Pursuit of a Chemical Management Principle
--Establishment of a Scientific Framework for the Management of Toxicity of Chemicals based on Environmental Risk-Benefit Analysis--

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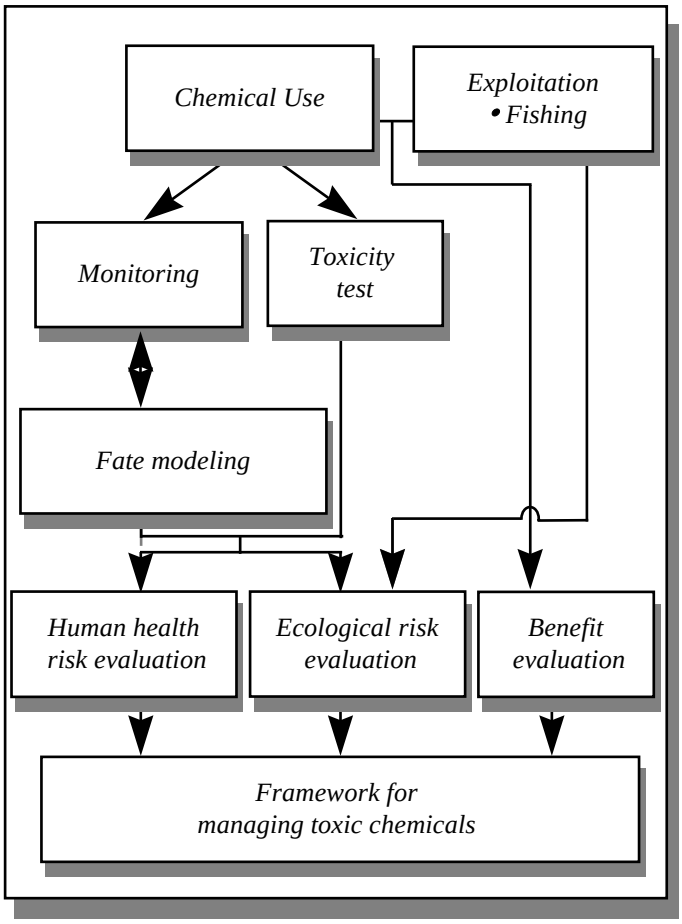
The objectives and the present state of the research project entitled " Establishment of a Scientific Framework for the Management of Toxicity of Chemicals based on Environmental Risk-Benefit Analysis" is mentioned. The urgent task is development of methodologies for evaluating human health risks and ecological risks so that thus calculated risks are appropriate for use in the risk-benefit analysis.

1. Overview of the research project

The research project is aimed at developing a scientific framework for the management of chemical use based on risk-benefit analysis which is a variation of cost-benefit analysis and is often referred to as a type of cost-effectiveness analysis. In the process, the methodologies for evaluating the risks posed by chemicals to human health, for balancing the benefits against risks from chemical use and for balancing the human health risks against the ecological risks will be developed. The research project includes the engineering, ecology and economic viewpoints. It is a basic scientific study in the sense that it aims at understanding the environmental behaviors of chemicals , and at the same time, a practical and policy-oriented study in the sense that the main motivation behind this project was the need to formulate environmental policies on a scientific and economic basis. This research is important because Japan lags behind other developed countries in chemicals regulation from a broad perspective. The chemical regulation policy in Japan has been established from a narrow perspective that considers just one chemical, one environmental medium and one risk, at a time. In addition, the policy only emphasizes only the human health protection, while overlooking need for the protection of ecological systems.

Furthermore, regulatory agencies and some proenvironment economists tend to believe that the risk-benefit analysis should not be applied to environmental policies, as doing so will provide great advantages to big industrial powers.



◆***Monitoring:*** monitoring of chemicals targeted for the project, in various environmental media.

◆***Fate modeling:*** development of models for estimating the behavior of chemicals in various environmental media.

◆***Human health risk evaluation:*** development of methodologies to evaluate human health risks in terms of Loss of life expectancy (LLE).

◆***Ecological risk evaluation:*** development of methodologies to evaluate ecological risks in terms of probability of species extinction.

◆***Benefit evaluation:*** evaluation of benefits associated with the use of each chemical such as economical benefits, convenience accruing from its use and conservation of resources.

◆***Final proposal:*** proposal of a framework for managing toxic chemicals based on risk-benefit analysis.

