

# Overview of Initial Risk Assessment Reports for Chemical Substances

## 1. The positioning and purpose of Initial Risk Assessment

### 1.1 Positioning and purpose

The Initial Risk Assessment is an early stage screening assessment in a multi-stage risk assessment of chemical substances. In the Initial Risk Assessment, the risk of a substance to human health and organisms in the environment in Japan is evaluated by using available information to determine the necessity of further investigation, analysis and assessment and to point out insufficient information and required action. Risks to human health and the environment posed by long-term (chronic) exposure via environment were evaluated.

### 1.2 Organization involved

National Institute of Technology and Evaluation (NITE) and the Chemicals Evaluation and Research Institute, Japan (CERI) conducted the Initial Risk Assessment jointly as part of a project funded by the New Energy and Industrial Technology Development Organization (NEDO) from 2001 to 2007. <sup>1)</sup>

## 2. Method of assessment

Initial Risk Assessment is conducted based on conservative assumptions, such as the highest possible exposure<sup>2)</sup> and the lowest toxic threshold data (e.g., NOAEL, NOEC).

Figure 1& 2 show procedures of environmental risk assessment and human health assessment respectively.

### 2.1 Subjects for Initial Risk Assessment

One hundred and fifty substances were selected from “Class 1 Designated Chemical Substances” stipulated by the Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (hereafter “PRTR Law”)<sup>3)4)</sup>. During the selection process, the hazardous properties of the substances and the magnitude of environmental exposure were also considered.

### 2.2 Effect assessment

#### (1) Effects on organisms in the environment

Risks to aquatic organisms are assessed with long-term toxicity data on the representative aquatic lives of three trophic levels in the food-chain, that is: algae, invertebrate (crustacea) and fish.

(2) Effects on human health

Following types of toxicological effects are considered.

- a) Repeated dose toxicity
- b) Reproductive and developmental toxicity
- c) Genotoxicity
- d) Carcinogenicity

**3. Characteristics of Initial Risk Assessment**

(1) Exposure assessment based on PRTR data and mathematical models

Concentrations of substances in the environment were estimated not only by environmental monitoring data but by using mathematical models<sup>5)</sup> and PRTR data. In the first few years of the project, assessment was conducted according to Guideline Version 1. Afterwards, Guideline Version 2 was applied.

The main differences of the two are below;

Guideline Version 1:

In the exposure assessment, priority is given to monitoring data over values estimated by mathematical models.

Guideline Version 2:

As use of the PRTR system spread, the estimated values by model became reliable enough for comparison with monitoring data. Therefore, in the exposure assessment, the larger value of the two is used.

(2) Risk characterization

Risk characterization is conducted by comparing the MOE<sup>6)</sup> with the product of uncertainty factor (UF)<sup>7)</sup>:

- When the MOE is larger than the UF, it is concluded that “the substance is considered to be of no immediate concern for the moment and a low priority for further work”.
- When the MOE is equal to or less than the UF, it is concluded that “the substance is considered to be of concern and further investigation, analysis and assessment are necessary”.

This method is useful in terms of that the MOE shows the scale factor by which the toxic threshold data (e.g., NOEC ,NOAEL) exceeds the estimated exposure, while the uncertainty factor (UF) shows the reliability of toxic data.

#### 4. Outline of the results of Initial Risk Assessment

Results of the Initial Risk Assessment of 150 substances are below:

		Substance of concern	Substance of no immediate concern	Impossible to assess	
				Lack of exposure data	Lack of toxicity data
Human health*	Inhalation	7	83	1	59
	Oral	7	118	4	21
Organisms in the environment		26	116	4	4

\*Risk assessment results on repeated dose toxicity

**Note:**

- 1) As a part of the NEDO project, National Institute of Advanced Industrial Science and Technology (AIST) has developed and released a number of “Risk Assessment Documents” on the chemical substances with known or expected risks to human health and/or ecosystems. ([http://unit.aist.go.jp/riss/crm/mainmenu/e\\_1.html](http://unit.aist.go.jp/riss/crm/mainmenu/e_1.html))
- 2) The Initial Risk Assessment was carried out by using the highest estimated exposure data.
- 3) Substances mainly used for agricultural chemicals and ozone-depleting substances were not selected because those substances are controlled by different laws respectively.
- 4) PRTR law: The purpose of this Act is to promote voluntary improvement of the management of chemical substances by business operators and to prevent impediments to the preservation of the environment. Business operators are required to confirm release amounts of specific chemical substances in the environment, and to report the data to the government. (<http://www.env.go.jp/en/chemi/prtr/about/overview.html>)
- 5) Mathematical models used in the Initial Risk Assessment:
  - (a) Atmospheric Dispersion Model for Exposure and Risk Assessment (AIST-ADMER), developed by AIST. ([http://www.aist-riss.jp/software/admer/en/index\\_e.html](http://www.aist-riss.jp/software/admer/en/index_e.html))
  - (b) Integrated River Model ver.1 (IRM1), developed by CERI.
  - (c) Initial Assessment System for PRTR chemicals (IAS), developed by the Japan Chemical Industry Association.
- 6) MOE: Margin of exposure. A ratio of toxic threshold data (e.g., NOEC, NOAEL) for the critical effect to the estimated exposure intake or concentration. When MOE is larger, that means there is a larger margin between exposure and NOEC (NOAEL).

