กรมโรงงานอุตสาหกรรม
DEPARTMENT OF INDUSTRIAL WORKS

Basic Understanding on Chemical Risk Assessment

RESPONSIBLE CARE ดูแลด้วยความรับผิดชอบ

Presented by:

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Basic Understanding on Chemical Risk Assessment

Chemical Substances surrounding us

Source: How to interact successfully with chemical substances, Risk Assessment of Chemical Substances, NITE, Japan

Basic Understanding on Chemical Risk Assessment

Understanding Risk Assessment

Risk = Hazard × Exposure

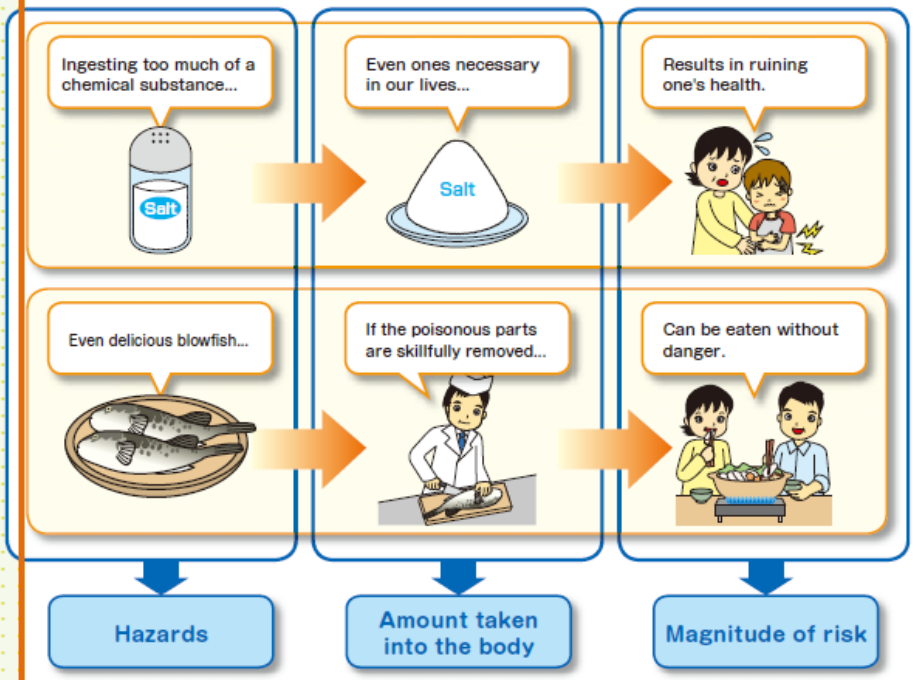
- Risk: **Probability** of *Adverse Effects* resulting from a given **exposure**
- Hazard: **Intrinsic properties** causing *Adverse Effects*

- Even if the substance has a **High** hazard,
  Low exposure can minimize the risk
- Even if the substance has a **Low** hazard,
  High exposure may cause high risk

It is important to **assess the "risk"** by substance in use

Basic Understanding on Chemical Risk Assessment

Understanding Risk Assessment



Source: How to interact successfully with chemical substances, Risk Assessment of Chemical Substances, NITE, Japan

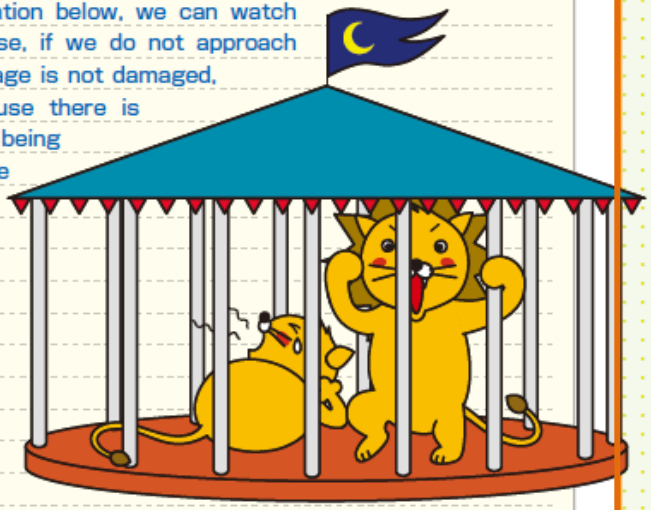
Let's see what hazards Chemical Substances have.

Have you heard of the word "risk" ?

The possibility of hazards is called risk. For example, lions indicate a high risk because they are dangerous animals. However, if lions are kept in a cage as described in the illustration below, we can watch them safely. In this case, if we do not approach too closely and if the cage is not damaged, risk is minimized because there is a lower possibility of being attacked. We can reduce high risk by adequate management.

Suppose these lions were replaced by chemical substances, the cage would become the device used to manage chemical substances.

Topic
Risk: Possibility of hazards



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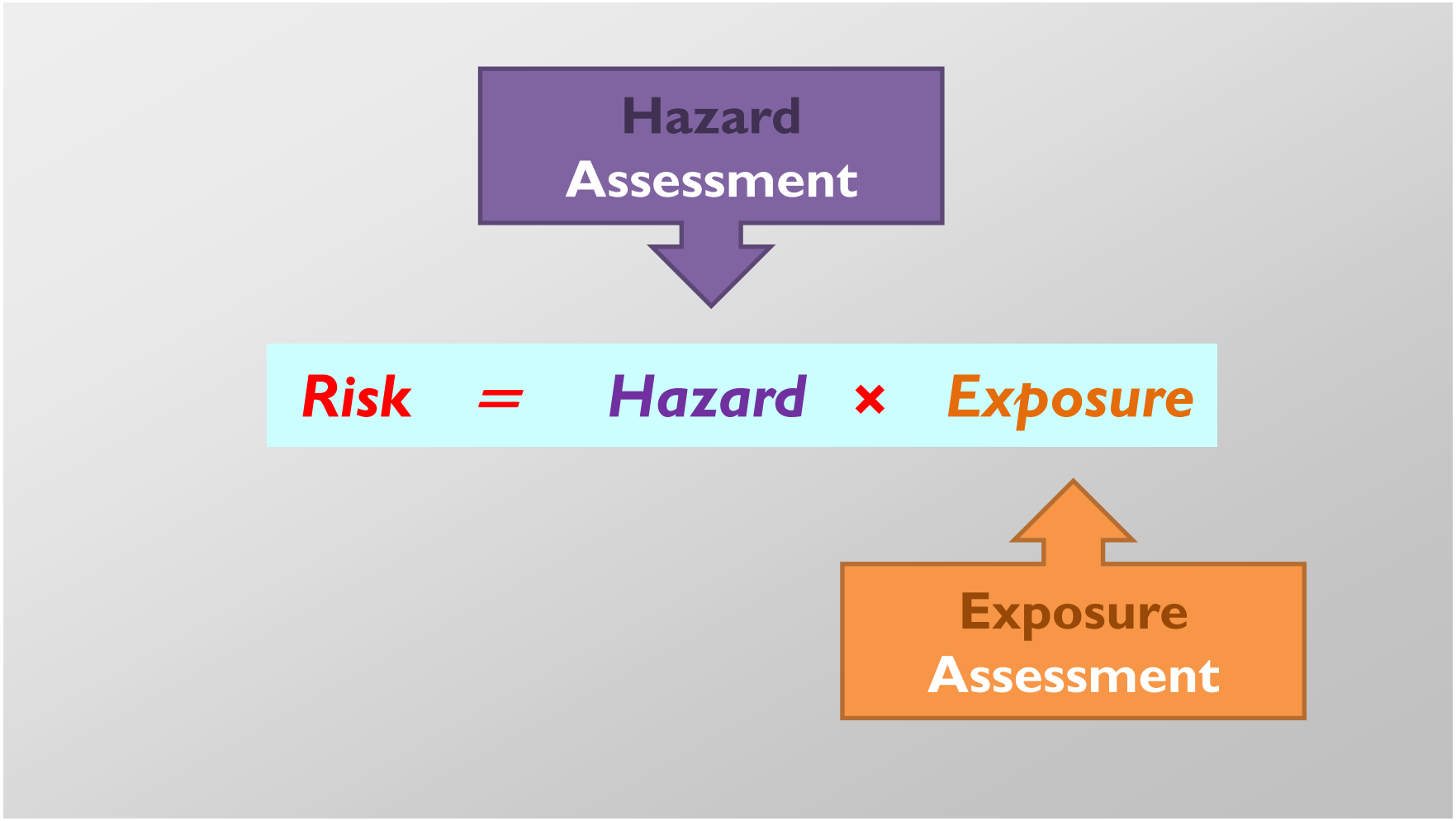
Understanding Risk Assessment



Basic Understanding on Chemical Risk Assessment

Understanding Risk Assessment

Health Risk Assessment

$$Risk = Hazard \times Exposure$$

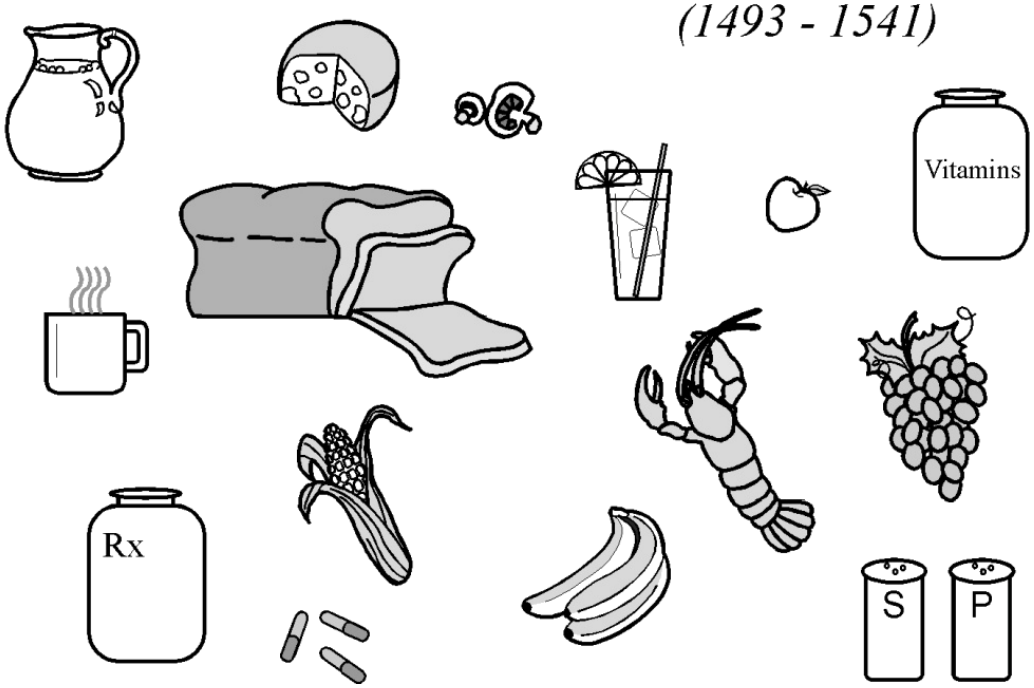
Environmental Risk Assessment

Basic Understanding on Chemical Risk Assessment

Hazard Identification

All substances are poisons; there is none which is not a poison. The right dose differentiates a poison and a remedy.

