complete, consideration may be given to authorisation requirements for exporters.

24. This list should include the details of any identified previous cases of export of illegal pesticides by the exporter.

Record keeping and templates/forms

25. Exporters should be required to record the details of stored and exported pesticides and to keep these records for a period of at least 5 years.

26. In order to facilitate the aforementioned record-keeping by exporters, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities.

27. As a minimum, the following details should be included in such a template or form: name of pesticide or active ingredient; name and address of exporter; name, address and country of consignee; date of shipment / delivery for shipment; quantity shipped.

28. In order to facilitate further backwards traceability, it is recommended that the template also includes fields for information about the origin of the pesticides (link to manufacturing records if the exporter also manufactured the pesticide; otherwise date received by exporter and name and address of the supplier of the pesticide).

29. In order to facilitate the international exchange of information on exports, it is recommended that the template or form be transmissible electronically, and that in addition to the national language of the exporting country, the information be recorded in English.

Registration in destination country

30. It should only be possible for pesticides to be exported to the destination country if a valid authorisation/registration and valid label for that pesticide exists in the destination country.

Export certificates

31. In order to facilitate the identification of illegal pesticides, it is recommended that export certificates (e.g. ICAMA certificates) for each consignment be issued by the competent regulatory authorities in the country of export. Alternatively, export certificates can be issued for a fixed amount of time.

32. Evidence of the existence of a valid registration and label for the exported pesticide in the destination country (point 30) can be requested during the issuance of the export certificate.

33. In order to facilitate the international exchange of information on exports, it is recommended that export certificates contain information in English in addition to the national language of the exporting

country, and that they are transmitted to the authorities of the destination country to facilitate pre-arrival checks.

34. In order to assist in the detection of exporters of illegal pesticides, national competent regulatory authorities should seek verification of the arrival of pesticide consignments in the destination country and follow up on any discrepancies. The use of export certificates may facilitate verification.

TRANSPORTATION

Pre arrival

35. With suitable pre-arrival information, the time during transportation can provide authorities in the destination country with the opportunity to perform checks on consignments before they arrive at points of entry, and hence facilitate the detection of suspicious consignment worthy of further investigation on arrival.

36. In order to facilitate such pre-arrival checks, information can be transmitted by the exporting country to the importing country. This pre-arrival information may include: invoices; material data safety sheets (MSDS); export certificates (see point 33); electronic export information, and; (if available) packaging lists.

37. Pre-notification of consignments received through the single window customs system, where implemented, can also be used to identify suspicious consignments prior to arrival. Suitable information sharing provisions for the main regulatory authorities involved may be needed to facilitate this (point 56).

38. Pre-arrival checks should enable a pre-arrival risk-profiling through the use of a system connected to the risk based analysis (ideally a keyword-based search) which is used for the identification of suspicious consignments at the moment of import (point 61).

In transit

39. The transit status of a consignment has considerable impacts on the ability of authorities to take action against illegal pesticides within the consignment. National laws and their interpretation may have a further impact.

40. Whether or not an in-transit consignment passing through the territory of one country on the way to another destination country is considered to be on the market in either country should be clarified between the countries involved, as it is likely to impact the possibility to take action against an illegal consignment or the range of actions that can be taken.

41. The legal possibilities to take action against consignments of illegal pesticides in transit should be considered. This should include: an examination of the possibility to take action against the infringements of intellectual property rights (IPR) based on the possibility to take preventative action against IPR infringements in the destination country, and; the existence of a valid authorisation / registration in the declared destination country.

42. There should be clarity about in-transit times between countries for consignments which pass through the entry point on route to a final destination in another country. This clarity on transit times is useful in the case a suspicious consignment exceeds the expected transit time.

43. The regulatory authorities responsible for the inspection of consignments of pesticides passing through its territory on route to a different destination country may be the same or different from those with primary responsibility for import inspections (point 56). Different authorities may be responsible for inspections on different forms of transport (ship, road, air).

44. The authorities responsible for inspections on different forms of transport should be identified. If different from those with primary responsibility for checks at points of entry, interaction between these authorities and those involved in the control of illegal pesticides should be formalised through a memorandum of understanding (MoU) similar to that outlined in point 56.

45. Practical guidance on how to perform physical inspection of transported goods should be available. This guidance should distinguish between different forms of transports (ship, road, air) and should include provisions for internet-based trade.

46. Inspections should include checks on documentation and the authorisation status of the pesticide in the country of destination. Transported pesticides should be accompanied with proper documentation at all times and authorised in the country of destination.

47. If possible, the weights of vehicles or containers with consignments of pesticides should be checked at the point of entry and point of exit of a transited country. If present, GPS navigators may be checked to confirm routes used during transit.

IMPORT

48. The import stage is a critical stage in the supply chain as illegal pesticides can be prevented from entering economic zones or countries at this stage. Control and inspection of pesticides at the border is therefore crucial.

Importer obligations

49. National competent regulatory authorities should maintain up-to-date lists of operators importing pesticides into their territory in order to facilitate the identification of pesticide imports and further inspection of importers.

50. To ensure that lists are current and complete, consideration may be given to authorisation requirements for importers.

51. This list should include the details of any identified previous cases of export of illegal pesticides by the importer.

52. Importers should be required to record the details of imported and stored pesticides and to keep these records for a period of at least 5 years.

53. In order to facilitate the aforementioned record-keeping by importers, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities.

54. As a minimum, the following details should be included in such a template or form: name of pesticide or active ingredient; name and address of importer; date of import/arrival; name, address and country of consignor; date of shipment by consignor; quantity imported.

55. In order to facilitate the international exchange of information on imports, it is recommended that the template or form be transmissible electronically; in addition to the national language of the importing country, the information be recorded in English.

Inspectors

56. The main regulatory authorities (e.g. customs, pesticide regulatory authority) involved in the control of illegal pesticides at points of entry should be identified and the interaction between these authorities should be formalised through a memorandum of understanding (MoU), a law or similar. This formalisation should contain clear provisions on practical data-sharing methods and protocols that ensure that the authorities with primary responsibility for the detection of illegal pesticides at points of entry have, directly or indirectly, access to the data necessary to enable them to detect and subsequently investigate consignments of illegal or suspicious pesticides.

57. Where necessary, the main regulatory authorities should interact with other relevant authorities, notably those responsible for hazardous goods at points of entry, those involved in the day-to-day operation of points of entry, and those involved in subsequent criminal investigations (e.g. port or airport authorities, port or local police) to facilitate inspections and any required further action.

58. A strategic analysis on methods of entry of illegal pesticides into the country should be completed and periodically updated by the national regulatory competent authority. This strategic analysis should identify higher risk entry points of illegal pesticides into the country, higher-risk pathways at these entry points, possible seasonal variations, and any pesticides or active ingredients which are a particularly common targets of illegal operators.

59. A tactical analysis identifying actors (both importers in the country and exporters based in other countries) involved in trade in illegal pesticides and the current modus operandi of illegal traders, should be completed and frequently updated by the national competent authority. It should also include any common features of illegal traders such as the use of shell companies, unconventional address (e.g. residential addresses or PO boxes) and imports by non-registration holders.

60. In addition to identifying actors with previous or suspected involvement in the illegal import of pesticides, the tactical analysis should focus specifically on the modus operandi most commonly used by illegal traders. This should include the following: the use of any specific HS or CN codes; common product descriptions and key words used on customs declarations and other documentation; other common features of customs declarations (such as declaration in-transit or the absence of any declaration); common inconsistencies between documents and declarations; and common features of labelling and packaging (or the absence thereof).

61. The strategic and tactical analyses should be used together to enable inspections based on risk analysis. The risk-based analysis should ideally use a keyword-based search of relevant databases, with the list of keywords based on the aforementioned analyses and frequently updated in conjunction with them.

62. Officials should be trained on how to perform targeted inspections, and up-to-date guidance based on the strategic and tactical analyses should be provided to officials to ensure they have knowledge of current common features of illegal consignments.

63. A rolling workplan of training for officials on inspection protocol and methods should be developed. The training should cover, *inter-alia*: an overview of the complete inspection process; methods of identification of illegal consignments; documentary checks; procedural matters for blocking transports for further inspection/investigation (including any necessary co-operation with other authorities); methods of physical inspection including any safety measures to be taken during these inspections; methods of further investigation (e.g. requests for additional information from the parties involved); the use of analytical methods such as chemical analyses, and; the protocol to arrive at a final decision. This rolling workplan should be constantly updated to ensure that officials are kept up to date with adaptations made by illegal traders.

64. A protocol for arriving at a final decision regarding a consignment should be developed, and follow-up actions defined. Such action may include: release with no further action; return or forwarding, and; destruction. The protocol should also include clear procedures in each case, with provisions for appropriate contact with the authorities of other countries.

65. Records should be kept of identified illegal pesticides and the actors (manufacturers, importers and/or distributers) involved. These records should be used to update the tactical and strategic analyses.

66. These records should use a harmonised template or form, both to ensure the consistency of recorded information and to facilitate the exchange between countries of information on cases of imported illegal pesticides, including for network analyses of the actors involved.

67. Information recorded in these records should include: dates of departure and arrival; country and port of origin or point of departure; any transit countries; port or entry point of arrival and detection; transporter/shipping line; consignor; consignee; pesticide or active substance involved; results of any chemical analyses; volume/weight; descriptions used on different documentation; HS or CN codes used; the nature of the illegality (e.g. IPR infringement, non-authorised product); and the final decision/action taken. Further information on key methods used to disguise the consignment should also be recorded.

68. In order to facilitate the international exchange of information on cases of imported illegal pesticides, it is recommended that: (1) efforts be made between countries to harmonise the templates

or forms used; (2) the template or form be transmissible electronically, and; (3) in addition to the national language of the importing country, the information be recorded in English.

SALE/RETAIL

Distributors (wholesalers/retailers)

69. National competent regulatory authorities should maintain up-to-date lists of distributors of pesticides (wholesalers and retailers) in order to facilitate inspections. To ensure that lists are current and complete, consideration may be given to authorisation requirements for distributors.

70. This list should include the details of any identified previous cases of the retail of illegal pesticides by the distributor.

Record keeping and templates/forms

71. Distributors should be required to record the details of stored and distributed pesticides and to keep these records for a period of at least 5 years. These records should cover both goods in i.e. purchases and goods out i.e. sales.

72. In order to facilitate the aforementioned record-keeping by distributors, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities.

73. As a minimum, the following details should be included in such a template or form: (1) goods in: name of pesticide or active ingredient; name and address of supplier; date of purchase; batch numbers; pack size; quantity/volume; (2) goods out: name of pesticide or active ingredient; name and address of purchaser; date of sale; batch numbers; pack size; quantity/volume. Records of any returns should also be indicated under goods in or goods out accordingly with a clear note that the transaction was a return.

74. Whether or not the purchaser is a professional user should be indicated in the template or form. If a list of professional users including a registration number is kept by the national regulatory competent authority (point 69), the template or form should contain a field for this reference number.

75. In order to facilitate the international exchange of information on illegal pesticide sales, it is recommended that the template or form be transmissible electronically and that in addition to the national language of the country, the information be recorded in English.

Inspectors and inspections

76. Controls of pesticide products on the market in a country may be organised by different authorities at different geographical levels (e.g. national, regional and district). The jurisdictions of the different authorities should be clearly defined, and co-operation between the authorities involved outlined.

77. Inspectors should be trained on how to perform inspections in accordance with a defined inspection protocol, and should have knowledge of storing and packaging requirements of pesticides.

78. Basic marketing controls of distributors for the identification of illegal pesticides should include checks on the authorisation of the product; visual checks of packaging and labelling, and; the verification of distribution records.

79. Alternative channels which may be used for the distribution of illegal pesticides (e.g. outdoor markets, internet, other direct sales channels) should also be monitored by authorities.

80. Follow-up actions and their procedures in the case of detection of suspicious pesticides during marketing controls should be defined. These may include chemical analyses and further documentary

investigations. In the case that pesticides are considered illegal, further actions and the procedures for these actions should be defined.

81. Records of illegal pesticides identified during market controls of should be kept by authorities. These records should include: the date of detection; distributor at which the illegal pesticide was identified; pesticide or active substance; origin of illegal pesticide (importer or manufacturer), if identified; the nature of the illegality (e.g. IPR infringement, non-authorised product); and the final decision/action taken.

82. In order to facilitate the international exchange of information on illegal pesticides detected on the market (e.g. when performing a network analysis of the actors involved), it is recommended that a template or form be developed and used. In addition to the national language of the country, the information should be recorded in English.

Education

83. Distributors should be educated in the identification of illegal pesticides. This should include easily identifiable common features of illegal pesticides such as packaging and labels; higher risk channels; documentation/traceability issues; and price. This education should include information on the risks and hazards of illegal pesticides; the possible penalties for the storage or distribution of them, and how distributors can notify authorities of suspicious pesticides or activity.

USE

Professional users

84. National competent regulatory authorities should maintain up-to-date lists of professional users of pesticides. This list should include the details of any identified previous cases of the use of illegal pesticides by professional users.

85. Professional users should be required to record the details of bought, stored and used pesticides and to keep these records for a period of at least 5 years.

86. In order to facilitate the aforementioned record-keeping by professional users, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities.

87. As a minimum, the following details should be included in such a template or form specifically to help ensure the legality of used pesticides: (1) goods in: name of pesticide or active ingredient; name and address of supplier; date of purchase; batch numbers; pack size; quantity/volume (2) use or disposal: name of pesticide or active ingredient; date of use or disposal; batch numbers; quantity/volume; type of treatment or disposal. These details may be integrated into a broader template with other record-keeping criteria or legal obligations for pesticide users (e.g. in relation to storage, treatments or disposals).

88. In order to facilitate the international exchange of information on illegal pesticide usage, it is recommended that the template or form be transmissible electronically and that in addition to the national language of the country, the information be recorded in English.

Inspectors

89. The detection of illegal pesticides during the use phase on-farm is generally less resource efficient than in other phases for various reasons, *inter-alia:* the high number/level of dispersion of actors and hence pesticides compared to earlier phases in the chain; the potential break-up of uniform batches / heterogeneity of pesticides stored and use; and the wide range of other checks which may already be performed on users of pesticides.

90. Nonetheless, certain methods of distribution of illegal pesticides such as just-in-time delivery and network sales may attempt to bypass the traditional pesticide distribution chain as much as possible, meaning that it may be difficult to detect certain illegal pesticide until the use phase.

91. In view of the above, resources for the detection of illegal pesticides are generally better employed on phases further up the chain. Nonetheless, targeted inspections of farms should be performed by the competent regulatory authorities on the basis of gathered intelligence.

92. Other compliance and enforcement activities related to pesticides such as the inspection of Maximum Residue Levels (MRLs) may result in the detection of illegal pesticides.

93. If the compliance and enforcement officers responsible for such other activities are not the same as those responsible for the detection of illegal pesticides, awareness of the issue of illegal pesticides should be raised among these officers, either through a basic training in the subject or through the provisions of a guidance document. Clear communication channels between these officers responsible for such other checks and the competent regulatory authority responsible for the detection of illegal pesticides should be established.

94. The use of illegal pesticides can be intentional or unintentional. Authorities should raise awareness among users, and educate them on the risks, types, features and recognition of illegal pesticides.

95. As well as targeting professional users directly, awareness-raising and education activities should target farmer associations and co-operatives in order to increase reach and impact.

96. Education on the risks of using illegal pesticides should include: potential for yield loss / crop damage and loss; long-term environmental damage to the farm; reputational risks and supply chain instability; impacts on user health; impacts on the food chain and the broader human health of consumers; and, if relevant, penalties for intentional use.

97. Farmers should be made aware of the main types of illegal pesticides: (1) counterfeit pesticides which are packaged and labelled to look like legal products; (2) fake products or counterfeit pesticides with poor or limited labelling and packaging that is clearly different from the original, and; (3) pesticide products without a registration in the country.

98. Education on the features and methods of recognition of illegal pesticides should be provided. In addition to labelling/packaging, this should cover elements such as: higher risk supply chains / distribution channels and methods; abnormal colour and smell of the product; and any other red flags like abnormally low pricing.

99. The education should also include a clear indication of who to contact for further information or to report any suspicions in relation to illegal pesticides.

DISPOSAL

Pesticide packaging

100. The proper disposal of legitimate pesticide packaging is important to avoid its reuse for the packaging of illegal pesticides.

101. Users of pesticides should be advised or required to triple-rinse and pierce containers after use in order to avoid their reuse for the packaging of illegal pesticides.

Illegal pesticides

102. The destruction of identified illegal pesticides and obsolete pesticides is important to avoid their re-appearance on the market.

103. Suitable specialised quarantine warehouses and disposal facilities should be available.

104. In the case that private operators are used for storage or disposal, suitable due diligence on the private operator should be performed prior to their engagement.

105. Given the potentially high cost of storage and disposal of obsolete and illegal pesticides, consideration should be given to the introductions of mechanisms or legal provision for the financing of these activities. There should be legal obligations to impose these costs upon those companies or individuals responsible for the illegal pesticides.

REFERENCES

Carter, B. and Durrant, C. (2015). *Counterfeit and illegal pesticides in food supply chains-what should businesses be doing to minimise the risk?*

Chemical Inspection and Regulation Service (CIRS) (2012). *The Future of Export - only Pesticides Registration in China?*

CropLife International (n.d.) *Know your Customer*. Available on: https://croplife.org/crop-protection/anti-counterfeiting/

Department of Agriculture, Food and the Marine, Ireland (2012). *Record keeping requirements for wholesalers and retailers of pesticides*

Fishel, F.M. (2009). *The Global Increase in Counterfeit Pesticides*. University of Florida, IFAS Extension

Food Chain Evaluation Consortium (FCEC) (2015). *Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU*. Study for European Commission, Executive Summary

Malkov, M. et al (2015). *Counteraction to counterfeit and contraband pesticides*, Environment and Security, OSCE

Meeting of Registration Committee (RC) 11 April 2014 (2014) *Guidelines for dealing applications for registration under export only category as approved by the RC in 347th meeting*.

United Nations Economic Commission for Europe (2003). *The Single Window Concept*

Appendix 1: Parallel trade

1. Parallel trade concerns countries that are part of economic zones or common markets which allow this particular form of pesticide trade, such as the European Union.

2. Illegal operators may attempt to abuse the parallel trade system in order to place illegal pesticides on the market. In view of this, the provisions in this appendix should be taken into account by countries that are part of economic zones or common markets which allow this particular form of pesticide trade.

3. National competent regulatory authorities should maintain up-to-date lists of parallel traders in order to facilitate their inspection and inclusion, if necessary, in investigations by regulatory authorities. To ensure that lists are current and complete, consideration may be given to authorisation requirements for parallel traders.

4. Consideration should be given as to whether the further parallel trading of already parallel-traded pesticides is permitted. In the case it is permitted, suitable provisions and requirements should exist to ensure the traceability of the product.

5. Parallel traders should be required to record the details of traded pesticides and to keep these records for a period of at least 5 years. These records should include: (1) goods in: pesticide name; name and address of supplier; date of purchase; batch numbers; pack size; quantity or volume; (2) goods out: pesticide name; name and address of purchaser; date of sale; name of country where the pesticide will be placed on the market (destination country); batch numbers; pack size; quantity or volume.

6. In order to facilitate the aforementioned record-keeping by parallel traders, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities. As a minimum, the details indicated above in point 5 should be included in such a template or form.

7. In order to facilitate the international exchange of information on parallel trade, it is recommended that the template or form be transmissible electronically, and in addition to the national language of the country of the parallel trader, the information be recorded in English.

Appendix 2: Repackaging

1. The repackaging of pesticides, if permitted in a country, may take place following parallel trade (see Appendix 1). Provisions in this section are only relevant if a country permits the repackaging of pesticides on its territory

2. Illegal operators may attempt to abuse the repackaging system in order to place illegal pesticides on the market by interrupting the traceability of a pesticide.

3. National competent regulatory authorities should maintain up-to-date lists of repackaging plants in order to facilitate their inspection and inclusion, if necessary, in investigations by regulatory authorities. To ensure that lists are current and complete, consideration may be given to authorisation requirements for repackaging plants.

4. Repackagers should be required to record the details of repacked pesticides and to keep these records for a period of at least 5 years. These records should include: (1) goods in: pesticide name; name and address of supplier; date of purchase; batch numbers; pack size; quantity or volume; (2) goods out: name and address of purchaser; date of sale; name of country where the pesticide will be placed on the market (destination country); pack size; quantity or volume.

5. In order to facilitate the aforementioned record-keeping by repackagers, ensure the harmonisation of records and facilitate inspection, a template or form should be developed by national competent regulatory authorities. As a minimum, the details indicated above in point 4 should be included in such a template or form.

6. In order to facilitate the international exchange of information on repackaging, it is recommended that the template or form be transmissible electronically, and in addition to the national language of the country of the repackager, the information be recorded in English.

7. Repackaged pesticides should have an authorisation/registration for the destination country.

8. In order to facilitate the further traceability of repackaged products, a requirement for “double labelling” i.e. the inclusion of a copy of the original label on the repackaged pesticide, and/or the indication of the original batch number on the repackaged product should be considered.

9. Basic controls of repackagers for the identification of illegal pesticides should include checks on the origin and destination of pesticides; visual checks of packaging and labelling; and the verification of records.

10. Follow-up actions and their procedures in the case of detection of suspicious pesticides during controls on repackagers should be defined. These may include composition tests and further documentary investigations. In the case that pesticides are considered illegal following these follow-up actions, procedures for further action should be defined.

Appendix 3: Acronyms

Acronym	Full term
CN	Common nomenclature (European Union)
EPA	Environmental Protection Agency (US)
EU	European Union
GPS	Global Positioning System
HS	Harmonized Commodity Description and Coding System/Harmonized System (World Customs Organization)
ICAMA	The Institute for the Control of Agrochemicals (China)
IPR	Intellectual Property Rights
MoU	Memorandum of Understanding
MRL	Maximum Residue Levels
MSDS	Material Safety Data Sheets
OECD	Organisation for Economic Co-operation and Development
ONIP	OECD Network on Illegal Trade of Pesticides
PO	Post Office
PPPAMS	Plant Protection Products Application Management System
SDS	Safety Data Sheet
WGP	Working Group on Pesticides

Appendix 4: Glossary

Term	Definition
Active substance / ingredient	A substance, either chemical or biological (including micro-organisms such as fungi or bacteria) in nature, that has general or specific action against harmful organisms or on plants, parts of plants or plant products.
Administrative seizure	A follow-up action in the case of identification of illegal pesticides whereby the regulatory authority takes possession of the pesticides
Chemical analysis	Examination/study of the chemical composition and structure of substances.
Co-formulant	A substance used in a pesticide which is not an active substance, safeners or synergists.
Common market	Group formed by countries within a geographical area to promote duty free trade and free movement of labour and capital among its members.
Counterfeit pesticide	An illegal copy of a legitimate, branded pesticide which may be difficult to distinguish from the legal product due to the high quality branding and packaging..
Destination country	The country to which a pesticide is destined for placing on the market.
Economic zone	Designated areas in countries with special economic regulations that differ from other areas in the same country, which tend to contain measures conducive to foreign direct investment (such as tax incentives and lower tariffs).
Equivalent source	A source which is compositionally similar to an (authorised) reference source and has the same or less harmful effects due to its impurities compared to the (authorised) reference source.
Export certificate	A certificate issued by the competent authority of the exporting (country of origin) declaring the registration status and range of applications of a pesticide.
Fake pesticide	An illegal copy of a legitimate, branded pesticide which may make some effort to imitate the original product but which can be identified with relative ease due to the poor quality of the product and packaging. the legal product due to the high quality branding and packaging..
Free trade zone	A geographic area where goods may be landed, stored, handled, manufactured, or reconfigured, and re-exported under specific customs regulation and generally not subject to customs duty.
Illegal pesticide	Any pesticide which, for whatever reason, is not legal in the country of destination. This includes the sub categories of counterfeits, fakes, obsolete and unauthorised pesticides.
In transit	Status of goods which are crossing the customs territory of a country on their way from a different country of origin to a different destination country.
Maximum residue level (MRL)	The highest level of a pesticide residue that is legally tolerated in or on food or feed when pesticides are applied correctly.
National competent regulatory authority	Authority with competence to implement national legislation including the authorisation, registration and monitoring of active substances and pesticides.
Obsolete pesticide	A pesticide product which is no longer authorised.

Packaging list	List of articles in a consignment, normally providing quantity, description and weight of contents.
Parallel trade	Import of a non-counterfeit product from another country without the permission of the intellectual property owner in accordance with any permit requirements set out by the destination country.
Placing on the market	The holding of a pesticide product for the purpose of sale within a country. This includes offering for sale and other forms of transfer.
Point of entry	A place (land crossing, seaport or airport) where people and merchandise can enter or leave a country.
Professional user	A person who uses pesticides in the course of their professional activities. This may include operators, technicians, employers and self-employed people, in the farming and in other sector.
Shell company	Non-trading company, which serves as a vehicle for business transactions without itself having any significant assets or operations.
Single window customs system	A system that allows traders to lodge information with a single body to fulfil all import or export related regulatory requirements.
Toll manufacturer / formulator	A company providing manufacturing services (for a fee) to another company, on the basis of a contract for provision of those services.
Unauthorised pesticide	A pesticide that is not authorised for use by the regulatory authorities in the country in which it is being placed on the market.

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals*, OECD/LEGAL/0441

Series: OECD Legal Instruments

Photo credit: © PowerUp/Shutterstock.com

Date(s)

Adopted on 25/05/2018

Background Information

The Decision-Recommendation on the Co-operative Investigation and Risk Reduction of Chemicals was adopted on 25 May 2018 by the OECD Council on the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. It revises and replaces a 1991 Decision-Recommendation of the Council. The Decision-Recommendation is composed of two parts: Part A focuses on the development of harmonised hazard and exposure assessment methodologies for chemicals, collaborative assessment, information dissemination and sharing the burden of information generation. Part B focuses on risk prevention and reduction including the establishment and strengthening of national risk reduction programmes, the implementation of the Globally Harmonised System of Classification and Labelling, the undertaking of concerted activities to prevent or reduce the risks of chemicals taking into account a life-cycle perspective and the sharing of best practices regarding risk management approaches including socioeconomic assessment .

For more information on OECD work, please consult our webpage on the assessment of chemicals at http://www.oecd.org/chemicalsafety/risk-assessment/ and on the risk management of chemicals at http://www.oecd.org/chemicalsafety/risk-management/.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and the Environment [C(77)97/FINAL], the Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals [C(87)90(Final)], the Recommendation of the Council on Integrated Pollution Prevention and Control [C(90)164/FINAL], and the Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials [C(2013)107];

HAVING REGARD to the experience gained through the implementation of the Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/FINAL], which this Decision-Recommendation replaces;

HAVING REGARD to the work done by the United Nations in the area of chemical safety, in particular in the development of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), an internationally agreed system for hazard classification and hazard communication for chemicals for improving harmonisation globally;

HAVING REGARD to paragraph 23(c) of the Plan of Implementation of the World Summit on Sustainable Development, which encourages United Nations' members to implement the GHS;

HAVING REGARD to the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy, adopted by the International Conference on Chemicals Management of 4 to 6 February 2006, as part of the Strategic Approach to International Chemicals Management (SAICM);

HAVING REGARD to the Resolution of the Council on the Implementation of the Strategic Approach to International Chemicals Management (SAICM) [C(2008)32];

HAVING REGARD to the United Nations Environment Assembly (UNEA) Resolution 1/5 on chemicals and waste of June 2014 which "[r]ecognizes the continued relevance of the sound management of chemicals and waste beyond 2020" and "[e]mphasizes that the sound management of chemicals and waste is an essential and integral cross-cutting element of sustainable development and is of great relevance to the sustainable development agenda".

HAVING REGARD to the 17 Sustainable Development Goals (SDGs) of the 2030 Agenda for Sustainable Development of September 2015 (A/RES/70/1), in particular SDG 12 and Target 12.4 which refer to the sound management of chemicals and waste, SDG 3 on good health and well-being, and SDG 6 on clean water and sanitation;

HAVING REGARD to the precautionary approach articulated in Principle 15 of the United Nations 1992 Rio Declaration on the Environment and Development (A/CONF.151/26), which provides that lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation;

CONSIDERING that concerted identification, assessment and management of chemicals can produce more efficient use of national and international resources towards prevention or reduction of any risks to the environment or to the health of the general public or workers uncovered in all phases of the life cycle of the chemicals;

CONSIDERING that due consideration should be given to protecting potentially sensitive sub-populations (such as pregnant women, children and the elderly) or ecosystems;

CONSIDERING that decision-making following the assessment of the effects on health and/or the environment for the purpose of preventing or reducing risks should be informed by an understanding of the economic costs and benefits of introducing a control action and an evaluation of the benefits of using the substance and its substitutes;

CONSIDERING that co-operative international efforts constitute an efficient and effective way to apply economic and regulatory approaches for the systematic investigation and prevention or reduction of the risks of hazardous chemicals throughout their life-cycle;

CONSIDERING that strengthened national and co-operative international efforts to investigate, prevent and reduce the risks of hazardous chemicals will substantially alleviate threats of serious or irreversible damage to the environment or human health;

CONSIDERING the efforts to raise awareness of chemicals management within related policy areas such as waste management and resource efficiency in order to increase the sustainability of material cycles;

CONSIDERING that assessments integrate various types of information from predictive models (e.g. animal models, in vitro models, in silico models), epidemiological studies and field studies in order to identify the potential hazards, exposure and risks of a chemical and that the relative level of confidence and uncertainty in the information is weighed in the context of the particular use and regulatory framework;

On the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology:

I. **AGREES** that all references to "chemicals" in this Decision-Recommendation cover bulk form and nanoforms of chemicals, including manufactured nanomaterials.

Co-operative Investigation and Assessment

II. **DECIDES** that Members and non-Members having adhered to this Decision-Recommendation (hereafter the "Adherents") shall co-operatively develop harmonised hazard and exposure assessment methodologies for chemicals in order to align approaches for identifying those chemicals which may pose a hazard or risk to the environment or human health. This will also include methodologies to prioritise chemicals for regulatory consideration.

III. **DECIDES** that Adherents shall co-operatively elaborate and disseminate agreed hazard, exposure or risk assessments on chemicals of mutual interest and, if relevant, classification and labelling designations for these chemicals.

IV. **RECOMMENDS** that Adherents, when developing harmonised hazard and exposure assessment methodologies, consider:

i) the risks arising from the combined exposure to multiple chemicals;

ii) the elaboration of integrated approaches to testing and assessment including harmonised testing strategies; and

iii) the regulatory applicability of the methods and identify areas of uncertainty which need to be accounted for in their use, especially when assessing hazards of potentially higher concern such as carcinogenicity, mutagenicity or toxicity for reproduction or the combination of persistence, bioaccumulation and toxicity.

V. **DECIDES** that Adherents shall make information on hazards and exposure to chemicals obtained from their investigations publicly available, respecting the protection of confidential data and proprietary rights.

VI. **RECOMMENDS** that, in order to promote efficiencies and effectiveness in chemical assessment, Adherents use the results of investigations of chemicals carried out by other Adherents in preparing assessments of the potential health and environmental impacts of chemicals.

VII. **RECOMMENDS** that Adherents co-operate to share the burden for data generation and improve access to information on chemicals throughout their life-cycle, respecting data ownership rights.

Risk Prevention or Reduction

VIII. **DECIDES** that Adherents shall establish or strengthen national programmes aimed at the prevention or reduction of risks from chemicals to the environment and the health of the general public or workers.

IX. **DECIDES** that Adherents shall implement the GHS in order to further hazard communication in the supply chain. Such implementation can be done by Adherents applying those elements of the GHS that are appropriate to them and may vary by product category and stage in the lifecycle.

X. **RECOMMENDS** that Adherents communicate and share classifications derived pursuant to the GHS with other Adherents.

XI. **RECOMMENDS** that, where appropriate, Adherents identify and undertake concerted activities to prevent or reduce the risks of identified chemicals taking into account the entire life-cycle of the chemicals. These activities could encompass both regulatory and non-regulatory measures including: the promotion of new business models such as chemical leasing; the use of cleaner products and technologies; emissions inventories; product labelling; limitations on production or use; economic incentives; substitution with safer alternatives including non-chemical alternatives; and the phase-out or banning of chemicals.

XII. **RECOMMENDS** that Adherents communicate and share the outcomes of risk assessments, particularly when chemicals are identified as requiring risk management.