Figure 1. Project Overview

The overview of the project is shown in Figure 1 and mainly includes the following three objectives under which some sub-objectives have been listed;

1) to evaluate the human health risks from chemical use

2) to evaluate the risks to ecological systems from chemical use ,various types of exploitation and fishing

3) to balance the risks against the benefits from chemical use.

The final goal of the project is to propose a chemical management principle based on the results of case studies of several target chemicals selected for the research project and to propose a framework for establishing the chemical management principle.

2. Original approach to the research

The following three methods will be used in the research, the first two of which had been originally proposed by some researchers in our group.

1) A method for evaluating cancer and noncancer risks on the same scale, a loss of life expectancy (LLE) (Gamo et al,1995, Gamo et al.,1996, and Oka et al., 1997) Conventionally, regulatory policies with respect to toxic chemicals, in particular noncarcinogenic toxic chemicals, have been established on the basis of a yes or no decision. However, this approach has critical limitations. The most serious limitation is that it is unsuitable for risk-benefit analysis as well as for striking a balance between a broad spectrum of risks. To overcome these difficulties, we developed a method for evaluating the population risks associated with cancer and noncancer human health risks on the same scale, namely LLE. We have constructed a hierarchical structure of endpoints as shown in Figure 2, in which relative significance of the endpoints of lower level endpoints is determined by its importance with respect to a higher level endpoint. In this case, the respective diseases or symptoms, such as the development of cancer or Minamata Disease, is lower level endpoints and human death is higher level endpoint.

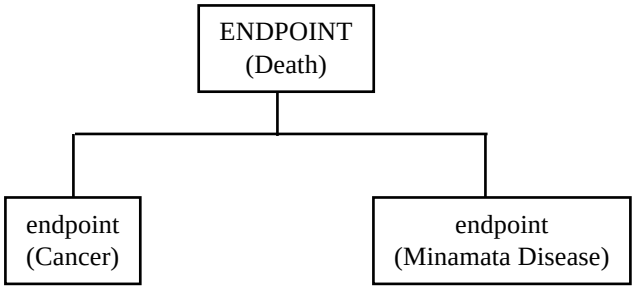


Figure 2. A hierarchical structure of endpoints.

For instance, the average LLE values for cancer and Minamata Disease in the case of comparatively milder symptoms were calculated to be 12.6 years and 1.75 years, respectively, which indicates the Minamata Disease risk multiplied by 1.75 can be compared with the cancer risk multiplied by 12.6. In this research, this method will be used to evaluate and compare various types of human health risks.

2) A method for evaluating ecological risk in terms of the probability of species extinction (Nakanishi, 1995, Nakanishi, 1997): The protection of ecological systems is more essential for future generations than for the present generation , because the ecological system contains resource for supporting the survivals of future generations. In this context, ecological risk can be defined as a risk to environmental or ecological resources which are of potential use to future generations. Considering that a key factor for the survival of ecological systems is diversity of species in the biological world, we can define species extinction as the assessment endpoint of

the ecological risk. This method of evaluating ecological risk in terms of species extinction has some other advantages: i) this method is available for the evaluation of, not only risks from chemical use but also, risks from exploitation or fishing, ii) the endpoint, namely species extinction, can be understood and accepted as undesirable effect by the public and the government, and iii) finally, this risk assessment method is likely to be the only way to avoid controverses regarding the distribution of resources and risks between generations.