Paracelsus
(1493 - 1541)



THE CONCEPT:
"THE DOSE MAKES POISON"

Basic Understanding on Chemical Risk Assessment

Hazard Terms & Definitions

Dangerous

Hazardous

Deleterious

Poison

Harmful

Toxic

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Understanding Hazards

All Chemical Substances have some kind of hazards.

For example, although we cannot live without water, excessive intake may damage the digestive track or result in body swelling.

When handling chemical substances, we need to know the hazards.

So, when do all the above hazards of Chemical Substances appear?

Topic
Hazards of alcohol

Alcohol contains a chemical substance called Ethanol. Excessive intake causes Hazards.

Acute toxicity :
Acute alcohol poisoning results from drinking too much alcohol at one time.

Chronic toxicity :
Liver damage results from drinking too much alcohol over a long period of time.

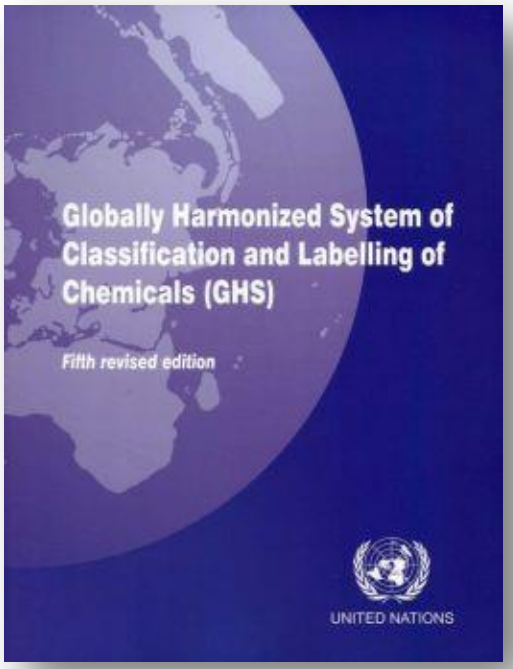
Hazards of alcohol are categorized by the length of time until hazards appear.

Source: How to interact successfully with chemical substances, Risk Assessment of Chemical Substances, NITE, Japan

Basic Understanding on Chemical Risk Assessment

Hazard Classification under GHS

Physical Hazards	16 Hazards Classes	Division, Type, Hazard Category
Health Hazards	10 Hazard Classes	Hazard Category
Environmental Hazards	2 Hazard Classes	Hazard Category



GHS (**G**lobally **H**armonized **S**ystem of Classification and Labelling of Chemicals)

"The Purple Book" Latest Edition: 5th Revised Edition, Issued year: 2013

Thai Regulations: 3rd Revised Edition, Issued year: 2011

Basic Understanding on Chemical Risk Assessment

Hazard Classification under GHS

2. Physical Hazards	GHS Recommendation Hazard Classes						
2.1 Explosives	Unstable Explosives	Division 1.1	Division 1.2	Division 1.3	Division 1.4	Division 1.5	Division 1.6
2.2 Flammable gases	Category 1	Category 2					
2.3 Flammable aerosols	Category 1	Category 2					
2.4 Oxidizing gases	Category 1						
2.5 Gases under pressure	Compressed gas	Liquefied gas	Refigerated liquefied gas	Dissolved gas			
2.6 Flammable liquids	Category 1	Category 2	Category 3	Category 4			
2.7 Flammable solids	Category 1	Category 2					
2.8 Self-reactive substances and mixtures	Type A	Type B	Type C	Type D	Type E	Type F	Type G
2.9 Pyrophoric liquids	Category 1						
2.10 Pyrophoric solids	Category 1						
2.11 Self-heating substances and mixtures	Category 1	Category 2					
2.12 Substances and mixtures which in contact with water emits flammable gases	Category 1	Category 2	Category 3				
2.13 Oxidizing liquids	Category 1	Category 2	Category 3				
2.14 Oxidizing solids	Category 1	Category 2	Category 3				
2.15 Organic peroxides	Type A	Type B	Type C	Type D	Type E	Type F	Type G
2.16 Corrosive to metals	Category 1						

GHS (**G**lobally **H**armonized **S**ystem of Classification and Labelling of Chemicals)

Hazard Classification above is based on 3rd Revised Edition, Issued year: 2011

Basic Understanding on Chemical Risk Assessment

Hazard Classification under GHS

3. Health Hazards	GHS Recommendation Hazard Classes				
3.1 Acute Toxicity	Category 1	Category 2	Category 3	Category 4	Category 5
3.2 Skin Corrosion/Irritation	Category 1A	Category 1B	Category 1C	Category 2	Category 3
3.3 Serious eye damage/eye irritation	Category 1	Category 2A	Category 2B		
3.4 Respiratory or skin sensitization	Category 1	Category 1A	Category 1B		
3.5 Germ cell mutagenicity	Category 1A	Category 1B	Category 2		
3.6 Carcinogenicity	Category 1A	Category 1B	Category 2		
3.7 Reproductive toxicity	Category 1A	Category 1B	Category 2	Addtl Category (affects via lactation)	
3.8 Specific target organ toxicity - Single exposure)	Category 1	Category 2	Category 3		
3.9 Specific target organ toxicity - Repeated exposure)	Category 1	Category 2			
3.10 Aspiration hazard	Category 1	Category 2			

4. Environmental Hazards	GHS Recommendation Hazard Classes			
4.1 Hazardous to the aquatic environment - Acute toxicity	Category 1	Category 2	Category 3	
- Chronic toxicity	Category 1	Category 2	Category 3	Category 4
4.2 Hazardous to the ozone layer	Category 1			

GHS (**G**lobally **H**armonized **S**ystem of Classification and Labelling of Chemicals)

Hazard Classification above is based on 3rd Revised Edition, Issued year: 2011

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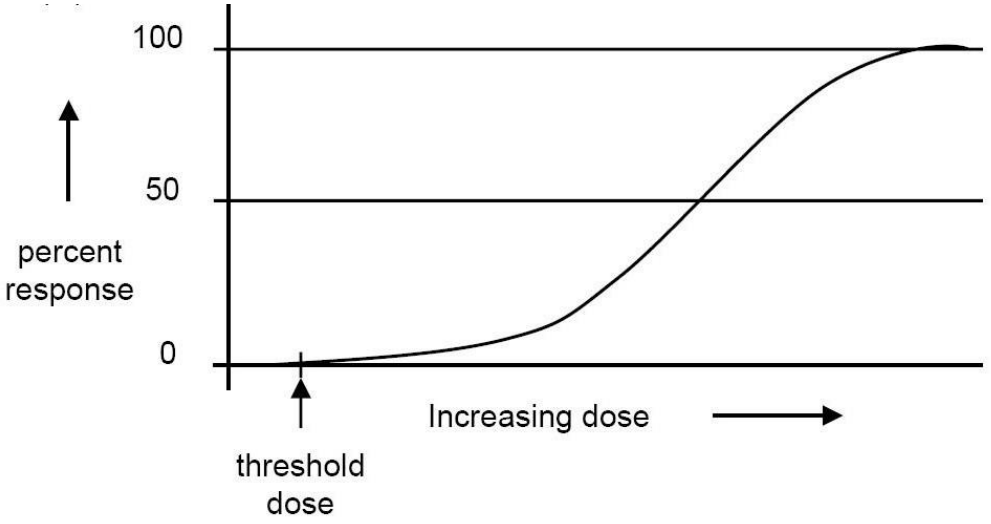
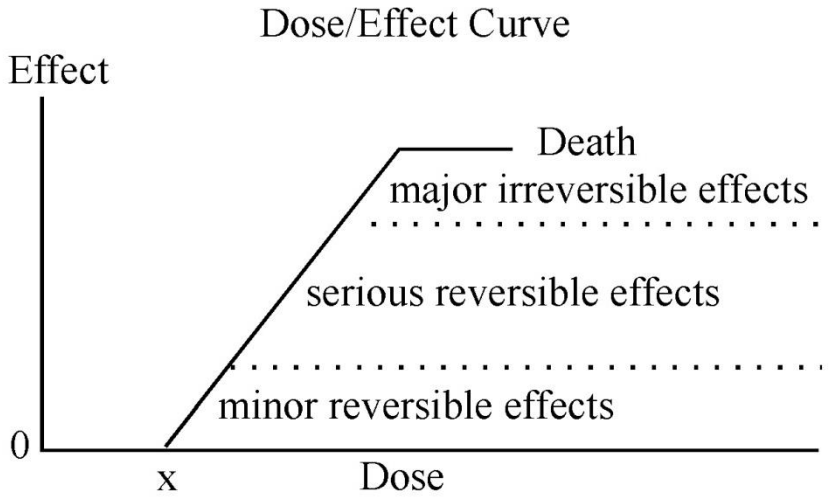
Understanding Hazard Assessment

Dose Response Curve (Animal Testing)





At dose x the first measurable effect occurs. As the dose increases the effects become more serious, and possibly irreversible. The most serious effect is death.