XIII. **RECOMMENDS** that Adherents communicate and share best practices regarding risk management approaches in general and approaches developed for specific chemicals of mutual concern.

XIV. **RECOMMENDS** that Adherents communicate and share best practices for the socioeconomic assessment of chemicals management.

Dissemination and implementation

XV. **INVITES** Adherents and the Secretary-General to disseminate this Decision-Recommendation and take the necessary steps to ensure that this work is carried out in co-operation with other international organisations, in particular with the other Participating Organisations of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).

XVI. **INVITES** non-Adherents to take account of and adhere to this Recommendation.

XVII. **INSTRUCTS** the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, to:

i) Facilitate the implementation of this Decision-Recommendation, notably through:

- conducting co-operative work to develop harmonized hazard and exposure assessment methodologies;
- the development of procedures for the notification and exchange of information on Adherents' activities on assessment of chemicals and on preventing or reducing the risks posed by chemicals;
- encouraging, where one or more Adherents identify that a chemical may pose a hazard or risk, or implement risk reduction measures in relation to a chemical, other Adherents to report on what similar activities they are engaged in in relation to that identified chemical and associated risk or hazard; and
- conducting concerted activities to prevent or reduce the risk of specific chemicals or groups of chemicals;

ii) Promote international awareness of this Decision-Recommendation, with a view to informing, advising and encouraging non-Adherents to participate in the OECD's work in the field of cooperative investigation and risk reduction of chemicals; and

iii) Monitor the implementation of this Decision-Recommendation and report to the Council no later than five years following its adoption and regularly thereafter.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council on Establishing and Implementing Pollutant Release and Transfer Registers (PRTRs)

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council on Establishing and Implementing Pollutant Release and Transfer Registers (PRTRs)*, OECD/LEGAL/0440

Series: OECD Legal Instruments

Date(s)

Adopted on 10/04/2018

Background Information

The Recommendation on Implementing Pollutant Release and Transfer Registers (PRTRs) was adopted by the OECD Council on 10 April 2018 on the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. It replaces the 1996 Recommendation on Implementing Pollutant Release and Transfer Registers in order to taken into account new experiences, knowledge and good practices that emerged due to the wide-spread development of PRTRs. The revised Recommendation aims to provide a coherent guidance for Adherents, especially those establishing and revising their PRTRs, and eventually generate high quality and compatible PRTR data across all Adherents.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the experience and best practices that emerged from the implementation of the Recommendation of the Council on Implementing Pollutant Release and Transfer Registers (PRTRs) [C(96)41/FINAL] amended by [C(2003)87], which this Recommendation replaces;

HAVING REGARD to the series of OECD Guidance Documents on PRTRs, as they may be developed and revised by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology;

HAVING REGARD to Principle 10 of the 1992 Rio Declaration on Environment and Development, adopted by the United Nations Conference on Environment and Development (including all OECD Members) and endorsed by the United Nations General Assembly (A/RES/47/190), which states that "each individual shall have appropriate access to information concerning the environment that is held by public authorities, and the opportunity to participate in decision-making processes" and that countries "shall facilitate and encourage public awareness and participation by making information widely available";

HAVING REGARD to Chapter 19 of the Report of the United Nations Conference on Environment and Development of 3 to 14 June 1992 (Agenda 21), which states, inter alia, that governments, with the cooperation of Industry, should "[i]mprove databases and information systems on toxic chemicals, such as emission inventory programmes", and that "[t]he broadest possible awareness of chemical risks is a prerequisite for achieving chemical safety";

HAVING REGARD to Paragraphs 18 (b) and 23 (f) of the 2002 Johannesburg Plan of Implementation of the World Summit on Sustainable Development;

HAVING REGARD to the Dubai Declaration on International Chemicals Management and the Overarching Policy Strategy, adopted by the International Conference on Chemicals Management of 4 to 6 February 2006, as part of the Strategic Approach to International Chemicals Management (SAICM);

HAVING REGARD to the Resolution of the Council on the Implementation of the Strategic Approach to International Chemicals Management (SAICM) [C(2008)32];

HAVING REGARD to the Sustainable Development Goals, in particular targets 3.9, target 6.3, target 9.4, target 12.4, target 12.5, target 12.8, and target 16.10 set out in the 2030 Agenda for Sustainable Development adopted by the United Nations General Assembly (A/RES/70/1);

RECOGNISING the value of PRTRs as a tool for measuring and promoting improved environmental performance of industrial activities;

RECOGNISING that reducing releases and transfers of pollutants that are harmful or potentially pose risks to human health and the environment while promoting green growth is a foundation for achieving sustainable development;

RECOGNISING the work of the United Nations Environmental Programme (UNEP) in the protection of human health and the environment related to chemicals;

RECOGNISING the work of the United Nations Economic Commission for Europe (UNECE), in particular the Kiev Protocol on Pollutant Release and Transfer Registers to the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters;

NOTING that a number of countries within the OECD and the European Union are operating PRTRs and that countries which do not have PRTRs are also exploring ways to establish and implement PRTRs;

On the proposal of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology:

Goals and objectives of PRTRs

I. **AGREES** that PRTRs should be used to:

a. Provide data to support the identification and assessment of possible risks to human health and/or the environment by identifying sources and amounts of pollutant releases and transfers to all environmental media;

b. Promote the prevention of pollution at source, e.g., by encouraging implementation of cleaner technologies or closed processes;

c. Evaluate the progress of environmental policies and assess to what extent environmental goals are or can be achieved;

d. Promote corporate accountability and compliance with environmental obligations; and

e. Strengthen access and participation by the public in environmentally related decision-making.

Establishment of PRTRs

II. **RECOMMENDS** that Members and non-Members having adhered to this Recommendation (hereafter the "Adherents") estimate the potential benefits and costs of PRTRs to data reporters, government, and society as a whole, prior to the establishment of a PRTR.

III. **RECOMMENDS** that Adherents, through a transparent and objective process, design and establish PRTRs.

IV. **RECOMMENDS** that Adherents:

a. Define the following components that trigger reporting:

   i. A list of chemicals, groups of chemicals, and other relevant categories of pollutants that are harmful or potentially pose risks to human health and/or the environment when released or transferred;

   ii. A list of sectors with point sources, including both public and private sectors, from which relevant pollutants might be released or transferred, and a list of diffuse sources taking into account the need for such data in the Adherent concerned; and

   iii. Thresholds for quantities of chemicals that are manufactured, processed, or used in a facility, or for quantities of chemicals that are released or transferred from a facility.

b. Foster enhanced international comparability of PRTR data and cooperation between national PRTRs by promoting harmonised elements as defined in the series of OECD Guidance Documents on PRTRs;

c. Allow, where the reporting sources are defined, the reporting of data by source;

d. Encompass data for all media, including releases to air, water and land, and transfers for treatment, recovery, and disposal;

e. Request reporting on a periodic basis, preferably annually;

f. Include an online or electronic reporting system and integrate such a system where relevant with existing reporting systems, such as licenses or operating permits, to reduce duplicate reporting;

g. Use voluntary and mandatory reporting mechanisms for collecting data where appropriate;

h. Use data management systems which allow for verification of inputs and outputs;

i. Make data accessible to the public on a timely and regular basis and in a user friendly manner, in order to meet the needs of data reporters and the public. This could be done in a

variety of forms, including electronic, which should provide appropriate multi-query search criteria or tools to enable better location of information. Data should also be provided in such a manner that it is possible to determine the geographical distribution of relevant releases and transfers; and

j. Provide the flexibility to adapt the PRTRs to the changing needs of affected and interested parties.

Implementation of PRTRs

V. **RECOMMENDS** that Adherents implement PRTRs through a transparent and objective process, by which they:

a. Provide guidance and support to data reporters to assist them in meeting their reporting obligations;

b. Ensure data is generated in a transparent and documented manner through analytical monitoring or applying scientifically-sound release estimation techniques, such as those included in the series of OECD Guidance Documents on PRTRs;

c. Assess the quality of data provided by the data reporters as to their completeness, consistency, credibility, and accuracy before making the data public;

d. Ensure timely availability of data to the public with appropriate context for increased understanding by data users;

e. Use data to derive indicators for measuring environmental performance and progress toward meeting local, national, and international commitments to environmental and health protection goals and targets, evaluating the impact of environmental policies, assessing the risks of pollutants, identifying environmental hot-spots, and addressing chemical accidents as suggested in the series of OECD Guidance Documents on PRTRs; and

f. Set up and put in place a compliance mechanism which should be agreed by affected and interested parties.

VI. **RECOMMENDS** that Adherents share the results of implementing their PRTRs periodically, in particular collected data and best practices, among themselves and also with potentially affected neighbouring countries with particular emphasis on sharing data from border areas.

VII. **RECOMMENDS** that Adherents co-operate with affected and interested parties such as data reporters, local governments, and the public at all stages of the establishment, revision, and implementation of PRTRs.

Evaluation and Revision of PRTRs

VIII. **RECOMMENDS** that Adherents:

a. Evaluate regularly, through a transparent and objective process, the effectiveness of the system and the potential to enhance international comparability of PRTR data; and

b. When revising the system, take into account the provisions above related to the establishment of PRTRs, the series of OECD Guidance Documents on PRTRs, and the latest scientific knowledge regarding the harmfulness or potential risks of pollutants.

Dissemination and Implementation

IX. **INVITES** the Secretary-General to disseminate this Recommendation.

X. **INVITES** Adherents to disseminate this Recommendation at all levels of government.

XI. **INVITES** non-Adherents to take account of, and adhere to, this Recommendation.

XII. **INSTRUCTS** the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology to:

a. Monitor the implementation of this Recommendation in consultation with the Environment Policy Committee, and report to Council five years from the date of its adoption and regularly thereafter; and

b. Administer and update, as appropriate, the series of OECD Guidance Documents on PRTRs and identify priority issues for improving PRTRs.

Adherents*

OECD Members		Non-Members	Other
Australia	United States	Brazil	
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

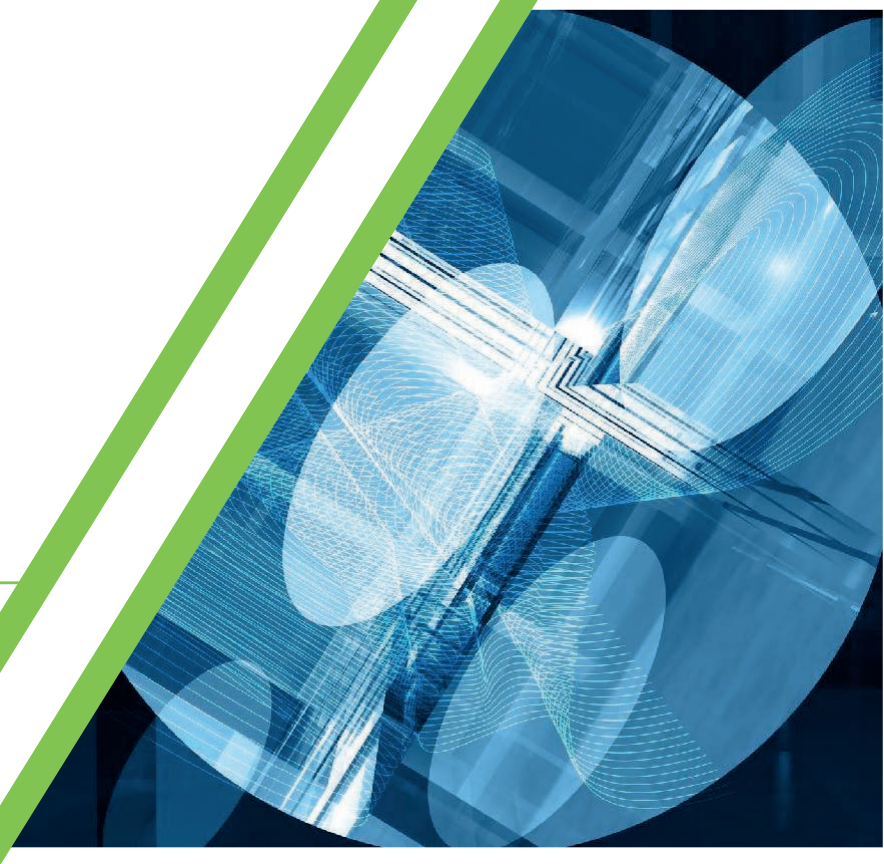
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials



OECD Legal Instruments

OECD

BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council on the Safety Testing and Assessment of Manufactured Nanomaterials*, OECD/LEGAL/0400

Series: OECD Legal Instruments

Date(s)

Adopted on 19/09/2013
Amended on 30/05/2017

Background Information

The Recommendation on the Safety Testing and Assessment of Manufactured Nanomaterials was adopted by the OECD Council on the 19 September 2013 on the proposal of the Chemicals Committee. The Recommendation aims to align the safety testing and assessment of nanomaterials with measures for the safety testing and assessment of chemicals as described in existing OECD Council Acts, notably, those on the Mutual Acceptance of Data in the Assessment of Chemicals (MAD). It recognises that existing regulatory systems can be adapted to cover nanomaterials including the provisions and instruments associated with them to address safety testing and assessment. Hence, the Recommendation calls on Adherents to apply the existing international and national chemical regulatory frameworks and use the tools listed in the Annex for testing and assessment, in conjunction with the OECD Test Guidelines that have been adapted as appropriate to take into account the specific properties of manufactured nanomaterials.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Decision of the Council of 12 May 1981, concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended];

HAVING REGARD to the Recommendation of the Council, concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)] and the Recommendations concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)] and the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)], all dated 26 July 1983;

HAVING REGARD to the Decision-Recommendation of the Council of 2 October 1989 on Compliance with Principles of Good Laboratory Practice [C(89)87(Final), as amended];

HAVING REGARD to the Decision of the Council of 26 November 1997, concerning the Adherence of non-Member Countries to the Council Acts Related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)] [C(97)114/FINAL];

HAVING REGARD to the conclusions of the Chemicals Committee's mid-term evaluation of the programme on the safety of manufactured nanomaterials [ENV/JM/M(2012)2] noting "that the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials";

RECOGNISING that adherence to the OECD Council Acts on Mutual Acceptance of Data in the Assessment of Chemicals does not preclude use or acceptance of test data obtained in accordance with other scientifically valid and specified test methods, as developed for specific chemical product areas;

CONSIDERING the Resolution of the Council on the Implementation of the Strategic Approach to International Chemicals Management (SAICM) [C(2008)32];

CONSIDERING the SAICM Resolutions II/4 E and III/2 E: Emerging policy issues; Nanotechnology and manufactured nanomaterials;

CONSIDERING that Members and non-Members derive economic, human health and environmental benefits from participation in the OECD Council Acts related to Mutual Acceptance of Data in the Assessment of Chemicals;

CONSIDERING that Members and industry have an interest in harmonised testing and assessment requirements and will benefit from the elimination of costly, duplicative testing and the avoidance of non-tariff barriers to trade, in particular in the field of nanomaterials;

CONSIDERING that expanded international co-operation to reduce duplicative testing would diminish the use of animals for safety testing;

CONSIDERING the increasing use of manufactured nanomaterials in commercial products;

On the proposal of the Chemicals Committee;

I. RECOMMENDS that Members, to manage the risks of manufactured nanomaterials, apply the existing international and national chemical regulatory frameworks or other management systems, adapted to take into account the specific properties of manufactured nanomaterials. For the purpose of such adaptation, Members should use the tools in the documents listed in the Annex to this Recommendation of which it forms an integral part. This Annex may be amended by the Chemicals Committee, in accordance with Section VII below.

II. RECOMMENDS that Members, in the testing of manufactured nanomaterials, apply the OECD Test Guidelines, adapted as appropriate to take into account the specific properties of manufactured nanomaterials and using the tools listed in Section I of the Annex to this Recommendation, and the OECD Principles of Good Laboratory Practice, set forth respectively in Annexes I and II to the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended].

III. RECOMMENDS that Members update, according to OECD rules and procedures, the OECD Test Guidelines set out in Annex I to the Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final), as amended] to include new test guidelines specific to, or existing test guidelines amended in the light of experience with, manufactured nanomaterials.

IV. RECOMMENDS that Members apprise the Chemicals Committee on a regular basis of any technical issues related to the safety testing and assessment of nanomaterials that need to be addressed, including engagement with other international initiatives, development or update of specific tools for manufactured nanomaterials, and any possible amendment to the documents in the Annex to this Recommendation.

V. RECOMMENDS that Members make safety data related to nanomaterials available to the public.

VI. INVITES:

i) Non-Members adherents to the Council Acts on Mutual Acceptance of Data [C(81)30(Final), as amended C(89)87(Final), as amended] to adhere to this Recommendation;

ii) Other non-Members to adhere to this Recommendation and collaborate with Members and non-Members adherents to the Council Acts on Mutual Acceptance of Data in its implementation;

iii) Members and adhering non-Members to disseminate this Recommendation to all stakeholders and other international organisations.

VII. INSTRUCTS the Chemicals Committee to amend the documents listed in the Annex according to Section I and add new documents as appropriate in light of the information provided by Members in accordance with Section IV above.

VIII. INSTRUCTS the Chemicals Committee to promote international awareness of this Recommendation, with a view to informing, advising and encouraging non-Members to participate in the programmes and activities developed by the OECD and its Members in the field of nanomaterials.

IX. INSTRUCTS the Chemicals Committee to monitor closely the technical aspects of implementation of this Recommendation and to report to Council within three years of its adoption and thereafter as appropriate.

ANNEX

Tools for the adaptation of the existing chemical regulatory frameworks or other management systems to the specific properties of manufactured nanomaterials include:

I. Testing

Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials [ENV/JM/MONO(2009)21]: and

Guidance on Sample Preparation and Dosimetry for the Safety Testing of Manufactured Nanomaterials [ENV/JM/MONO(2012)40].

II. Exposure Assessment

Harmonised Tiered Approach to Measure and Assess the Potential Exposure to airborne emissions of engineered nano-objects and their agglomerates at workplaces [ENV/JM/MONO(2015)19].

III. Risk Assessment

Important Issues in Risk Assessment of Manufactured Nanomaterials [ENV/JM/MONO(2012)8].

Adherents*

OECD Members		Non-Members	Other
Australia	United States	Argentina	
Austria		Brazil	
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning Chemical Accident Prevention, Preparedness and Response

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning Chemical Accident Prevention, Preparedness and Response*, OECD/LEGAL/0319

Series: OECD Legal Instruments

Date(s)

Adopted on 15/01/2004

Background Information

The Recommendation concerning Chemical Accident Prevention, Preparedness and Response was adopted by the OECD Council on 15 January 2004 on the proposal of the Environment Policy Committee and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (today under the responsibility of the Chemicals Committee). Under this instrument, Adherents are recommended to establish or strengthen national programmes for the prevention of, preparedness for, and response to accidents involving hazardous substances and to take into account the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response (the Guiding Principles) and the OECD Guidance on Safety Performance Indicators (the Guidance on SPI). The Guiding Principles were first developed between 1989 and 1992 building on a series of workshops that were designed to address the wide range of issues associated with accident prevention, preparedness and response, and to consider the roles and responsibilities of the various parties who are necessarily involved in such activities. The Guidance on SPI were then developed to facilitate implementation of the Guiding Principles, and to help stakeholders assess whether actions taken to enhance chemical safety in fact lead to improvements over time.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Decision of the Council of 8 July 1988 on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage [C(88)84(Final)];

HAVING REGARD to the Decision-Recommendation of the Council of 8 July 1988 concerning Provision of Information to the Public and Public Participation in Decision-Making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances [C(88)85(Final)];

HAVING REGARD to the Recommendation of the Council of 7 July 1989 concerning the Application of the Polluter-Pays Principle to Accidental Pollution [C(89)88(Final)];

HAVING REGARD to the Environment Chapter in the OECD Guidelines for Multinational Enterprises as adopted by the Council on 27 June 2000 [C/M(2000)17];

HAVING REGARD to the Declaration on Environment: Resource for the Future, adopted at the session of the Environment Committee at Ministerial Level on 20 June 1985 stating that "they will ensure the existence of appropriate measures to control potentially hazardous installations including measures to prevent accidents";

HAVING REGARD to the Communiqué of the Environment Committee meeting at Ministerial Level on 31 January 1991; "An Environmental Strategy in the 1990s", in which Ministers pledged to strengthen the capacity of the international community to prevent and confront environmental disasters, taking particular account of the situation of developing countries;

HAVING REGARD to the conclusions adopted by the Third High-Level Meeting of the Chemicals Group on 18 March 1987 regarding the prevention of, and response to, unintended releases of hazardous substances to the environment;

HAVING REGARD to the Concluding Statement of the OECD Conference on Accidents Involving Hazardous Substances of 10 February 1988 in which Ministers and other high-level officials called on the OECD to elaborate a Code of Good Practice relating to accident prevention and response and guiding principles for investments and aid programmes with respect to hazardous installations in developing countries [Environment Monograph No. 24, page 12];

HAVING REGARD to the “OECD Environmental Strategy for the First Decade of the 21st Century”, adopted by OECD Environment Ministers on 16 May 2001 which states that with regard to environmental issues related to health and safety risks, OECD countries would take action to "reduce potential effects on human health from environmental and ecosystems changes, including those resulting from natural and man-made disasters and climate changes";

HAVING REGARD to the international co-operation work through the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) Co-ordinating Group on Chemical Accidents initiated in 1995;

HAVING REGARD to the conclusions and recommendations of all the workshops organised under the auspices of the OECD on the subject;

CONSIDERING the need for strengthening efforts related to prevention of accidents involving hazardous substances and for limiting adverse consequences should such an accident occur;

CONSIDERING that appropriate accident prevention, preparedness and response requires the active involvement of public authorities, management of hazardous installations, employees at hazardous installations at all levels and their representatives where they exist, as well as the public;

CONSIDERING that certain general principles for accident prevention, preparedness and response apply to hazardous installations irrespective of location;

CONSIDERING that, in applying general principles, due account must be taken of the specific circumstances of the local community where the installation is located;

CONSIDERING increased co-operation between Member countries will help to address international problems which can arise with hazardous installations located in their frontier regions;

CONSIDERING the economic and practical benefits that result from the application of similar safety objectives for hazardous installations in all OECD Member countries including the avoidance of distortions of trade;

CONSIDERING that sharing of experience among countries can help lead to improvements in safety of hazardous installations;

CONSIDERING that the first edition of the Guiding Principles were widely used world wide, translated into many languages, and supported by relevant international organisations;

RECOGNISING that representatives of industry, labour, non-governmental organisations, and international organisations were actively involved in the preparation of the second edition of the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response;

RECOGNISING the experience gained by countries and international organisations since the first edition of the Guiding Principles in 1992;

RECOGNISING the value of assessing performance to help industry, authorities and communities measure the extent to which actions help improve safety.

On the proposal of the Environment Policy Committee and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology:

I. RECOMMENDS that Member countries establish or strengthen national programmes for the prevention of, preparedness for, and response to accidents involving hazardous substances and that in doing so, to the extent it has not already been undertaken, they:

a) Develop overall safety objectives related to the prevention of, preparedness for, and response to accidents involving hazardous substances;

b) Develop and implement control frameworks covering all aspects of accident prevention, emergency preparedness and mitigation of accidents, emergency response, and follow-up to incidents, recognising appropriate roles of all stakeholders including industry, labour and the public;

c) Consider the use of safety performance indicators to assess the performance related to the prevention of, preparedness for, and response to chemical accidents;

d) Encourage and/or facilitate processes in which all stakeholders, including industry, public authorities, communities, and other stakeholders, can take action and help ensure effective communication and co-operation;

e) Establish arrangements for monitoring safety of hazardous installations and for enforcing any requirements related to the control framework;

f) Arrange for the development and implementation of compatible off-site and on-site emergency preparedness plans for hazardous installations;

g) Establish appropriate arrangements for siting new hazardous installations and for preventing inappropriate developments near existing hazardous installations in order to mitigate possible off-site effects of an accident involving hazardous substances, recognising also the need to take into account the possibility of accidents which are capable of causing transfrontier damage;

h) Share information and experience on accident case histories by reporting past accidents to the Major Accident Reporting System (MARS) scheme; and

i) Support and promote related research, including co-operative international activities.

II. **RECOMMENDS** that, in undertaking the activities referred to in Paragraph I above, Member countries take into account the second edition of the OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response[1] and the OECD Guidance on Safety Performance Indicators[2].

III. **RECOMMENDS** that, in relation to transfer of technology and international investments related to hazardous installations in non-OECD countries and in relation to bilateral technical and financial assistance, Member countries actively promote application of the relevant parts of the OECD Guiding Principles, and use of the Guidance on SPI.

IV. **RECOMMENDS** that Member countries promote the wide dissemination and use of the OECD Guiding Principles and of the OECD Guidance on SPI among all relevant parties in their countries and support their application in non-OECD countries.

V. **INSTRUCTS** the Secretary-General to take the necessary steps to facilitate the wide distribution of the OECD Guiding Principles and Guidance on SPI, both within and outside the Member countries;

VI. **INVITES** other international organisations to use and disseminate the OECD Guiding Principles and Guidance on SPI; and

VII. **INSTRUCTS** the Environment Policy Committee and the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology to pursue a programme of work designed to facilitate the implementation of the OECD Guiding Principles and Guidance on SPI, and to review within three years the implementation of this Recommendation.

This Recommendation replaces the Recommendation of the Council C(92)1/FINAL which is hereby repealed.

---

1 Published by OECD on the responsibility of the Secretary General as Environment, Health and Safety Publication, Series on Chemical Accidents, No. 10; and referred to herein as the "OECD Guiding Principles".

2 Published by OECD on the responsibility of the Secretary General as Environment, Health and Safety Publication, Series on Chemical Accidents No. 11; and referred to herein as the "OECD Guidance on SPI".

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

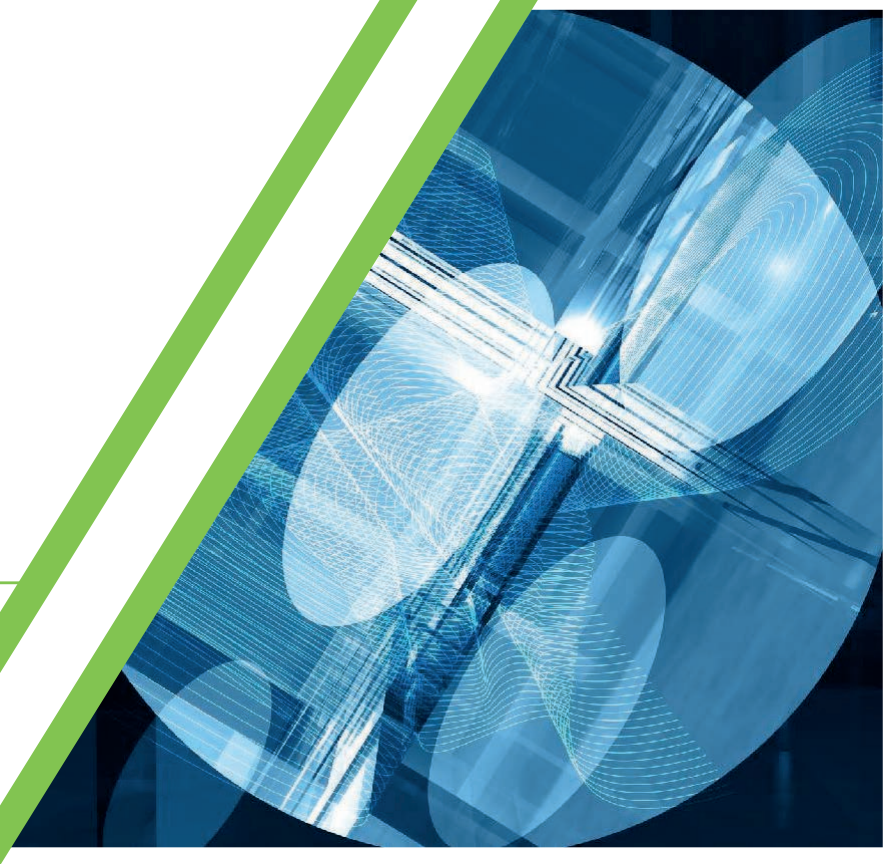
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Declaration on Risk Reduction for Lead



OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Declaration on Risk Reduction for Lead*, OECD/LEGAL/0285

Series: OECD Legal Instruments

Date(s)

Adopted on 20/02/1996
Noted by the Council on 20/02/1996

Background Information

The Declaration on Risk Reduction for Lead was adopted on the 20 February 1996 on the occasion of the Ministerial Meeting of the Environment Policy Committee. The Declaration seeks to advance national and co-operative efforts to reduce risks from exposure to lead. In this instrument, Adherents declare, among other things, that they will develop, continue or strengthen, as appropriate, national and co-operative efforts considered necessary to reduce risks from exposure to lead while giving highest priority to actions which address the risk of exposure from potential pathways in accordance with Annex I of the Declaration. Implementation of the Declaration is on-going and includes such activities as a joint project with UNEP's Industry and Environment Office to co-ordinate the activities of international organisations and industry to reduce the use of lead in gasoline.

THE GOVERNMENTS OF OECD MEMBER COUNTRIES,

HAVING REGARD to the call of the Environment Ministers for risk reduction action in Member countries as set out in their 1991 Communiqué "An Environmental Strategy in the 1990's" ;

HAVING REGARD to the Decision-Recommendation of the Council concerning Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/FINAL] as well as to its Recommendation concerning Integrated Pollution Prevention and Control [C(90)164/FINAL];

HAVING REGARD to the conclusions of the meeting of the United Nations Commission on Sustainable Development in May 1994 concerning the health impact to humans exposed to lead in gasoline, and encouraging further efforts to reduce exposure of humans to lead in gasoline (UN Economic and Social Council Official Records, 1994, Supplement No. 13, pp 32-34);

RECOGNISING the risks to human health, in particular for children and other high risk and sensitive populations, and risks to the environment associated with lead exposure and the need for co-operative commitments to reduce any transboundary exposure;

RECOGNISING the differing needs and circumstances of Member countries which call for flexible national risk reduction strategies and time frames;

RECOGNISING the value of national and international risk assessments in setting priorities for action on lead risk reduction and in determining the risks and benefits of proposed alternative solutions;

RECOGNISING the willingness of industry to share their experience in the sound management and prudent use of products containing lead including development of alternative solutions;

WELCOMING the willingness of the lead industry to share responsibility for risk reduction of lead and benefits of such co-operation in the management of the risks;

WISHING to build upon the results of work to date and the significant reductions in exposure that have been achieved by Member countries and noting with approval the valuable contribution of the OECD Chemicals Programme;

CONSIDERING that the sound management of risk from lead exposure is beneficial to all countries and that the range of national actions taken by OECD Member countries could assist and serve as examples to non-member countries;

DECLARE THAT THEY WILL:

1. Develop, continue or strengthen, as appropriate, national and co-operative efforts considered necessary to reduce risks from exposure to lead through actions which take into account national priorities, policies, programmes and achievements -- recognising that implementation may take the form of voluntary, economic, and/or regulatory actions;

2. Give highest priority to actions which address the risk of exposure from food and beverages, water, air, occupational exposure and other potential pathways in accordance with Annex I;

3. Continue to review lead levels in the environment and exposure to lead of sensitive populations (such as children and pregnant women) and of high risk populations (such as certain groups of workers) using the results to evaluate the effectiveness of national programs in reducing risks from exposure to lead and to identify priorities and opportunities for future actions;

4. Promote and maximise the use of environmentally sound and economically viable collection and recycling programmes for lead and lead containing products in order to reduce the release of lead to the environment from waste streams;

5. Extend co-operative efforts to share, including with non-OECD countries, information about exposures of concern, risk reduction options and environmentally sound and economically viable technologies in order to reduce risks from exposure to lead;

6. Encourage the lead producing and using industries to make best use of their expertise on the management of risks from lead and encourage them to make this expertise available to OECD and non-OECD countries;

7. Work with the lead producer industry to develop its voluntary programme of action to reduce exposure to lead, which will be implemented in co-operation with national authorities in OECD and interested non-OECD countries and encourage user industries to develop similar programmes;

FURTHER DECLARE THAT THE OECD SHOULD:

8. Support Member countries in implementing this Declaration;

9. Review progress by Member countries in pursuance of this Declaration three years after adoption and assess the need for further action;

10. Develop a framework for the co-operation of industry in implementing voluntary industry programmes for risk reduction on lead with a view to its wider applicability to other risk reduction activities;

11. Compile a guide on risk reduction of lead drawing on the extensive experience of Member countries and the work of the OECD risk reduction programme to assist OECD and non-OECD countries in developing and implementing lead risk reduction programmes;

12. Bring this Declaration to the attention of the United Nations Commission for Sustainable Development and other intergovernmental bodies and forums concerned with the sound management of chemicals.