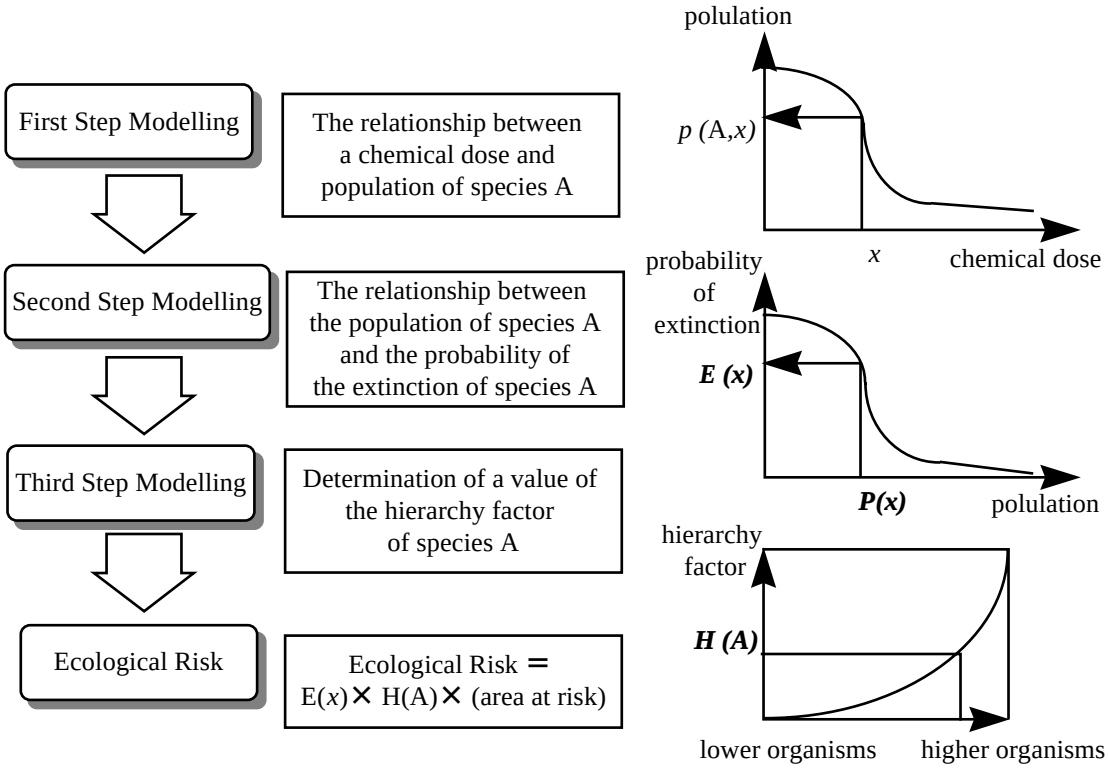


Fig 3. Basic concept of the method of evaluating ecological risks in terms of the species extinction.

The basic concept of this method is illustrated in Figure 3 and consists of the following three steps ; i) determination of the relationship between a chemical dose and population of species A, ii) the modeling of the relationship between the population of species A and the probability of extinction of species A , and iii) the assumption of a value for the hierarchy factor in the context of the ecological world of species A which exists in the biological world, where a hierarchy factor is defined as an indicator of the extent of impact of extinction of species A on the entire ecosystem. Finally, the ecological risk in this case is calculated by the products of (the extinction probability of A)×(hierarchy factor of A)×(area at risk), in which the ecological risk is represented in dimensions of area. It is worth mentioning here, that this is the first and primitive method, parts of which have already been revised.

3) The value of the benefit -risk ratio (BRR) obtained from the risk-benefit analysis is used to determine whether a policy is cost-effective. A suitable range of values for the BRR can be obtained by analyzing the BRR values of other policies which include alternatives to the policy in question, as well as those already put into practice.

3. The present state of the research

A list of members involved in the research project is printed in page x. The research group consists mainly of faculty members of Institute of Environmental Science and Technology, Yokohama National University and members of other institutions such as the Department of Biology, Kyushu University.

The topics being researched include:

Ⅰ. The human health risk research led by Professor S. Masunaga.

1) Monitoring of chemicals in the various environmental media

1-1) Levels of dioxins in various environmental media including atmospheric deposition and in living creatures such as fish and birds

1-2) Levels of benzene in the atmosphere originating from vehicular exhaust

1-3) Levels of indoor air pollutants

2) Investigation of the behaviors of chemicals in environmental media , for example, the decomposition of organic halogen compounds in aqueous environments and the heterogeneous reaction of volatile organic carbon compounds and SOx in air

3) Construction and validation of fate models of chemicals in various environmental media: construction of a watershed model supported by the GIS (geographical information system) and characterization of uncertainty associated with exposure analysis using multimedia fate models

4) Construction of a model describing the distribution and transport of chemicals in the human body and other living organisms using the PBPK model

Ⅱ. The ecological risk evaluation led by Professor Y. Iwasa

1) Development of methodologies for representing the ecological adverse effects from exposure to chemicals in terms of the probability of species extinction:

1-1) Mathematical and analytical approach

1-2) Approach using age-structured projection matrices related to the reproductive potential model

2) Formulating of a model describing the adverse effects from exposure to chemicals on various species for a multispecies system or microcosm where competitive and predator-prey relationship exist among species.

3) Field studies regarding the probability of extinction of Minami Maguro (tuna) due to fishing and the ecological risk due to agricultural development in Thailand

4) Laboratory toxicity tests using daphnia and some test fish species, in terms of the age-specific survival and reproduction of the test organisms.

The achievements of the research project will be presented to this Workshop and printed in the Proceedings of the Workshop.

Acknowledgments

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