Results of Preliminary Environmental Risk Assessment of Chemical Substances (FY 1997–2000 Pilot Project)

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The Ministry of the Environment carried out a four-year pilot project beginning in FY 1997 with the objective of establishing the methodology for a full-scale environmental risk assessment of chemical substances. After deliberation by the Special Committee for the Assessment of Chemical Substances, the Environment and Health Section of the Central Environment Council, the results were put together in this report.

The pilot project succeeded in establishing the basic methodology for systematically implementing preliminary assessment of environmental risk in the future. Through the preliminary assessment of 39 chemical substances in the project, those in need of in-depth assessment were determined.

1. Objective

About 100,000 chemical substances are said to be in circulation in the world and about 50,000 in Japan. Since many of them are harmful to human health and the ecosystem, environmental pollution caused by these substances in the environmental media (e.g. air, water and soil) is feared to have adverse effects on human health and the ecosystem.

In order to prevent any negative effects caused by chemical substances that are potentially hazardous to human health and the ecosystem, it is important to quantitatively assess the environmental risk of these substances. Based on the results of assessment, appropriate measures should be taken to reduce the risk of these substances.

To prepare for a full-scale assessment of the environmental risk of these chemical substances, the Ministry of the Environment conducted a pilot project for environmental risk assessment from FY 1997 to 2000 with the objective of establishing the methodology for implementation.

2. Contents of Environmental Risk Assessment in the Project

(1) Definition of Environmental Risk Assessment

The environmental risk assessment of a chemical substance consists of the following three steps: (a) toxicity assessment (identify the toxicity of the chemical substance to human health and the ecosystem, and establish the dosage (concentration)–reaction (effects) relationship); (b) exposure assessment (estimate the amount of exposure via environment on humans and the ecosystem; and (c) determine the risk level by comparing the results of these two assessments.

The environmental risk assessment undertaken in this pilot project basically followed this approach.

(2) Preliminary Assessment and In-depth Assessment

There are two types of environmental risk assessment. The "preliminary assessment" is used for sorting out chemical substances that have relatively high environmental risk from among a myriad of chemical substances. The "in-depth assessment" is used for obtaining information about the toxicity of and exposure to a chemical substance after the preliminary assessment in order to assess the substance's environment risk and formulate measures for its reduction.

The pilot project covered the "preliminary assessment." Specifically, it targeted 39 substances and conducted environmental risk assessment of these substances based on information obtained from literature available in Japan and from overseas.

3. Framework for the Implementation of the Environmental Risk Assessment in the Project

(1) Guidance from Experts and Formulation of Guidelines

Committees made up of experts were set up for the following three areas to formulate guidelines of standardized procedures for implementing the environmental risk assessment of various substances.

- Exposure assessment
  Chairman: 申杉修身 (Director, Research Center for Environmental Risk, National Institute for Environmental Studies)
- Health risk assessment (assessment of toxicity and risk to human health)
  Chairman: 内山巌雄 (Professor, Faculty of Engineering, Graduate School, Kyoto University)
- Ecological risk assessment (assessment of toxicity and risk to the ecosystem)
  Chairman: 安野正之 (Professor, School of Environmental Science, University of Shiga Prefecture)

(2) Selection of Substances for Assessment

In view of the fact that one of the pilot project's objectives was to establish methodology for the preliminary assessment of environmental risk, 39 substances were selected between FY 1997 and 2000 from among the substances targeted for the PRTR pilot project. Substances known to be components of large emissions into the environment and had assessment literature available that contained comparatively plentiful information on the toxicity of the substances were selected.

(3) Scope of the Effects for Assessment

Basically, assessment was conducted based on knowledge and information of the kinds of toxicity using established methods of assessment at this time.

For the preliminary assessment of health risk, general toxicity and reproductive and developmental toxicity, except carcinogenicity, were assessed quantitatively. Carcinogenicity, which had many quantification issues pending review, was assessed only qualitatively based on assessment-related literature. For the preliminary assessment of ecological risk, only the effects of chemical substances on life in the aquatic environment were assessed. Because testing methods for assessing the toxicity of endocrine disruptors are still in the development stage, endocrine disruptors were not included in the assessment of health risk and ecological risk.