Source: The HazCom Training Program, McManus, Neil/Green, Gilda (1999)

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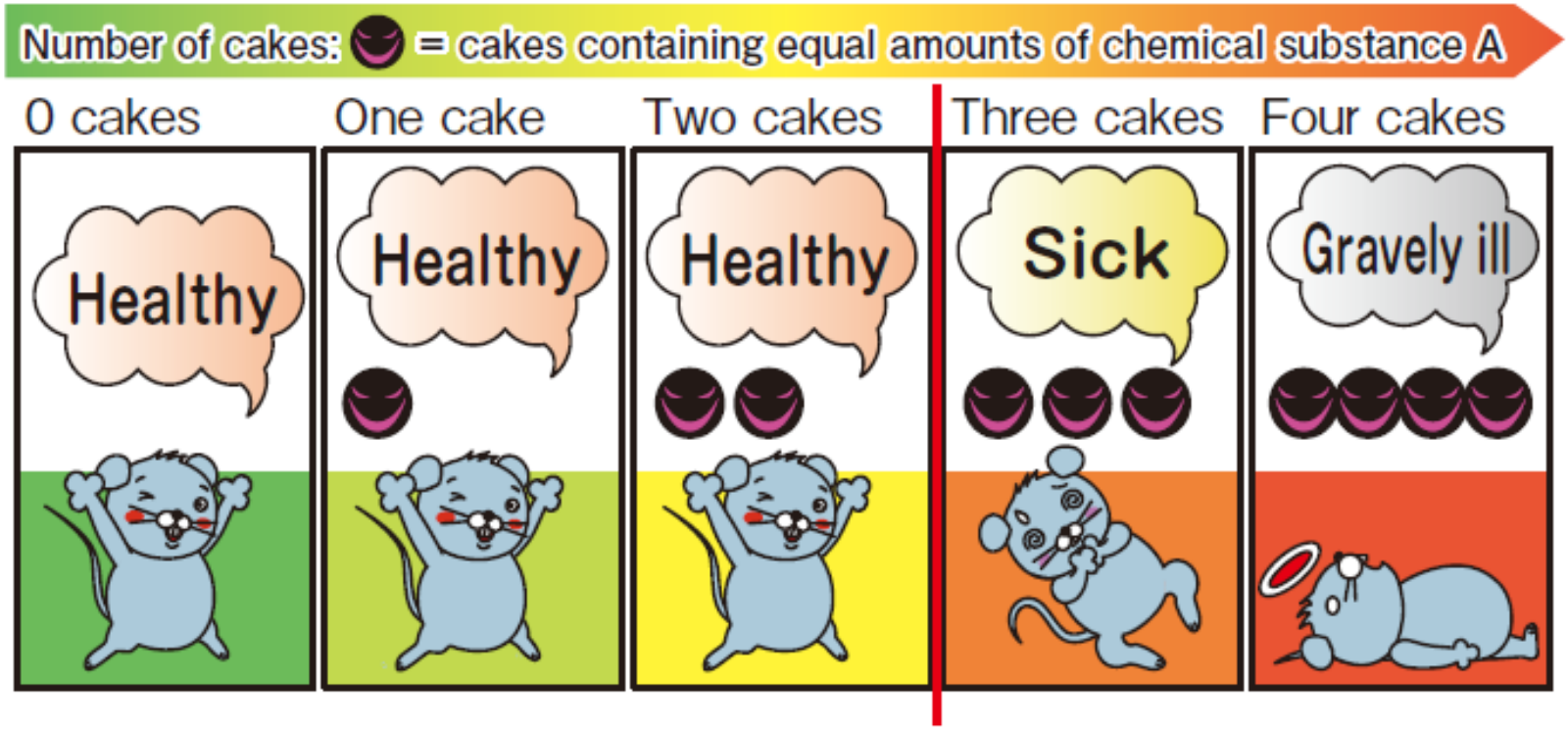
Understanding Hazard Assessment

Dose Response Curve (Animal Testing)



Source: How to interact successfully with chemical substances, Risk Assessment of Chemical Substances, NITE, Japan

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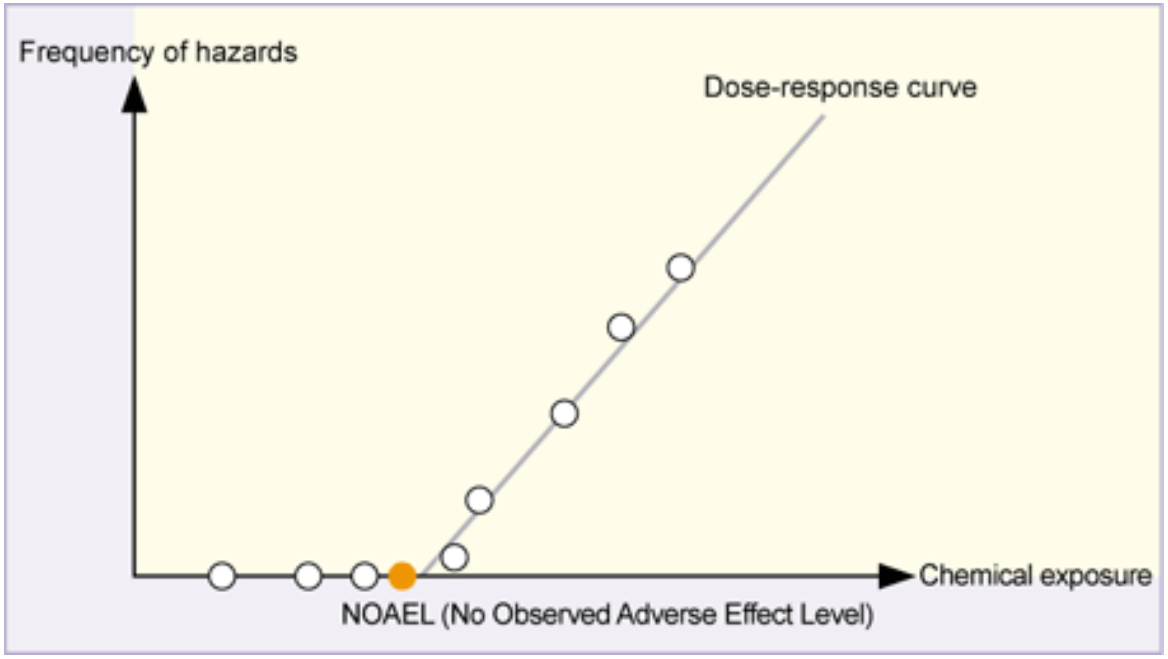
Understanding Hazard Assessment

Dose Response Curve (Animal Testing)

What is NOAEL ? (No Observed Adverse Effect Level)



No Observed Adverse Effect Level (NOAEL) is the highest exposure of a chemical, determined in toxicity tests etc., having no adverse effect (e.g., onset of sickness) even when the chemical is taken (exposed) daily for a rest of one's life. (mg/kg/day)

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Understanding Hazard Assessment

Dose Response Curve (Animal Testing)

NOAEL (No Observed Adverse Effect Level)

NOAEL is determined by the toxicity tests etc. listed below.

Long-term toxicity*1	Toxicity appearing following a long-term continued exposure (repeated exposure)
Reproductive and developmental toxicity	Toxicity exerting adverse effects on parent's reproductive function and fetuses
Carcinogenicity*2	Potential of causing cancer of various types
Respiratory tract irritation	Potential of causing respiratory tract allergies (asthma, etc.)

*1: Also called "repeated dose toxicity"

*2: In some cases there is no NOAEL for carcinogenicity.

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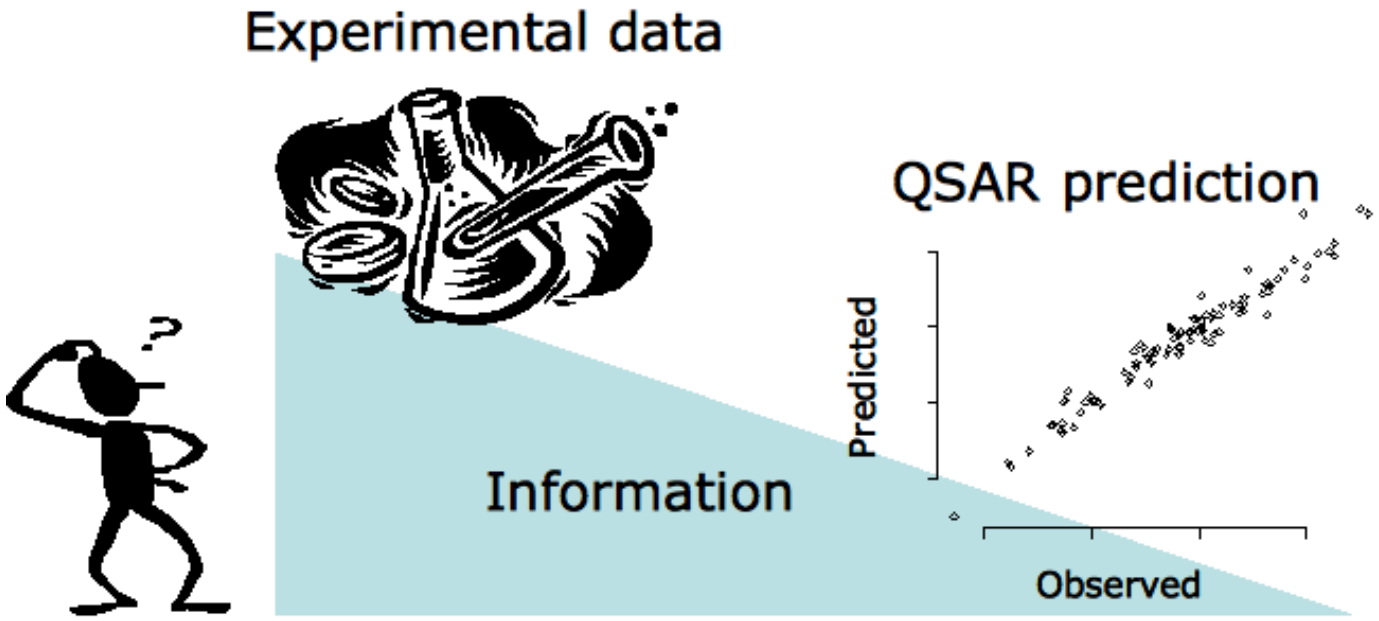
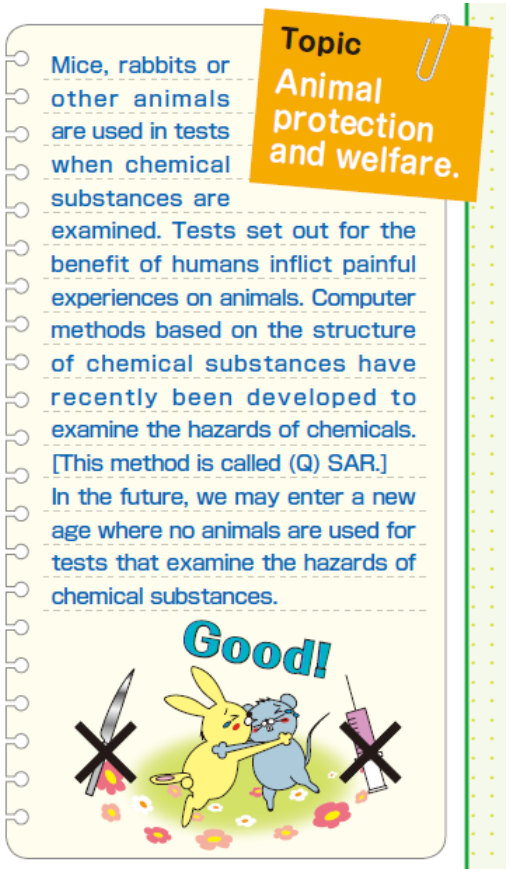
Understanding Hazard Assessment