$$\text{MOE} = \text{NOEC (NOAEL)} / \text{EEC (EHI)}$$

where; EEC: Estimated environmental concentration

EHI: Estimated human intake

In the Initial Risk Assessment, MOE is calculated separately for oral route and inhalation route exposure.

- 7) Product of uncertainty factor (UF):

A reductive factor by which an observed or estimated no-observed-adverse effect level (NOAEL) is divided to arrive at a criterion or standard that is considered safe or without appreciable risk. (IPCS Risk Assessment Terminology/Definitions of key generic terms, <http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf>)

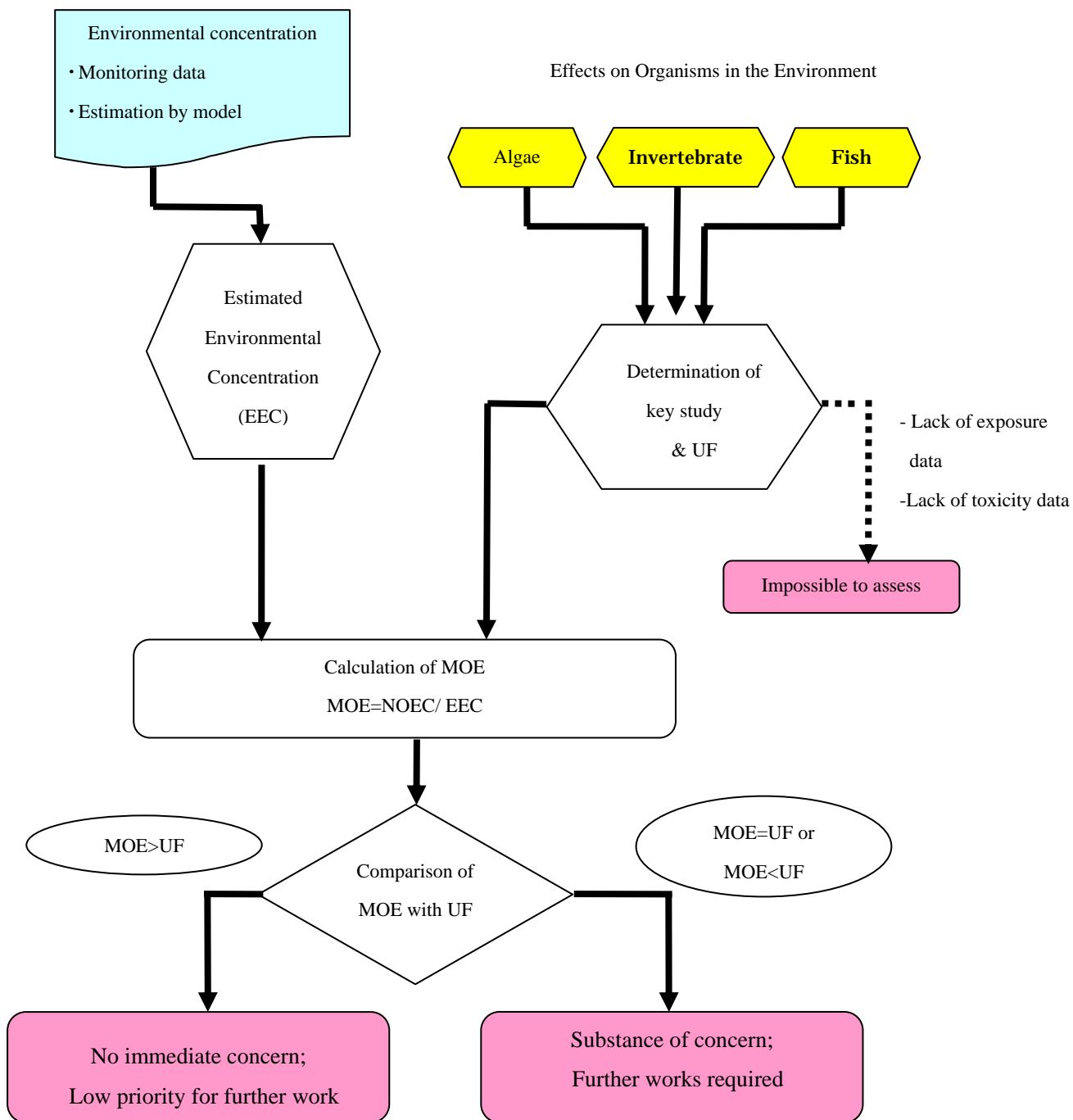


Fig.1 Procedure of Initial Risk Assessment for organisms in the environment (Environmental risk assessment)