On the other hand, exposure assessment was conducted based on the measurement values of the concentration of substances in the environment. Basically, only exposure in a general environment without the influence of any specific emission sources was assessed.

4. Results of the Pilot Project and Future Measures

(1) Results of 39 Substances for Preliminary Assessment

① As a direct result of this pilot project, the preliminary assessment of the environmental risk of 39 substances helped determine and screen out substances that require in-depth assessment and substances that require further collection of information.

	Health Risk	Ecological Risk
A. Substances with relatively high risk that "require in-depth assessment"	di (2-ethylhexyl) phtalate, acetaldehydes, p-dichlorobenzene, formaldehyde	di (2-ethylhexyl) phtalate, formaldehyde, dieldrin
B. Substances with lower risk than "A" but require "further collection of information"	8 substances including xylene, o-dichlorobenzene, methyl bromide, etc.	6 substances including aniline, endrin, xylene, etc.
C. Substances with relatively low risk that "do not need further assessment"	18 substances	15 substances
D. Substances for which the "risk cannot be determined" with the acquired information	9 substances	15 substances

(Note) This table was compiled using substance as the unit. Please refer to tables 1 and 2 for the details of assessment.

② Based on the results, the Ministry of the Environment takes the following measures for substances that "require in-depth assessment." With regard to substances that require "further collection of information" and substances for which the "risk cannot be determined," the Ministry will gather related information and carry out the necessary preliminary assessment based on information that becomes available.

i) Health risk of di (2-ethylhexyl) phtalate

Exposure to this substance through the intake of food may pose a relatively high risk to human health. At present, businesses are asked to voluntarily stop using gloves made of vinyl chloride when preparing food. Since there are many unknown factors concerning the exposure to this substance through the environment, further investigation will be carried out and then an in-depth risk assessment will be conducted.

ii) Health risk of acetaldehydes, p-dichlorobenzene, and formaldehyde

Exposure to these substances through the intake of indoor air may pose a relatively high risk to human health. Since some measures are being taken to mitigate risk, including the establishment of guideline values for indoor concentration by the Ministry of Health, Labor and Welfare from a similar perspective, focus will be placed for the time being on collecting information on the effects of these measures.

iii) Ecological risk of di (2-ethylhexyl) phtalate and formaldehyde

Because these two substances are included in the PRTR system, their emissions into the environment are being monitored and target values for water quality are being reviewed for the conservation of aquatic life. The Ministry will carry out in-depth risk assessment while gathering information on the results of these efforts.

iv) Ecological risk of dieldrin

The Chemical Substances Control Law has already banned the manufacture and use of this substance. It is assumed that the result obtained from this project is due to residual amounts of the substance in the environment. Necessary environmental monitoring will be carried out to determine the state of residual amounts in the environment.

(2) Establishing Methodology for the Preliminary Assessment of Environmental Risk