Dose Response Curve (Animal Testing)

QSAR (Quantitative Structure Activity Relationship)





Source: How to interact successfully with chemical substances, Risk Assessment of Chemical Substances, NITE, Japan

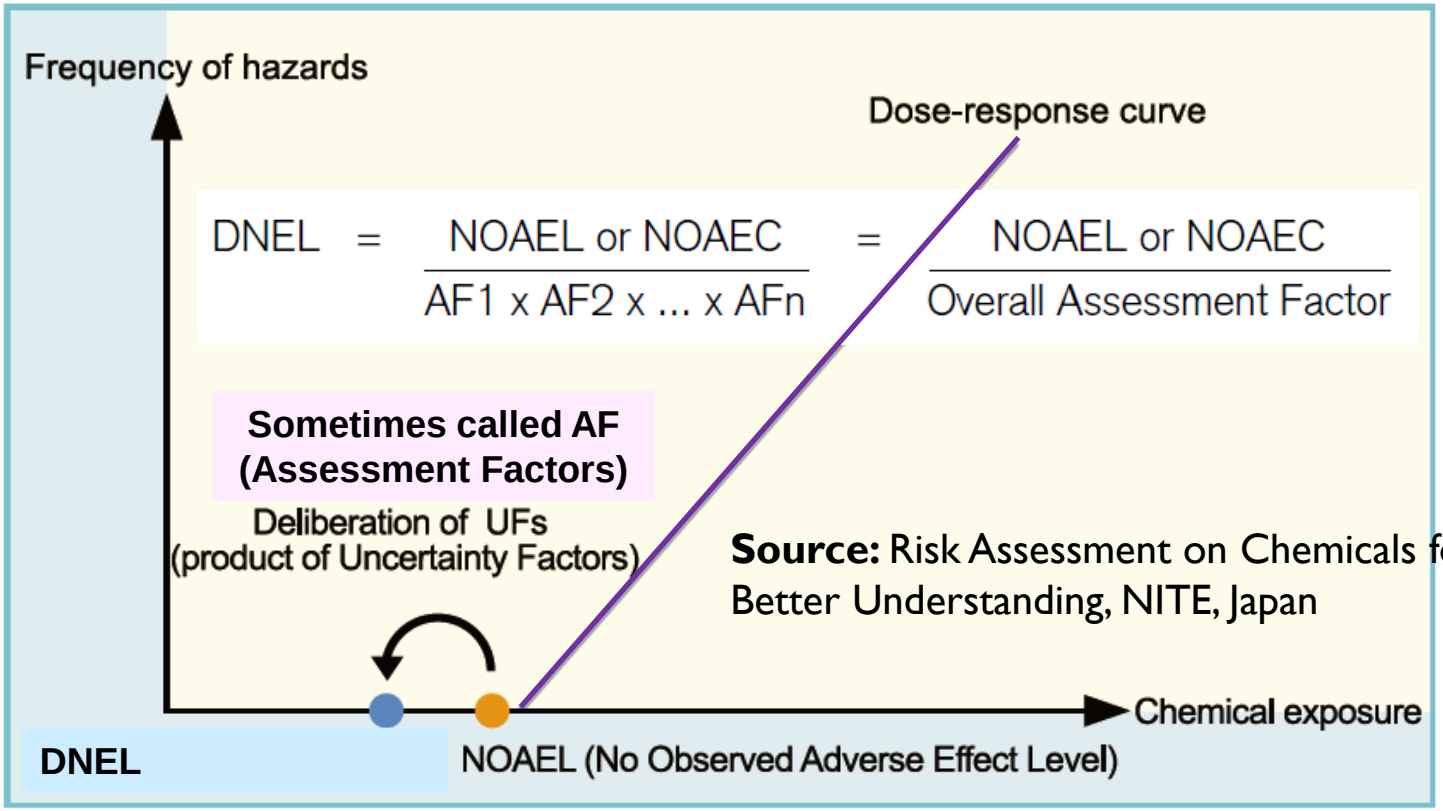
Basic Understanding on Chemical Risk Assessment

Understanding Hazard Assessment

Dose Response Curve (Conversion to Human Value)

DNEL (Derived No Effect Level) – NOAEL for Humans

also called Tolerable Daily Intake (TDI) /Acceptable Daily Intake (ADI) /Reference Dose (RfD)



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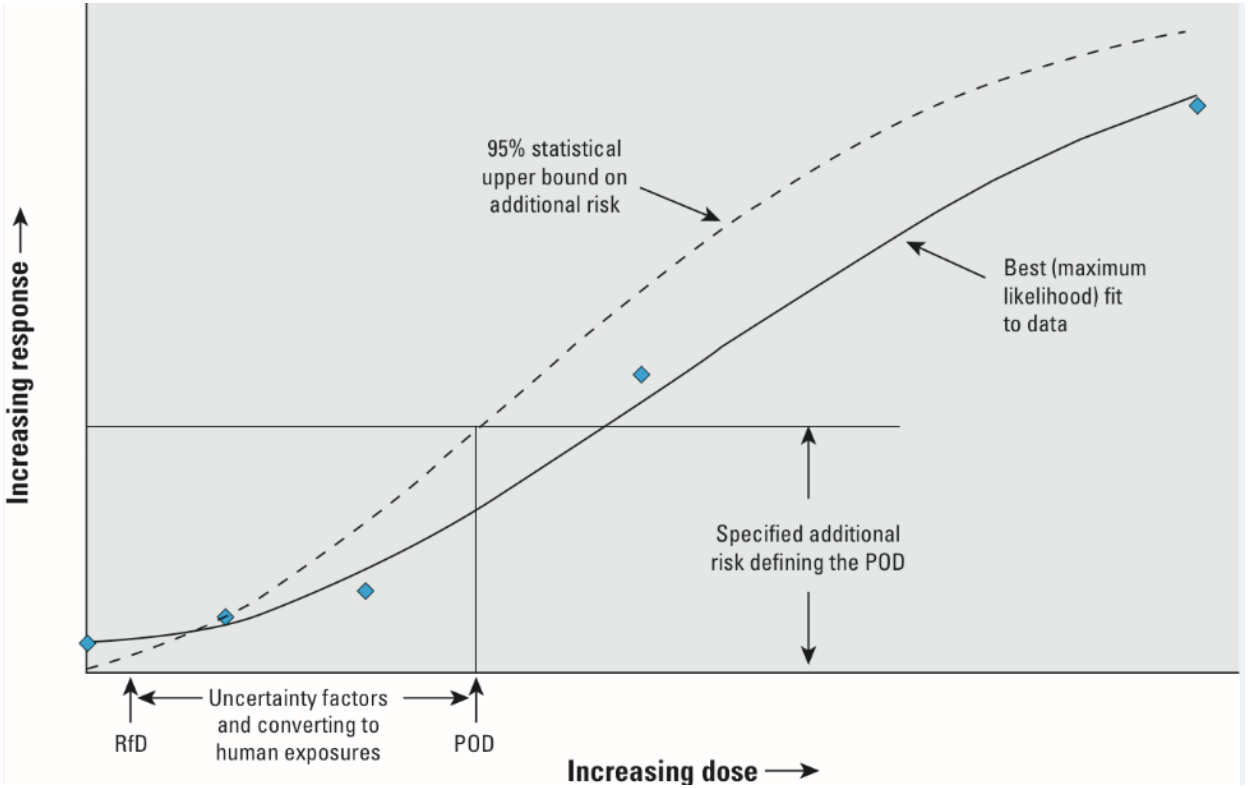
Understanding Hazard Assessment

Dose Response Curve (Conversion to Human Value)

Reference Dose (RfD) – NOAEL for Humans



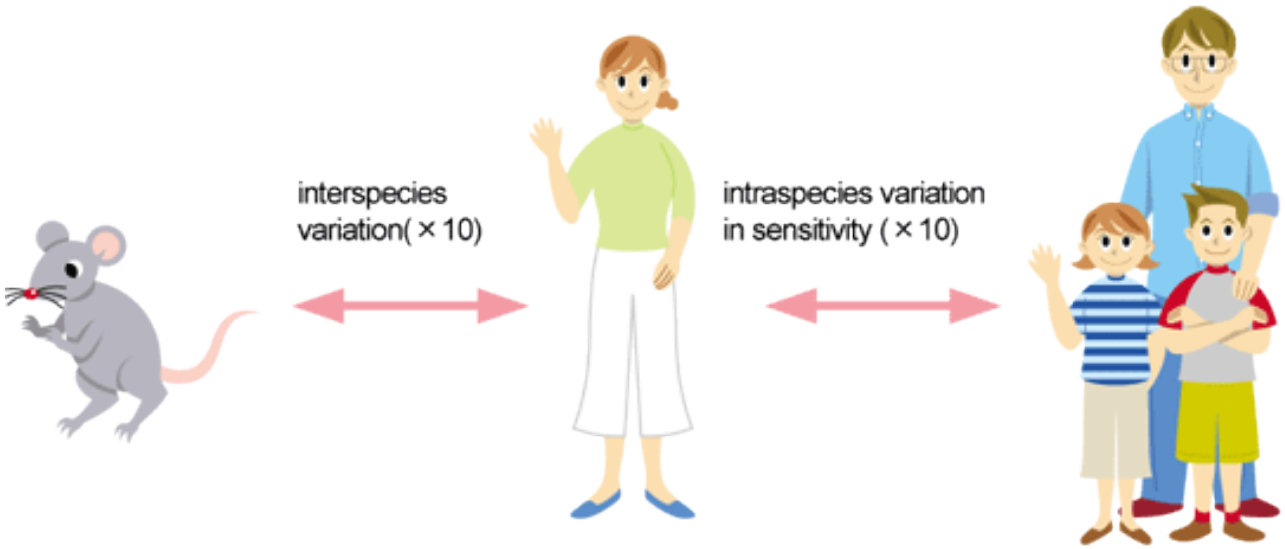
Source: http://ehp.niehs.nih.gov/1001931/

Basic Understanding on Chemical Risk Assessment

Understanding Hazard Assessment

Dose Response Curve (Conversion to Human Value)

Uncertainty (Assessment) Factors (Safety Margin)



At present there are no global rules about UF (AF). Individual countries and evaluation organizations select a value of UF (AF) deemed as appropriate.