INVITE:

13. Non-member countries to take account of the terms of this Declaration, to associate themselves with it and to implement the measures therein;

14. The relevant international standards organisations (including the International Standards Organisation), to develop or modify, as appropriate, international standards, testing procedures and definitions for products with a view to reducing the release of lead;

15. Other international organisations, involved with the protection of public health and the environment, to take this Declaration into consideration as they develop or revise goals, guidelines, and associated codes of practice for protection of human health and the environment.

ANNEX

a) Progressively phase-down use of lead in gasoline except where needed for essential or specialised uses for which there are no practical, viable alternatives;

b) Eliminate exposure of children to lead resulting from products intended for use by children (e.g., toys, cribs, crayons);

c) Eliminate exposure to lead from food packaging (e.g., for cans, by phasing down use of lead solder in existing canning lines, not using lead solder in new caning lines, or where these are not practical, using functional barriers to prevent lead migration; for wine-bottle capsules, substituting other materials);

d) Phase down the use of lead in paint and rust-proofing agents except in cases of essential or specialised uses for which there are no practical alternatives;

e) Restrict exposure to lead from the leaching of lead from ceramic ware and crystal ware used for food and beverages (e.g., by effective production and process controls);

f) Restrict the use of lead shot in wetlands and promote the use of alternatives to lead sinkers in shallow waters;

g) Reduce lead levels in drinking water through appropriate measures (e.g. treatment of the water, use of materials in the distribution system which do not release lead into the water);

h) Reduce levels of lead in occupational settings;

i) Limit air emissions from major point sources;

j) Establish strategies, including public information programmes, to abate significant exposures arising from the historic use of lead-containing materials in buildings.

Adherents*

OECD Members		Non-Members	Other
Australia	United States	Brazil	European Union
Austria		Kazakhstan	
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice

OECD Legal Instruments

OECD

BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice* , OECD/LEGAL/0252

Series: OECD Legal Instruments

Date(s)

Adopted on 02/10/1989
Amended on 09/03/1995

Background Information

The Decision-Recommendation on Compliance with Principles of Good Laboratory Practice was adopted by the OECD Council on 2 October 1989 on the proposal of the Joint Meeting of the Management Committee of the Special Programme on the Control of Chemicals and the Chemicals Group. The Decision-Recommendation establishes procedures for monitoring Good Laboratory Practice compliance through government inspections and study audits as well as a framework for international liaison among monitoring and data-receiving authorities. It is part of the OECD System of Mutual Acceptance of Data (MAD), a multilateral agreement which allows participating countries to share the results of various non-clinical tests done on chemicals. Under MAD, a non-clinical chemical safety study developed using OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP) in one Adherent country must be accepted for assessment purposes in all adhering countries.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960,

HAVING REGARD to the Recommendation of the Council of 7 July 1977 Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 12 May 1981 concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)] and, in particular, the Recommendation that Member countries, in the testing of chemicals, apply the OECD Principles of Good Laboratory Practice, set forth in Annex 2 to that Decision;

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the Mutual Recognition of Compliance with Good Laboratory Practice [C(83)95(Final)];

HAVING REGARD to the conclusions of the Third High-Level Meeting of the Chemicals Group (OECD, Paris, 1988);

CONSIDERING the need to ensure that test data on chemicals provided to regulatory authorities for purposes of assessment and other uses related to the protection of human health and the environment are of high quality, valid and reliable;

CONSIDERING the need to minimise duplicative testing of chemicals, and thereby to utilise more effectively scarce test facilities and specialist manpower, and to reduce the number of animals used in testing;

CONSIDERING that recognition of procedures for monitoring compliance with good laboratory practice will facilitate mutual acceptance of data and thereby reduce duplicative testing of chemicals;

CONSIDERING that a basis for recognition of compliance monitoring procedures is an understanding of, and confidence in, the procedures in the Member country where the data are generated;

CONSIDERING that harmonized approaches to procedures for monitoring compliance with good laboratory practice would greatly facilitate the development of the necessary confidence in other countries' procedures;

On the proposal of the Joint Meeting of the Management Committee of the Special Programme on the Control of Chemicals and the Chemicals Group, endorsed by the Environment Committee;

PART I: GLP Principles and Compliance Monitoring

I. DECIDES that Member countries in which testing of chemicals for purposes of assessment related to the protection of health and the environment is being carried out pursuant to principles of good laboratory practice that are consistent with the OECD Principles of Good Laboratory Practice as set out in Annex 2 of the Council Decision C(81)30(Final) (hereafter called "GLP Principles") shall:

i) Establish national procedures for monitoring compliance with GLP Principles, based on laboratory inspections and study audits;

ii) Designate an authority or authorities to discharge the functions required by the procedures for monitoring compliance; and

iii) Require that the management of test facilities issue a declaration, where applicable, that a study was carried out in accordance with GLP Principles and pursuant to any other provisions established by national legislation or administrative procedures dealing with good laboratory practice.

II. **RECOMMENDS** that, in developing and implementing national procedures for monitoring compliance with GLP Principles, Member countries apply the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" and the "Guidance for the Conduct of Laboratory Inspections and Study Audits", set out respectively in Annexes I and II which are an integral part of this Decision-Recommendation.

PART II: Recognition of GLP Compliance among Member Countries

I. **DECIDES** that Member countries shall recognise the assurance by another Member country that test data have been generated in accordance with GLP Principles if such other Member country complies with Part I above and Part II paragraph 2 below.

II. **DECIDES** that, for purposes of the recognition of the assurance in paragraph 1 above, Member countries shall:

i) Designate an authority or authorities for international liaison and for discharging other functions relevant to the recognition as set out in this Part and in the Annexes to this Decision-Recommendation;

ii) Exchange with other Member countries relevant information concerning their procedures for monitoring compliance, in accordance with the guidance set out in Annex III which is an integral part of this Decision-Recommendation; and

iii) Implement procedures whereby, where good reason exists, information concerning GLP compliance of a test facility (including information focussing on a particular study) within their jurisdiction can be sought by another Member country.

III. **DECIDES** that the Council Recommendation concerning the Mutual Recognition of Compliance with Good Laboratory Practice [C(83)95(Final)] shall be repealed.

PART III: Future OECD Activities

I. **INSTRUCTS** the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to ensure that the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" and the "Guidance for the Conduct of Laboratory Inspections and Study Audits" set out in Annexes I and II are updated and expanded, as necessary, in light of developments and experience of Member countries and relevant work in other international organisations.

II. **INSTRUCTS** the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to pursue a programme of work designed to facilitate the implementation of this Decision-Recommendation, and to ensure continuing exchange of information and experience on technical and administrative matters related to the application of GLP Principles and the implementation of procedures for monitoring compliance with good laboratory practice.

III. **INSTRUCTS** the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Decision-Recommendation.

ANNEX I

GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GOOD LABORATORY PRACTICE

To facilitate the mutual acceptance of test data generated for submission to Regulatory Authorities of OECD Member countries, harmonization of the procedures adopted to monitor good laboratory practice compliance, as well as comparability of their quality and rigour, are essential. The aim of this document is to provide detailed practical guidance to OECD Member countries on the structure, mechanisms and procedures they should adopt when establishing national Good Laboratory Practice compliance monitoring programmes so that these programmes may be internationally acceptable.

It is recognised that Member countries will adopt GLP Principles and establish compliance monitoring procedures according to national legal and administrative practices, and according to priorities they give to, e.g., the scope of initial and subsequent coverage concerning categories of chemicals and types of testing. Since Member countries may establish more than one Good Laboratory Practice Monitoring Authority due to their legal framework for chemicals control, more than one Good Laboratory Practice Compliance Programme may be established. The guidance set forth in the following paragraphs concerns each of these Authorities and Compliance Programmes, as appropriate.

DEFINITIONS OF TERMS

The definitions of terms in the "OECD Principles of Good Laboratory Practice" [Annex 2 to Council Decision C(81)30 (Final)] are applicable to this document. In addition, the following definitions apply:

GLP Principles: Principles of good laboratory practice that are consistent with the OECD Principles of Good Laboratory Practice as set out in Annex 2 of Council Decision C(81)30(Final).

GLP Compliance Monitoring: The periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP Principles.

(National) GLP Compliance Programme: The particular scheme established by a Member country to monitor good laboratory practice compliance by test facilities within its territories, by means of inspections and study audits.

(National) GLP Monitoring Authority: A body established within a Member country with responsibility for monitoring the good laboratory practice compliance of test facilities within its territories and for discharging other such functions related to good laboratory practice as may be nationally determined. It is understood that more than one such body may be established in a Member country.

Test Facility Inspection: An on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP Principles. During inspections, the management structures and operational procedures of the test facility are examined, key technical personnel are interviewed, and the quality and integrity of data generated by the facility are assessed and reported.

Study audit: A comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and Standard Operating Procedures, to obtain additional information not provided in the report, and to establish whether practices were employed in the development of data that would impair their validity.

Inspector: A person who performs the test facility inspections and study audits on behalf of the (National) GLP Monitoring Authority.

GLP Compliance Status: The level of adherence of a test facility to the GLP Principles as assessed by the (National) GLP Monitoring Authority.

Regulatory Authority: A national body with legal responsibility for aspects of the control of chemicals.

COMPONENTS OF GOOD LABORATORY PRACTICE COMPLIANCE MONITORING PROCEDURES

Administration

(National) GLP Compliance Programme should be the responsibility of a properly constituted, legally identifiable body adequately staffed and working within a defined administrative framework.

Member countries should:

- Ensure that the (National) GLP Monitoring Authority is directly responsible for an adequate "team" of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a "team"
- Publish documents relating to the adoption of GLP Principles within their territories;
- Publish documents providing details of the (National) GLP Compliance Programme, including information on the legal or administrative framework within which the programme operates and references to published acts, normative documents (e.g., regulations, codes of practice), inspection manuals, guidance notes, periodicity of inspections and/or criteria for inspection schedules, etc.;
- Maintain records of test facilities inspected (and their GLP Compliance Status) and of studies audited for both national and international purposes.

Confidentiality

(National) GLP Monitoring Authorities will have access to commercially valuable information and, on occasion, may even need to remove commercially sensitive documents from a test facility or refer to them in detail in their reports.

Member countries should:

- Make provision for the maintenance of confidentiality, not only by Inspectors but also by any other persons who gain access to confidential information as a result of GLP Compliance Monitoring activities;
- Ensure that, unless all commercially sensitive and confidential information has been excised, reports of Test Facility Inspections and Study Audits are made available only to Regulatory Authorities and, where appropriate, to the test facilities inspected or concerned with Study Audits and/or to study sponsors.

Personnel and Training

(National) GLP Monitoring Authorities should:

- **Ensure that an adequate number of Inspectors is available**

  The number of Inspectors required will depend upon:

  i) The number of test facilities involved in the (National) GLP Compliance Programme;

  ii) The frequency with which the GLP Compliance Status of the test facilities is to be assessed:

  iii) The number and complexity of the studies undertaken by those test facilities;

  iv) The number of special inspections or audits requested by Regulatory Authorities.

- **Ensure that Inspectors are adequately qualified and trained**

  Inspectors should have qualifications and practical experience in the range of scientific disciplines relevant to the testing of chemicals. (National) GLP Monitoring Authorities should:

i) Ensure that arrangements are made for the appropriate training of GLP Inspectors, having regard to their individual qualifications and experience;

ii) Encourage consultations, including joint training activities where necessary, with the staff of (National) GLP Monitoring Authorities in other Member countries in order to promote international harmonization in the interpretation and application of GLP Principles, and in the monitoring of compliance with such Principles.

- **Ensure that inspectorate personnel, including experts under contract, have no financial or other interests in the test facilities inspected, the studies audited or the firms sponsoring such studies**

- **Provide Inspectors with a suitable means of identification (e.g., an identity card)**

  Inspectors may be:

  - On the permanent staff of the (National) GLP Monitoring Authority;
  - On the permanent staff of a body separate from the (National) GLP Monitoring Authority; or
  - Employed on contract, or by another way, by the (National) GLP Monitoring Authority to perform Test Facility Inspections or Study Audits.

  In the latter two cases, the (National) GLP Monitoring Authority should have ultimate responsibility for determining the GLP Compliance Status of test facilities and the quality/acceptability of a Study Audit, and for taking any action based on the results of Test Facility Inspections or Study Audits which may be necessary.

(National) GLP Compliance Programmes

GLP Compliance Monitoring is intended to ascertain whether test facilities have implemented GLP Principles for the conduct of studies and are capable of assuring that the resulting data are of adequate quality. As indicated above, Member countries should publish the details of their (National) GLP Compliance Programmes. Such information should, *inter alia*:

- **Define the scope and extent of the Programme**

  A (National) GLP Compliance Programme may cover only a limited range of chemicals, e.g., industrial chemicals, pesticides, pharmaceuticals, etc., or may include all chemicals. The scope of the monitoring for compliance should be defined, both with respect to the categories of chemicals and to the types of tests subject to it, e.g., physical, chemical, toxicological and/or ecotoxicological.

- **Provide an indication as to the mechanism whereby test facilities enter the Programme**

  The application of GLP Principles to health and environmental safety data generated for regulatory purposes may be mandatory. A mechanism should be available whereby test facilities may have their compliance with GLP Principles monitored by the appropriate (National) GLP Monitoring Authority.

- **Provide information on categories of Test Facility Inspections/Study Audits**

  A (National) GLP Compliance Programme should include:

  i) Provision for Test Facility Inspections. These inspections include both a general Test Facility Inspection and a Study Audit of one or more on-going or completed studies;

  ii) Provision for special Test Facility Inspections/Study Audits at the request of a Regulatory Authority - e.g., prompted by a query arising from the submission of data to a Regulatory Authority.

- **Define the powers of Inspectors for entry into test facilities and their access to data held by test facilities (including specimens SOP's, other documentation, etc.)**

  While Inspectors will not normally wish to enter test facilities against the will of the facility's management, circumstances may arise where test facility entry and access to data are essential to protect public health or the environment. The powers available to the (National) GLP Monitoring Authority in such cases should be defined.

- **Describe the Test Facility Inspection and Study Audit procedures for verification of GLP compliance**

  The documentation should indicate the procedures which will be used to examine both the organisational processes and the conditions under which studies are studies are planned, performed, monitored and recorded. Guidance for such procedures is available in Guidance for Conduct of Test Facility Inspections and Study Audits (No.3 in the OECD series on Principles of GLP and Compliance Monitoring).

- **Describe actions that may be taken as follow-up to Test Facility Inspections and Study Audits**

Follow-up to Laboratory Inspections and Study Audits

When a Test Facility Inspection or Study Audit has been completed, the Inspector should prepare a written report of the findings.

Member countries should take action where deviations from GLP Principles are found during or after a Test Facility Inspection or Study Audit. The appropriate actions should be described in documents from the (National) GLP Monitoring Authority.

If a Test Facility Inspection or Study Audit reveals only minor deviations from GLP Principles, the facility should be required to correct such minor deviations. The Inspector may need, at an appropriate time, to return to the facility to verify that corrections have been introduced.

Where no or where only minor deviations have been found, the (National) GLP Monitoring Authority may:

- Issue a statement that the test facility has been inspected and found to be operating in compliance with GLP Principles. The date of inspections and, if appropriate, the categories of tests inspected in the test facility at that time should be included. Such statements may be used to provide information to (National) GLP Monitoring Authorities in other Member countries;

  and/or

- Provide the Regulatory Authority which requested a Study Audit with a detailed report of the findings.

Where serious deviations are found, the action taken by (National) GLP Monitoring Authorities will depend upon the particular circumstances of each case and the legal or administrative provisions under which GLP Compliance Monitoring has been established within their countries. Actions which may be taken include, but are not limited to, the following:

- Issuance of a statement, giving details of the inadequacies or faults found which might affect the validity of studies conducted in the test facility;
- Issuance of a recommendation to a Regulatory Authority that a study be rejected;
- Suspension of Test Facility Inspections or Study Audits of a test facility and, for example and where administratively possible, removal of the test facility from the (National) GLP Compliance Programme or from any existing list or register of test facilities subject to GLP Test Facility Inspections;

- Requiring that a statement detailing the deviations be attached to specific study reports;
- Action through the courts, where warranted by circumstances and where legal/administrative procedures so permit.

Appeals Procedures

Problems, or differences of opinion, between Inspectors and test facility management will normally be resolved during the course of a Test Facility Inspection or Study Audit. However, it may not always be possible for agreement to be reached. A procedure should exist whereby a test facility may make representations relating to the outcome of a Test Facility Inspection or Study Audit for GLP Compliance Monitoring and/or relating to the action the GLP Monitoring Authority proposes to take thereon.

ANNEX II

GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

INTRODUCTION

The purpose of this document is to provide guidance for the conduct of Test Facility Inspections and Study Audits which would be mutually acceptable to OECD Member countries. It is principally concerned with Test Facility Inspections, an activity which occupies much of the time of GLP Inspectors. A Test Facility Inspection will usually include a limited Study Audit or "review" as a part of the inspection, but Study Audits will also have to be conducted from time to time at the request, for example, of a Regulatory Authority. General guidance for the conduct of Study Audits will be found at the end of this document.

Test Facility Inspections are conducted to determine the degree of conformity of test facilities and studies with GLP Principles and to determine the integrity of data to assure that resulting data are of adequate quality for assessment and decision-making by national Regulatory Authorities. They result in reports which describe the degree of adherence of a test facility to the GLP Principles. Test Facility Inspections should be conducted on a regular, routine basis to establish and maintain records of the GLP Compliance Status of test facilities.

Further clarification of many of the points in this document may be obtained by referring to the OECD Consensus Documents on GLP (on, e.g., the role and responsibilities of the Study Director).

DEFINITIONS OF TERMS

The definitions of terms in the "OECD Principles of Good Laboratory Practice" [Annex II to Council Decision C(81)30 (Final)] and in the "Guides for Compliance Monitoring Procedures for Good Laboratory Practice" [Annex I to Council Decision-Recommendation C(89)87(Final)] are applicable to this document.

TEST FACILITY INSPECTIONS

Inspections for compliance with GLP Principles may take place in any test facility generating health or environmental safety data for regulatory purposes. Inspectors may be required to audit data relating to the physical, chemical, toxicological or ecotoxicological properties of a substance or preparation. In some cases, Inspectors may need assistance from experts in particular disciplines.

The wide diversity of facilities (in terms both of physical layout and management structure), together with the variety of types of studies encountered by Inspectors, means that the Inspectors must use their own judgement to assess the degree and extent of compliance with GLP Principles. Nevertheless, Inspectors should strive for a consistent approach in evaluating whether, in the case of a particular test facility or study, an adequate level of compliance with each GLP Principle has been achieved.

In the following sections, guidance is provided on the various aspects of the testing facility, including its personnel and procedures, which are likely to be examined by Inspectors. In each section, there is a statement of purpose, as well as an illustrative list of specific items which could be considered during the course of a Test Facility Inspection. These lists are not meant to be comprehensive and should not be taken as such.

Inspectors should not concern themselves with the scientific design of the study or the interpretation of the findings of studies with respect to risks for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for regulatory purposes.

Test Facility Inspections and Study Audits inevitably disturb the normal work in a facility. Inspectors should therefore carry out their work in a carefully planned way and, so far as practicable, respect the wishes of the management of the test facility as to the timing of visits to certain sections of the facility.

Inspectors will, while conducting Test Facility Inspections and Study Audits, have access to confidential, commercially valuable information. It is essential that they ensure that such information is seen by authorised personnel only. Their responsibilities in this respect will have been established within their (National) GLP Compliance Monitoring Programme.

INSPECTION PROCEDURES

Pre-Inspection

PURPOSE: To familiarise the Inspector with the facility which is about to be inspected in respect of management structure, physical layout of buildings and range of studies.

Prior to conducting a Test Facility Inspection or Study Audit, Inspectors should familiarise themselves with the facility which is to be visited. Any existing information on the facility should be reviewed. This may include previous inspection reports, the layout of the facility, organisation charts, study reports, protocols and curricula vitae (CVs) of personnel. Such documents would provide information on:

- The type, size and layout of the facility;
- The range of studies likely to be encountered during the inspection;
- The management structure of the facility.

Inspectors should note, in particular, any deficiencies from previous Test Facility Inspections. Where no previous Test Facility Inspections have been conducted, a pre-inspection visit can be made to obtain relevant information.

Test Facilities may be informed of the date and time of Inspectors' arrival, the objective of their visit and the length of time they expect to be on the premises. This could allow the test facility to ensure that the appropriate personnel and documentation are available. In cases where particular documents or records are to be examined, it may be useful to identify these to the test facility in advance of the visit so that they will be immediately available during the Test Facility Inspection.

Starting Conference

PURPOSE: To inform the management and staff of the facility of the reason for the Test Facility Inspection or Study Audit that is about to take place, and to identify the facility areas, study(ies) selected for audit, documents and personnel likely to be involved.

The administrative and practical details of a Test Facility Inspection or Study Audit should be discussed with the management of the facility at the start of the visit. At the starting conference, Inspectors should:

- Outline the purpose and scope of the visit;
- Describe the documentation which will be required for the Test Facility Inspection, such as lists of on-going and completed studies, study plans, standard operating procedures, study reports, etc. Access to and, if necessary, arrangements for the copying of relevant documents should be agreed upon at this time;
- Clarify or request information as to the management structure (organisation) and personnel of the facility;
- Request information as to the conduct of studies not subject to GLP Principles in the areas of the test facility where GLP studies are being conducted;
- Make an initial determination as to the parts of the facility to be covered during the Test Facility Inspection;
- Describe the documents and specimens that will be needed for on-going or completed study(ies) selected for Study Audit;
- Indicate that a closing conference will be held at the completion of the inspection.

Before proceeding further with a Test Facility Inspection, it is advisable for the Inspector(s) to establish contact with the facility's Quality Assurance (QA) unit.

As a general rule, when inspecting a facility, Inspectors will find it helpful to be accompanied by a member of the QA unit.

Inspectors may wish to request that a room be set aside for examination of documents and other activities.

Organisation and Personnel

PURPOSE: To determine whether: the test facility has sufficient qualified personnel, staff resources and support services for the variety and number of studies undertaken; the organisational structure is appropriate; and management has established a policy regarding training and staff health surveillance appropriate to the studies undertaken in the facility.

The management should be asked to produce certain documents, such as:

- Floor plans;
- Facility management and scientific organisation charts;
- CVs of key personnel involved in the type(s) of studies selected for the Study Audit;
- List(s) of on-going and completed studies with information on the type of study, initiation/completion dates, test system, method of application of test substance and name of Study Director;
- Staff health surveillance policies;
- Staff job descriptions and staff training programmes and records;
- An index to the facility's Standard Operating Procedures (SOPs);
- Specific SOPs as related to the studies or procedures being inspected or audited;
- List(s) of the Study Directors and sponsors associated with the study(ies) being audited.

The Inspector should check, in particular:

- Lists of on-going and completed studies to ascertain the level of work being undertaken by the test facility;
- The identity and qualifications of the Study Directors, the Head of the Quality Assurance unit and other personnel;
- Existence of SOPs for all relevant areas of testing.

Quality Assurance Programme

PURPOSE**:** To determine whether the mechanisms used to assure management that studies are conducted in accordance with GLP Principles are adequate.

The Head of the Quality Assurance (QA) unit should be asked to demonstrate the systems and methods for QA inspection and monitoring of studies, and the system for recording observations made during QA monitoring. Inspectors should check:

- The qualifications of the Head of QA, and of all QA staff;
- That the QA unit functions independently from the staff involved in the studies;
- How the QA unit schedules and conducts inspections, how it monitors identified critical phases in a study, and what resources are available for QA inspections and monitoring activities;

- That where studies are of such short duration that monitoring of each study is impracticable, arrangements exist for monitoring on a sample basis;
- The extent and depth of QA monitoring during the practical phases of the study;
- The extent and depth of QA monitoring of routine test facility operation;
- The QA procedures for checking the final report to ensure its agreement with the raw data;
- That management receives reports from QA concerning problems likely to affect the quality or integrity of a study;
- The actions taken by QA when deviations are found;
- The QA role, if any, if studies or parts of studies are done in contract laboratories;
- The part played, if any, by QA in the review, revision and up-dating of SOPs.

Facilities

PURPOSE: To determine whether the test facility, whether indoor or outdoor, is of suitable size, construction, design and location to meet the demands of the studies being undertaken.

The Inspector should check that:

- The design enables an adequate degree of separation so that, e.g., test substances, animals, diets, pathological specimens, etc. of one study cannot be confused with those of another;
- Environmental control and monitoring procedures exist and function adequately in critical areas, e.g., animal and other biological test systems rooms, test substance storage areas, laboratory areas;
- The general housekeeping is adequate for the various facilities and that there are, if necessary, pest control procedures.

Care, Housing and Containment of Biological Test Systems

PURPOSE: To determine whether the test facility, if engaged in studies using animals or other biological test systems, has support facilities and conditions for their care, housing and containment, adequate to prevent stress and other problems which could affect the test system and hence the quality of data.

A test facility may be carrying out studies which require a diversity of animal or plant species as well as microbial or other cellular or sub-cellular systems. The type of test systems being used will determine the aspects relating to care, housing or containment that the Inspector will monitor. Using his judgement, the Inspector will check, according to the test systems, that:

- There are facilities adequate for the test systems used and for testing needs;
- There are arrangements to quarantine animals and plants being introduced into the facility and that these arrangements are working satisfactorily;
- There are arrangements to isolate animals (or other elements of a test system, if necessary) known to be, or suspected of being, diseased or carriers of disease;
- There is adequate monitoring and record-keeping of health, behaviour or other aspects, as appropriate to the test system;
- The equipment for maintaining the environmental conditions required for each test system is adequate, well maintained, and effective;
- Animal cages, racks, tanks and other containers, as well as accessory equipment, are kept sufficiently clean;

- Analyses to check environmental conditions and support systems are carried out as required;
- Facilities exist for removal and disposal of animal waste and refuse from the test systems and that these are operated so as to minimise vermin infestation, odours, disease hazards and environmental contamination;
- Storage areas are provided for animal feed or equivalent materials for all test systems; that these areas are not used for the storage of other materials such as test substances, pest control chemicals or disinfectants, and that they are separate from areas in which animals are housed or other biological test systems are kept;
- Stored feed and bedding are protected from deterioration by adverse environmental conditions, infestation or contamination.

Apparatus, Materials, Reagents and Specimens

PURPOSE: To determine whether the test facility has suitably located, operational apparatus in sufficient quantity and of adequate capacity to meet the requirements of the tests being conducted in the facility and that the materials, reagents and specimens are properly labelled, used and stored.

The Inspector should check that:

- Apparatus are clean and in good working order;
- Records have been kept of operation, maintenance, verification, calibration and validation of measuring equipment and apparatus (including computerised systems);
- Materials and chemical reagents are properly labelled and stored at appropriate temperatures and that expiry dates are not being ignored. Labels for reagents should indicate their source, identity and concentration and/or other pertinent information;
- Specimens are well identified by test system, study, nature and date of collection;
- Apparatus and materials used do not alter to any appreciable extent the test systems.

Test Systems

PURPOSE: To determine whether adequate procedures exist for the handling and control of the variety of test systems required by the studies undertaken in the facility, e.g., chemical and physical systems, cellular and microbic systems, plants or animals.

Physical and Chemical Systems

The Inspector should check that:

- Where required by study plans, the stability of test and reference substances was determined and that the reference substances specified in test plans were used;
- Iin automated systems, data generated as graphs, recorder traces or computer print-outs are documented as raw data and archived.

Biological Test Systems

Taking account of the relevant aspects referred to above relating to care, housing or containment of biological test systems, the Inspector should check that:

- Test systems are as specified in study plans;
- Test systems are adequately and, if necessary and appropriate, uniquely identified throughout the study; and that records exist regarding receipt of the test systems and document fully the number of test systems received, used, replaced or discarded;

- Housing or containers of test systems are properly identified with all the necessary information;
- There is an adequate separation of studies being conducted on the same animal species (or the same biological test systems) but with different substances;
- There is an adequate separation of animal species (and other biological test systems) either in space or in time;
- The biological test system environment is as specified in the study plan or in SOPs for aspects such as temperature, or light/dark cycles;
- The recording of the receipt, handling, housing or containment, care and health evaluation is appropriate to the test systems;
- Written records are kept of examination, quarantine, morbidity, mortality, behaviour, diagnosis and treatment of animal and plant test systems or other similar aspects as appropriate to each biological test system;
- There are provisions for the appropriate disposal of test systems at the end of tests.

Test and Reference Substances

PURPOSE: To determine whether the test facility has procedures designed i) to ensure that the identity, potency, quantity and composition of test and reference substances are in accordance with their specifications, and ii) to properly receive and store test and reference substances.

The Inspector should check that:

- There are written records on the receipt (including identification of the person responsible), and for the handling, sampling, usage and storage of test and reference substances;
- Test and reference substances containers are properly labelled;
- Storage conditions are appropriate to preserve the concentration, purity and stability of the test and reference substances;
- There are written records on the determination of identity, purity, composition, stability, and for the prevention of contamination of test and reference substances, where applicable;
- There are procedures for the determination of the homogeneity and stability of mixtures containing test and reference substances, where applicable;
- Containers holding mixtures (or dilutions) of the test and reference substances are labelled and that records are kept of the homogeneity and stability of their contents, where applicable;
- When the test is of longer than four weeks' duration, samples from each batch of test and reference substances have been taken for analytical purposes and that they have been retained for an appropriate time;
- Procedures for mixing substances are designed to prevent errors in identification or cross-contamination.

Standard Operating Procedures

PURPOSE: To determine whether the test facility has written SOPs relating to all the important aspects of the operations, considering that one of the most important management techniques for controlling facility operations is the use of written SOPs. These relate directly to the routine elements of tests conducted by the test facility.

The Inspector should check that:

- Each test facility area has immediately available relevant, authorised copies of SOPs;
- Procedures exist for revision and updating of SOPS;
- Any amendments or changes to SOPs have been authorised and dated;
- Historical files of SOPs are maintained;
- SOPs are available for, but not necessarily limited to, the following activities:
    i) Receipt; determination of identity, purity, composition and stability; labelling, handling, sampling, usage and storage of test and reference substances;
    ii) Use, maintenance, cleaning, calibration and validation of measuring apparatus and environmental control equipment;
    iii) Preparation of reagents and dosing formulations;
    iv) Record-keeping, reporting, storage and retrieval of records and reports;
    v) Preparation and environmental control of areas containing the test systems;
    vi) Receipt, transfer, location, characterisation, identification and care of test systems;
    vii) Handling of the test systems before, during and at the termination of the study;
    viii) Disposal of test systems;
    ix) Use of pest control and cleaning agents;
    x) Quality Assurance programme operations.

Performance of the Study

PURPOSE: To verify that written study plans exist and that the plans and the conduct of the study are in accordance with GLP Principles.

The Inspector should check that:

- The study plan was signed by the Study Director;
- Any amendments to the study plan were signed and dated by the Study Director.
- The date of the agreement to the study plan by the sponsor was recorded (where applicable);
- Measurements, observations and examinations were in accordance with the study plan and relevant SOPs;
- The results of these measurements, observations and examinations were recorded directly, promptly, accurately and legibly and were signed (or initialled) and dated;
- Any changes in the raw data, including data stored in computers, did not obscure previous entries, included the reason for the change and identified the person responsible for the change and the date it was made;
- Computer-generated or stored data have been identified and that the procedures to protect them against unauthorised amendments or loss are adequate;
- The computerised systems used within the study is reliable, accurate and can be validated;
- Any unforeseen events recorded in the raw data have been investigated and evaluated;
- The results presented in the reports of the study (interim or final) are consistent and complete and that they correctly reflect the raw data.

Reporting of Study Results

PURPOSE: To determine whether final reports are prepared in accordance with GLP Principles.