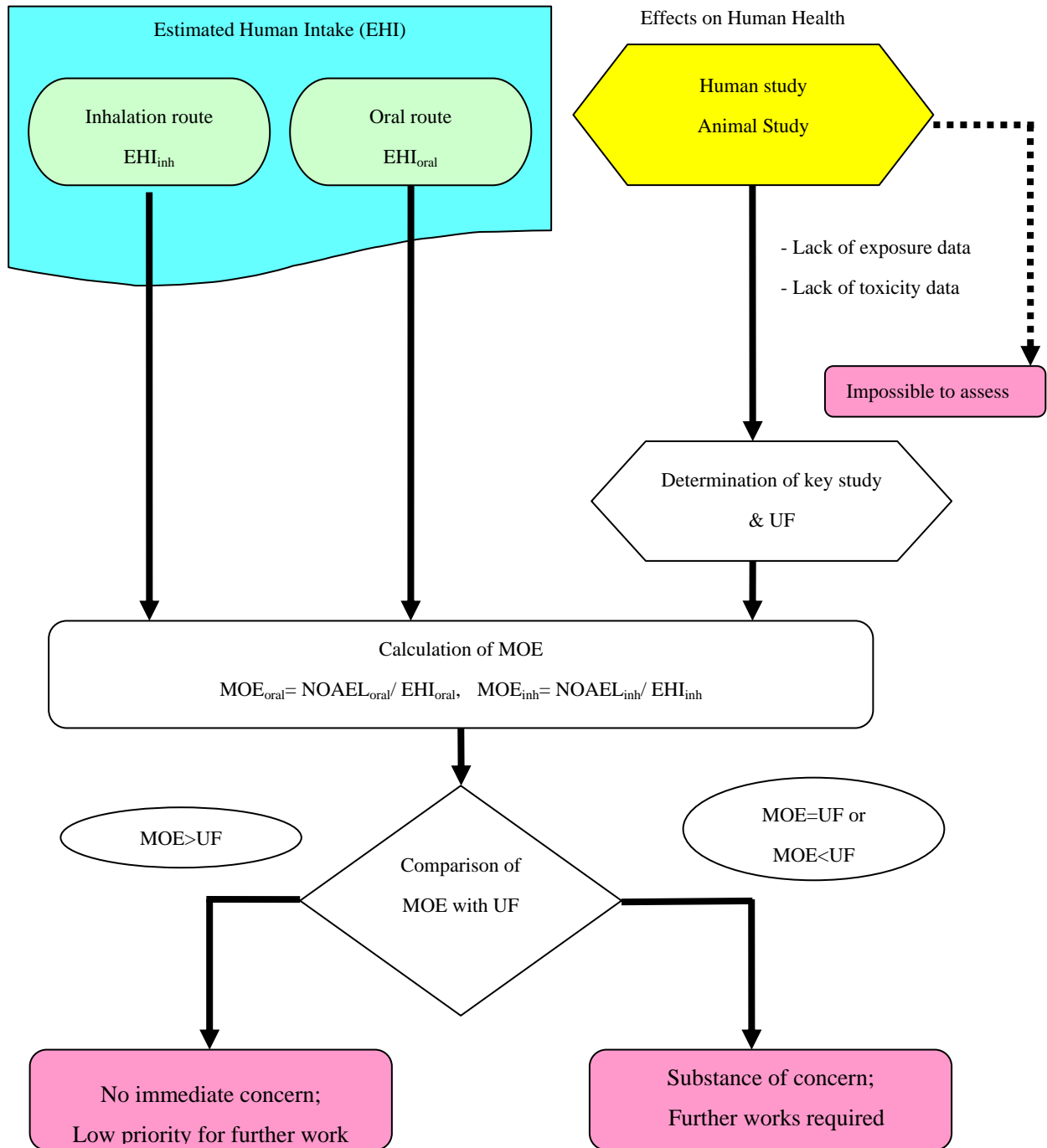


Fig.2 Procedure of Initial Risk Assessment for human health