Source: Risk Assessment on Chemicals for Better Understanding, NITE, Japan

Basic Understanding on Chemical Risk Assessment

Understanding Hazard Assessment

Dose Response Curve (Conversion to Human Value)

Uncertainty (Assessment) Factors (Safety Margin)

If this value is excessively high, it is possible that "no risk" is judged to be "a risk" because of low reliability of the data used as the rationale. So it is essential to carefully interpret the results of risk assessment.

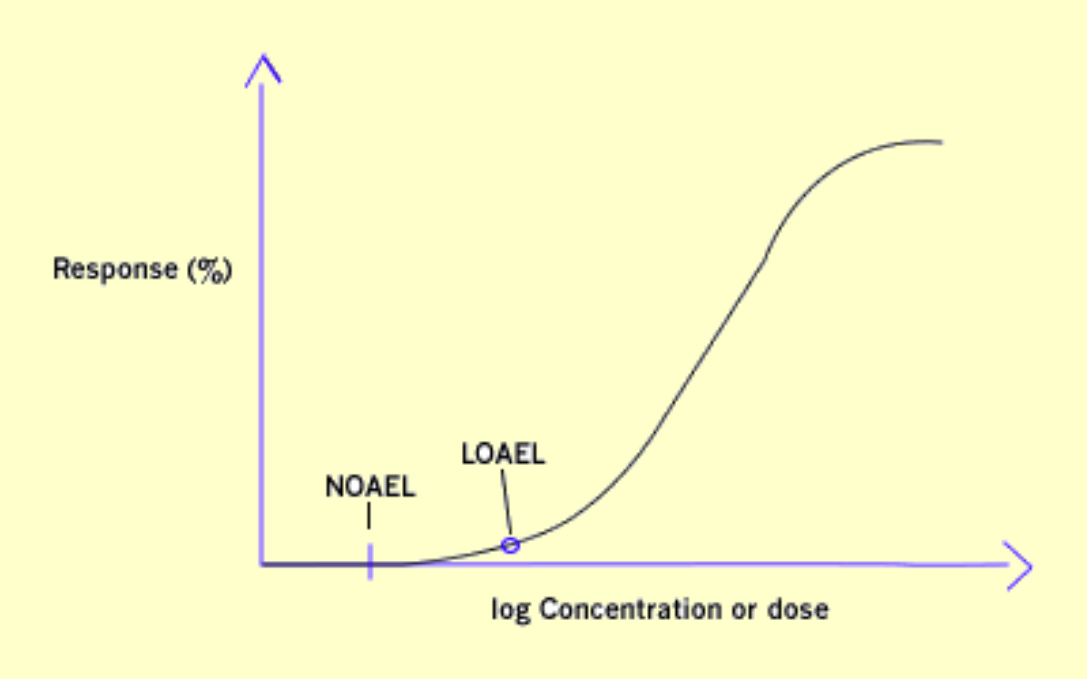
Source: Risk Assessment on Chemicals for Better Understanding, NITE, Japan

Basic Understanding on Chemical Risk Assessment

Understanding Hazard Assessment

Dose Response Curve (Animal Testing)

LOAEL (Lowest Observed Adverse Effect Level)



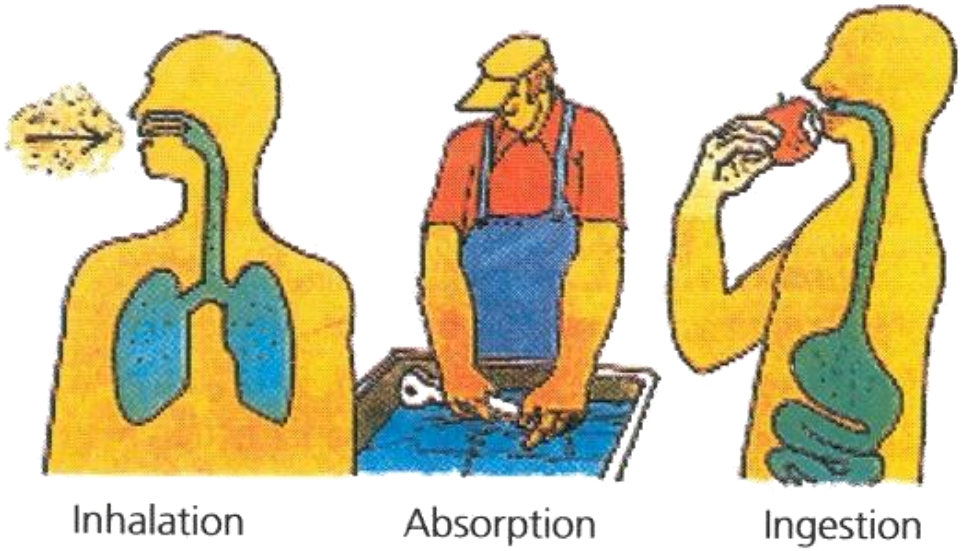
When NOAEL may not be available, LOAEL may also be used but the conversion to human value with a product of UF (AF) is called Derived Minimal Effect Level (DMEL)

Understanding Exposure Assessment

Routes of Exposure

It is important to learn how we are exposed to the chemical substances:-

1. **Inhalation** : Breathing in through mouth or nose into the lungs
2. **Absorption / Dermal** : Passing through the skin or eyes
3. **Ingestion / Oral** : Eating, Drinking and Swallowing
4. **Transfer across the placenta of a pregnant woman to the unborn baby**



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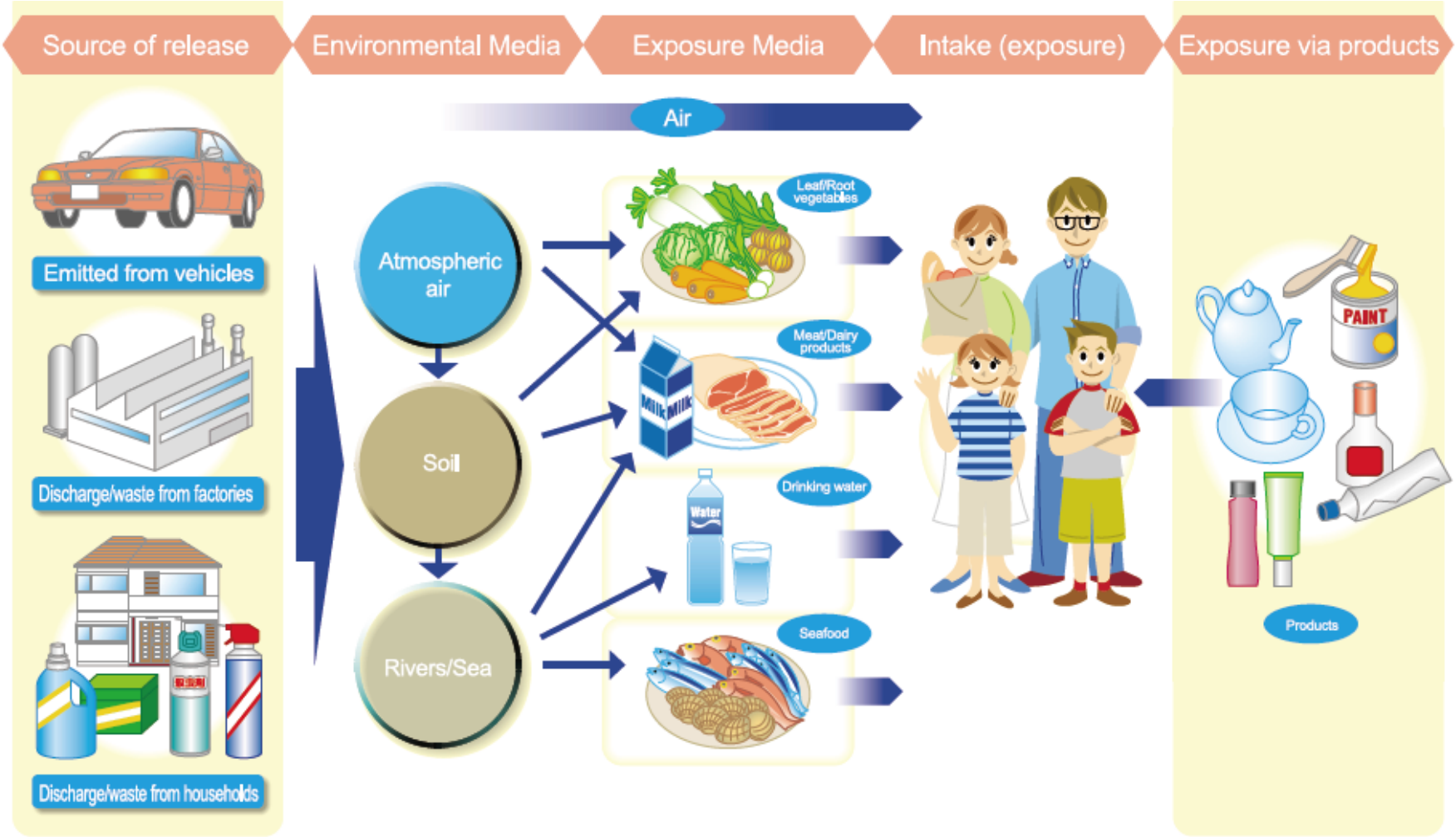
Understanding Exposure Assessment