When examining a final report, the Inspector should check that:

- It is signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the study and confirming that the study was conducted in accordance with GLP Principles;
- It is signed and dated by other principal scientists, if reports from co-operating disciplines are included;
- A Quality Assurance statement is included in the report and that it is signed and dated;
- Any amendments were made by the responsible personnel;
- It lists the archive location of all samples, specimens and raw data.

Storage and Retention of Records

PURPOSE: To determine whether the facility has generated adequate records and reports and whether adequate provision has been made for the safe storage and retention of records and materials.

The Inspector should check:

- That a person has been identified as responsible for the archive;
- The archive facilities for the storage of study plans, raw data (including that from discontinued GLP Studies), final reports, samples and specimens and records of education and training of personnel;
- The procedures for retrieval of archived materials;
- The procedures whereby access to the archives is limited to authorised personnel and records are kept of personnel given access to raw data, slides, etc.;
- That an inventory is maintained of materials removed from, and returned to, the archives;
- That records and materials are retained for the required or appropriate period of time and are protected from loss or damage by fire, adverse environmental conditions, etc.

STUDY AUDITS

Test Facility inspections will generally include, inter alia, Study Audits, which reviews on-going or completed studies. Specific Study Audits are also often requested by Regulatory Authorities, and can be conducted independently of Test Facility Inspections. Because of the wide variation in the types of studies which might be audited, only general guidance is appropriate, and Inspectors and others taking part in Study Audits will always need to exercise judgement as to the nature and extent of their examinations. The objective should be to reconstruct the study by comparing the final report with the study plan, relevant SOPs, raw data and other archived material.

In some cases, Inspectors may need assistance from other experts in order to conduct an effective study audit, e.g., where there is a need to examine tissue sections under the microscope.

When conducting a Study Audit, the Inspector should:

- Obtain names, job descriptions and summaries of training and experience for selected personnel engaged in the study(ies) such as the Study Director and principal scientists;
- Check that there is sufficient staff trained in relevant areas for the study(ies) undertaken;
- Identify individual items of apparatus or special equipment used in the study and examine the calibration, maintenance and service records for the equipment;
- Review the records relating to the stability of the test substances, analyses of test substance and formulations, analyses of feed, etc.;

- Attempt to determine, through the interview process if possible, the work assignments of selected individuals participating in the study to ascertain if these individuals had the time to accomplish the tasks specified in the study plan or report;
- Obtain copies of all documentation concerning control procedures or forming integral parts of the study, including:
    i) The study plan;
    ii) SOPs in use at the time the study was done;
    iii) Log books, laboratory notebooks, files, worksheets, print-outs of computer-stored data, etc.;
    iv) The final report.

In studies in which animals (i.e., rodents and other mammals) are used, the Inspectors should follow a certain percentage of individual animals from their arrival at the test facility to autopsy. They should pay particular attention to the records relating to:

- Animal body weight, food/water intake, dose formulation and administration, etc.;
- Clinical observations and autopsy findings;
- Clinical chemistry;
- Pathology.

COMPLETION OF INSPECTION OR STUDY AUDIT

When a Test Facility Inspection or Study Audit has been completed, the Inspector should be prepared to discuss his findings with representatives of the test facility at a Closing Conference and should prepare a written report, i.e., the Inspection Report.

A Test Facility Inspection of any large facility is likely to reveal a number of minor deviations from GLP Principles but, normally, these will not be sufficiently serious to affect the validity of studies emanating from that test facility. In such cases, it is reasonable for an Inspector to report that the facility is operating in compliance with GLP Principles according to the criteria established by the (National) GLP Monitoring Authority. Nevertheless, details of the inadequacies or faults detected should be provided to the test facility and assurances sought from its senior management that action will be taken to remedy them. The Inspector may need to revisit the facility after a period of time to verify that necessary action has been taken.

If a serious deviation from the GLP Principles is identified during a Test Facility Inspection or Study Audit which, in the opinion of the Inspector, may have affected the validity of that study, or of other studies performed at the facility, the Inspector should report back to the (National) GLP Monitoring Authority. The action taken by that Authority and/or the regulatory authority, as appropriate, will depend upon the nature and extent of the non-compliance and the legal and/or administrative provisions within the GLP Compliance Programme.

Where a Study Audit has been conducted at the request of a Regulatory Authority, a full report of the findings should be prepared and sent via the relevant (National) GLP Monitoring Authority to the Regulatory Authority concerned.

ANNEX III

GUIDANCE FOR THE EXCHANGE OF INFORMATION CONCERNING NATIONALPROGRAMMES FOR MONITORING OF COMPLIANCE WITH PRINCIPLES OF GOOD LABORATORY PRACTICES

Part II, paragraph 2 of the Council Act contains a Decision that Member countries exchange information related to their programmes for monitoring of compliance with GLP Principles. This Annex provides guidance concerning the types of information which should be exchanged. While information concerning all of the aspects covered in the "Guides for Compliance Monitoring Programmes procedures for Good Laboratory Practice" (Annex I) are relevant to an understanding of other Member countries' procedures for GLP Compliance Monitoring, certain types of information are of particular importance. These include:

- The GLP Principles adopted nationally;
- The scope of the national programme for monitoring compliance with GLP Principles in terms of the types of chemicals and tests covered;
- The identity, legal status, and organisational structure of the (National) GLP Monitoring Authority(ies);
- The procedures followed during Test Facility Inspections and Study Audits, and the periodicity of inspections and/or criteria for inspection schedules;
- The number and qualifications of Inspectors;
- The actions available to the (National) GLP Monitoring Authority(ies) in cases of non-compliance, including the ability to inform other Member countries, when necessary, of the results of Laboratory Inspections and Study Audits;
- The arrangements for protecting confidentiality of information;
- The procedures for initiating, conducting and reporting on Test Facility Inspections and Study Audits at the request of other Member countries;
- The procedures for obtaining information on test facilities which have been inspected by a (National) GLP Monitoring Authority of another Member country, including such facilities' compliance status; and
- The nature of test facility certifications that studies were carried out following GLP Principles.

Where serious deviations which may have affected specific studies are found, the (National) GLP Monitoring Authority should consider the need to inform relevant (National) GLP Monitoring Authorities in other Member countries of their findings.

The names of test facilities subject to Test Facility Inspections within a (National) GLP Compliance Programme, their levels of compliance with the national GLP Principles and the date(s) the Inspections were conducted should be made available annually to (National) GLP Monitoring Authorities in other Member countries upon request (see "Guidance for GLP Monitoring Authorities for the Preparation of Annual Overviews of Test Facilities Inspected" set out in the Appendix to this Annex.)

Recognition of national programmes for monitoring compliance with GLP Principles may not be immediately forthcoming from other Member countries. Member countries should be prepared to meet genuine concerns in a co-operative way. It may be that a Member country is unable to judge the acceptability of the GLP Compliance Monitoring programmes of another solely on the basis of the exchange of written information. In such cases, Member countries may seek the assurance they require through consultation and discussion with relevant (National) GLP Monitoring Authorities. In this context, OECD provides a forum for the discussion and solving of problems relating to the international harmonization and acceptance of GLP Compliance Monitoring programmes.

To facilitate international liaison and the continuing exchange of information, the establishment of a single GLP Monitoring Authority covering all good laboratory practice activities within a Member

country has obvious advantages. Where more than one Authority exist, a Member country should ensure that they operate in a consistent way, and have similar GLP Compliance Programmes. The Authority or Authorities with responsibilities for international contacts should be identified by Member countries.

Situations will arise where a national Regulatory Authority of a Member country will need to request information on the GLP Compliance Status of a test facility located in another Member country. On rare occasions, and where good reason exists, a particular Study Audit may be requested by a Regulatory Authority of another Member country. Arrangements should be provided whereby these requests may be fulfilled and the results reported back to the requesting Regulatory Authority.

Formal international contact should be established for the exchange of information between GLP Monitoring Authorities. However, this should not be understood to prevent informal contacts between Regulatory Authorities and the GLP Monitoring Authority in another Member country, to the extent that such contacts are accepted by the Member countries concerned.

National authorities should note that authorities from another Member country may wish to be present at a Test Facility Inspection or Study Audit that they have specifically requested; or they may wish that representative(s) from the Member country seeking a special Test Facility Inspection or Study Audit be present at that Inspection or Audit. In these cases, Member countries should enable Inspectors from another Member country to participate in facility Inspections and Study Audits carried out by their GLP Monitoring Authority.

APPENDIX TO ANNEX III

GUIDANCE FOR GOOD LABORATORY PRACTICE MONITORING AUTHORITIES FOR THE PREPARATION OF ANNUAL OVERVIEWS OF TEST FACILITIES INSPECTED

Overviews of GLP inspections should be circulated to Members of the OECD Panel on GLP and the OECD Secretariat annually before the end of March. The following minimum set of information should allow harmonisation of the overviews exchanged among national GLP monitoring authorities:

1. Identification of the Facility Inspected: Sufficient information should be included to make the identification of the facility unequivocal, i.e. the name of the test facility the city and country in which it is located, including inspections abroad.

2. Dates of Inspections and Decisions: month and year of inspection, and, if appropriate, date of final decision on GLP compliance status.

3. Nature of Inspection: A clear indication should be given of whether a full GLP inspection or only a study audit was carried out, as well as whether the inspection was routine or not and any other authorities which were involved.

4. Areas of Expertise of the Facility Inspected: Since GLP compliance is related to the tests performed by a facility, the area(s) of expertise of the test facilities inspected should be included in the annual overviews, using the following broad categories:

1) Physical-chemical testing
2) Toxicity studies
3) Mutagenicity studies
4) Environmental toxicity studies on aquatic and terrestrial organisms
5) Studies on behaviour in water, soil and air; bioaccumulation
6) Residue studies
7) Studies on effects on mesocosms and natural ecosystems
8) Analytical and clinical chemistry testing
9) Other studies, specify

It is emphasised that these categories are to be used in a flexible manner on a case-by-case basis and that the aim is to provide information related to GLP compliance of test facilities that will be useful for other national monitoring authorities.

5. Compliance Status: The three following categories should be used to report the compliance status of facilities:

- In compliance
- Not in compliance
- Pending (with explanation)

In light of the fact that "pending" is interpreted differently by Member countries and that the varying legal and administrative systems do not allow for harmonised use of the term, explanations must accompany the use of the "pending" status in the national overview of test facilities inspected. Such explanations could include, e.g., "pending reinspection", "pending responses from test facility", "pending completion of administrative procedures". etc.

6. **Comments**: If appropriate, further comments can be made.

7. **Major Deficiencies**: At a minimum, individual studies for which a study audit has revealed serious GLP deficiencies and which have consequently been rejected by receiving authorities should be reported in the annual overviews of test facilities inspected. Since many studies are submitted to authorities in several countries at the same time, however, it is recommended that this kind of information be circulated among national authorities as rapidly as possible on an ad hoc basis, when necessary in addition to the annual overviews.

8. **Statements of Compliance**: When statements of compliance are provided to facilities by national monitoring authorities, they should use the same terminology and categories as the annual overviews.

9. **Circulation of Annual Overviews**: Overviews should be circulated annually before the end of March to the Members of the GPL Panel and the OECD Secretariat. This information can be released to the public on request.

Adherents*

OECD Members		Non-Members	Other
Australia	United States	Argentina	
Austria		Brazil	
Belgium		India	
Canada		Malaysia	
Chile		Singapore	
Czech Republic		South Africa	
Denmark		Thailand	
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning the Application of the Polluter-Pays Principle to Accidental Pollution*, OECD/LEGAL/0251

Series: OECD Legal Instruments

Date(s)

Adopted on 07/07/1989

Background Information

The Recommendation concerning the Application of the Polluter-Pays Principle to Accidental Pollution was adopted by the OECD Council on 7 July 1989 on the proposal of the Environment Committee. The Recommendation calls on Adherents to apply the Polluter-Pays Principle (PPP) in the case of accidental pollution at “hazardous installations”. Most importantly, this implies that the costs of reasonable measures to prevent and control the accidental pollution should be borne by the operators of the hazardous facilities or by those who are at the origin of the accident. The Recommendation recognises that in order for accident prevention to be more effective, neither the risk nor the consequences of accidental pollution should be paid from public funds.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 26 May 1972 on Guiding Principles Concerning International Economic Aspects of Environmental Policies [C(72)128];

HAVING REGARD to the Recommendation of the Council of 14 November 1974 on the Implementation of the Polluter-Pays Principle [C(74)223];

HAVING REGARD to the Recommendation of the Council of 28 April 1981 on Certain Financial Aspects of Action by Public Authorities to Prevent and Control Oil Spills [C(81)32(Final)];

HAVING REGARD to the Concluding Statement of the OECD Conference on Accidents Involving Hazardous Substances held in Paris on 9 and 10 February 1988 [C(88)83];

CONSIDERING that this Conference concluded that "operators of hazardous installations have the full responsibility for the safe operation of their installations and for taking all appropriate measures to prevent accidents" and that "operators of hazardous installations should take all reasonable measures... to take emergency actions in case of an accident";

CONSIDERING that such responsibility has repercussions on the allocation of the cost of reasonable measures aimed at preventing accidents in hazardous installations and limiting their consequences and that the Conference concluded that "the Polluter-Pays Principle should be applied, as far as possible, in connection with accidents involving hazardous substances";

CONSIDERING that public authorities are often required to take expensive action in case of accidental pollution from hazardous installations and may find it necessary to undertake costly accident preparedness measures in relation to certain hazardous installations;

CONSIDERING that closer harmonisation of laws and regulations relating to the allocation of the cost of measures to prevent and control accidental pollution is likely to reduce distortions in international trade and investment;

On the proposal of the Environment Committee;

I. RECOMMENDS that, in applying the Polluter-Pays Principle in connection with accidents involving hazardous substances, Member countries take into account the "Guiding Principles Relating to Accidental Pollution" set out in the Appendix which is an integral part of this Recommendation.

II. INSTRUCTS the Environment Committee to review the actions taken by Member countries pursuant to this Recommendation and to report to the Council within three years of the adoption of this Recommendation.

APPENDIX

GUIDING PRINCIPLES RELATING TO ACCIDENTAL POLLUTION

Scope and Definition

1. The Guiding Principles described below concern some aspects of the application of the Polluter-Pays Principle to hazardous installations.

2. For the purposes of this Recommendation:

   a) "Hazardous installations" means those fixed installations which are defined under applicable law as being capable of giving rise to hazards sufficient to warrant the taking of precautions off-site, excluding nuclear or military installations and hazardous waste repositories[1];

   b) "Accidental pollution" means substantial pollution off-site resulting from an accident in a hazardous installation;

   c) "Operator of a hazardous installation" means the legal or natural person who under applicable law is in charge of the installation and is responsible for its proper operation[2].

The Polluter-Pays Principle

3. According to the Recommendation of the Council of 26 May 1972, on the Guiding Principles Concerning International Economic Aspects of Environmental Policies [C(72)128] the "Principle to be used for allocating the costs of pollution prevention and control is the so called Polluter-Pays Principle". The implementation of this principle will "encourage rational use of scarce environmental resources". According to the Recommendation of the Council of 14 November 1974 on the Implementation of the Polluter-Pays Principle [C(74)223] "the Polluter-Pays Principle... means that the polluter should bear the expenses of carrying out the pollution prevention and control measures introduced by public authorities in Member countries, to ensure that the environment is in an acceptable state. In other words, the cost of these measures should be reflected in the cost of goods and services which cause pollution in production and/or consumption". In the same Recommendation the Council recommended that, "as a general rule, Member countries should not assist the polluters in bearing the costs of pollution control whether by means of subsidies, tax advantages or other measures".

Application of the Polluter-Pays Principle

4. In matters of accidental pollution risks, the Polluter-Pays Principle implies that the operator of a hazardous installation should bear the cost of reasonable measures to prevent and control accidental pollution from that installation which are introduced by public authorities in Member countries in conformity with domestic law prior to the occurrence of an accident in order to protect human health or the environment.

5. Domestic law which provides that the cost of reasonable measures to control accidental pollution after an accident should be collected as expeditiously as possible from the legal or natural person who is at the origin of the accident, is consistent with the Polluter-Pays Principle.

6. In most instances and notwithstanding issues concerning the origin of the accident, the cost of such reasonable measures taken by the authorities is initially borne by the operator for administrative convenience or for other reasons[3]. When a third party is liable for the accident, that party reimburses to the operator the cost of reasonable measures to control accidental pollution taken after an accident.

7. If the accidental pollution is caused solely by an event for which the operator clearly cannot be considered liable under national law, such as a serious natural disaster that the operator cannot reasonably have foreseen, it is consistent with the Polluter-Pays Principle that public authorities do not charge the cost of control measures to the operator.

8. Measures to prevent and control accidental pollution are those taken to prevent accidents in specific installations and to limit their consequences for human health or the environment. They can include, in particular, measures aimed at improving the safety of hazardous installations and accident preparedness, developing emergency plans, acting promptly following an accident in order to protect human health and the environment, carrying out clean-up operations and minimizing without undue delay the ecological effects of accidental pollution. They do not include humanitarian measures or other measures which are strictly in the nature of public services and which cannot be reimbursed to the public authorities under applicable law, nor measures to compensate victims for the economic consequences of an accident.

9. Public authorities of Member countries that "have responsibilities in the implementation of policies for prevention of, and response to, accidents involving hazardous substances"[4], may take specific measures to prevent accidents occuring at hazardous installations and to control accidental pollution. Although the cost entailed is as a general rule met by the general budget, public authorities may, with a view to achieving a more economically efficient resource allocation, introduce specific fees or taxes payable by certain installations on account of their hazardous nature (e.g. licensing fees), the proceeds of which are to be allocated to accidental pollution prevention and control.

10. One specific application of the Polluter-Pays Principle consists in adjusting these fees or taxes, in conformity with domestic law, to cover more fully the cost of certain exceptional measures to prevent and control accidental pollution in specific hazardous installations which are taken by public authorities to protect human health and the environment (e.g. special licensing procedures, execution of detailed inspections, drawing up of installation-specific emergency plans or building up special means of response for the public authorities to be used in connection with a hazardous installation), provided such measures are reasonable and directly connected with accident prevention or with the control of accidental pollution released by the hazardous installation. Lack of laws or regulations on relevant fees or taxes should not, however, prevent public authorities from meeting their responsibilities in connection with accidents involving hazardous substances.

11. A further specific application of the Polluter-Pays Principle consists in charging, in conformity with domestic law, the cost of reasonable pollution control measures decided by the authorities following an accident to the operator of the hazardous installation from which pollution is released. Such measures taken without undue delay by the operator or, in case of need, by the authorities would aim at promptly avoiding the spreading of environmental damage and would concern limiting the release of hazardous substances (e.g., by ceasing emissions at the plant, by erecting floating barriers on a river), the pollution as such (e.g., by cleaning or decontamination), or its ecological effects (e.g., by rehabilitating the polluted environment).

12. The extent to which prevention and control measures can be considered reasonable will depend on the circumstances under which they are implemented, the nature and extent of the measures, the threats and hazards existing when the decision is taken, the laws and regulations in force, and the interests which must be protected. Prior consultation between operators and public authorities should contribute to the choice of measures which are reasonable, economically efficient, and provide adequate protection of human health and the environment.

13. The pooling among operators of certain financial risks connected with accidents, for instance by means of insurance or within a special compensation or pollution control fund, is consistent with the Polluter-Pays Principle.

Exceptions

14. Exceptions to the Polluter-Pays Principle could be made under special circumstances such as the need for the rapid implementation of stringent measures for accident prevention, provided this does not lead to significant distortions in international trade and investment. In particular, any aid to be granted to operators for prevention or control of accidental pollution should be limited and comply with the conditions set out previously[5]. In the case of existing hazardous installations, compensatory payments or measures for changes in zoning decisions in the framework of the local land use plan might be envisaged with a view to facilitating the relocation of these installations so as to lessen the risks for the exposed population.

15. Likewise, exceptions to the above Guiding Principles could be made in the event of accidental pollution if strict and prompt implementation of the Polluter-Pays Principle would lead to severe socio-economic consequences.

16. The allocation to the person at the origin of the accident or the operator, as the case may be, of the cost of reasonable measures taken by public authorities to control accidental pollution does not affect the possibility under domestic law of requiring the same person to pay other costs connected with the public authorities' response to an accident (e.g., the supply of potable water) or with the occurrence of the accident. In addition, public authorities may, as appropriate, seek compensation from the party liable for the accident for costs incurred by them as a result of the accident when such costs have not yet been paid to the authorities.

---

[1] Hazardous installations covered by this Recommendation are as defined in the law applicable in the country of the installation (domestic law and in some instances, European Community law). Countries are not prevented from making provisions under their national laws to the effect that the Guiding Principles also apply to installations excluded under subparagraph 2 a) of this Appendix.

[2] The concept of operator is defined in the law applicable in the country of the installation, in which attention may be given to criteria such as ownership of certain hazardous substances or possession of a license or permit.

[3] In cases where a party other than the operator has, under the law applicable in the country of the installation, strict liability for an accident, the cost of reasonable control measures taken by the authorities would be charged to that party, not to the operator. Whenever national laws provide a regime of strict liability, this regime would be applied in respect of the reimbursement of costs of control measures taken after the accident.

[4] Concluding Statement of the OECD Conference on Accidents Involving Hazardous Substances, C(88)83.

[5] Recommendation of the Council of 14 November 1974 on the Implementation of the Polluter Pays Principle [C(74)223].

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

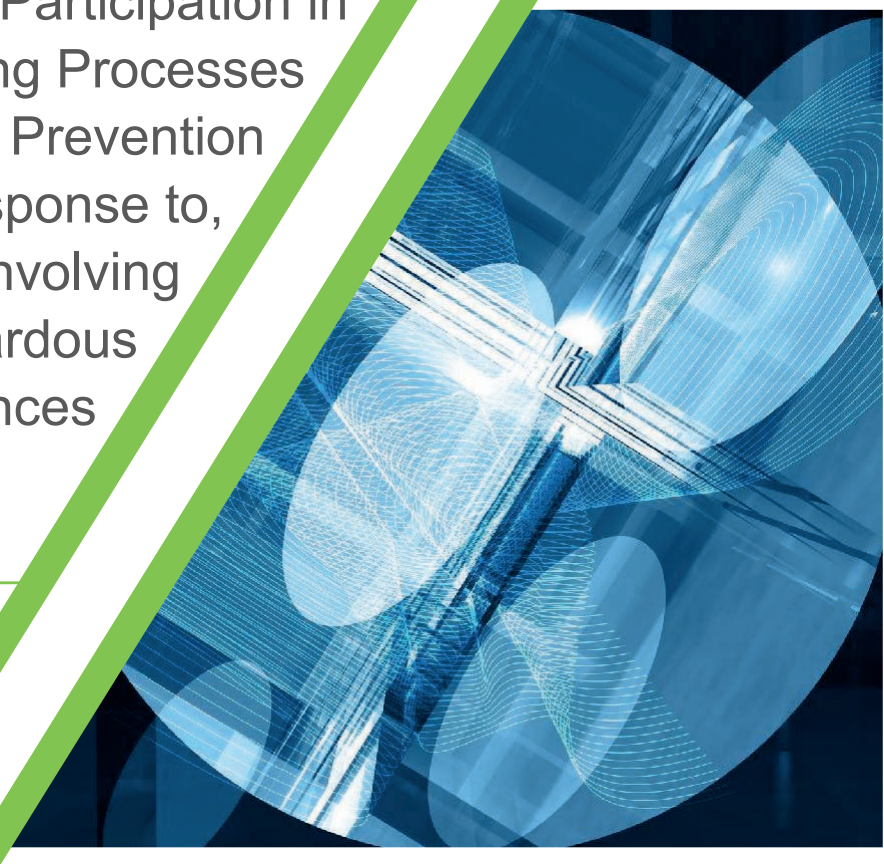
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision-Recommendation of the Council concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances



OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision-Recommendation of the Council concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances* , OECD/LEGAL/0239

Series: OECD Legal Instruments

Date(s)

Adopted on 08/07/1988

Background Information

The Decision-Recommendation concerning Provision of Information to the Public and Public Participation in Decision-making Processes related to the Prevention of, and Response to, Accidents Involving Hazardous Substances was adopted by the OECD Council on 8 July 1988 on the proposal of the Environment Committee. The Decision-Recommendation follows from such accidents as the ones in Seveso (1976), Bhopal (1984), Basel (1986) and Chernobyl (1986) which have brought attention to accidents involving hazardous substances that pose a threat to human life and health and to the environment. The Recommendation sets a duty for public authorities to provide information to both, the public about the hazards which could arise from accidents occurring at hazardous installations, and to persons potentially affected in the event of such an accident about the measures which need to be taken by them in order to mitigate adverse consequences.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to paragraph 3 of Article 6 of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Declaration on Anticipatory Environmental Policies adopted by the Governments of OECD Member countries and of Yugoslavia at the session of the Environment Committee at Ministerial Level on 8 May 1979 stating that "they will encourage public participation, where possible, in the preparation of decisions with significant environmental consequences, *inter alia*, by providing, as appropriate, information on the risks, costs and benefits associated with the decisions";

HAVING REGARD to the Recommendation of the Council of 8 May 1979 on the Assessment of Projects with Significant Impact on the Environment [C(79)116] in which Member governments were recommended to "introduce, where appropriate, practical measures for informing the public and for participation by those who may be directly or indirectly affected, at suitable stages in the process of arriving at decisions on projects" having a potentially significant impact on the environment;

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to the Declaration on “Environment: Resource for the Future” adopted by the Governments of OECD Member countries and of Yugoslavia at the session of the Environment Committee at Ministerial Level on 20 June 1985 stating that "they will ensure the existence of appropriate measures to control potentially hazardous installations, including measures to prevent accidents";

HAVING REGARD to the conclusions adopted by the Third High-Level Meeting of the Chemicals Group on 17-18 March 1987 regarding the prevention of, and response to, unintended releases of hazardous substances to the environment;

CONSIDERING that the potentially affected public has a right to be informed about the hazards to human health or the environment, including property, which could arise from accidents occurring at hazardous installations;

CONSIDERING that persons potentially affected in the event of an accident at a hazardous installation should be well-informed of measures which need to be taken by them in order to mitigate adverse consequences of such an accident;

CONSIDERING that such persons should have the opportunity to be heard, as appropriate, in decision-making processes related to prevention of, and response to, accidents involving hazardous substances;

On the proposal of the Environment Committee:

I. DECIDES that Member countries shall ensure, through the legal and procedural means they deem appropriate, that the potentially affected public:

a) Is provided with specific information on the appropriate behaviour and safety measures they should adopt in the event of an accident involving hazardous substances;

b) Is provided with general information on the nature, extent and potential off-site effects on human health or the environment, including property, of possible major accidents at a planned or existing hazardous installation[2]; and

c) Has access to such other available information needed to understand the nature of the possible effects of an accident (such as information on hazardous substances capable of

causing serious off-site damage) and to be able to contribute effectively, as appropriate, to decisions concerning hazardous installations and the development of community emergency preparedness plans.

II. **RECOMMENDS** that Member countries take action to facilitate, as appropriate, opportunities for the public to comment prior to decisions being made by public authorities concerning siting and licensing of hazardous installations and the development of community emergency preparedness plans.

III. **RECOMMENDS** that, in implementing this Decision-Recommendation, Member countries take into account the Guiding Principles set out in the Appendix.

IV. **INSTRUCTS** the Environment Committee to review, within three years, actions taken by Member countries in pursuance of this Decision-Recommendation.

APPENDIX

GUIDING PRINCIPLES ON PROVISION OF INFORMATION TO THE PUBLIC AND PUBLIC PARTICIPATION IN DECISION-MAKING PROCESSES RELATED TO THE PREVENTION OF, AND RESPONSE TO, ACCIDENTS INVOLVING HAZARDOUS SUBSTANCES

I. General Principles

1. The following Guiding Principles are designed to facilitate the implementation by Member countries of programmes and policies to ensure that the potentially affected public is well informed about existing or planned hazardous installations and to facilitate the opportunities for the public to provide input, as appropriate, into decision-making by public authorities concerning such installations. These Principles do not prejudice public authorities from instituting more extensive requirements related to provision of information to the public or public participation.

2. These Guiding Principles relate to such hazardous installations defined under applicable law as being capable of giving rise to hazards sufficient to warrant the taking of precautions off-site, excluding nuclear or military installations.

3. These Guiding Principles focus on objectives to be achieved with respect to provision of information to the public and public participation, and not on the procedural approaches which should be followed. It is recognized that Member countries allocate responsibility differently between the public and private sectors and among national, regional and local governments and that Member countries have differing legal and administrative frameworks with regard to prevention of accidents and development of community emergency plans.

4. In implementing this Decision-Recommendation, Member countries should give consideration to the protection of confidential information, as defined under domestic law, including both proprietary data and information protected for reasons of national security.

II. Division of Responsibilities

5. Industry and public authorities each have responsibilities to the public concerning prevention of, and response to, accidents involving hazardous substances.

6. Industry is a primary source of that information which should be made publicly available. It therefore has a responsibility to provide this information to public authorities and, directly or indirectly, to the public. Industry should be prepared to work with the authorities which develop community emergency plans.

7. Public authorities have the responsibility of ensuring that adequate and timely information is provided to the potentially affected public and that appropriate opportunities are available for public participation in certain decision-making processes. Public authorities also have the responsibility of ensuring that adequate community emergency plans are in effect.

III. Provision of Information to the Public

Information to be Provided without Request

8. Those members of the public who might be affected were an accident to occur should be provided with certain information, without request, so that they will be aware of the hazards arising from the installation and will be able to respond appropriately should an accident occur.

9. This information should include specific guidance related to public response in the event of an accident, such as:

- Details on how the potentially affected public will be warned in the event of an accident;
- Details of the actions and behaviour the potentially affected public should take in the event of an accident; and

- The source of post-accident information (e.g., radio or television frequencies).

It should clearly be indicated therein that the information should be read immediately and be kept in a convenient place for reference in the event of an accident.

10. The guidance on what to do in the event of an accident should be adapted to meet the needs of groups of sensitive persons, for example in schools, hospitals and homes for aged people.

11. The following information should also be provided, without request, to the potentially affected public:

- The name of the operator of the installation and the address of the installation;
- The common names or, if more appropriate, the generic names or the general danger classification of the substances involved at the installation which could give rise to an accident capable of causing serious off-site damage, with an indication of their principal harmful characteristics;
- General information relating to the nature of the hazards of accidents capable of causing serious off-site damage, as well as their potential effects on human health and the environment, including property; and
- Details of how further explanatory information can be obtained.

12. The information described in paragraphs 9 and 11 should be comprehensible to the general public and be provided in a format which is easily read and understood.

13. This information should be provided in a timely fashion, be reissued periodically as appropriate, and be updated as necessary.

14. The potentially affected public should also be provided with notification of applications for siting or licensing of a hazardous installation. Decisions concerning such applications should also be publicised.

15. In those cases in which a hazardous installation is located in a frontier region and the country of such installation has transmitted to the other country information referred to above in paragraphs 9 and 11, the country receiving this information should ensure that such information is provided to all persons within its jurisdiction potentially affected in the event of an accident.

16. Arrangements should be made, before an accident, for the timely transmission of information to the public and the media in the case of an accident in order to mitigate adverse effects and to allay unjustified fears.

Information Available upon Request

17. The public should have access, upon request, to certain additional information to allow it to understand the nature of the hazards arising from hazardous installations, understand the reasons for guidance provided, and participate effectively in decision-making processes, as appropriate. Such information would include, for example:

- Any information concerning the hazardous installation which has previously been made publicly available by the installation or public authorities (as appropriate, licenses, environmental impact assessments, operating permits, safety reports, hearing documents);
- A general description of the types of activities undertaken at the installation;
- Additional guidance concerning actions to be taken by the public to protect human health and the environment, including property, in case of an accident and the reasons for such guidance; and
- Other information necessary for effective participation in decision-making, as appropriate.

IV. Public Participation

18. Whenever possible and appropriate, the potentially affected public should be given the opportunity to participate, by providing their views and concerns, when decisions related to siting and licensing of hazardous installations and the development of community emergency plans are being made by public authorities.

19. In all cases, adequate information about the opportunity to participate should be given.

20. As appropriate, a variety of mechanisms for public participation in decision-making processes can be used. These mechanisms can include those for direct public participation, such as open public hearings, and those for indirect public participation by means of, for example, open consultative procedures.

21. In some Member countries, local safety committees have been established with representatives of the installation, local authorities and local residents which, *inter alia*, facilitate the flow of information from the installation to persons who live and work in the area and co-ordinate local participation in appropriate decision-making processes.