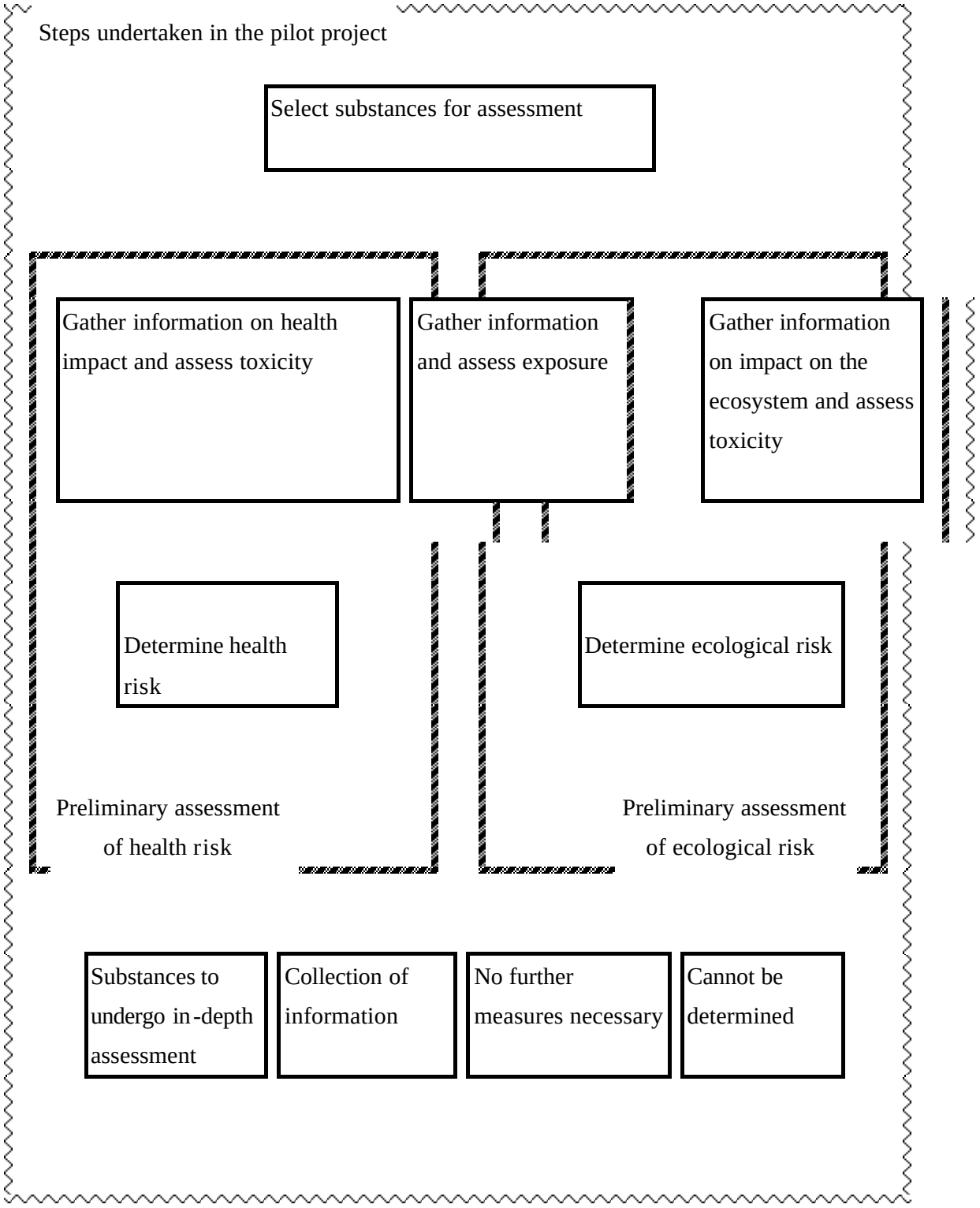
① As a pilot project for the preliminary assessment of environmental risk, the project has succeeded in establishing the basic methodology for preliminary assessment of environmental risk by putting together various guidelines specifying the procedures for conducting exposure assessment, health risk assessment, and ecological risk assessment.

② Based on this methodology, the Ministry will select substances known to be emitted in large amounts into the environment and induce large amounts of exposure based on the PRTR data and substances considered highly hazardous to human health and the ecosystem based on the information from Japan and overseas. The Ministry will conduct preliminary environmental risk assessment of these substances systematically.

At the same time, the following investigation and review will be carried out in relation to the guidelines.

- For exposure assessment, development and utilization of exposure models using PRTR data, etc.
- For health risk assessment, quantitative methods for assessing carcinogenicity
- For ecological risk assessment, methods for assessing effects on living organisms, besides aquatic life

Diagram: Outline of Preliminary Assessment of Environmental Risk



In-depth assessment of environmental risk
Review measures for reducing risk