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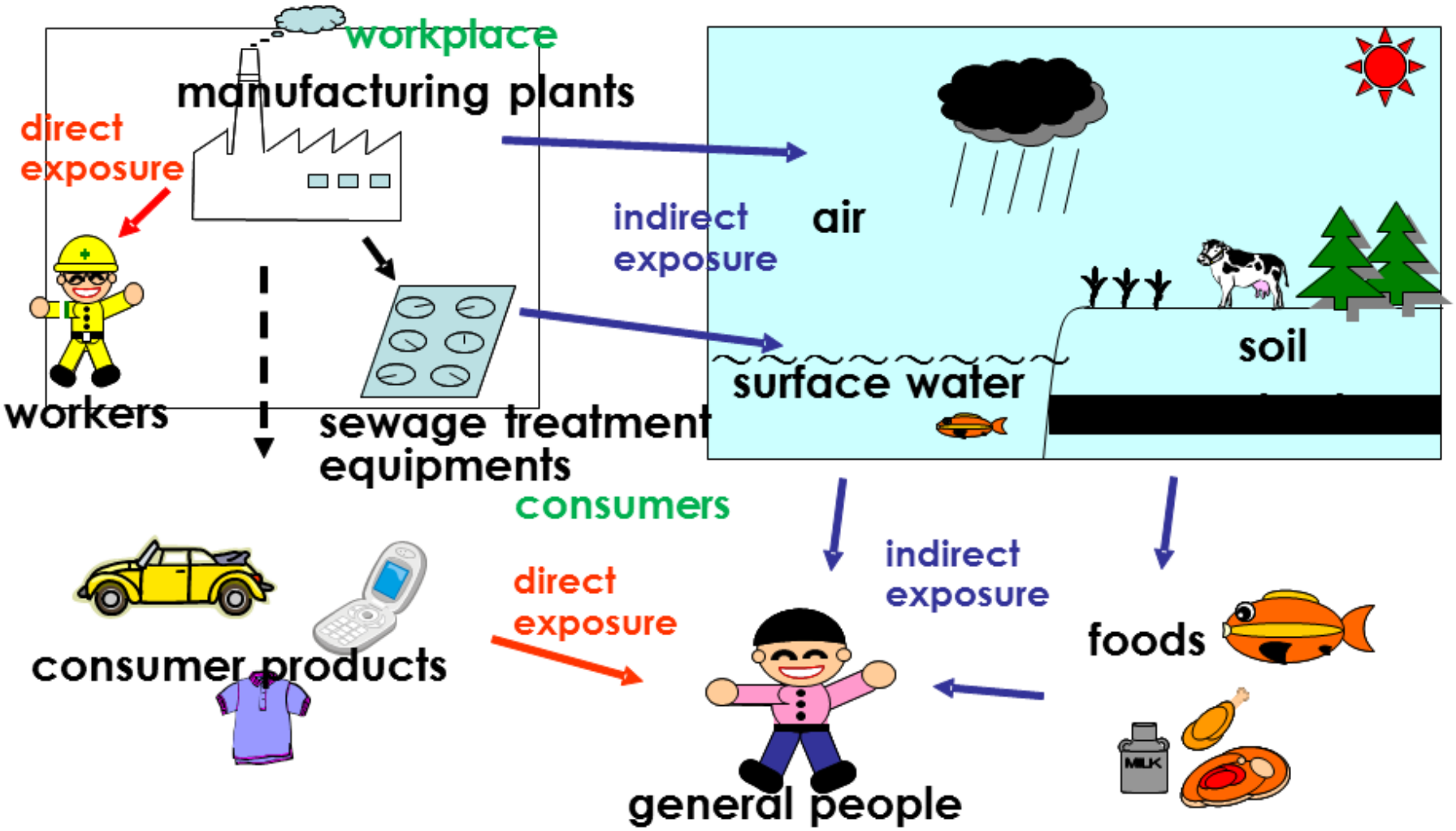
Understanding Exposure Assessment



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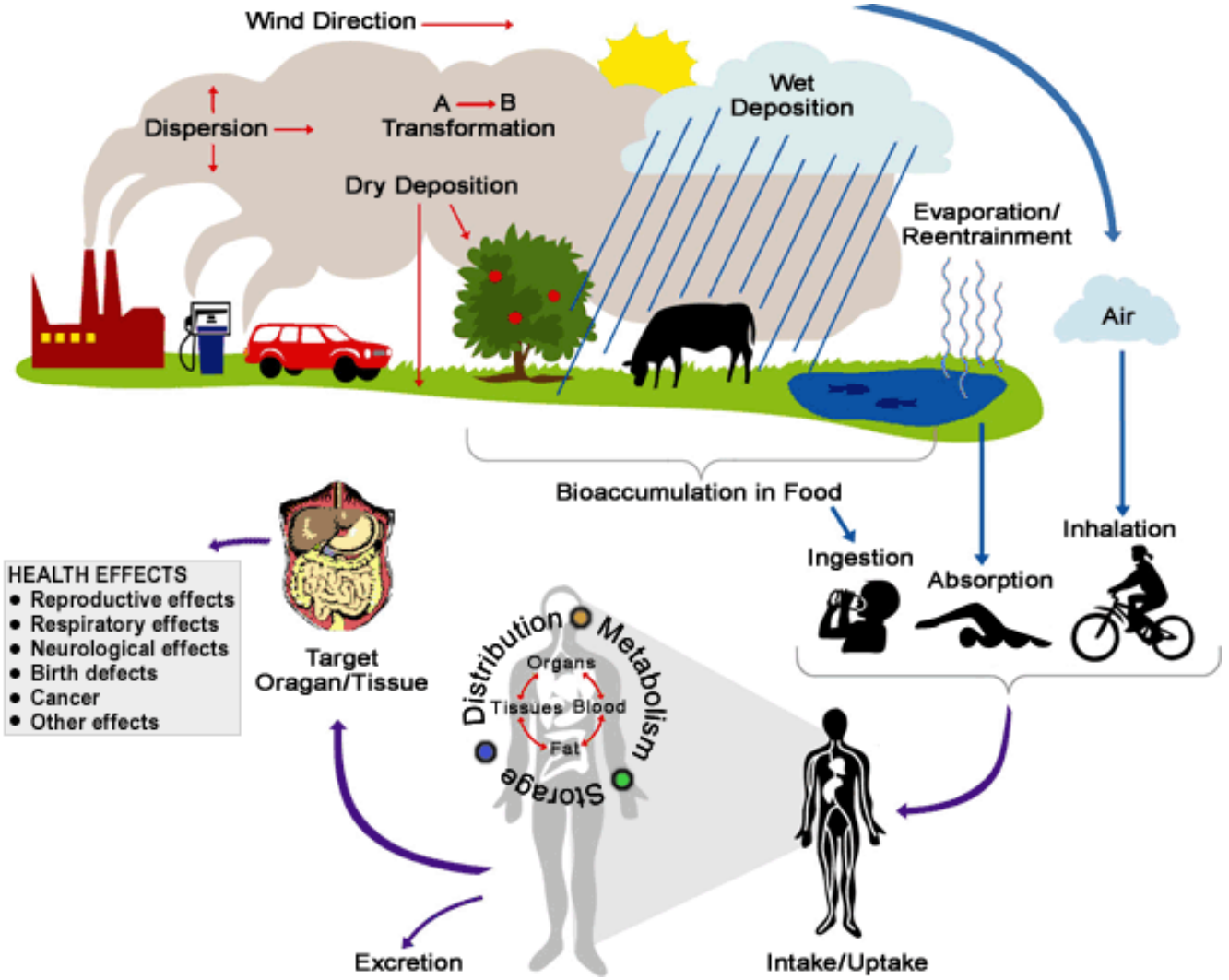
Understanding Exposure Assessment



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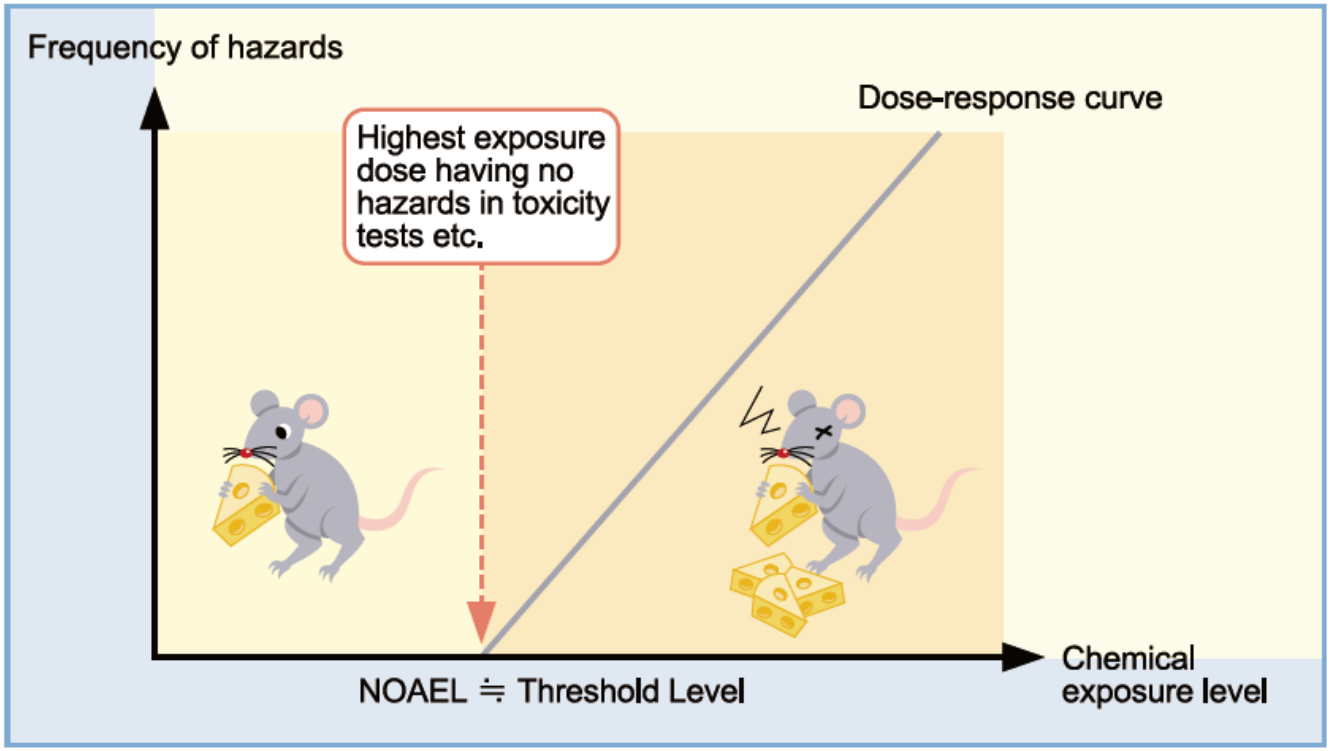
Understanding Risk Assessment