22. The mechanisms for public participation and the scope of participation should be adapted to the nature of the decision being made and to who may be affected by the decision, while taking account of applicable law and practice.

23. In determining who should be given the opportunity to participate in decision-making processes, public authorities should consider which persons are seriously threatened by a potential accident and the nature of the decision being made. For example, in the case of the development of a community emergency preparedness plan, the local community near the hazardous installation might have the opportunity to participate. In the case of a siting decision for an installation which could have serious adverse effects on a watershed, national park or natural resources of more than local concern, provision might be made for broader participation, for example by allowing comments by representatives of public-interest organisations (e.g., environmental, agricultural or forestry groups).

24. Providing an opportunity for public participation should not affect the ultimate responsibilities of the public authorities with respect to decision-making in this area.

---

[2] The definition of "hazardous installation" for purposes of this Decision-Recommendation is set out in paragraph 2 of the Appendix.

Adherents*

OECD Members	Non-Members	Other
Austria		
Belgium		
Canada		
Chile		
Czech Republic		
Denmark		
Estonia		
Finland		
France		
Germany		
Greece		
Hungary		
Iceland		
Ireland		
Israel		
Italy		
Japan		
Korea		
Latvia		
Lithuania		
Luxembourg		
Mexico		
Netherlands		
New Zealand		
Norway		
Poland		
Portugal		
Slovak Republic		
Slovenia		
Spain		
Sweden		
Switzerland		
Turkey		
United Kingdom		
United States		

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision of the Council on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage*, OECD/LEGAL/0240

Series: OECD Legal Instruments

Date(s)

Adopted on 08/07/1988

Background Information

The Decision on the Exchange of Information concerning Accidents Capable of Causing Transfrontier Damage was adopted by the OECD Council on 8 July 1988 on the proposal of the Environment Committee. The Decision recognises that increased cooperation between Adherents is needed to address problems arising from the location of hazardous installations in their frontier regions. Hence, under this instrument, Adherents have a duty to exchange information and consult one another with the objective of preventing accidents capable of causing transfrontier damage. Hazardous installations are defined as those which contain more than a threshold quantity of any of the hazardous substances mentioned in Appendix III of this Decision. The Decision only refers to exchanging information amongst Adherents who border one another.

THE COUNCIL,

HAVING REGARD to Article 5 a) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to paragraph 3 of Article 6 of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendations of the Council of 14 November 1974 on Principles Concerning Transfrontier Pollution, of 11 May 1976 on Equal Right of Access in Relation to Transfrontier Pollution, of 17 May 1977 for the Implementation of a Regime of Equal Right of Access and Non-Discrimination in Relation to Transfrontier Pollution, and of 21 September 1978 for Strengthening International Co-operation on Environmental Protection in Frontier Regions [C(74)224, C(76)55(Final), C(77)28(Final), C(78)77(Final)];

HAVING REGARD to the Recommendations of the Council of 26 July 1983 concerning the Exchange of Confidential Data on Chemicals and concerning the OECD List of Non-Confidential Data on Chemicals [C(83)97(Final), C(83)98(Final)];

HAVING REGARD to the Declaration on “Environment: Resource for the Future” adopted by the Governments of OECD Member countries and of Yugoslavia at the session of the Environment Committee at Ministerial Level on 20 June 1985 stating that "they will ensure the existence of appropriate measures to control potentially hazardous installations, including measures to prevent accidents”;

HAVING REGARD to the Conclusions adopted by the Third High-Level Meeting of the Chemicals Group on 17-18 March 1987 regarding the prevention of, and response to, unintended releases of hazardous substances in the environment;

CONSIDERING that certain hazardous installations are likely to cause serious damage to human health and the environment in the event of a major accident;

CONSIDERING that it is necessary to promote new measures for the prevention of accidents involving hazardous substances and for limiting the adverse consequences of such accidents;

CONSIDERING the need to ensure that frontiers between Member countries do not constitute an obstacle to the transmission of information needed in order to protect human health and the environment in the event of accidents capable of causing transfrontier damage;

CONSIDERING that increased co-operation between Member countries should help to address the international problems which can arise with hazardous installations located in their frontier regions;

On the proposal of the Environment Committee:

DECIDES:

1. Member Countries concerned shall exchange information and consult one another, on a reciprocal basis if so desired, with the objective of preventing accidents capable of causing transfrontier damage and reducing damage should such an accident occur.

2. Member countries shall take all necessary practical steps to implement, on a reciprocal basis if so desired, the provisions set out in Appendix I to this Decision, which is an integral part of this Decision, including, as need be, to conclude arrangements or agreements aimed at specifying procedures for exchanging information relating to accidents capable of causing transfrontier damage.

3. Definitions of terms used in this Decision are given in Appendix II, which is integral part of this Decision.

4. The Environment Committee will examine, within three years, actions taken by Member countries pursuant to this Decision.

5. The Environment Committee will review Appendix III, which is an integral part of this Decision, within three years and will propose, as need be, a revised minimum list for the identification of hazardous installations.

APPENDIX I

PROVISIONS RELATING TO THE EXCHANGE OF INFORMATION

Title A. Exchange of Information on Hazardous Installations

1. Countries concerned shall exchange relevant information for the prevention of, and the response to, accidents at hazardous installations. To this end, the country of the installation shall provide to the exposed country relevant information concerning existing or planned hazardous installations located in the area under its national jurisdiction and capable of causing transfrontier damage in the event of an accident, and the exposed country shall provide to the country of the installation relevant information concerning the area under its jurisdiction capable of being affected by such transfrontier damage.

2. Relevant information supplied by the country of the installation shall include the following information in so far as it is available in accordance with domestic law to the public authorities of the country of the installation:

a) Location and general description of the hazardous installation capable of causing transfrontier damage;

b) Common chemical names or, if more appropriate, the generic names or general danger classifications of the main hazardous substances which may cause transfrontier damage in the event of a major accident;

c) The legislative, regulatory and administrative requirements, including any conditions imposed by the licensing authorities, under which the installation operates;

d) General information concerning the nature, extent and likely effects off-site of a major accident on human health or the environment, including property; and

e) Information on the off-site emergency plan relevant to the exposed country.

3. Relevant information supplied by the exposed country relating to the area under its national jurisdiction capable of being affected by transfrontier damage in the event of an accident at the hazardous installation shall include the following information, in so far as it is available in accordance with domestic law to the public authorities of the exposed country:

a) Distribution of the population, including sensitive groups;

b) Location and general description of pertinent properties and activities which could be adversely affected; and

c) Location of natural resources, protected areas, sensitive ecosystems and historical monuments which could be damaged.

4. The countries concerned shall consult one another in case of difficulties in the identification of those hazardous installations under their respective national jurisdictions which shall be subject to an exchange of information.

Title B. Proposals for a Hazardous Installation

5. Where a Member country, through any forum or by any process to which the public has access and through which it can make representations, determines any human health or environmental risks which may be posed by an accident at a proposed hazardous installation or where a Member country requires the completion of a study concerning the impact on human health or the

environment of a proposed hazardous installation in the event of an accident, it shall transmit to an exposed country any conclusions of the enquiry or of the study which it makes available to the public and shall implement the procedures described in Title A above.

6. Where the country of the installation has transmitted to the exposed countries the conclusions referred to in paragraph 5 above, it shall allow a reasonable amount of time for consultations with the exposed countries prior to implementing the proposal for a hazardous installation.

7. Where a Member country convenes or holds, as part of existing procedures, a meeting, enquiry, hearing or session of a tribunal, at which a decision is to be taken or an advice given on the establishment of a hazardous installation, it shall provide the exposed countries with the venues and dates of such a meeting, enquiry, hearing or session at which the proposed hazardous installation will be considered.

8. The country of the installation shall transmit to the exposed countries a copy of the documents concerning any proposal for a hazardous installation which are made available to the public in the country of the installation in accordance with its domestic law.

Title C. Organisation of Emergency Measures

9. The countries concerned shall consult one another with a view to co-ordinating the off-site emergency plans relating to a hazardous installation capable of causing transfrontier damage. They shall inform one another of the communication systems to be used, the main features of their emergency plans and the means available for emergency response in the event of an accident capable of causing transfrontier damage.

10. The countries concerned shall inform one another of the instructions given to their respective populations on how to respond in the event of an accident capable of causing transfrontier damage and on any evacuation or protection measures to be taken in the event of such an accident or imminent threat of such an accident.

Title D. Transmission of the Emergency Warnings

11. In the event of an accident or imminent threat of an accident capable of causing transfrontier damage, the country of the installation shall immediately transmit an emergency warning to the exposed countries.

Title E. Organisation of the Subsequent Transmission of Information Relating to the Accident

12. In the absence of an agreed system for transmitting information relating to an accident, the country of the installation shall communicate to the authorities responsible for receiving emergency warnings in the exposed countries appropriate information relating to the accident or imminent threat of an accident.

13. The countries concerned shall draw up, as need be, procedures and practical arrangements for rapid and effective transmission of information relating to an accident or to the imminent threat of an accident capable of causing transfrontier damage, and they shall set up, as need be, systems for communication of pertinent information following an accident. The information to be transmitted shall include:

a) Accident location and brief description of the circumstances;

b) Immediate effects of the accident;

c) Emergency measures planned and actions taken;

d) Chemical identity, quantity and physical form of the hazardous substances which may affect an exposed country; and

e) Data available for evaluating the probable impact of the accident in an exposed country.

Title F. Confidentiality

14. The obligations of the countries concerned to transmit the relevant information referred to above shall be subject to the limitations of their domestic law concerning the protection of confidential information, including both proprietary data and information protected for reasons of national security.

15. The receiving country shall respect the confidentiality of the information received. It shall not make available to its public information that is not made available to the public in the country supplying it.

16. The information supplied in the framework of the implementation of this Decision may be used only for assessing the nature and extent of the potential transfrontier damage and for reducing the consequences of an accident beyond the frontier or for coping with the imminent threat of an accident capable of causing transfrontier damage.

Title G. Identification of Competent Authorities

17. The countries concerned shall notify one another of the identity and details of the following:

a) National, regional and/or local authorities responsible for transmitting or receiving the relevant information referred to in paragraphs 2 and 3 above;

b) Authorities responsible for implementing the off-site emergency plans referred to in paragraphs 9 and 10 above; and

c) Authorities responsible for transmitting and receiving the emergency warnings referred to in paragraph 11 above at national, regional and/or local levels.

Title H. Information from other Sources

18. The above provisions shall not prejudice the direct transmission of information by the operator of a hazardous installation to the authorities or to the public in the exposed countries with the objective of preventing accidents in the hazardous installation or reducing transfrontier damage should an accident occur.

Title I. Strengthening International Co-operation

19. The countries concerned shall co-operate in ensuring that persons in the exposed country who might be affected by an accident in the country of the installation receive the same information that is provided to persons who might be affected in the country of the installation.

20. The above provisions shall be taken into account by Member countries when preparing agreements or arrangements with non-member countries on the subject area covered by this Decision.

21. The above provisions shall not prejudice the organisation of wider exchanges of information or consultations between the countries concerned with the objective of preventing accidents involving hazardous substances and reducing transfrontier damage should an accident occur; nor shall it prejudice the conclusion of subsequent agreements intended to specify the scope and extent of the exchanges of information provided for under this Decision.

APPENDIX II

DEFINITIONS

For the purpose of this Decision,

a) "Hazardous installation" means an industrial installation which contains more than the threshold quantity of any of the hazardous substances mentioned in Appendix III and in which are used, stored or produced such hazardous substances which are capable, in the

event of an accident, of causing serious damage to human health or the environment, including property, outside the installation site, with the exclusion of military or nuclear installations;

b) "Proposal for a hazardous installation" means any proposal made to a competent authority to set up a new hazardous installation and any proposal involving substantial modification of an existing hazardous installation;

c) "Accident" means any occurrence involving a hazardous substance such as a major emission, fire or explosion at a hazardous installation leading to serious damage to human health or the environment, including property;

d) "Hazardous substance" means any substance which is capable of causing serious damage to human health or the environment, including property, in the event of an accident in a hazardous installation and which is identified in Appendix III;

e) "Transfrontier damage" means any serious damage to human health or the environment, including property, suffered by an exposed country in the event of an accident and, in general, by the country of the accident;

f) "Sensitive group" means any group of persons particularly sensitive to the consequences of an accident as a result of their age, health conditions or way of life;

g) "Country of the installation" means any Member country within whose jurisdiction there is a hazardous installation or a proposal for a hazardous installation;

h) "Exposed country" means any Member country other than the country of the installation which suffers serious damage as a result of an accident, or which is capable of being affected by such damage in an area under its national jurisdiction;

i) "Countries concerned" means the country of the installation and the exposed country or countries.

APPENDIX III

THRESHOLD QUANTITIES OF HAZARDOUS SUBSTANCES

Hazardous Substances / Threshold quantity (tonnes)

1. Flammable, explosive or oxidizing substances:

Flammable gases

including liquified flammable gases[1] / 200

Highly flammable liquids[2] / 50 000

Ethylene oxide / 50

Sodium chlorate / 250

Ammonium nitrate / 2 500

2. Substances toxic to man and/or the environment:

Ammonia / 500

Chlorine / 25

Hydrogen cyanide / 20

Hydrogen fluoride / 50

Methyl isocyanate / 0.15

Sulphur dioxide / 250

Acrylonitrile / 200

Hydrogen sulphide / 50

Phosgene / 0.75

Methylbromide / 200

Tetraethyl lead / 50

Disulfoton / 0.1

Parathion / 0.1

Warfarin / 0.1

Aldicarb / 0.1

The hazardous substances and threshold quantities mentioned above are without prejudice to those used in more extensive lists of hazardous installations developed in a national or international context.

---

[1] Flammable gases: substances which in the gaseous state at normal pressure and mixed with air become flammable and the boiling point of which at normal pressure is 20° C or below.

[2] Highly flammable liquids: substances which have a flash point lower than 21° C and the boiling point of which at normal pressure is above 20° C.

Adherents*

OECD Members	Non-Members	Other
Austria		
Belgium		
Canada		
Chile		
Czech Republic		
Denmark		
Estonia		
Finland		
France		
Germany		
Greece		
Hungary		
Iceland		
Ireland		
Israel		
Italy		
Japan		
Korea		
Latvia		
Lithuania		
Luxembourg		
Mexico		
Netherlands		
New Zealand		
Norway		
Poland		
Portugal		
Slovak Republic		
Slovenia		
Spain		
Sweden		
Switzerland		
Turkey		
United Kingdom		
United States		

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals* , OECD/LEGAL/0232

Series: OECD Legal Instruments

Date(s)

Adopted on 26/06/1987

Background Information

The Decision-Recommendation on the Systematic Investigation of Existing Chemicals was adopted by the OECD Council on 26 June 1987 on the proposal of the Third High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), as approved by the Environment Committee. This instrument aims to address the need for shared and co-ordinated efforts among Adherents in order to efficiently and effectively protect man and the environment from the potential hazards of existing chemicals. Hence, this instrument requires that Adherents establish or strengthen national programmes to systematically investigate existing chemicals in order to identify those which need to be managed.

THE COUNCIL,

HAVING REGARD to Articles 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 7 July 1977, establishing Guidelines in respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the conclusions concerning the control of existing chemicals reached at the First and Second High-Level Meetings of the Chemicals Group of 12 May 1980 and 15 November 1982;

HAVING REGARD to the Recommendation of the Council of 26 July 1983, concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to point 6 of the Declaration on Environment: Resource for the Future, of 20 June 1985 adopted by the governments of OECD Member countries and of Yugoslavia that more effective control of both new and existing chemicals from their manufacture to ultimate disposal will be achieved through shared and co-ordinated efforts;

CONSIDERING that, although different kinds of work on existing chemicals are undertaken in Member countries, most existing chemicals have not been subjected to a systematic investigation of their potential hazards to man and the environment and that, for a large number of these chemicals, the available information is not adequate to undertake such an investigation;

CONSIDERING the need to establish the management and control of existing chemicals on a more anticipatory and systematic basis, whereby those existing chemicals which may pose an as yet unrecognised threat to man and the environment can be identified, assessed and, if necessary, controlled;

CONSIDERING the large scale and complexity of efforts required to ensure adequate control of existing chemicals and the limited resources available in Member countries for this purpose;

CONSIDERING, therefore, the need for shared and co-ordinated efforts among Member countries in order to efficiently and effectively protect man and the environment from the potential hazards of existing chemicals;

On the proposal of the Third High-Level Meeting of the Chemicals Group, as approved by the Environment Committee:

I. **DECIDES** that Member countries shall establish or strengthen national programmes to systematically investigate existing chemicals[1], in order to identify those which need to be managed and/or controlled.

II. **RECOMMENDS** that Member countries:

1. When investigating existing chemicals systematically, take into account the principles and technical guidance summarised in Annex I entitled Chemicals on which Data are Currently Inadequate: Selection Criteria for Health and Environment Purposes, which is an integral part of this Act;

2. When reviewing the information on an existing chemical for any of the various purposes associated with its systematic investigation, take into account Annex II entitled, Guidelines for Preparing Chemicals Reviews, which is an integral part of this Act;

3. Establish the means to collect, estimate or generate the information needed for a systematic investigation of existing chemicals;

4. Provide, to the extent possible and in accordance with existing OECD Council Acts on chemicals, the available information on an existing chemical when requested by another Member country for the purpose of investigating that chemical and that they establish mechanisms for such information exchange.

III. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in implementing this Decision-Recommendation and to pursue a programme of work designed: a) to facilitate such implementation; and b) to assist Member countries to co-operate in systematically investigating existing chemicals.

ANNEX I

CHEMICALS ON WHICH DATA ARE CURRENTLY INADEQUATE: SELECTION CRITERIA FOR HEALTH AND ENVIRONMENTAL PURPOSES

I. Introduction

1. Since the resources needed to satisfactorily and expediently identify all of the existing chemicals which may pose as yet unrecognised threats to human health or the environment are limited, it is necessary to develop mechanisms for selecting existing chemicals and establishing priorities among them for further study. In response to this need, the Management Committee of the Special Programme on the Control of Chemicals established two Expert Groups in 1982 to develop Selection Criteria for Health and Environmental Purposes to assist Member countries in identifying these existing chemicals.

2. The Expert Groups identified and analysed:

a) **Selection Elements** which could be used individually or in combination to select chemicals in need of further information development for health or environmental purposes;

b) **Priority Setting Processes** to weigh, combine and assemble Selection Elements in order to produce management tools for the systematic selection of chemicals;

c) **Data sources**, including major inventories and compilations, where information might be found which could be of use in that context.

3. This Annex summarises the sections of the Final Reports of the Expert Groups relating to Selection Elements and Priority Setting Processes which provide technical guidance in the development and use of the Priority Setting Processes to select chemicals for further study of their potential effects on human health and the environment. Those sections, and a compilation of data sources for existing chemicals, will be found in the complete Expert Groups Report, *Existing Chemicals: Systematic Investigation - Priority Setting and Chemicals Reviews* (OECD, 1986).

II. Selection Elements

4. Selection Elements include both the parameters and characteristics of a chemical; its use (from manufacture to disposal) and occurrence; and the characteristics of exposed human populations or ecosystems.

5. A number of exposure- and effects-related Selection Elements are identified, including both primary exposure and effects parameters and surrogates which can be used to estimate these parameters when such substitute information is more readily available. An example of a surrogate Selection Element would be production volume, which can be used to estimate potential exposure.

6. Although they are presently limited in scope, qualitative or quantitative structure-activity relationships (SAR) or techniques and other techniques, such as property-property correlations, for estimating some of the following exposure- and effects-related Selection Elements can play an important role in the processing of large numbers of chemicals for which little if any data are available.

The approach most commonly used at present is qualitative. It involves the examination of a chemical's structure and the use of expert knowledge and suitable compilations of data. Since a quantitative approach involves analysis of relatively large numerical data bases for chemicals and specific effects, its applicability is presently limited to a few types of health and environmental effects and, even for these, is still undergoing development. Expert judgement is necessary in applying these techniques since a full understanding of their assumptions and limitations as well as their implications for the selection of chemicals is required.

Exposure-related Selection Elements

7. The exposure-related Selection Elements are divided into three groups. Those especially relevant for each group are the following:

a) Workplace Exposure:[2]

- Production and import volume/industrial use volume;
- Industrial use patterns;
- Physical-chemical characteristics;
- In-plant operating conditions and activities;
- Route of exposure;
- Extent of exposure;
- Characteristics of the exposed worker population.

b) General Population Exposure:[3]

- Production and import volume/volume in commerce;
- Use patterns;
- Release to the environment;
- Physical-chemical characteristics (including physical form and matrix);
- Environmental fate;
- Characteristics of the exposed population;
- Monitoring information.

c) Environmental Exposure:

- Detection in the environment;
- Release potential to the environment, including:

  i) Production and import volume/consumption volume;

  ii) Environmental release during manufacture and processing;

  iii) Use patterns;

  iv) Mode of waste disposal.

- Environmental fate, including:

  i) Environmental distribution;

  ii) Transformation/degradation;

iii) Bioaccumulation.

Effects-related Selection Elements

8. The effects-related Selection Elements are divided into two groups. Those especially relevant for each group are the following:

a) Health Effects:

- Mutagenic effects;
- Carcinogenic effects;
- Embryotoxic and teratogenic effects;
- Effects on reproduction;
- General toxicity and specific organ effects, including:

  i) Effects on the immune system;

  ii) Neurotoxic effects;

  iii) Irritation of eye, skin and mucous membranes.

b) Environmental Effects:

- Effects on aquatic ecosystems;
- Effects on terrestrial ecosystems;
- Effects on other target systems, including:

  i) Function of biological sewage treatment systems;

  ii) Atmospheric changes.

For each Selection Element, the following aspects are presented:

- A short description;
- Relevant primary and surrogate information and/or data related to the Selection Element;
- Applicability and use of the Selection Element in the priority setting process;
- Scope, strengths and weaknesses, as well as assumptions and limitations associated with its use;
- Data availability.

III. Priority Setting for Health or Environmental Purposes

9. The two priority setting processes, one for health and the other for environmental purposes, describe how the relevant Selection Elements can be applied individually or in combination to select those chemicals that most urgently need further information development. They have similar overall structures characterised by flexibility sufficient to assist in the design and conduct of various selection exercises, taking into account differing specific purposes, national needs and priorities and varying availability of information and resources. Under certain circumstances, they may be combined in the same process.

Aspects Common to Both Processes

10. Identifying the purpose and scope of a priority setting exercise is of paramount importance since they may influence the approaches to inclusion or exclusion of chemicals in or from the exercise, the choice of Selection Elements, and other practical considerations. Clarification of scope and purpose may entail the defining of practical constraints under which the process is undertaken, legislative/administrative considerations, and scientific/technical considerations. Such definition would involve the determination of factors such as the time in which the results are required; availability of resources; national priorities, regulatory requirements and policies; effect(s) of interest (e.g. carcinogenicity, toxicity for aquatic organisms); and specific broad category(ies) of chemicals of interest (e.g. chemicals in food, chemicals found at a waste disposal site).

11. To reduce to a manageable number the chemicals under consideration about which further information may be sought, a four-stage process (**Compilation, Screening, Refinement** and **Review**) is recommended.

12. The quantity and complexity of the information needed, as well as the resources used to process each chemical, increase from the Compilation Stage to the Review Stage, so that the optimum use of resources for retrieving and evaluating the information is ensured. The information most readily available (e.g. least expensive or time-consuming to obtain) is used in the early stages, when the largest number of chemicals is being dealt with. In the later stages, when the number of chemicals involved is considerably smaller, data acquisition can be more comprehensive (and expensive) based on, e.g., in-depth literature searches. Information used at the Screening Stage could, for instance, be obtained primarily from the tertiary literature, machine-readable data bases and SAR, whereas that used at the Refinement Stage could come largely from medium-depth information searches. In the initial stages, care must be taken not to miss chemicals of concern (i.e. to limit the number of false negatives). In the Review Stage, on the other hand, the selection of chemicals should be much more specific, i.e. only chemicals which are of high concern should be selected (thus limiting the number of false positives). It is important at this stage that the quality of the data used throughout the process be evaluated and the "concern" for a chemical be adjusted as appropriate.

13. Although the two processes allow flexibility in the choice and application of Selection Elements at the different stages, in both it is recommended that data on exposure- and effects-related Selection Elements be used in combination. It is also recognised that information on only one type of Selection Element may be sufficient to move a chemical to the next stage. In neither process is the combining of priorities, or degrees of concern for different types of toxic responses, recommended. Instead, an output matrix is proposed which sets out priorities by types of specific toxic responses, specific target organisms, specific exposure situations or media, and/or information needs. By treating concerns and priorities in this way, those areas in which efforts would be best concentrated for further information gathering can be identified.

14. When a selection exercise has been completed, the main output is the group of "selected priority chemicals" from the Review Stage (Figure 1). But at both the Screening and Refinement Stages another group of so-called "incompletely processed/standby chemicals" is identified about which information sufficient for processing is lacking at that selection stage (Figure 1). These chemicals, too, are associated with some degree of concern, depending on the amount of information characteristic of the selection stage at which they were produced. This category of chemicals for which data appear to be insufficient, and for which there is no method of estimating data so that they can be considered appropriately in the process, is an important one. Possible approaches are suggested for further processing of these chemicals through more extensive data gathering.

15. By-products of the selection exercise are groups of "non-selected/lower priority chemicals" and of "non-relevant chemicals" from the Screening, Refinement and Review Stages (Figure 1). These non-relevant chemicals are either outside the scope of the selection exercise, or they are chemicals for which data are adequate.

16. At no stage should the selection exercise be solely mechanical. There is a need throughout for expert judgement involving the use of techniques such as SAR and other methods to provide estimates of missing information when appropriate. Each of the two processes allows for the fact that information available on a chemical could be sufficient either to move it directly to the subsequent stages or to drop it from the ongoing selection exercise altogether (i.e. into the group of non-relevant chemicals). Moreover, initial stages of the process may be bypassed if the number of chemicals

involved is small enough to be handled with the resources available at a higher stage. The selection process should be repeated at intervals to reconsider chemicals not selected in previous exercises (including those previously designated as "non-relevant"), rectify possible errors, take into account new data and improve the selection methods. This is particularly important in that existing chemicals must be selected for further review on the basis of limited information. Consequently, some harmless chemicals are likely to be selected and some hazardous ones missed.

Aspects Specific to Each Process

17. The two priority setting processes differ primarily in the Selection Elements chosen for use, and in the ways they are used and/or combined with other Selection Elements at each stage.

Priority Setting for Health Purposes

18. The process of selecting chemicals on the basis of their potential to cause adverse health effects begins at the **Compilation Stage** designed to compile the list of chemicals to be subjected to the selection process. Various approaches to the inclusion of chemicals on the candidate list (or their exclusion therefrom) are described which may require the use of expert judgement. These approaches are based on production/import volume data, chemical analogy, selected physical chemical properties, monitoring data, spill statistics, effects-monitoring data and case-by-case nominations. The information needed for these approaches can be obtained from national inventories, industry and trade data, lists of chemicals for toxic effects, and lists of chemicals found in the workplace, environment, etc.

19. At the **Screening Stage**, chemicals from the candidate list are selected for further processing. Chemicals are identified about which information is insufficient for an evaluation to be made. Readily available information is used for Selection Elements related to workplace or general population exposure (e.g. production and import volume; volume in commerce; use patterns) and/or to relevant health effects (e.g. lethal acute dose; mutagenicity). The Selection Elements for which data are best estimated by SAR are most useful at this stage. Combining information on exposure and effects is recommended when establishing broad categories of concern. Thus, health effects could be described as "likely" or "unlikely" without specifying the type of effect. Volume and use-pattern information could be broadly categorised ("high" or "low") in relation to the level, frequency and duration of exposure, and the size of the exposed population.

20. At the **Refinement Stage**, the Selection Elements already applied at the Screening Stage are used more critically and in greater detail, possibly together with some additional ones, to further define the potential concern for chemicals selected at the Screening Stage. Data on exposure-related Selection Elements are used to give a more precise estimate of the level, frequency and duration of exposure and to identify relevant target population groups (size and composition). There are cases in which total exposure to a chemical is significantly greater than exposure derived from either general population or workplace considerations alone, or in which the priority setting exercise includes considerations of total exposure. In such cases it may be necessary to evaluate human exposure in an integrated way by the combined use of all the relevant exposure-related Selection Elements. Data on health effects-related Selection Elements are used to evaluate concern for specific types of effect(s). Estimates concerning exposures and specific types of effect(s) can then be integrated. Scoring approaches may be used at this stage. The chemicals selected for the Review Stage are listed in an "output matrix" which sets out priorities concerning the potential for specific toxic responses determined in combination with more detailed exposure considerations and/or priorities for further information needs.

21. At the **Review Stage** the quality or adequacy of the data used to select a chemical is evaluated and an attempt is made to specifically identify health effects or exposure data which are needed to establish priorities. Specific methods are not described; rather, data acquisition and evaluation on a case-by-case basis is recommended.

Priority Setting for Environmental Purposes

22. The process of selecting chemicals on the basis of their potential for adverse environmental effects begins with the identification of "chemicals of interest" from the universe of chemicals. Those chemicals which are non-relevant for administrative/legal or technical/scientific reasons are excluded.

When the number of chemicals is larger than can be handled at the Screening Stage, they are reviewed at the **Compilation Stage** using three broad groups of Selection Elements related to potential exposure of the environment, detection in the environment and potential effects on the environment. Selection is based on expert judgement and on information contained in existing lists of chemicals related to one or more of these three groups of Selection Elements. Thus, only minimal data collection takes place at this stage.

23. At the **Screening Stage**, the potential of each chemical for environmental exposure and effects is assessed. Exposure potential is estimated on the basis of the release potential of the chemical to the environment, its detection in the environment, or its persistence and/or bioaccumulation. Effects potential is the potential for any adverse effect on any aquatic or terrestrial species. Without recommending a standard procedure for estimating these potential effects, the relevant Selection Elements and considerations related to their use are described. Exposure and effects potentials can be categorised into broad classes of concern (e.g. "high/low" or "high/medium/low"). Chemicals can be selected by choosing cut-off values for certain Selection Elements and considering exposure and general effects potentials in an integrated way.

24. At the **Refinement Stage**, the number of chemicals is further reduced through more sophisticated consideration of exposure to, and effects on, target organisms in the environment. Information on all relevant Selection Elements is used to characterise the exposure pattern of a chemical in various media (air, water and soil) and to estimate its effect on specific target organisms. Each Selection Element for environmental effects should be considered separately at this stage and then combined with exposure estimates for relevant environmental media (target/media combinations). Scoring approaches may be used at this stage. For those chemicals selected for the Review Stage, the concern areas (e.g. aquatic organisms, terrestrial ecosystems, etc.) and important data gaps may be identified. A matrix is useful in relating chemicals with concern area(s) and corresponding data gaps.

25. The purpose of the **Review Stage**, which is similar to the priority setting process for health purposes, is to evaluate the quality of the data used to select a chemical so that it does not become a priority chemical on the basis of incorrect or incomplete information. The main difference between the Refinement Stage and the Review Stage is that data on a chemical are scrutinised more intensively, and on a case-by-case basis, in the latter.

IV. Data Sources

26. In order to provide some guidance in finding the information and/or data necessary to carry out the selection of priority existing chemicals for further development of information, the Report of the Expert Groups contains a Data Sources Section that includes:

i) A compilation of 195 handbooks and tables, 335 monographs, reports and other printed documents, and 54 computerised data bases;

ii) A compilation of many existing public sources of information on the use of industrial chemicals;

iii) A review of the principles used to compile the major available chemical inventories.

Figure 1 **FRAMEWORK FOR HEALTH AND ENVIRONMENTAL SELECTION PROCESSES**

(not available electronically)

ANNEX II

GUIDELINES FOR PREPARING CHEMICALS REVIEWS[4]

I. Introduction

1. Review documents and reports on chemicals differ widely in their purpose, format and content. The various reasons for preparing chemicals reviews include:

a) Identifying chemicals for further data development;

b) Reviewing a specific property of a chemical;

c) Supporting decisions to regulate or not to regulate chemicals.

Whatever the ultimate reason for preparing a chemicals review may be, it will generally involve some assessment of the potential hazard of the chemical concerned.