Source: Risk Assessment on Chemicals for Better Understanding, NITE, Japan

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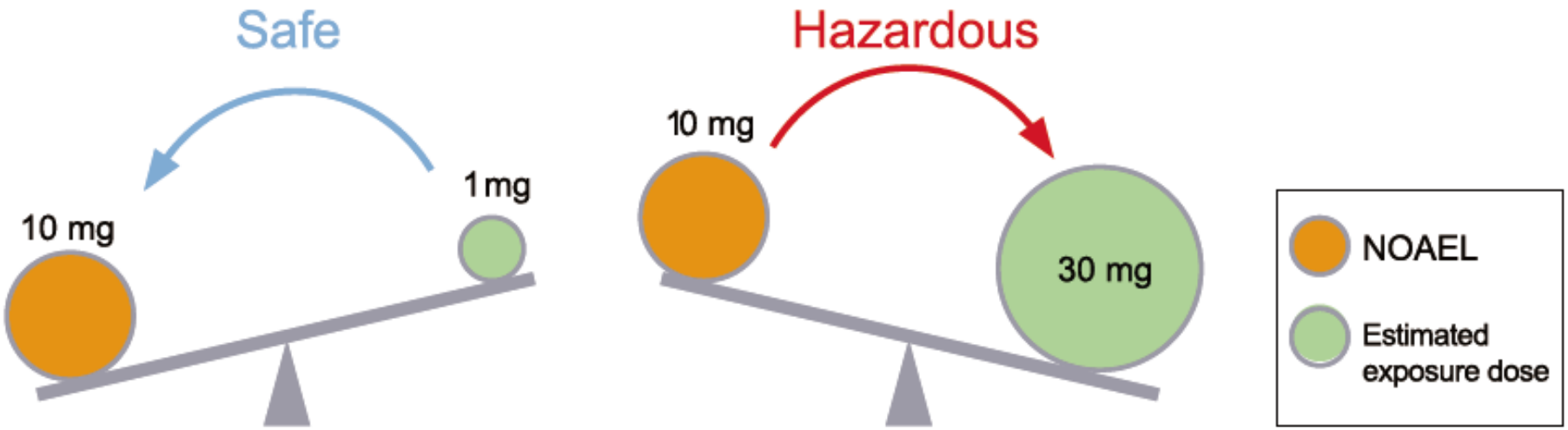
Understanding Risk Assessment



NOAEL	10 mg/kg/day
Estimated exposure dose	1 mg/kg/day

NOAEL	10 mg/kg/day
Estimated exposure dose	30 mg/kg/day

Source: Risk Assessment on Chemicals for Better Understanding, NITE, Japan

Understanding Risk Characterization

- **Two main approaches** - both follow the same basic methodology however, the ways the outcomes presented are different:

1) **DNEL:** In Europe, REACH legislation has established the **Derived No Effect Level (DNEL)**. Assessment factors are accounted for in the process of the DNEL derivation and therefore are included in the result.

2) **MOS/MOE:** The classical approach is the derivation of a **Margin of Safety (MOS), also termed Margin of Exposure (MOE)**. Here, assessment factors are considered after deriving the result.

Basic Understanding on Chemical Risk Assessment

Understanding Risk Characterization

1) Risk Characterization Ratio (RCR)

- **Human Health** (Threshold or non-threshold effect)
  - » RCR = EXPOSURE / DNEL
  - » RCR = EXPOSURE / DMEL
- **Environmental**
  - » RCR = PEC / PNEC

RCR ≥ 1 Risk is high
Detailed assessment and RMMs required
RCR < 1 Risk is controlled
No further action required

2) Margin of Exposure (MoE)

- MOE = NOAEL or NOAEC / Exposure
  - »If MOS > Overall Assessment Factor → No concern
  - »If MOS < Overall Assessment Factor → Concern

MOE > 100 No concerns
MOE < 100 Concern
Refine analysis or control exposures
MOE < 1 Cause for high concern
Direct measures needed

Understanding Risk Characterization

Risk Characterization Ratio (RCR) for human health

RCR = EXPOSURE / DNEL

If Exposure < DNEL → Risk is adequately controlled
If Exposure > DNEL → Risk is NOT adequately controlled

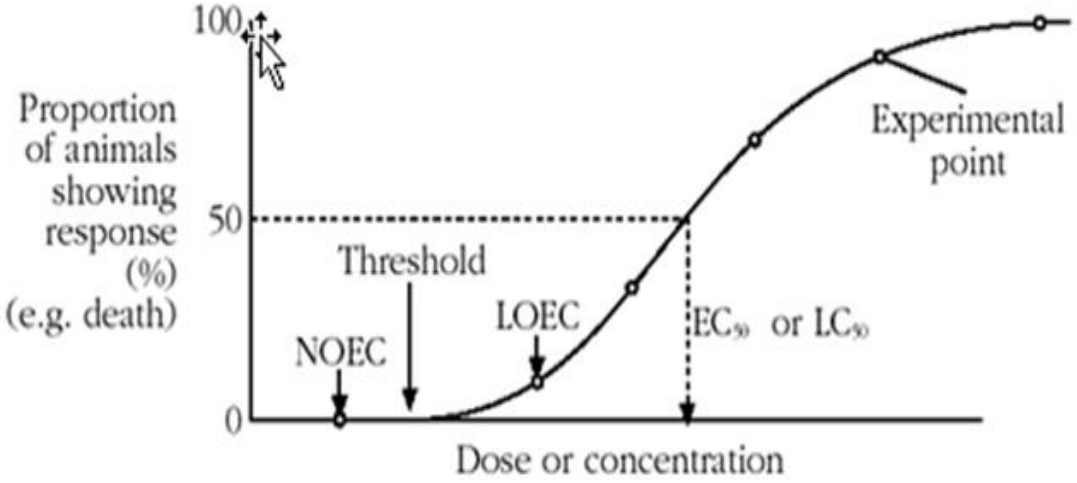
RCR ≥ 1: Risk is high: detailed assessment and risk reduction measures required

RCR < 1: Risk is controlled: No further action required

Basic Understanding on Chemical Risk Assessment

Understanding Hazard Assessment

Environmental Risk Assessment



NO(A) EC (No Observed (Adverse) Effect Concentration) The test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control.

LO(A)EC (Lowest Observed (Adverse) Effect Concentration) The lowest tested concentration with statistically significant adverse effect.

LC50 (50% Lethal Concentration)
The Concentration of a Chemical **in air** or of a chemical **in water** which causes the death of 50% (one half) of a group of test animals.

EC50 (Effective Concentration)
The effective concentration of substance that causes 50% of the maximum response

Source: GHS 5th Revised Edition

Understanding Hazard Assessment

Environmental Risk Assessment

- Environmental hazard characterization is conducted in a similar manner as for human health.

  Here **PNECs** (predicted no effect concentration) are used as dose descriptors and derived from the data collected.

- **PNECs** usually result from single species laboratory toxicity tests (e.g. fish, algae, and daphnia). Data are typically reported as the concentrations at which x% (e.g. 50%) mortality or inhibition of function (e.g. growth) is observed.

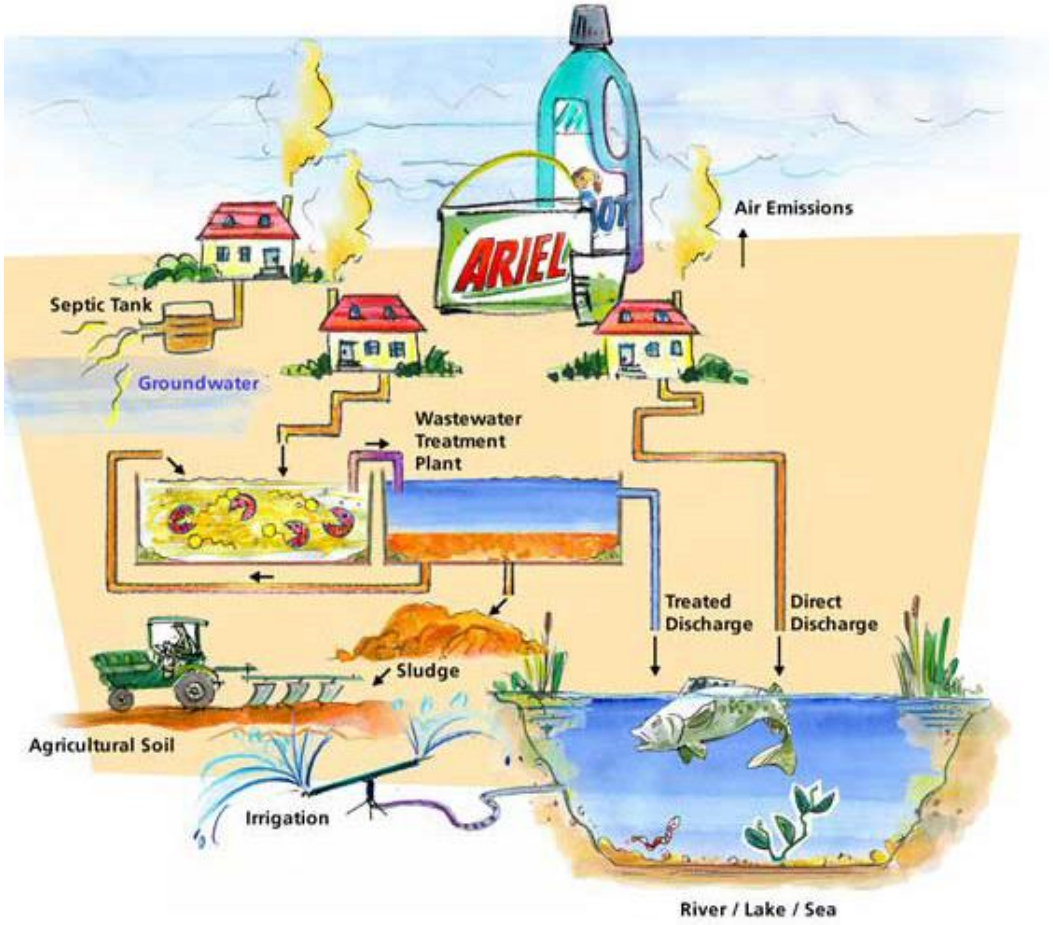
- **PNECs** are expressed as the lethal concentration (LCx) or the effect concentration (ECx), e.g. LC_{50} or EC_{50}.