2. These Guidelines are intended to promote the consistent presentation of information in chemicals reviews, which will:

a) Facilitate international use and exchange of chemicals review documents;

b) Provide the reader with an indication of the amount of available information or the lack thereof;

c) Allow the reader to locate information of interest.

The exchange of reviews would avoid duplication of efforts, thereby conserving scarce resources.

3. While these Guidelines are aimed at achieving consistency, flexibility in their application is essential. Since chemicals reviews may be developed for a wide variety of purposes and reflect a broad range of information needs and availability, all reviews will not contain the same data elements. Whether certain data elements are included will also depend on the type of chemical under review.

4. A list of data elements for possible inclusion in chemicals reviews is found in paragraphs 9 through 21.

5. The Guidelines address the following points:

a) Elements to be considered in a chemicals review;

b) Quality of data;

c) Format of review documents.

II. Elements to Consider

6. Prior to the preparation of any review document, it is important to consider the potential hazard of the chemical in order to determine the amount of scrutiny which may be necessary. The selection of data elements to be included in a chemicals review depends upon this preliminary hazard assessment and the importance of the data elements relative to the specific purpose of the review. The depth at which properties of a chemical are reviewed also depends upon the degree of concern derived from the preliminary hazard assessment. Technical knowledge and sound scientific judgement are of importance both in selecting data elements and in determining the depth of the review.

7. A review process usually begins with the gathering of available information. In some cases, sufficient information is available for the preparation of a chemicals review. In other situations, gaps in information elements may be identified.

8. Since the broad dissemination of chemicals reviews is desirable, non-confidential data should be used to the greatest extent possible. Nonetheless, in certain situations the use of confidential data may be unavoidable. This will not necessarily preclude the exchange of review documents. The problems associated with the exchange of confidential information have been addressed by the OECD. Its work resulted in three Recommendations, adopted by the OECD Council in 1983, concerning:

- The Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];
- The Exchange of Confidential Data on Chemicals [C(83)97(Final)];
- The OECD List of Non-Confidential Data on Chemicals [C(83)98 (Final)].

These Recommendations should be taken into account when preparing and exchanging chemicals reviews.

III. Elements for Possible Inclusion in Chemicals Reviews

9. Data elements for possible inclusion in a chemicals review may be categorised in the following way:

Executive Summary

10. Under this heading would be included: the purpose of the review, a description of substance(s) reviewed, major findings and deficiencies, a general statement describing whether quality considerations were included, major conclusions, and recommendations (in the national language and a translation into English or French, as appropriate).

Chemical Identity

11. Under this heading would be found the constituent(s) of product(s) under review including:

a) Primary constituent:

- IUPAC-name (with indication of system used);
- Other names - common, (registered) trade, CAS-name;
- Empirical formula;
- Structural formula (where relevant, isomeric composition);
- CAS-number;
- Molecular weight;
- Spectral data.

b) Impurities (identity, range of percentage composition);

c) Additives (identity, range of percentage composition).

Physical and Chemical Properties

12. The data included here are those relevant for assessing exposure and effects, such as: physical state (including colour, smell, taste); melting and boiling points; vapour pressure; density; solubility in water and organic solvents; partition co-efficient (specifying solvents pairs used, e.g., n-octanol/water, oil/water, etc.); surface tension; reactivity (e.g. oxidising properties, flammability, explosive properties); soil absorption constant; dissociation constant; Henry's constant; volatility; particle size.

Analytical Methodology

13. Methods used,[5] including media and sampling procedures and preparations, would be given under this heading.

Exposure Data

14. The data to be included here are:

a) Those relevant for assessing exposure via the workplace, consumer products or the environment, such as:

- Natural occurence;
- Production volume and trends;
- Consumption, import, export;
- Production process types;
- Handling (including transportation) and distribution aspects;
- Plant releases during manufacture and processing;
- Waste disposal (including incineration);
- Use pattern (types of use, dispersiveness of use, exposed populations and special sub-populations, routes, frequency and duration of exposure).

b) Those relevant for assessing transport, distribution and transformation/degradation in the environment, such as:

- Transport and distribution between different media;
- Biotic and abiotic degradation;
- Bioaccumulation;
- Soil absorption constants;
- Interaction with other physical factors;
- Ultimate fate following use.

c) Those relevant for monitoring data, such as level in air, water, soil/sediments, plants, food, feed, working environment, domestic environment, biological samples and consumer products.

Effects on Experimental Animals and In Vitro Test Systems

15. Data to be included here are those relevant to assessing the metabolism and effects of the chemical, or the lack thereof, on animal and in vitro systems used to model human health, such as:

- Metabolism (absorption, distribution, metabolic transformation, elimination, and retention);
- Acute toxicity, short-term repeated dose toxicity, subchronic toxicity, chronic toxicity, allergenicity, embryotoxicity and teratogenicity, mutagenicity, carcinogenicity; effects on the reproductive system, immune system, nervous system, behaviour, cardiovascular system, hemapoietic system; effects on skin, eye and mucous membranes; organ-specific effects on gastrointestinal tract, kidney, liver, etc.; effect on cellular, sub-cellular and biochemical structures or processes (e.g. DNA damage, cell transformation, clastogenic alterations, enzyme inhibition, etc.); data related to synergistic phenomena or antagonistic effects; and other phenomena which modify the toxicity profile of the chemical (e.g. age, sex, nutritional status).

Effects on Man

16. Data included here are those obtained in observations from exposed persons which are relevant in a hazard evaluation:

a) Studies and observations of:

- Acute toxicity;
- Poisoning incidents;

- Subacute effects;
- Effects of longterm exposure.

b) Epidemiological studies of:

- General populations;
- Sub-populations (samples with reference to age, sex, occupational exposure).

Effects on the Environment

17. Data to be included here are those relevant for estimating the impact on the ecosystem and the bioaccumulation potential, such as toxicity to aquatic organisms, toxicity to terrestrial organisms, toxicity to micro-organisms, effects on ecological processes and biotransformation, population and ecosystem effects, and effects on the abiotic environment.

Other Pertinent Data

18. Data to be included here are those which are not relevant to any other heading but which may be of importance in a hazard evaluation, such as combustion products and transformation products from use or disposal techniques.

Current Regulations, Guidelines and Standards

19. Under this heading would be found: regulations, guidelines, and advice issued by relevant international or national bodies or by the manufacturers.

Hazard Assessment

20. Included here would be:

a) Assessment of exposure;

b) Assessment of health effects;

c) Assessment of environmental effects;

d) Overall assessment of hazards - human health and the environment, general population or ecosystem, special sub-populations or ecosystems (workers, etc., aquatic, terrestrial, etc.) or a more specific part of them (fish, birds, etc.);

e) Gaps in knowledge.

References

21. A list of sources of data consulted should also be included. Citations should give all information needed to identify and locate each reference.

IV. Quality of Data

22. Confidence in the quality of information used in preparing the review is fundamental to confidence in the conclusions of the review itself. Deficiencies in a certain investigation of a chemical do not preclude the use of that information, but they may reduce confidence in the use of such data for hazard assessment. Nonetheless, the reviewer is often faced with the task of making use of data partly derived from deficient studies.

23. Chemicals reviews are produced for different purposes, and consequently data quality requirements will vary depending on the user's needs. Data which are acceptable to one user under a specific set of conditions may not be acceptable under other circumstances.

24. It is important to inform the reader of the type of criteria and the purpose of the review when selecting, assessing, using and presenting the data. This can be accomplished in two ways: first, by a general statement describing whether quality considerations were included and, if so, the specific methods used to do so; second, by indicating in the report, as far as is practicable, the reasons for selecting key references and excluding others.

25. Assessment of data quality is a process which involves:

a) A review of individual data elements with respect to how the study was conducted and how the results were interpreted;

b) A critical selection (and rejection) of data in its proper context and in accordance with the purpose of the review.

26. Since any information related to toxicological effect or to exposure is potentially useful, general principles for quality assessment should be applied in the review process. Rather than telling the user how "good" or "bad" the data are, such principles should be used to assess the limitations of the data within the context of the user's specific needs.

27. In some cases certain studies (when compared with currently accepted, standardized guidelines) may be regarded as unacceptable. Nevertheless, it should be emphasized that in a specific context such studies contain information which, when viewed together with results from other studies, may be useful. This is particularly important with regard to highly specialised studies intended to resolve specific issues. In such situations, quality standards will be difficult to apply. Such information can be reviewed only on a case-by-case basis and in its proper context.

28. Sound scientific judgement acquired through experience cannot be superseded by any set of general rules for quality evaluation.

29. Current references should be used to assist the reviewer in determining standards for evaluating the quality of individual data elements. Such standards ought to be developed by experts in each individual discipline. In this regard, it should be noted that a great deal of progress has been made and that a number of references are available to guide the reviewer.

30. In evaluating the quality of data in a particular study, the reviewer should take into account other contemporary studies of similar design to that of the study under review. It is obvious that the reviewer cannot control the conduct of reported studies. Moreover, the information available to the reviewer is rarely sufficient to assess how well a study was conducted. On the other hand, serious deficiencies in description of design, procedures used for generating the data, and reporting of results may suggest that important aspects of the conduct of the study have been neglected. It is in this context that the reviewing of other contemporary studies of similar design is desirable.

31. If a study fails to meet modern requirements, it may still satisfy some less rigorous minimum requirements and be judged of sufficient quality to be useful in a review. For certain specific review purposes, it may therefore be useful to develop such minimum standards.

V. Format of Review Documents

32. The review document should begin with a brief executive summary highlighting the purpose of the review, a description of substances reviewed, major findings and deficiencies, a general statement describing whether quality considerations were included, and major conclusions and recommendations. At the end of the document there should be a list of sources of data consulted in the preparation of the review.

33. Closely related types of data can be grouped together in various ways to form separate data categories or information clusters. The data elements in the review should be presented in the sequence set out in paragraphs 9 through 21 above.

34. The review document should give information about the purpose for which it was prepared. Such information allows the reader to evaluate the relevance of the review to his particular needs.

35. The title, tables and diagrams contained in the review, as well as the executive summary, should be presented in one of the OECD languages, that is, in English or French.

36. It should be assumed that if a data element has not been included in the review, it has not been searched for. If a data element has been searched for and not found, this should be indicated. When data are searched for and found, but not included (e.g. for reasons of data quality, confidentiality or irrelevance), this should also be indicated.

---

[1] For purposes of the Decision-Recommendation, systematic investigation of existing chemicals may include the following steps: identification of relevant chemicals; priority-setting, including collection or estimation of information needed for the setting of priorities; generation of necessary further information, including testing; performance of hazard assessments.

[2] Monitoring information is discussed under General Population Exposure.

[3] Pathways of general population exposure may not only involve contact with a substance during its use, but may also arise from contact with contaminated environmental or natural sources within the environment. Guidance in estimating the route and extent of general population exposure is included (as appropriate) in the Selection Elements listed. Route and extent of exposure have not, therefore, been developed as specific Selection Elements.

[4] These Guidelines have been harmonised with the recommended format for environmental Health Criteria Documents of the International Programme for Chemical Safety.

[5] It will sometimes be preferable to indicate the source where a full description will be found.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

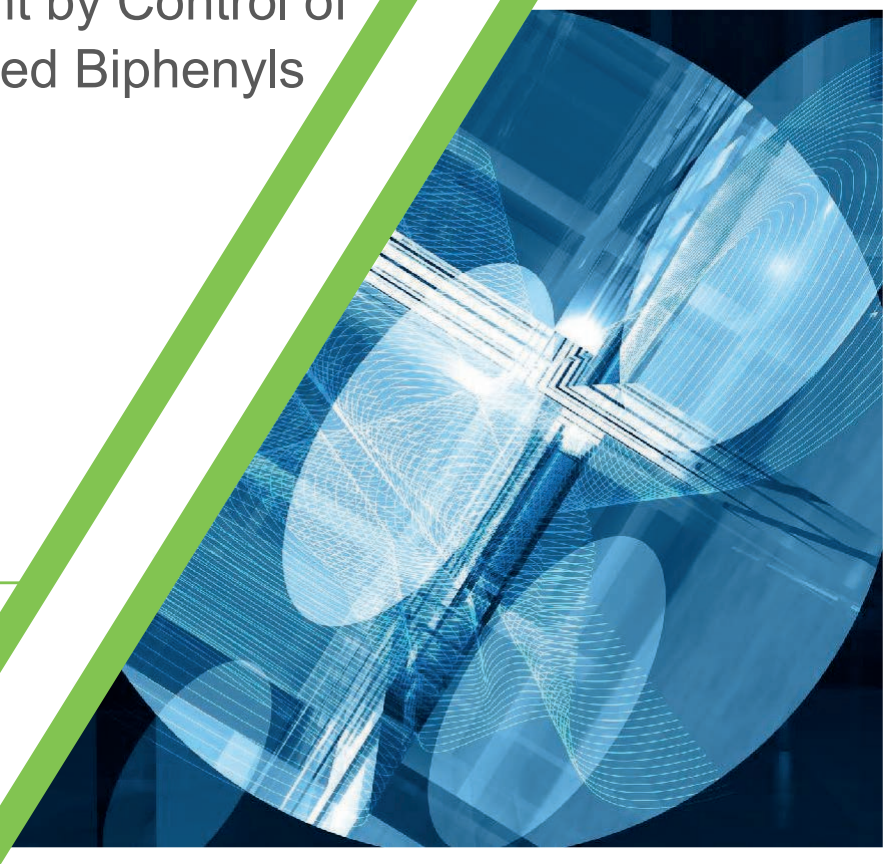
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision-Recommendation of the Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls



OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision-Recommendation of the Council on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls*, OECD/LEGAL/0230

Series: OECD Legal Instruments

Date(s)

Adopted on 13/02/1987

Background Information

The Decision-Recommendation on Further Measures for the Protection of the Environment by Control of Polychlorinated Biphenyls was adopted by the OECD Council on 13 February 1987 on the proposal of the Environment Committee. Under this instrument, Adherents shall ensure the cessation – except in a few cases - of the manufacture, import, export and sale of Polychlorinated Biphenyls (PCBs), products, articles or equipment containing PCBs, and equipment which specifically requires the use of PCBs. For existing uses of PCBs, Adherents shall ensure that appropriate controls are applied to such uses, as well as to any associated storage and transport, in order to prevent the release of PCBs into the environment or fires involving PCBs. The Decision-Recommendation also addresses existing products, articles or equipment contaminated by PCBs, as well as the disposal of PCBs and other wastes containing PCBs.

THE COUNCIL,

HAVING REGARD to Articles 3, 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Decision of the Council of 13 February 1973 on Protection of the Environment by Control of Polychlorinated Biphenyls [C(73)1(Final)];

HAVING REGARD to the Recommendation of the Council of 28 September 1976 on a Comprehensive Waste Management Policy [C(76)155(Final)];

HAVING REGARD to the results of the PCB Seminar hosted by the Netherlands under patronage of the OECD in Scheveningen, Netherlands, 28-30 September 1983;

HAVING REGARD to the Decision-Recommendation of the Council of 1 February 1984 on Transfrontier Movements of Hazardous Waste [C(83)180(Final)];

HAVING REGARD to the Recommendation of the Council of 4 April 1984 concerning Information Exchange Related to Export of Banned or Severely Restricted Chemicals [C(84)37(Final)];

HAVING REGARD to the Resolution of the Council of 20 June 1985 on International Co-operation concerning Transfrontier Movements of Hazardous Waste [C(85)100];

HAVING REGARD to operative paragraphs 3, 6 and 7 of the Declaration on Environment: Resource for the Future, of 20 June 1985, adopted by the Governments of OECD Member countries and of Yugoslavia at the meeting of the Environment Committee at Ministerial level;

CONSIDERING that current controls of polychlorinated biphenyls (PCBs) have not led to a clear and consistent downward trend of environmental levels of PCBs, except in certain local situations, and that previous concerns about environmental contamination by PCBs, and their health and environmental effects, remain unabated;

CONSIDERING that new concerns have arisen over the use of PCBs, particularly in situations where highly toxic products such as chlorinated dioxins or chlorinated dibenzofurans might be produced by their decomposition in fires;

CONSIDERING that the ultimate objective of international action to control PCBs is to eliminate entirely their release to the environment;

CONSIDERING, therefore, the need for additional, more stringent measures to control new and existing uses of PCBs and the disposal of PCBs and wastes containing PCBs;

CONSIDERING that alternatives exist, and are being used, for the major industrial and commercial applications of PCBs;

CONSIDERING that the desirability of withdrawing PCBs from use must be balanced against the feasibility of taking such action without increasing the risk of environmental contamination by PCBs and must take due account of the availability of appropriate disposal facilities;

On the proposal of the Environment Committee;

I. Uses of PCBs

A. New Uses of PCBs

1. **DECIDES** that, in respect of new uses of PCBs, Member countries shall ensure that not later than 1st January 1989 the following activities cease:

- The manufacture, import, export and sale of:

a) PCBs;

b) Products, articles or equipment containing PCBs; and

c) Equipment which specifically requires the use of PCBs;

- Except for the following cases:

  i) For research purposes or use as a reference standard;

  ii) For the export or import of waste fluids or other waste containing or contaminated by PCBs, for the sole purpose of disposal; or

  iii) If the competent authority of a Member country has received a request for a derogation from these provisions and, on the basis of the information submitted in support of this request, has authorized such a derogation for a limited period of time after having ensured that:

    - No alternative to PCBs exists for the proposed use;

    - No significant amount of PCBs would reach the environment during the proposed use and subsequent disposal; and

    - Human health or environment would not be endangered as a result of the proposed use.

B. Existing Uses of PCBs

1. **DECIDES** that, in respect of existing uses of PCBs, Member countries shall ensure that appropriate controls are applied to such uses, as well as to any associated storage and transport, in order to prevent the release of PCBs into the environment or fires involving PCBs.

2. **RECOMMENDS** that, in respect of existing uses of PCBs, Member countries take steps to accelerate the withdrawal of PCBs from use, particularly where potential accidents or leaks could endanger human health or the environment, in so far as such withdrawal would not otherwise increase the risk of environmental contamination by PCBs.

II. Products, Articles or Equipment Contaminated by PCBs

1. **DECIDES** that Member countries shall apply control measures to products, articles or equipment contaminated by PCBs in order to reduce contamination in such items to levels which do not endanger human health or the environment.

2. **RECOMMENDS** that Member countries ensure that for contaminated fluids and soils, the levels of contamination are no greater than 50 parts per million.

III. Disposal of PCBs and other Wastes Containing PCBs

1. **DECIDES** that Member countries shall ensure that disposal of waste fluids and solids containing PCBs at levels greater than 100 parts per million and of equipment which has contained PCBs and has not been adequately cleaned, is carried out in adequate disposal facilities by means of high temperature incineration, or a comparably effective method, in a manner which does not endanger human health or the environment.

2. **RECOMMENDS** that, as far as practicable, Member countries ensure that the disposal of wastes containing or contaminated by PCBs at levels of 100 parts per million or less is carried out in adequate disposal facilities and in a manner that avoids the release of PCBs into the environment.

3. **DECIDES** that Member countries shall prohibit the deliberate dilution of wastes containing PCBs where such activity is intended to contravene Section III.1 of this Decision-Recommendation or disregard Section III.2 of this Decision-Recommendation.

4. **RECOMMENDS** that Member countries strengthen their efforts to ensure that facilities exist for effective disposal of PCBs and wastes containing PCBs.

IV. Implementation and Review

1. **DECIDES** that Member countries shall inform each other of any derogations from the controls on new uses of PCBs as set out in Section I.A.iii) of this Decision-Recommendation.

2. **RECOMMENDS** that Member countries exchange information on new developments concerning the control of PCB use, storage, transport and safe disposal.

3. **INVITES** Member countries to inform the Organisation of any derogations from the controls on new uses of PCBs as set out in Section I.A.iii) of this Decision-Recommendation.

4. **INSTRUCTS** the Environment Committee to pursue a programme of work to facilitate the practical implementation of the provisions of Section III of this Decision-Recommendation.

5. **INSTRUCTS** the Environment Committee to review actions taken by Member countries in pursuance of this Decision-Recommendation, including the granting of derogations, and to report thereon to Council in 1990.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals* , OECD/LEGAL/0210

Series: OECD Legal Instruments

Date(s)

Adopted on 04/04/1984

Background Information

The Recommendation concerning Information Exchange related to Export of Banned or Severely Restricted Chemicals was adopted by the OECD Council on 4 April 1984 on the proposal of the Joint Meeting of the Management Committee of the Special Programme on the Control of Chemicals and the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. This instrument recommends that if a chemical is banned or severely restricted in an Adherent, and that chemical is exported, information should be provided from that country to the importing country to enable the latter to make timely and informed decisions concerning that chemical. Further, when exchanging such information, Adherents should take into account the Guiding Principles which are set out in the Appendix to the Act.

THE COUNCIL,

HAVING REGARD to Articles 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Resolution of the Council of 18 May 1971, concerning a Procedure for Notification and Consultation on Measures for Control of Substances Affecting Man and His Environment [C(71)73(Final)], and the agreement of the Council of 18 July 1974 to continue the Procedure [C/M(74)18 Part II(Final), Item 197];

HAVING REGARD to the Decision of the Council of 21 September 1978 concerning a Special Programmme on the Control of Chemicals and the Programme of Work established therein and the Resolution of the Council of 12 May 1981, extending the duration of that Programme [C(78)127(Final) and C/M(81)7(Final), Item 86];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the Exchange of Confidential Data on Chemicals [C(83)97(Final)];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to the Decision-Recommendation of the Council of 1 February 1984, on Transfrontier Movements of Hazardous Waste [C(83)180(Final)];

BEARING IN MIND that the Governments of the OECD Member countries have recognised "the responsibility they share to safeguard and improve the quality of the environment, both nationally and in a global context" (Declaration on Environmental Policy, 1974);

CONSIDERING that the export of chemicals hazardous to man and the environment is a matter of increasing international concern;

CONSIDERING that importing countries have the primary responsibility for the protection of man and the environment from the hazards associated with chemicals imported into their territories;

CONSIDERING that OECD Member countries are among the major producers, exporters and importers of chemicals and that, by virtue of the experience and expertise they possess concerning chemicals control, they can assist each other as well as non-member importing countries to make timely and informed decisions about chemicals entering their territories;

CONSIDERING that concerted action in this regard could contribute to and support national efforts to control the hazards associated with chemicals while minimising competitive and trade distortions;

On the proposal of the Joint Meeting of the Management Committee of the Special Programme on the Control of Chemicals and the Chemicals Group, endorsed by the Environment Committee:

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

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

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

IV. INVITES non-member countries to take note of the provisions contained in this Recommendation and to consider applying them.

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

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

APPENDIX

GUIDING PRINCIPLES ON INFORMATION EXCHANGE RELATED TO EXPORT OF BANNED OR SEVERELY RESTRICTED CHEMICALS

Introduction

1. While importing countries have the primary responsibility for protection of health and the environment from risks associated with imports of chemicals which have been banned or severely restricted for use in exporting countries, exporting Member countries should take steps to assist importing countries in making timely and informed decisions.

2. These Guiding Principles:

   i) Provide for an information exchange which will give an importing country a better opportunity to determine its need for action on chemicals banned or severely restricted in the exporting Member country; they do not deal with the control of export of such chemicals;

   ii) Should not preclude, in any way, national authorities from instituting wider and more frequent information exchange;

   iii) Apply to exports from one Member country to another, as well as to exports to non-member countries;

   iv) May be implemented by countries through public or private entities designated or authorised by them to do so;

   v) Are not designed to apply to export of hazardous waste.

Scope

3. For purposes of these Guiding Principles, a banned or severely restricted chemical includes any chemical that is the subject of a control action taken by a competent authority in the exporting Member country:

   i) To ban or severely restrict the use or handling of the chemical in order to protect human health or environment domestically; or

   ii) To refuse a required authorisation for a proposed first time use of the chemical based upon a decision in the exporting Member country that such use would endanger human health or the environment.

Guiding Principles

4. Where an exporting Member country has taken control action to ban or severely restrict chemicals, such exporting Member country should make relevant information available to importing countries.

5. If an export of a banned or severely restricted chemical occurs, the exporting Member country should ensure that necessary steps are taken to provide the importing country with relevant information so as to alert it to that fact. It is the intention that, in so far as possible, the alert information should be provided prior to export, but it is recognised that this may not always be possible, and that the procedures of the exporting country should not be such as to delay or control the export.

6. The minimum information needed to alert the importing country would be:

i) The fact that an export is expected or about to occur;

ii) The chemical identification/specification;

iii) A summary of control action taken in the exporting Member country. If the control action bans or restricts certain uses but allows other uses, such information should be included. Information on the rationale for the control action may also be included;

iv) The fact that additional information is available and the indication of the contact point in the exporting Member country to which a request for additional information should be addressed.

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

8. The exporting Member country should also take the necessary steps to provide to the importing country, at its request, additional available information which would assist the importing country in determining its needs for action in relation to assessment of chemicals in protection of man or the environment.

9. The provision of information by the exporting Member country must take into account the protection of the confidentiality of data in the importing country and the protection of proprietary rights and also the resources which would be required in the exporting Member country to provide this information.

10. The additional information needed in the importing country to determine its need for action would be:

i) Rationale for the control action taken, and the readily available data used by the exporting Member country to reach its control decision; and

ii) Such other information surrounding the circumstances of the export/import transaction as may be agreed upon by the exporting and importing countries.

11. While the procedures in exporting Member countries for providing relevant information to importing countries will vary, there are certain elements which should be common to the procedures established in all exporting Member countries:

i) Provision for determining when a control action has been taken which would initiate the information exchange and for informing exporters and other appropriate parties of such determination;

ii) Provision for assuring that the information exchange to each importing country is initiated when the first export to that country following the control action in the exporting Member country occurs;

iii) Provision for sending the alert information to the importing country on a one-time-notification basis, except where the exporting Member country wishes to have more frequent information exchange.

12. The importing Member country should establish internal procedures for the receipt and handling of information from the exporting Member country. While these internal procedures will vary from one importing Member country to another, there are certain matters which should be provided for:

i) The designation of a recipient by the importing Member country to receive the alert information;

ii) Procedures for reviewing the alert information to determine the need for additional information;

iii) Internal procedures for receiving and acting on the additional information before requesting such information;

iv) Procedures for determining whether the additional information needed in the importing Member country is available from sources other than the exporting Member country;

v) Procedures to maintain confidentiality of information and to protect proprietary rights when claimed by the exporting Member countries.

13. Any control measures applied to an imported chemical for which information has been received within the framework of the Guiding Principles should not be more restrictive than those applied to the same chemical produced domestically or imported from a country other than the one that supplied the information.

Adherents*

OECD Members		Non-Members	Other
Australia	United States	Brazil	
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals*, OECD/LEGAL/0203

Series: OECD Legal Instruments

Date(s)

Adopted on 26/07/1983

Background Information

The Recommendation concerning the Protection of Proprietary Rights to Data submitted in Notifications of New Chemicals was adopted by the OECD Council on 26 July 1983 on the proposal of the Second High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. This Recommendation ensures the protection of proprietary information in two ways. One, it recommends that authorities in Adherent countries who receive, from companies, notifications of new chemicals (which include proprietary test data) require each notifier to identify the laboratories which produced such data, or provide certification of the right to use the data. Two, it recommends that such authorities not accept from a notifier, data for which the notifier cannot provide a certification of the right of use, if the laboratories are not owned or otherwise affiliated with the notifier.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 b), 2 d), 3 and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 14 November 1974 on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 7 July 1977 Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 21 September 1978 concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by Council on 12 May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

HAVING REGARD to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on proprietary rights [ENV/CHEM/HLM/M/82.1];

CONSIDERING the importance of production and international trade in chemicals and the mutual economic and trade advantages which accrue to OECD Member countries from harmonization of policies for chemicals control;

CONSIDERING the economic value of certain data on chemicals, in particular health, safety, and environmental data, and the possible adverse effects of the disclosure of these data on the competitive position of the person or company who developed the data;

CONSIDERING therefore the need to protect data from unauthorised use in notifications of new chemicals;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

I. RECOMMENDS that authorities responsible in Member countries for receiving notifications of new chemicals require each notifier to identify the laboratories which produced each of the health, safety, and environmental data in the notification and, if the laboratories are not owned or otherwise affiliated with the notifier, to provide certification of the right to use the data.

II. RECOMMENDS that authorities responsible in Member countries for receiving notifications of new chemicals not accept from a notifier health, safety, and environmental data for which the notifier cannot provide a certification of the right of use, if the laboratories are not owned or otherwise affiliated with the notifier.

III. INVITES Member countries to report to the Organisation on measures taken to implement this Recommendation.

IV. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and report thereon to the Council.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning the OECD List of Non-Confidential Data on Chemicals* , OECD/LEGAL/0205

Series: OECD Legal Instruments

Date(s)

Adopted on 26/07/1983

Background Information

The Recommendation concerning the OECD List of Non-Confidential Data on Chemicals was adopted by the OECD Council on 26 July 1983 on the proposal of the Second High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. This instrument recommends that Adherents, for purposes of assessment and for other uses relating to protection of man and the environment, facilitate the disclosure and exchange of data belonging to the OECD List of Non-Confidential Data which is set out in the appendix to the Recommendation.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 b), 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 7 July 1977 Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 21 September 1978 concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by the Council of 12 May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

HAVING REGARD to the Decision of the Council of 12 May 1981 concerning the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)] and Addendum 1 to that Decision [C/M(82)22(Final), Item 215];

HAVING REGARD to the Decision of the Council of 8 December 1982 concerning the Minimum Pre-marketing Set of Data in the Assessment of Chemicals [C(82)196(Final)];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the Protection of Proprietary Rights to Data Submitted in Notifications of New Chemicals [C(83)96(Final)];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

HAVING REGARD to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on non-confidential data [ENV/CHEM/HLM/M/82.1];

CONSIDERING the need to avoid unnecessary duplication of effort in developing data on chemicals, to make better use of existing data, to utilize more effectively scarce specialist manpower and test facilities, and to reduce the number of animals used in testing;

CONSIDERING the need of governments to inform the public and the need to disclose certain data related to the assessment of chemicals or to other purposes connected with the protection of man and the environment;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

I. RECOMMENDS that Member countries, for purposes of assessment and for other uses relating to protection of man and the environment, facilitate the disclosure and exchange of data belonging to the OECD List of Non-Confidential Data, set out in the Appendix hereto, which is an integral part of this Recommendation, and other data which may be deemed by the Member country concerned to be non-confidential.

II. INSTRUCTS the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and report thereon to the Council.

APPENDIX

THE OECD LIST OF NON-CONFIDENTIAL DATA ON CHEMICALS

Certain data, of value for hazard assessment of chemicals and for other purposes connected with the protection of man and the environment, may be termed non-confidential.

In this context, "non-confidential" means that no restrictions should be put on the exchange of the data between governments nor on the disclosure of such data to the public. Proprietary Rights to data are not affected by the non-confidential status of such data. Data should be exchanged between governments on request and not as a matter of routine.

The following list is not restrictive. It is recognised, on the contrary, that in some circumstances there may be other data which are considered non-confidential both by the government and the submitter and that if these are useful for hazard assessment of chemicals, they should also be exchanged. The list below is inspired by the OECD Minimum Pre-marketing Set of Data, but is not meant to be restricted to information on new chemicals. Non-confidentiality, as defined above, applies to all chemicals.

- Trade name(s) or name(s) commonly used (in the United States of America, trade names or names commonly used may mean a generic name of a chemical substance);
- General data on uses (the uses need to be described only broadly, like: closed or open system, agriculture, domestic use, etc.);
- Safe handling precautions to be observed in the manufacture, storage, transport and use of the chemical;
- Recommended methods for disposal and elimination;
- Safety measures in case of an accident;
- Physical and chemical data with the exception of data revealing the chemicals identity (e.g. Spectra). If the physical and chemical data make it possible to deduce therefrom the chemical identity only ranges of values need be given;
- Summaries of health, safety, and environmental data including precise figures and interpretations. (the submitter of the health, safety, and environmental data should participate in the preparation of the summaries.)

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

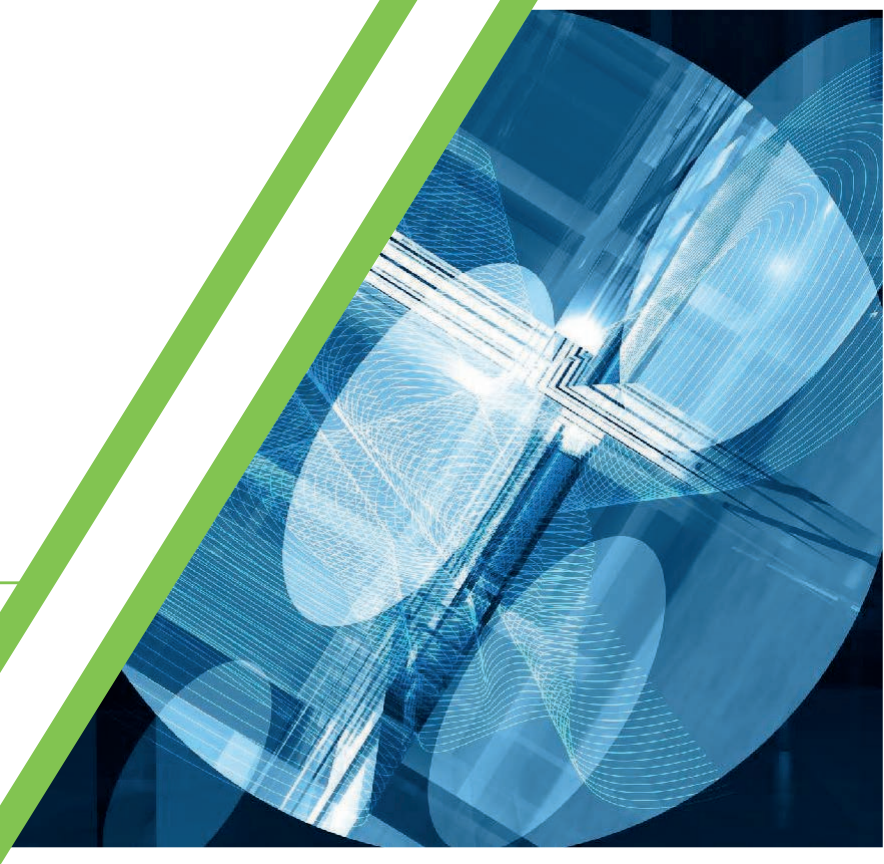
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council concerning the Exchange of Confidential Data on Chemicals



OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council concerning the Exchange of Confidential Data on Chemicals*, OECD/LEGAL/0204

Series: OECD Legal Instruments

Date(s)

Adopted on 26/07/1983

Background Information

The Recommendation concerning the Exchange of Confidential Data on Chemicals was adopted by the OECD Council on 26 July 1983 on the proposal of the Second High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. Considering the need to avoid necessary duplication of effort in developing data on chemicals and to make better use of existing data, this instrument recommends that Adherents take steps towards creating conditions which will allow the exchange of confidential data among Adherents. Principles by which to do so are provided in the Appendix to the Recommendation.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 b), 2 d), 3, and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 14 November 1974 on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 7 July 1977 Establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 21 September 1978 concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the extension of the duration of the Programme by the Council of 12th May 1981 [C(78)127(Final) and C/M(81)7(Final), Item 86];

HAVING REGARD to the Recommendation of the Council of 26 July 1983 concerning the OECD List of Non-Confidential Data on Chemicals [C(83)98(Final)];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of May 1980, concerning the confidentiality of data [ENV/CHEM/HLM/80.M/1];

HAVING REGARD to the conclusions of the Second High-Level Meeting of the Chemicals Group of November 1982, on the transfer of confidential data [ENV/CHEM/HLM/M/82.1];

CONSIDERING the need to avoid necessary duplication of effort in developing data on chemicals and to make better use of existing data;

CONSIDERING the economic value of certain data and the possible effects of the disclosure of such data on the competitive position of the person or company who develops the data;

CONSIDERING that Member countries differ widely in their assessment of the confidentiality of data under national legislative or administrative provisions and that confidentiality of data is the factor most often limiting the exchange of data on chemicals between countries;

CONSIDERING that the exchange of health, safety, and environmental data on chemicals between Member countries is necessary for purposes of assessment and for other uses relating to the protection of man and the environment;

On the proposal of the Second High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

I. **RECOMMENDS** that Member countries take steps towards creating conditions which will allow the exchange of confidential data.

II. **INVITES** Member countries to explore the use of the principles set out in the Appendix which is an integral part of this Recommendation, and any other relevant principles in bilateral or multilateral arrangements for the transmission of confidential data.

III. **INVITES** Member countries to report to the Organisation as the above-mentioned arrangements evolve.

IV. **INSTRUCTS** the Environment Committee and the Management Committee of the Special Programme on the Control of Chemicals to review actions taken by Member countries in pursuance of this Recommendation and to report thereon to the Council.

APPENDIX

SUGGESTED PRINCIPLES TO GOVERN THE EXCHANGE OF CONFIDENTIAL DATA AND INFORMATION ON CHEMICALS BETWEEN MEMBER COUNTRIES

Preamble

1. The Chemicals Group at its High-Level Meeting in May 1980 stated that the exchange of health, safety and environmental data between Member countries was necessary for the purpose of assessing chemicals with the object of protecting man and the environment. It instructed the Group of Experts on the Confidentiality of Data to work out the principles applicable to the exchange of confidential data.

2. The Group of Experts, in its discussions, defined the scope of such exchange; it was agreed that the exchange of information between the authorities in Member countries responsible for the control of chemicals should complement the company submissions to these authorities and secondly should allow for exchange on request when companies are not involved. Given the worldwide scarcity of material and intellectual resources for conducting tests, exchange, avoiding duplication of tests as far as possible, should enable better use to be made of existing data. Exchangeable data should be both for new chemicals and for existing chemicals.

3. Member countries differ very widely in their assessment of the confidentiality of data submitted in response to regulations or administrative practice for chemicals control. While it is generally recognised that the notifier is entitled to claim confidentiality for some of the data he makes available to a competent authority, the final decision lies with the authority. As a result certain data, which cannot be disclosed in some countries, may be disclosable in others. The extent to which confidential data are circulated within government departments may also vary from one country to another. The exchange of data between countries therefore raises a problem of widening the access to confidential data.

Confidentiality of data is certainly the factor most often limiting exchange of information on chemicals between countries. The Group therefore considered it opportune to recommend that certain types of data should not be designated as confidential and that their exchange should not be limited by principles.

4. It would seem to be premature, at the present stage, to try to solve these problems by proposals aiming at international harmonization of the relevant laws. Even if greater harmonization of chemicals control regulations can be achieved, the purpose underlying the work of the OECD chemicals programme, the fact remains that concepts of administrative secrecy, and of industrial and commercial secrecy, in different countries derive from fundamental principles associated with national law, which must act as a curb on harmonization. The Group has pointed out that the OECD work towards harmonization should, in particular, encourage those Member countries which have not yet adopted legislation on chemicals control to do so in the years ahead.

5. The exchange of confidential data between countries should be governed by principles taking account of the differences between legislation and administrative practice in different countries, and enable countries to participate in such exchange without infringing the law or practice prevailing in their own territories. Clearly, a list of principles extensively respecting the traditions of countries strictly applying the rule of administrative secrecy to any information imparted to the government imposes restrictions on the possibilities for exchange. A competent authority will only transmit confidential information if it can be certain that the requesting authority will treat it at least with the same degree of confidentiality as is practised in the transmitting country. Countries whose laws or administrative practices favour disclosure could agree to follow less restrictive principles in transmitting data which originated in these countries.

6. The principles were defined by the Group on the following basis:

- The exchange system must respect the sovereignty of the country transmitting information in its decision on the confidential nature of the information;

- A competent authority must make every reasonable effort to obtain the information available in its country before requesting confidential information from the competent authority in another country;
- Exchanges of confidential data between competent authorities in different countries should not distort competition and in particular, should not have the effect:
    - of subjecting nationals in the solicited country to a more severe testing or reporting requirement than would apply to a national of the soliciting country in the same situation;
    - or exempting nationals of the soliciting country from conforming to the notification procedures prevailing in their country;
- All data made available to a competent authority must remain the property of the submitter, even after exchange with competent authorities elsewhere, to the extent recognised in the original country.

The text of the principles drawn up by the Group is presented below, accompanied by explanatory comments reflecting the various opinions expressed during the work of the Group.

Principle No. 1

The exchange of confidential information on chemicals between the competent authorities of countries is intended solely to facilitate the hazard assessment of chemicals and the protection of man and the environment.

Comments

7. The Group distinguished three categories of confidential information that might be available to a competent authority and might be exchangeable between Member countries: data reported under chemical control legislation or regulation, or in the normal course of chemical control administration, data supplied by companies voluntarily or upon request, and data produced under the sponsorship of government departments and other public services. The Group was mainly interested in the exchange of data in the first category, pointing out that such exchange should not be an alternative to ordinary submissions by companies to competent authorities.

8. It seemed difficult if not impossible to establish principles which could govern the exchange in the two other categories. The discretionary power exercised by the competent authority in deciding or declining to transmit its own data, or data provided voluntarily by companies, lends itself to no general rule and will be different from case to case. However, there should be nothing to prevent such data from being exchanged when appropriate.

9. From the standpoint of protecting man and the environment, the Group considered that it should not define the term "chemicals". The Group also made no distinction between existing chemicals and new chemicals. This distinction becomes very difficult in an instance where data are exchanged between countries whose systems of notification of new chemicals are different in scope. For similar reasons, it did not appear desirable to distinguish chemicals in terms of the particular use made of them, and to exclude some categories from eligibility for exchange.

10. Exchange is intended to transmit data already available to the competent authority, and not to have the transmitting authority gather and develop new data for this purpose.

Principle No. 2

A country having received information in response to a request must in no circumstances use such information for any purpose other than the assessment of hazards of chemicals and the protection of man and the environment.

Comments

11. This limitation of the uses that can be made of information transmitted accurately reflects the need recognised by the Chemicals Group at its May 1980 High-Level Meeting. Any extension of the use of information received would prejudice the smooth running of the exchange and the maintenance of the commitment entered into by the countries participating in it.

Principle No. 3

A country, whenever requesting information about a chemical, must substantiate the need for the information, on the grounds that:

a) The chemical is present or is shortly to be marketed in its territory; and

b) The information is necessary for the assessment of its hazards and the protection of man and the environment.

Comments

12. Automatic exchange of the available data among all Member countries would be an administrative burden and is not considered worthwhile. Such an exchange would also increase the risk of disclosure of confidential data. Therefore, data would be exchanged only in response to a substantiated request.

13. Linking the acceptability of a request to the information needs as defined in the principle helps to avoid excessively frequent requests, making exchange impractical, and to avoid undue latitude in the reasons a country can give for declining it.

14. The expression "present ... in its territory" has been chosen to include not only the presence of a chemical on a country's market but also its presence in the country's territory due to transfrontier pollution. The expression "shortly to be marketed" was chosen to include chemicals for which the marketing process has been launched even though the chemical is not yet physically present in the territory.

15. Several experts considered that the principle above would be too restrictive and reduce the value of the exchange of information in respect to hazard assessment. They suggested supplementing the principle by:

> "or demonstrate the usefulness of the information because of a similarity in structure to a chemical present or shortly to be marketed in its territory".

However, other experts were of the opinion that the present state of scientific knowledge does not allow the establishment of a direct relationship between chemical structure and effect upon man and the environment which can be generally applied. Those experts also thought that the concept could harm the proprietary rights of a manufacturer of a chemical showing "similarity in structure" without its chemical being directly concerned or relevant to the case under consideration.

The Group agreed that Member countries could include a provision on structural similarity in bilateral exchange agreements.

Principle No. 4

A country requesting information:

a) Must abide by the decision made by the transmitting country with respect to the confidential nature of the information;

b) Must treat the transmitted information with at least the same degree of confidentiality as is practised in the country from which the information has been requested;

c) May make the information available to national, regional or local authorities only when necessary for purposes of hazard assessment of chemicals or protection of man and the

environment and only when such authorities are able to guarantee the same level of confidential treatment;

d) Shall not transmit the information received to any other country.

Comments

16. The national authority having recognised the confidentiality of information submitted to it has the first responsibility for ensuring that it is effectively safeguarded. The authority can only transmit such information if it is certain that the requesting country will respect the confidentiality of such information.

17. "Treat the transmitted information with at least the same degree of confidentiality as is practised in the country from which the information has been requested" means that the requesting country must treat the information in a manner that is the practical equivalent of the treatment of that information in the originating country. The Group understands that receiving countries will not have legislation identical to that in originating countries.

18. The Group recognised that different authorities within a country's government may need access to information, and that to make it accessible only to one competent authority would remove much of the value of an exchange of confidential information.

19. Each country should designate an authority to be responsible for transmitting confidential data to another country. The receiving country shall not transmit them elsewhere.

Principle No. 5

The requesting country shall not ask for the transmission of confidential information which it does not have the authority to collect and use under its legislation or in the normal course of its administration.

Comments

20. Exchangeable information would essentially be limited to data submitted under laws, regulations and practice of control of chemicals. It is therefore necessary to avoid a situation in which countries with stricter notification requirements than others find themselves constantly being asked to provide data.

21. OECD work under the chemicals programme, and especially work on exchanging confidential data, should be part of a broader effort to harmonize chemicals control procedures, and not be allowed to act as a substitute for harmonization. In particular, it should encourage Member countries which have not yet adopted legislation on the matter to do so over the coming years.

Principle No. 6

The solicited country should consult with the person who submitted the requested confidential data before transmitting them.

Comments

22. Since any exchange involves a further risk of disclosure, whose consequences cannot always be fully assessed by the government, it would seem normal to consult the submitter.

23. However, it should be clearly understood that this is a consultation and that the final decision must be taken by the government, and that consultation is without prejudice to specific agreements already in force between some Member countries and in accordance with national or international provisions.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals

OECD Legal Instruments

OECD

BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision of the Council concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals*, OECD/LEGAL/0199

Series: OECD Legal Instruments

Date(s)

Adopted on 08/12/1982

Background Information

The Decision concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals was adopted by the OECD Council on 8 December 1982 on the proposal of the Management Committee of the Special Programme on the Control of Chemicals (now called Chemicals Committee). This instrument requires that, in Adherent countries, sufficient information is available on the properties of new chemicals before they are marketed, and recommends that the minimum pre-marketing set of data listed in the Annex to the Decision serves as a basis for a meaningful first assessment of the hazards of a chemical to health and the environment.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 d), 3, 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 26 May 1972, on Guiding Principles concerning International Economic Aspects of Environmental Policies [C(72)128];

HAVING REGARD to the Recommendation of the Council of 14 November 1974, on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 26 August 1976, concerning Safety Controls over Cosmetics and Household Products [C(76)144(Final)];

HAVING REGARD to the Recommendation of the Council of 7 July 1977, establishing Guidelines in respect of Procedures and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 21 September 1978, concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein and the Decision of the Council of 12 May, 1981, extending the duration of that Programme [C(78)127(Final), and C/M(81)7(Final), Item 86];

HAVING REGARD to the conclusions of the First High-Level Meeting of the Chemicals Group of 19 May 1980, dealing with the control of health and environmental effects of chemicals [ENV/CHEM/HLM/80.M/1];

CONSIDERING the need for concerted action amongst OECD Member countries to protect man and his environment from exposure to hazardous chemicals;

CONSIDERING the importance of international production and trade in chemicals and the mutual economic and trade advantages which accrue to OECD Member countries from harmonization of policies for chemicals control;

CONSIDERING the need to reduce the cost burden associated with testing chemicals and the need to utilise more effectively scarce test facilities and specialist manpower in Member countries;

CONSIDERING the close relationship between the Mutual Acceptance of Data [C(81)30(Final)], the OECD Test Guidelines and OECD Principles of Good Laboratory Practice and the OECD Minimum Pre-marketing Set of Data;

CONSIDERING the need to have sufficient information in Member countries to allow an initial assessment to be made of the possible hazard presented by new chemicals;

PART I

I. **DECIDES** that in Member countries sufficient information on the properties of new chemicals should be available before they are marketed to ensure that a meaningful assessment of hazard to man and the environment can be carried out.

II. **NOTES** that some chemicals, owing to their intended use, may already be subject to specific legislation in a Member country, and insofar as this intended use is concerned are not subject to this Decision.

III. **NOTES** that legislation or administrative procedures in a Member country may provide for exemptions because of the nature of a chemical or the quantity manufactured.

IV. **INSTRUCTS** the Environment Committee to pursue a programme of work designed to lead to the development of an overall approach to step sequence testing of chemicals.

V. INSTRUCTS the Environment Committee to continue related work aimed at the harmonization of hazard assessment and the study of notification procedures associated with assessment of chemicals.

PART II

To implement the Decision set forth in Part I:

RECOMMENDS that the minimum pre-marketing set of data (MPD) together with its provisions for flexible application set forth as integral parts of this text in the Annex hereto can serve as a basis for a meaningful first assessment of the potential hazard of a chemical to health and the environment.

ANNEX

DATA COMPONENTS FOR, AND PROVISIONS FOR FLEXIBLE APPLICATION OF THE OECD MINIMUM PRE-MARKETING SET OF DATA

Data Components for the OECD Minimum Pre-Marketing Set of Data

Chemical Identification Data

Name according to agreed international nomenclature, e.g. IUPAC
Other names
Structural formula
CAS-number
Spectra ("finger-print spectral" from purified and technical grade product)
Degree of purity of technical grade product
Known impurities, and their percentage by weight
Essential (for the purposes of marketing) additives and stabilisers and their percentage by weight

Production/Use/Disposal Data

Estimated production, tons/year
Intended uses
Suggested disposal methods
Expected mode of transportation

Recommended Precautions and Emergency Measures

Analytical Methods

Physical/Chemical Data

Melting point
Boiling point
Density
Vapour pressure
Water solubility
Partition coefficient
Hydrolysis*
Spectra
Adsorption - Desorption*.
Dissociation constant
Particle size*

* Only the screening part to be done for base set.

Acute Toxicity Data

Acute oral toxicity
Acute dermal toxicity
Acute inhalation toxicity
Skin irritation
Skin sensitisation
Eye irritation

Repeated Dose Toxicity Data

14-28 days, repeated dose

Mutagenicity data

Ecotoxicity data

Fish LC50 - at least 96 hours exposure
Daphnia - reproduction 14 days
Alga - growth inhibition 4 days

Degradation/Accumulation data

Biodegradation: screening phase biodegradability data (readily biodegradable)

Bioaccumulation: screening-phase bioaccumulation data (partitioning coefficient, n-octanol/water, fat solubility, water solubility, biodegradability)

Provisions for Flexible Application of the OECD Minimum Pre-marketing Set of Data

The Member countries further note that:

1. Due regard may be given, on a case-by-case basis, to the scientific and economic factors that may influence the need for and the scope of testing.

2. Member countries may omit or substitute certain tests or ask for them in a later stage of initial assessment, as long as they can justify their course of action.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

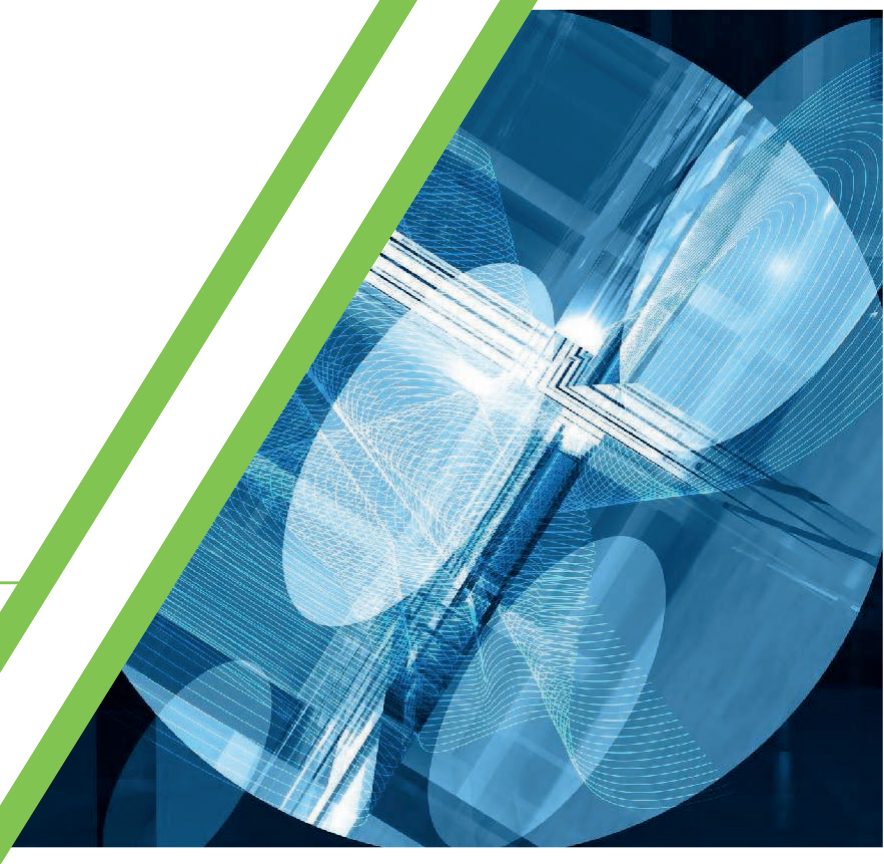
- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals



OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals*, OECD/LEGAL/0194

Series: OECD Legal Instruments

Date(s)

Adopted on 12/05/1981
Amended on 26/05/1983
Amended on 04/04/1984
Amended on 07/06/1984
Amended on 23/10/1986
Amended on 24/02/1987
Amended on 30/03/1989
Amended on 17/07/1992
Amended on 27/07/1995
Amended on 22/03/1996
Amended on 17/06/1996
Amended on 21/07/1997
Amended on 26/11/1997
Amended on 21/09/1998
Amended on 21/01/2000
Amended on 22/01/2000
Amended on 17/12/2001
Amended on 24/04/2002
Amended on 13/04/2004
Amended on 23/03/2006
Amended on 19/06/2006
Amended on 08/01/2007
Amended on 16/10/2007
Amended on 03/10/2008
Amended on 07/09/2009
Amended on 22/07/2010
Amended on 28/07/2011
Amended on 02/10/2012
Amended on 26/07/2013
Amended on 26/09/2014
Amended on 04/02/2015
Amended on 27/07/2015
Amended on 27/09/2016
Amended on 26/10/2017
Amended on 10/04/2018

Background Information

The Decision concerning the Mutual Acceptance of Data in the Assessment of Chemicals was adopted by the OECD Council on 12 May 1981 on the proposal of the High-Level Meeting of the Chemicals Group (today under the responsibility of the Chemicals Committee), endorsed by the Environment Committee. The Decision is part of the OECD System of Mutual Acceptance of Data (MAD), a multilateral agreement which allows participating countries to share the results of various non-clinical tests done on chemicals. The Decision contains two distinct parts, one which is legally binding, and one which is a non-legally binding. Part 1 requires that data generated in an Adherent country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice (GLP) shall be accepted in other Adherents for purposes of assessment and other uses relating to the protection of human health and the environment. Part II recommends that Adherents, in the testing of chemicals, apply the OECD Test Guidelines and the OECD Principles of GLP.
On 9 April 2018, the Council authorised the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology to amend Annex I of the Decision of the Council on the Mutual Acceptance of Data in the Assessment of Chemicals [C(2018)49], which provides the OECD Guidelines for Testing of Chemicals (the “Test Guidelines”). Council established a simplified procedure for the adoption of amendments to the Test Guidelines through a delegation of authority to the Joint Meeting with a view to ensure their efficient and effective implementation taking into account the purely technical nature of the Test Guidelines.

THE COUNCIL,

HAVING REGARD to Articles 2 a), 2 d), 3, 5 a) and 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 26 May 1972, on Guiding Principles concerning International Economic Aspects of Environmental Policies [C(72)128];

HAVING REGARD to the Recommendation of the Council of 14 November 1974, on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 26 August 1976, concerning Safety Controls over Cosmetics and Household Products [C(76)144(Final)];

HAVING REGARD to the Recommendation of the Council of 7 July 1977, establishing Guidelines in respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment [C(77)97(Final)];

HAVING REGARD to the Decision of the Council of 21 September 1978, concerning a Special Programme on the Control of Chemicals and the Programme of Work established therein [C(78)127(Final)];

HAVING REGARD to the Conclusions of the First High-Level Meeting of the Chemicals Group of 19 May 1980, dealing with the control of health and environmental effects of chemicals [ENV/CHEM/HLM/80.M/1];

CONSIDERING the need for concerted action amongst OECD Member countries to protect man and his environment from exposure to hazardous chemicals;

CONSIDERING the importance of international production and trade in chemicals and the mutual economic and trade advantages which accrue to OECD Member countries from harmonization of policies for chemicals control;

CONSIDERING the need to minimise the cost burden associated with testing chemicals and the need to utilise more effectively scarce test facilities and specialist manpower in Member countries;

CONSIDERING the need to encourage the generation of valid and high quality test data and noting the significant actions taken in this regard by OECD Member countries through provisional application of OECD Test Guidelines and OECD Principles of Good Laboratory Practice;

CONSIDERING the need for and benefits of mutual acceptance in OECD countries of test data used in the assessment of chemicals and other uses relating to protection of man and the environment;

On the proposal of the High-Level Meeting of the Chemicals Group, endorsed by the Environment Committee;

PART I

I. **DECIDES** that data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.

II. **DECIDES** that for the purposes of this Decision and other Council actions the terms OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall mean guidelines and principles adopted by the Council.

III. **INSTRUCTS** the Environment Committee to review action taken by Member countries in pursuance of this Decision and to report periodically thereon to the Council.

IV. **INSTRUCTS** the Environment Committee to pursue a programme of work designed to facilitate implementation of this Decision with a view to establishing further agreement on assessment and control of chemicals within Member countries.

PART II

To implement the Decision set forth in Part I:

I. **RECOMMENDS** that Member countries, in the testing of chemicals, apply the OECD Test Guidelines and the OECD Principles of Good Laboratory Practice, set forth respectively in Annexes I and II which are integral parts of this text.

II. **INSTRUCTS** the Management Committee of the Special Programme on the Control of Chemicals in conjunction with the Chemicals Group of the Environment Committee to establish an updating mechanism to ensure that the aforementioned Test Guidelines are modified from time to time, as required, through the revision of existing Guidelines or the development of new Guidelines.

III. **INSTRUCTS** the Management Committee of the Special Programme on the Control of Chemicals to pursue its programme of work in such a manner as to facilitate internationally-harmonized approaches to assuring compliance with the OECD Principles of Good Laboratory Practice and to report periodically thereon to the Council.

ANNEX I

OECD TEST GUIDELINES

These Guidelines have been published under the reference C(81)30, Annex I and Addenda. This document, which is updated periodically, can be purchased from the OECD Publications Service and is online at: http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm.

LIST OF AMENDMENTS TO THE DECISION OF THE COUNCIL C(81)30/FINAL CONCERNING TEST GUIDELINES

26 May 1983 - Addendum 2 to C(81)30(Final) (6 new Guidelines)

4 April 1984 - Addendum 3 to C(81)30(Final) (13 new Guidelines and 2 updated)

7 June 1984 - Addendum 4 to C(81)30(Final) (1 updated Guideline)

23 October 1986 - Addendum 5 to C(81)30(Final) (7 new Guidelines)

24 February 1987 - Addendum 6 to C(81)30(Final) (3 updated Guidelines)

30 March 1989 - C(89)23(Final) (1 new Guideline)

17 July 1992 - C(92)102/FINAL (3 new Guidelines and 5 updated)

27 July 1995 - C(95)106/FINAL (1 new Guideline and 10 updated)

22 March 1996 - C(96)14/FINAL (2 new Guidelines)

17 June 1996 - C(96)58/FINAL (3 new Guidelines and 1 updated)

21 July 1997 - C(97)94/FINAL (2 new Guidelines and 6 updated)

21 September 1998 - C(98)142/FINAL (4 new Guidelines and 3 updated)

21 January 2000 - C(99)189/FINAL (3 new Guidelines and 2 updated)

22 January 2001 - C(2000)228 (1 new Guideline and 3 updated)

17 December 2001 - C(2001)282 (3 updated Guidelines and 1 deleted)

24 April 2002 - C(2002)76 (3 new Guidelines and 2 updated)

13 April 2004 - C(2004)28 (11 new Guidelines and 3 updated)

23 March 2006 - C(2006)13 (4 new Guidelines and 3 updated)

19 July 2006 - C(2006)101 (2 new Guidelines and 1 updated)

8 January 2007 - C(2006)169 (6 new Guidelines and new Section 5: Other Test Guidelines - Part A: Pesticide Residue Chemistry)

16 October 2007 - C(2007)107 (6 new Guidelines)

3 October 2008 - C(2008)143 (6 new Guidelines, 2 updated and 1 corrected)

7 September 2009 - C(2009)103 (10 new Guidelines, 6 updated and 1 corrected)

22 July 2010 - C(2010)97 (7 new Guidelines, 3 updated and 1 corrected)

28 July 2011 - C(2011)101 (5 new Guidelines and 1 corrected)

2 October 2012 - C(2012)111 (2 new Guidelines, 7 updated, 1 corrected and 7 deleted)

26 July 2013 - C(2013)78 (3 new Guidelines, 8 updated and 1 corrected)

26 September 2014 - C(2014)104 (3 new Guidelines, 5 updated and 1 corrected)

4 February 2015 - C(2015)16 (2 new Guidelines)

27 July 2015 - C(2015)94 (6 new Guidelines and 11 updated)

27 September 2016 - C(2016)103 (4 new Guidelines, 10 updated, 9 corrected and 1 deleted)

ANNEX II

OECD PRINCIPLES OF GOOD LABORATORY PRACTICE

(as revised in 1997)

SECTION I: INTRODUCTION

Preface

Government and industry are concerned about the quality of non-clinical health and environmental safety studies upon which hazard assessments are based. As a consequence, OECD Member countries have established criteria for the performance of these studies.

To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member countries have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980, an international group of experts established under the Special Programme on the Control of Chemicals developed the "OECD Principles of Good Laboratory Practice" (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These Principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final)].

In 1995 and 1996, a new group of experts was formed to revise and update the Principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original Principles adopted in 1981.

The purpose of these Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

1. Scope

These Principles of Good Laboratory Practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the Principles of Good Laboratory Practice include work conducted in the laboratory, in greenhouses, and in the field.

Unless specifically exempted by national legislation, these Principles of Good Laboratory Practice apply to all non-clinical health and environmental safety studies required by regulations for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

2. Definitions of Terms

2.1 Good Laboratory Practice

1. *Good Laboratory Practice* (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2 Terms concerning the Organisation of a Test Facility

1. *Test facility* means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies, those which are conducted at more than one site, the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

2. *Test site* means the location(s) at which a phase(s) of a study is conducted.

3. *Test facility management* means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these Principles of Good Laboratory Practice.

4. *Test site management* (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these Principles of Good Laboratory Practice.

5. *Sponsor* means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

6. *Study Director* means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.

7. *Principal Investigator* means an individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibility for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

8. *Quality Assurance Programme* means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these Principles of Good Laboratory Practice.

9. *Standard Operating Procedures* (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

10. *Master schedule* means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3 Terms concerning the Non-clinical Health and Environmental Safety Study

1. *Non-clinical health and environmental safety study*, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

2. *Short-term study* means a study of short duration with widely used, routine techniques.

3. *Study plan* means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

4. *Study plan amendment* means an intended change to the study plan after the study initiation date.

5. *Study plan deviation* means an unintended departure from the study plan after the study initiation date.

6. *Test system* means any biological, chemical or physical system or a combination thereof used in a study.

7. *Raw data* means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10 below.

8. *Specimen* means any material derived from a test system for examination, analysis, or retention.

9. *Experimental starting date* means the date on which the first study specific data are collected.

10. *Experimental completion date* means the last date on which data are collected from the study.

11. *Study initiation date* means the date the Study Director signs the study plan.

12. *Study completion date* means the date the Study Director signs the final report.

2.4 Terms concerning the Test Item

1. *Test item* means an article that is the subject of a study.

2. *Reference item* ("control item") means any article used to provide a basis for comparison with the test item.

3. *Batch* means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

4. *Vehicle* means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

SECTION II: GOOD LABORATORY PRACTICE PRINCIPLES

1. Test Facility Organisation and Personnel

1.1 Test Facility Management's Responsibilities

1. Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.

2. At a minimum it should:

a) Ensure that a statement exists which identifies the individual(s) within a test facility who fulfill the responsibilities of management as defined by these Principles of Good Laboratory Practice;

b) Ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;

c) Ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;

d) Ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;

e) Ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures;

f) Ensure that there is a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these Principles of Good Laboratory Practice;

g) Ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated. Replacement of a Study Director should be done according to established procedures, and should be documented;

h) Ensure, in the event of a multi-site study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented;

i) Ensure documented approval of the study plan by the Study Director;

j) Ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel;

k) Ensure the maintenance of an historical file of all Standard Operating Procedures;

l) Ensure that an individual is identified as responsible for the management of the archive(s);

m) Ensure the maintenance of a master schedule;

n) Ensure that test facility supplies meet requirements appropriate to their use in a study;

o) Ensure for a multi-site study that clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality Assurance Programme(s) and study personnel;

p) Ensure that test and reference items are appropriately characterised;

q) Establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.

3. When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2 g), i), j) and o).

1.2 Study Director's Responsibilities

1. The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

2. These responsibilities should include, but not be limited to, the following functions. The Study Director should:

a) Approve the study plan and any amendments to the study plan by dated signature;

b) Ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study;

c) Ensure that study plans and amendments and Standard Operating Procedures are available to study personnel;

d) Ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study;

e) Ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study;

f) Ensure that all raw data generated are fully documented and recorded;

g) Ensure that computerised systems used in the study have been validated;

h) Sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these Principles of Good Laboratory Practice;

i) Ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

1.3 Principal Investigator's Responsibilities

The Principal Investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice.

1.4 Study Personnel's Responsibilities

1. All personnel involved in the conduct of the study must be knowledgeable in those parts of the Principles of Good Laboratory Practice which are applicable to their involvement in the study.

2. Study personnel will have access to the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s).

3. All study personnel are responsible for recording raw data promptly and accurately and in compliance with these Principles of Good Laboratory Practice, and are responsible for the quality of their data.

4. Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

2. Quality Assurance Programme

2.1 General

1. The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice.

2. The Quality Assurance Programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

3. This individual(s) should not be involved in the conduct of the study being assured.

2.2 Responsibilities of the Quality Assurance Personnel

1. The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should:

a) Maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule;

b) Verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented;

c) Conduct inspections to determine if all studies are conducted in accordance with these Principles of Good Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed.

Inspections can be of three types as specified by Quality Assurance Programme Standard Operating Procedures:

- Study-based inspections,
- Facility-based inspections,
- Process-based inspections.

Records of such inspections should be retained.

d) Inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;

e) Promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s)and the respective management, when applicable;

f) Prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

3. Facilities

3.1 General

1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.

2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

3.2 Test System Facilities

1. The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.

2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

3. There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.

3.3 Facilities for Handling Test and Reference Items

1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

2. Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

3.4 Archive Facilities

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

3.5 Waste Disposal

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

4. Apparatus, Material, and Reagents

1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.

2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.

3. Apparatus and materials used in a study should not interfere adversely with the test systems.

4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

5. Test Systems

5.1 Physical/Chemical

1. Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.

2. The integrity of the physical/chemical test systems should be ensured.

5.2 Biological

1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.

2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.

3. Records of source, date of arrival, and arrival condition of test systems should be maintained.

4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.

5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.

6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.

7. Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

6. Test and Reference Items

6.1 Receipt, Handling, Sampling and Storage

1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.

2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.

3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.

6.2 Characterisation

1. Each test and reference item should be appropriately identified (e.g., code, Chemical Abstracts Service Registry Number [CAS number], name, biological parameters).

2. For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

3. In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

4. The stability of test and reference items under storage and test conditions should be known for all studies.

5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes) these may be determined through separate laboratory experiments.

6. A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.

7. Standard Operating Procedures

7.1. A test facility should have written Standard Operating Procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to Standard Operating Procedures should be approved by test facility management.

7.2. Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published text books,

analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures.

7.3. Deviations from Standard Operating Procedures related to the study should be documented and should be acknowledged by the Study Director and the Principal Investigator(s), as applicable.

7.4. Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples.

1. Test and Reference Items

Receipt, identification, labelling, handling, sampling and storage.

2. Apparatus, Materials and Reagents

a) *Apparatus*: use, maintenance, cleaning and calibration

b) *Computerised Systems*: validation, operation, maintenance, security, change control and back-up

c) *Materials, Reagents and Solutions*: preparation and labelling

3. Record Keeping, Reporting, Storage, and Retrieval

Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.

4. Test System (where appropriate)

a) Room preparation and environmental room conditions for the test system.

b) Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.

c) Test system preparation, observations and examinations, before, during and at the conclusion of the study.

d) Handling of test system individuals found moribund or dead during the study.

e) Collection, identification and handling of specimens including necropsy and histopathology.

f) Siting and placement of test systems in test plots.

5. Quality Assurance Procedures

Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.

8. Performance of the Study

8.1 Study Plan

1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified in Section 2.2.1.b., above. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.

2. a) Amendments to the study plan should be justified and approved by dated signature of the Study Director and maintained with the study plan.

b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.

3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.

8.2 Content of the Study Plan

The study plan should contain, but not be limited to the following information:

1. Identification of the Study, the Test Item and Reference Item

   a) A descriptive title;

   b) A statement which reveals the nature and purpose of the study;

   c) Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.);

   d) The reference item to be used.

2. Information Concerning the Sponsor and the Test Facility

   a) Name and address of the sponsor;

   b) Name and address of any test facilities and test sites involved;

   c) Name and address of the Study Director;

   d) Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).

3. Dates

   a) The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed.

   b) The proposed experimental starting and completion dates.

4. Test Methods

   Reference to the OECD Test Guideline or other test guideline or method to be used.

5. Issues (where applicable)

   a) The justification for selection of the test system;

   b) Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information;

   c) The method of administration and the reason for its choice;

d) The dose levels and/or concentration(s), frequency, and duration of administration/ application;

e) Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

6. Records

A list of records to be retained.

8.3 Conduct of the Study

1. A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.

2. The study should be conducted in accordance with the study plan.

3. All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.

4. Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

5. Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

9. Reporting of Study Results

9.1 General

1. A final report should be prepared for each study. In the case of short term studies, a standardised final report accompanied by a study specific extension may be prepared.

2. Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.

3. The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.

4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

9.2 Content of the Final Report

The final report should include, but not be limited to, the following information:

1. Identification of the Study, the Test Item and Reference Item

a) A descriptive title;

b) Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.);

c) Identification of the reference item by name;

d) Characterisation of the test item including purity, stability and homogeneity.

2. Information Concerning the Sponsor and the Test Facility

a) Name and address of the sponsor;

b) Name and address of any test facilities and test sites involved;

c) Name and address of the Study Director;

d) Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable;

e) Name and address of scientists having contributed reports to the final report.

3. Dates

Experimental starting and completion dates.

4. Statement

A Quality Assurance Programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

5. Description of Materials and Test Methods

a) Description of methods and materials used;

b) Reference to OECD Test Guideline or other test guideline or method.

6. Results

a) A summary of results;

b) All information and data required by the study plan;

c) A presentation of the results, including calculations and determinations of statistical significance;

d) An evaluation and discussion of the results and, where appropriate, conclusions.

7. Storage

The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

10. Storage and Retention of Records and Materials

10.1 The following should be retained in the archives for the period specified by the appropriate authorities:

a) The study plan, raw data, samples of test and reference items, specimens, and the final report of each study;

b) Records of all inspections performed by the Quality Assurance Programme, as well as master schedules;

c) Records of qualifications, training, experience and job descriptions of personnel;

d) Records and reports of the maintenance and calibration of apparatus;

e) Validation documentation for computerised systems;

f) The historical file of all Standard Operating Procedures;

g) Environmental monitoring records.

In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

10.2 Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

10.3 Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

10.4 If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).

Adherents*

OECD Members	Non-Members	Other
Austria	Argentina	
Belgium	Brazil	
Canada	India	
Chile	Malaysia	
Czech Republic	Singapore	
Denmark	South Africa	
Estonia	Thailand	
Finland		
France		
Germany		
Greece		
Hungary		
Iceland		
Ireland		
Israel		
Italy		
Japan		
Korea		
Latvia		
Lithuania		
Luxembourg		
Mexico		
Netherlands		
New Zealand		
Norway		
Poland		
Portugal		
Slovak Republic		
Slovenia		
Spain		
Sweden		
Switzerland		
Turkey		
United Kingdom		
United States		

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment*, OECD/LEGAL/0154

Series: OECD Legal Instruments

Date(s)

Adopted on 07/07/1977

Background Information

The Recommendation establishing Guidelines in Respect of Procedure and Requirements for Anticipating the Effects of Chemicals on Man and in the Environment was adopted by the OECD Council on 7 July 1977 on the proposal of the Environment Committee. This instrument recommends that Adherents establish new procedures or extend existing procedures for anticipating the effects of chemicals taking into account the guidelines contained in the annexes to the Recommendation.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 14 November 1974 on the Assessment of the Potential Environmental Effects of Chemicals [C(74)215];

HAVING REGARD to the Recommendation of the Council of 26 May 1972 on Guiding Principles concerning International Economic Aspects of Environmental Policies [C(72)128];

HAVING REGARD to the Recommendation of the Council of 26 August 1976 concerning Safety Controls over Cosmetics and Household Products [C(76)144(Final)];

HAVING REGARD to the Recommendation of the Council of 28 September 1976 on a Comprehensive Waste Management Policy [C(76)155(Final)];

HAVING REGARD to the Report by the Environment Committee of 1 April 1977 on Anticipating the Effects from Chemicals in the Environment [ENV(77)20 and Addendum 1];

CONSIDERING the importance of international trade in chemicals and the fact that OECD Member countries account for most of the global production of chemicals towards the rest of the world;

CONSIDERING the value of internationally agreed guidelines at a time when governments are in the process of revising their approach to the control of chemicals by extending such controls from the protection of human health to the protection of the environment at large;

CONSIDERING the need to improve the acceptability to one country of information generated in another, and to avoid the creation of non-tariff barriers to trade;

On the proposal of the Environment Committee;

I. **RECOMMENDS** that Member countries in establishing new procedures or extending existing procedures for anticipating the effects of chemicals, take into account the Guidelines contained in Annexes I and II attached to this Recommendation, of which they form an integral part.

II. **INSTRUCTS** the Environment Committee to review action taken by Member countries in pursuance of this Recommendation, and to report thereon to the Council.

III. **INSTRUCTS** the Environment Committee to pursue a programme of work designed to facilitate the practical implementation of this Recommendation, with particular attention to the need for further development and improvement in respect of experimental techniques and for the validation of the capability of laboratories for performing tests.

ANNEX I

GUIDELINES IN RESPECT OF PROCEDURE AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND IN THE ENVIRONMENT

Introduction

1. The purpose of the Guidelines set out hereafter in this Annex is to assist Member countries in implementing new procedures or extending existing procedures for anticipating the effects of chemicals on man and in the environment.

2. Chemicals are not generally subjected to assessment for potential effects by legal or other official requirements. Existing official procedures are directed mainly towards human health effects, i.e. those governing radioactive substances, food and feed, pharmaceuticals and veterinary products, food and feed additives, cosmetics and toiletries, certain household products. Detergents are often required to be assessed for environmental but not for human effects. Pesticides are assessed for both human and environmental effects. Assessment of waste before disposal is also required by legislation in a few countries.

3. Recent legislation passed, proposed or in preparation in a number of Member countries, will now empower the authorities to request information from industry about any chemical irrespective of its intended purpose, and provides for the systematic assessment of such information with the aim to minimize exposure of man and the environment to chemicals which present unacceptable hazard.

4. Although it would be desirable to subject all chemicals to detailed assessment for potential hazard, the limited resources available in terms of laboratories as well as expertise, must be employed selectively. It is recognised that there are urgent problems of many existing chemicals that require detailed investigation but resources may not allow every existing chemical to be tested. It is, however, essential to ensure assessment of all new chemical substances so as to avoid unacceptable effects in the future from the uncontrolled introduction and use of hazardous materials.

5. The scheme outlined in the following Guidelines is intended to ensure that when chemicals are subjected to systematic assessment, they are considered in terms of both human health and environmental hazard. This can be achieved through the establishment of new assessment procedures or through the extension of existing procedures.

6. The assessment scheme also constitutes an important step towards facilitating the exchange of data about chemicals between countries. Such exchange is necessary in order to avoid wasteful use of resources by the renewed generation of data for the same chemical in each country. Further work is, however, necessary to improve the acceptability of data between countries.

I. Scope of Application

7. In the majority of cases, it is possible to determine no more than the likelihood of effects from chemicals on man or in the environment. Moreover, this can only be done through the application of expert judgment based on information generated by methods that are technically practicable as well as economically acceptable.

8. With a view to efficient use of the limited resources available, the assessment scheme is directed towards new chemical substances which enter a country for the first time, through manufacture or import, with the exception of those intended for limited research purposes, or which may be exempted by national authorities for specific reasons.

9. The scheme may further apply to existing chemical substances which are employed in distinctly new applications, or in considerably increased quantities, or selected because of newly discovered or possible harmful effects on human health or the environment.

10. The scheme could also be applied to determine the type of detailed investigations needed to elucidate the potential effects of other existing chemical substances which may cause particular concern. It is understood that in some countries resources will be devoted to such problems.

11. For the purpose of these Guidelines, chemical substances are: chemical elements and their compounds as they occur in the natural state or as produced by industry. Formulations should usually be excluded from any requirements for systematic assessment, except where a new chemical substance enters the country as a component of such formulations.

II. Approach and Data Requirements

12. The principal purpose of any assessment procedure is to identify the hazard of a chemical substance in order to determine the conditions of its use, thereby minimizing the risk of exposing man as well as the environment to hazard. For the purpose of assessing the potential effects of a chemical substance and the likelihood that man and/or the environment may be exposed to such a substance, a phased approach should be applied:

a) An initial assessment to determine the likelihood of

   i) Health hazard from the substance;

   ii) Environmental hazard from the substance;

b) Further assessments to elucidate, for selected chemical substances, their effects on man and/or in the environment.

13. The initial assessment is intended to segregate:

a) Those chemical substances which are least likely to create hazard and for which no further studies are deemed necessary at the time;

b) Those chemical substances which may create health hazard but are unlikely to reach the environment, and for which further studies are needed mainly on human health effects;

c) Those chemical substances (with or without health hazard) which reach the environment and for which detailed studies are needed of effects on the natural environment.

14. The initial assessment consists of two steps:

STEP I to determine, for the chemical substance under investigation, its

a) Physical and chemical properties (to indicate its likely behaviour);

b) Potential human health hazard (in the first instance for worker protection; in addition to indicate the need for further health studies);

c) Potential for access to the natural environment (to indicate the need for an assessment of environmental hazard).

STEP II to determine, for the chemical substances that could reach the environment in quantities which are significant with regard to toxicity, other effects and properties, their

a) Potential environmental hazard (to indicate the need for further studies of effects on the natural environment).

Types of basic data that may be of value for Steps I and II of the initial assessment are indicated in Annex II.

15. Where human health hazard has been indicated through Step I of the initial assessment, detailed studies should be made for further assessment of human health effects.

16. Where environmental hazard has been indicated through Step II of the initial assessment, detailed studies should be made for further assessment of effects on the natural environment.

17. Certain groups of chemicals are already subject to special procedures for detailed assessment of either human health effects or environmental effects. Such procedures should be extended to ensure that the chemicals are considered in terms of both human and environmental hazard.

18. Chemical substances presenting unreasonable hazard to health and the environment, should - unless prohibited - be allowed only for supervised use, and only when less hazardous substitutes are not available.

III. Administrative Requirements

19. Responsibility for generating and assessing the data necessary to determine the potential effects and the safe use of chemical substances with respect to man and the environment must be part of the overall function and liability of industry.

20. In respect of administrative requirements, several options are available to the authorities. Progressive options are:

a) An obligation on the manufacturer to maintain the results of his assessment for examination by the authorities upon request. This option should be followed by the gradual implementation of a notification system for new chemical substances.

b) An obligation on manufacturers and importers to notify their authorities of all new chemical substances, with a declaration of, for example,

   i) Nomenclature (identification),

   ii) Projected quantities to be manufactured or imported during a calendar year,

   iii) Intended usage.

   This option should be followed by the selection of priority substances for examination by the authorities.

c) An obligation on manufacturers and importers to submit to their authorities a dossier for the chemical substance under investigation including the information required for an initial assessment. This option should be followed automatically by an examination of the dossier resulting in

   i) No action, or

   ii) The establishment of testing programmes, or

   iii) Regulations for use.

   Requirements for notification or submission of dossiers will be dependent upon the resources available to the national authorities.

21. Provision should be made to ensure protection of confidential information.

22. When new procedures are established for the assessment of chemical substances, an integrated approach should be sought. Several authorities may have responsibility for treating notifications, declarations and dossiers required under different laws or schemes for the control of chemicals in a country. Arrangements should be made for optimum co-ordination of such activities.

23. Unless the authorities are adequately equipped to examine and act upon the dossiers required for new chemical substances, such requirements should not be prohibitory of the production, import, sale and use of the substance. It is understood, however, that the substance may later be withdrawn, completely or for certain use, or otherwise regulated in case harmful effects are identified.

24. Provision should be made for procedures by which emergency action may be taken to prohibit the importation, use or supply of a harmful substance.

25. Provision should be made for procedures, by which manufacturers of chemical substances may seek reconsideration of decisions taken by the authorities.

IV. Dissemination of Information

26. The transfer of chemical substances (as defined in paragraph 11) from the primary manufacturer through the commercial chain should be accompanied by:

a) An indication of origin (name and address of manufacturer, importer or distributor);

b) Information on potential hazard and on precautions to be observed for the intended use(s) of the substance;

c) Prescribed methods of disposal.

27. For purposes of collection and adequate disposal where appropriate, the presence in units of manufactured goods of an environmentally hazardous chemical substance should be indicated.

28. Chemical substances in transport should be labelled, marked, shipped and packaged according to appropriate national or international regulations. All efforts should be made towards international harmonization of such regulations.

29. When requested by the authorities either in the country of origin of the chemical substance or in importing countries, the information, on the basis of which the conditions of use of the substance was determined, should be accompanied by a specification of the experimental techniques used to generate the data.

V. Surveillance and Monitoring

30. Confirmation of the adequacy of assessments for effects on man and in the environment should be sought where appropriate, but selectively in view of the high costs involved, for example:

a) In the factory, through epidemiological records. All efforts should be made to ensure comparability of such records so that indications of effects in one factory may be set alongside the findings of others to assist in identifying the cause of such effects;

b) In the domestic environment, through full use of National Poisons Centres whose statistics should be reviewed regularly, and/or other appropriate mechanisms as available;

c) In the natural environment, through monitoring systems (i.e. periodic measurements of air, water, soil, living organisms, and food) in order to check for the appearance and possible unexpected effects of chemical substances released in significant quantities relative to persistence and mobility.

31. International exchange of data from surveillance and monitoring programmes should be encouraged. International Organisations might play an important role in collecting, collating and reviewing such information.

ANNEX II

INITIAL ASSESSMENT: STEP ONE

(TYPES OF DATA)

Some of the types of data which might be necessary to screen a chemical substance for potential human health hazard and for potential discharge to the natural environment are set forth below. In some cases, more information may be necessary while in other cases less information may be sufficient. In order to assess the data, information is needed on the methods used to generate it.

a) Physical and chemical properties

For identification of the chemical substance the data should include nomenclature, structural formula, purity and the nature of impurities, and by-products. Among the important properties to be determined are the following: melting point, boiling point, density, physical state, partition coefficients, corrosiveness, solubility in different media, vapour pressure, thermo-stability, photo-stability, degradability, and pH stability.

b) Data relevant to human health

This data should give a preliminary indication of the potential hazard to human health and can be obtained from acute and subacute toxicity studies (such as LD_{50} and maximum tolerated dose studies). Short-term studies that could indicate the possibility of long-term effects should also be carried out. When this preliminary screening indicates significant biological activity, long-term studies would be appropriate.

c) Discharge to the natural environment

The likelihood of discharge to the natural environment of the chemical substance or its by-products from production through disposal must be assessed. For this purpose the production rates and intended uses, an estimate of the amount reaching the environment, and the size and character of the exposed populations should be considered. Also of importance at this stage is a preliminary consideration of biodegradation and breakdown products.

INITIAL ASSESSMENT: STEP TWO

(TYPES OF DATA FOR ENVIRONMENTAL ASSESSMENT)

For chemical substances that could reach the environment in quantities which are significant with regard to toxicity or other effects or properties, or over long periods of time, a further step should be added to the initial assessment. Some of the types of data that might be necessary to assess the likelihood of hazard from a chemical substance in the environment are set forth below. In some cases more information may be necessary while in other cases less information may be sufficient. (In developing environmental data, special attention must be paid to the availability of appropriate analytical methods for measuring the chemical and its degradation products.)

a) Physical and chemical properties

Among the additional properties of environmental importance are chelating ability and absorption/desorption at various interfaces.

b) Data relevant to the natural environment

For a determination of pathways to and sinks in the environment both direct discharges (to water, air or soil) and indirect discharges (e.g. sewage and disposal methods) should be considered. Persistence and potential for bioaccumulation are frequently of critical importance.

An indication should be sought of acute and subacute toxicity of the chemical substance and its degradation products for species at risk under worst case conditions in the appropriate parts of the environment.

Consideration should also be given to the possibility of environmental movement, intermedia transfer, reactivity with atmospheric constituents and interaction with chemicals being introduced into the environment (e.g. chlorine used in water treatment).

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.

Recommendation of the Council on Measures to Reduce all Man-Made Emissions of Mercury to the Environment

OECD Legal Instruments

OECD
BETTER POLICIES FOR BETTER LIVES

Please cite this document as:
OECD, *Recommendation of the Council on Measures to Reduce all Man-Made Emissions of Mercury to the Environment*, OECD/LEGAL/0111

Series: OECD Legal Instruments

Date(s)

Adopted on 18/09/1973

Background Information

The Recommendation on Measures to Reduce all Man-made Emissions of Mercury to the Environment was adopted by the OECD Council on 18 September 1973 on the proposal of the Environment Committee. Seeking to address the use and hazards of mercury, the instrument recommends that Adherents adopt measures to reduce all man-made emissions of mercury to the environment to the lowest possible levels.

THE COUNCIL,

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 26 May 1972 on Guiding Principles concerning International Economic Aspects of Environmental Policies [C(72)128];

CONSIDERING the use and hazards of mercury, as well as the possibilities for emission control and the contingent economic effects thereof;

On the proposal of the Environment Committee;

I. **RECOMMENDS** that the Governments of Member countries should adopt measures:

a) To reduce all man-made emissions of mercury to the environment to the lowest possible levels, with particular attention to:

- The elimination of alkyl-mercury compounds from all uses that allow this material to reach the environment in any way;
- The maximum possible reduction of mercury in discharges from all industrial plants using or manufacturing products containing mercury chemicals;

b) For which immediate targets should be:

- The elimination of alkyl-mercury compounds in agriculture;
- The elimination of an mercury compounds from use in the pulp and paper industry;
- The maximum possible reduction in the discharges of mercury from mercury-cell chloralkali plants.

II. **INVITES** the Governments of Member countries:

a) To inform the Organisation of the measures taken pursuant to this Recommendation;

b) As from 1 January 1974, to proceed annually to an exchange of information, wherever possible, within the Environment Committee, on the following subjects:

- The quantity of alkyl-mercury used in agriculture and horticulture;
- The quantity of mercury used by the pulp and paper industry;
- The quantity of mercury discharged by the chloralkali industry in air and water and remaining in the solid wastes rejected by that same industry;
- The total national net consumption of mercury.

ANNEX

TECHNICAL NOTE AND CONCLUSIONS CONCERNING MERCURY

Nature of the Mercury Problem

1. Mercury and its compounds occur naturally in the environment but the use made of these by man can lead to high local concentrations which represent a serious risk to health. According to present knowledge, the most immediate hazard to man is created by methyl-mercury (an alkyl-mercury) and hence use of mercury in this form is of particular concern. However, in addition, it has been found that in adequate ecosystems other forms of mercury, including inorganic mercury, can be converted into methyl-mercury which can be absorbed and concentrated along the food chain. Although the efficiency of this process cannot at the present time be specified in advance, it evidently can occur in ways which are potentially harmful to higher organisms, including man, especially if this absorption and concentration are continued over a long period of time. This slower but more insidious effect gives rise to concern with regard to fresh water and marine products, and with regard to the discharge of mercury from industrial operations. Questions of mercury use and the toxicity of mercury in the environment have been discussed in reports on "The Biological Impact of Mercury" [NR/ENV/72.55] and "Control of Mercury Use and Emission, the Experience of Japan, Sweden, Canada and the United States" [NR/ENV/72.41].

International Agreements Relevant to the Mercury Problem

2. FAO/WHO

International actions relevant to control of the mercury problem fall into two categories. First, the Joint FAO/WHO Expert Committee on Food Additives has under continuous review the problem of the human intake of mercury compounds occurring in food. In 1967, this Committee recommended that "any use of mercury compounds that increases the level of mercury in food should be strongly discouraged". The report of the 16th meeting of this Expert Committee (April 1972) has recently been issued (WHO Technical Report Series, No. 505). It recommends a provisional tolerable weekly intake of 0.3 milligrams total mercury per person, of which no more than 0.2 milligrams should be present as methyl-mercury (expressed as weight of mercury).

Conventions on Dumping at Sea

3. Secondly, international action is developing rapidly with regard to questions of marine pollution and the dumping of chemicals at sea. Both the Convention for the Prevention of Marine Pollution by Dumping from Ships and Aircraft (Oslo Convention 1972), and the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter at sea (which is to be open for signature during December 1973), expressly prohibit the dumping of mercury and mercury compounds at sea. A Technical Memorandum of the latter Convention states that on the advice of a Technical Working Party, wastes containing small quantities of inorganic compounds of mercury, solidified by integration into concrete may be dumped only in depths of not less than 3 500 metres, in conditions which would cause no harm to the marine environment and its living resources. This method of disposal can be used for not longer than five years after the Convention comes into effect.

United Nations Conference on the Human Environment

4. In a more general sense the United Nations Stockholm Conference adopted for transmission to the General Assembly certain recommendations which are relevant, namely:

a) That Governments use the best practicable means available to minimise the release to the environment of dangerous or toxic substances, especially if they are persistent substances such as heavy metals and organochlorine compounds, until it has been demonstrated that their release will not give rise to unacceptable risks, or unless their use is essential to human health or food production, in which case appropriate control measures should be applied;

b) That the Secretary-General of the United Nations, drawing on the resources of the entire United Nations system and with active support of Governments and appropriate scientific and other international bodies, increase the capability of the United Nations system to provide awareness and advance warning of deleterious effects to human health and well-being from man-made pollutants.

Conclusions of the Investigation by the Environment Committee's Sector Group on the Unintended Occurrence of Chemicals in the Environment

5. The Working Group of Experts, appointed by Canada, Japan, Sweden and the United States to report on measures already taken by their Governments to reduce mercury emissions into the environment and the effectiveness, costs and justifications for these measures have, in their Report, given a summary of the common aspects of the policies adopted by their countries. From this it is clear that the dominant issue in relation to mercury is the protection of human health. The avoidance of ecological disturbance is also a major concern. In relation to the human health risk, Japanese experience emphasizes the importance of taking action before damage to health and welfare has occurred.

6. The regulatory approach to the problem has been focussed on prohibiting, restricting and preventing the introduction of mercury into the environment in order to limit, as far as practicable, its uptake in biological species and humans. The remedial measures taken have certain industrial and trade implications, but it would not appear that the establishment of stringent control with regard to the use of mercury compounds introduces major economic disturbances. However, failure to follow compatible policies in different Member countries could well lead to unnecessary problems in the industries directly concerned.

7. It is also important to note the extent to which Canada, Japan, Sweden and the United States have been able to take action against mercury use and discharge under existing laws, without the need to seek special authority. The compounds of mercury, falling as they do into the category of toxic materials, have been controlled variously under laws dealing with the use of pesticides, with waste discharge through sewers, waste discharge directly to receiving waters, food and drug laws, fisheries laws, as well as more recent legislation in some countries designed to enable administrative authorities to take action more widely on environmental pollution.

8. Finally, with regard to the longer term, the Working Group Report has drawn attention to the fact that further investigation of mercury and its compounds is necessary in several areas. These include the emission of mercury into the atmosphere from fossil fuel combustion, the emission to the environment of mercury used in electrical goods, the sub-clinical effects of mercury poisoning in man and the delayed onset of mercury poisoning.

9. Concerning the need for and feasibility of control action, certain detailed conclusions can be drawn from the situation as described:

a) In Canada, Japan, Sweden and the United States, mercury contamination of the environment, and risk of its accumulation through the food chain, were found as soon as measurements were made;

b) The sources and the priorities with regard to control of emissions vary widely from country to country;

c) Effective methods for the control of mercury emissions to the environment have been established in an area where the use of mercury has created identified problems of significant magnitude;

d) Where such problems have been identified as involving an imminent health hazard, counter-measures have been considered mandatory and independent of short-term economic costs;

e) In particular, the following controls have proved practical:

i) Alkyl-mercury compounds used in agriculture -- replacement by alternative compounds[1];

ii) Mercury compounds used in the pulp and paper industry -- replacement by alternative compounds or the use of alternative processes which do not require slimicides;

iii) Mercury metal used in the mercury cell chloralkali industry -- reduction in mercury content of plant effluents;

iv) Inorganic mercury catalysts used in the manufacture of chemicals from acetylene -- reduction in mercury content of plant effluents, or the use of alternative processes.

[1] The use of alkyl-mercury compounds for rice seed treatment has hitherto been permitted in Japan. However, administrative guidance is at present extended by the Government to ensure suspension of the production of alkyl-mercury compounds with a view to discouraging their use.

Adherents*

OECD Members		Non-Members	Other
Australia	United States		
Austria			
Belgium			
Canada			
Chile			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Iceland			
Ireland			
Israel			
Italy			
Japan			
Korea			
Latvia			
Lithuania			
Luxembourg			
Mexico			
Netherlands			
New Zealand			
Norway			
Poland			
Portugal			
Slovak Republic			
Slovenia			
Spain			
Sweden			
Switzerland			
Turkey			
United Kingdom			

*Additional information and statements are available in the Compendium of OECD Legal Instruments: http://legalinstruments.oecd.org

About the OECD

The OECD is a unique forum where governments work together to address the economic, social and environmental challenges of globalisation. The OECD is also at the forefront of efforts to understand and to help governments respond to new developments and concerns, such as corporate governance, the information economy and the challenges of an ageing population. The Organisation provides a setting where governments can compare policy experiences, seek answers to common problems, identify good practice and work to co-ordinate domestic and international policies.

The OECD Member countries are: Australia, Austria, Belgium, Canada, Chile, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Latvia, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The European Union takes part in the work of the OECD.

OECD Legal Instruments

Since the creation of the OECD in 1961, around 450 substantive legal instruments have been developed within its framework. These include OECD Acts (i.e. the Decisions and Recommendations adopted by the OECD Council in accordance with the OECD Convention) and other legal instruments developed within the OECD framework (e.g. Declarations, international agreements).

All substantive OECD legal instruments, whether in force or abrogated, are listed in the online Compendium of OECD Legal Instruments. They are presented in five categories:

- **Decisions**: OECD legal instruments which are legally binding on all Members except those which abstain at the time of adoption. While they are not international treaties, they entail the same kind of legal obligations. Adherents are obliged to implement Decisions and must take the measures necessary for such implementation.

- **Recommendations**: OECD legal instruments which are not legally binding but practice accords them great moral force as representing the political will of Adherents. There is an expectation that Adherents will do their utmost to fully implement a Recommendation. Thus, Members which do not intend to do so usually abstain when a Recommendation is adopted, although this is not required in legal terms.

- **Declarations**: OECD legal instruments which are prepared within the Organisation, generally within a subsidiary body. They usually set general principles or long-term goals, have a solemn character and are usually adopted at Ministerial meetings of the Council or of committees of the Organisation.

- **International Agreements**: OECD legal instruments negotiated and concluded within the framework of the Organisation. They are legally binding on the Parties.

- **Arrangement, Understanding and Others**: several ad hoc substantive legal instruments have been developed within the OECD framework over time, such as the Arrangement on Officially Supported Export Credits, the International Understanding on Maritime Transport Principles and the Development Assistance Committee (DAC) Recommendations.