- A **PNEC** must be calculated for each environmental compartment in which exposure is expected (air, water, sediment and soil).

Basic Understanding on Chemical Risk Assessment

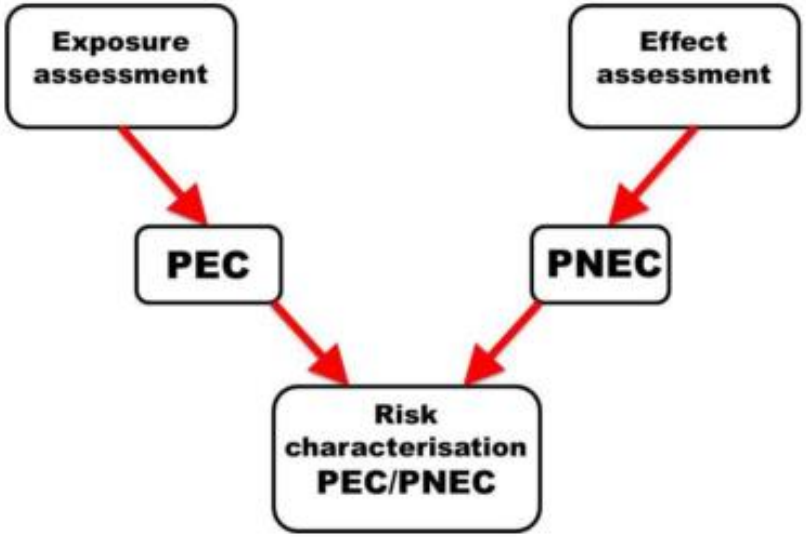
Understanding Exposure Assessment

Environmental Risk Assessment



Understanding Risk Characterization

Risk Characterization Ratio (RCR) for environment

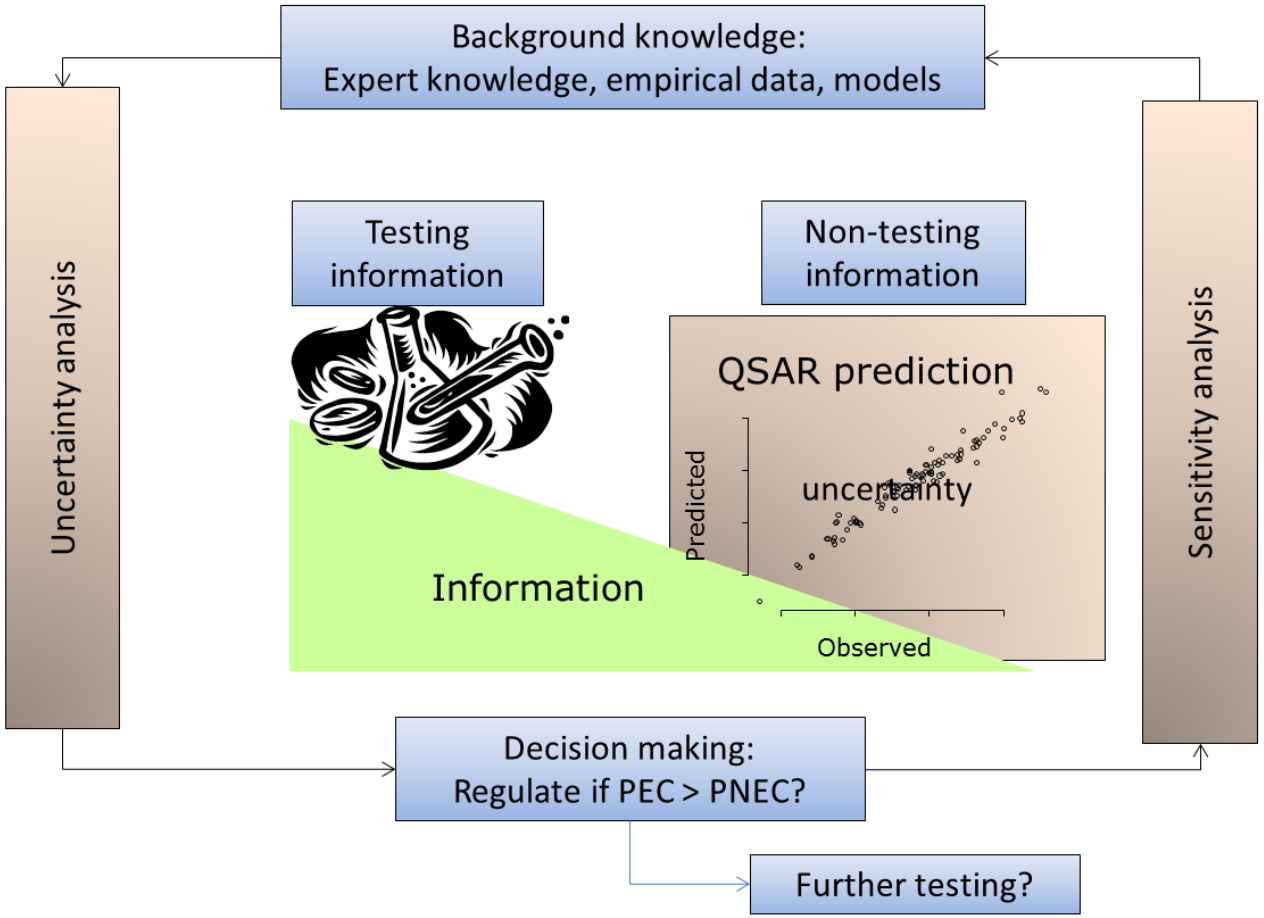


PEC
(Predicted Environment Concentration)
<Exposure>

PNEC
(Predicted No Effect Concentration)
<Threshold Dose/Reference Dose>

Understanding Risk Characterization

Environmental Risk Assessment



Understanding Risk Characterization

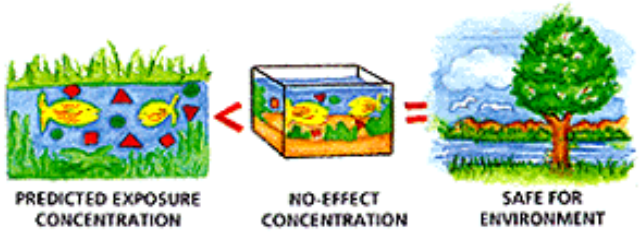
Risk Characterization Ratio (RCR) for environment

$$RCR = PEC / PNEC$$

If PEC < PNEC -> Risk is adequately controlled
If PEC > PNEC -> Risk is NOT adequately controlled

RCR ≥ 1: Risk is high: detailed assessment and risk reduction measures required

RCR < 1: Risk is controlled: No further action required



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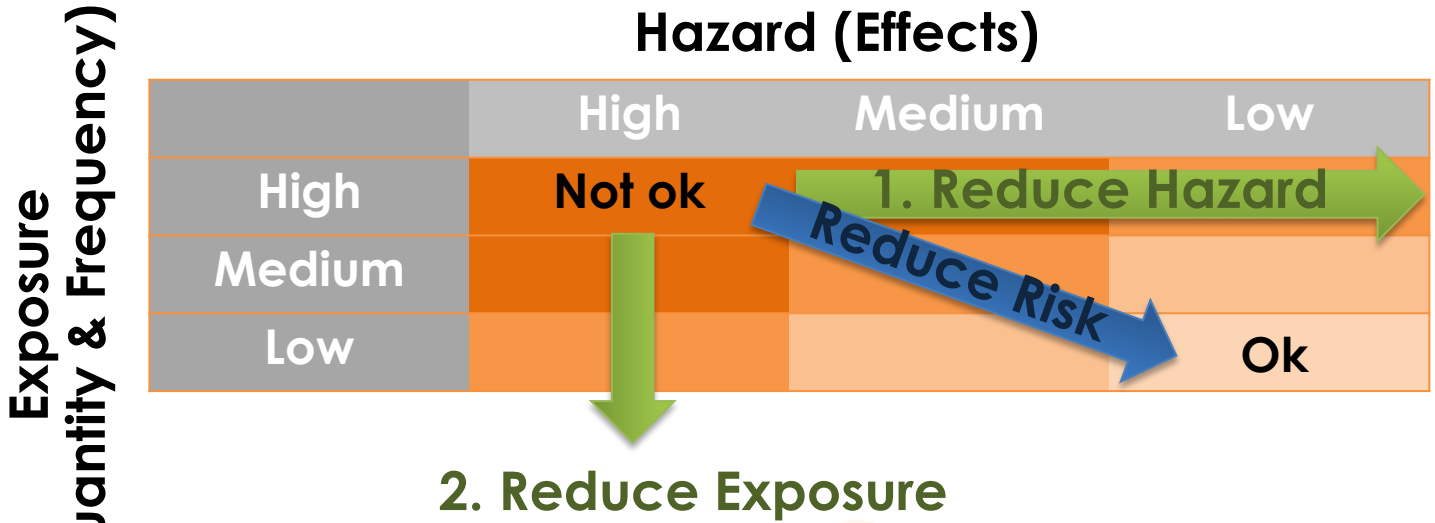
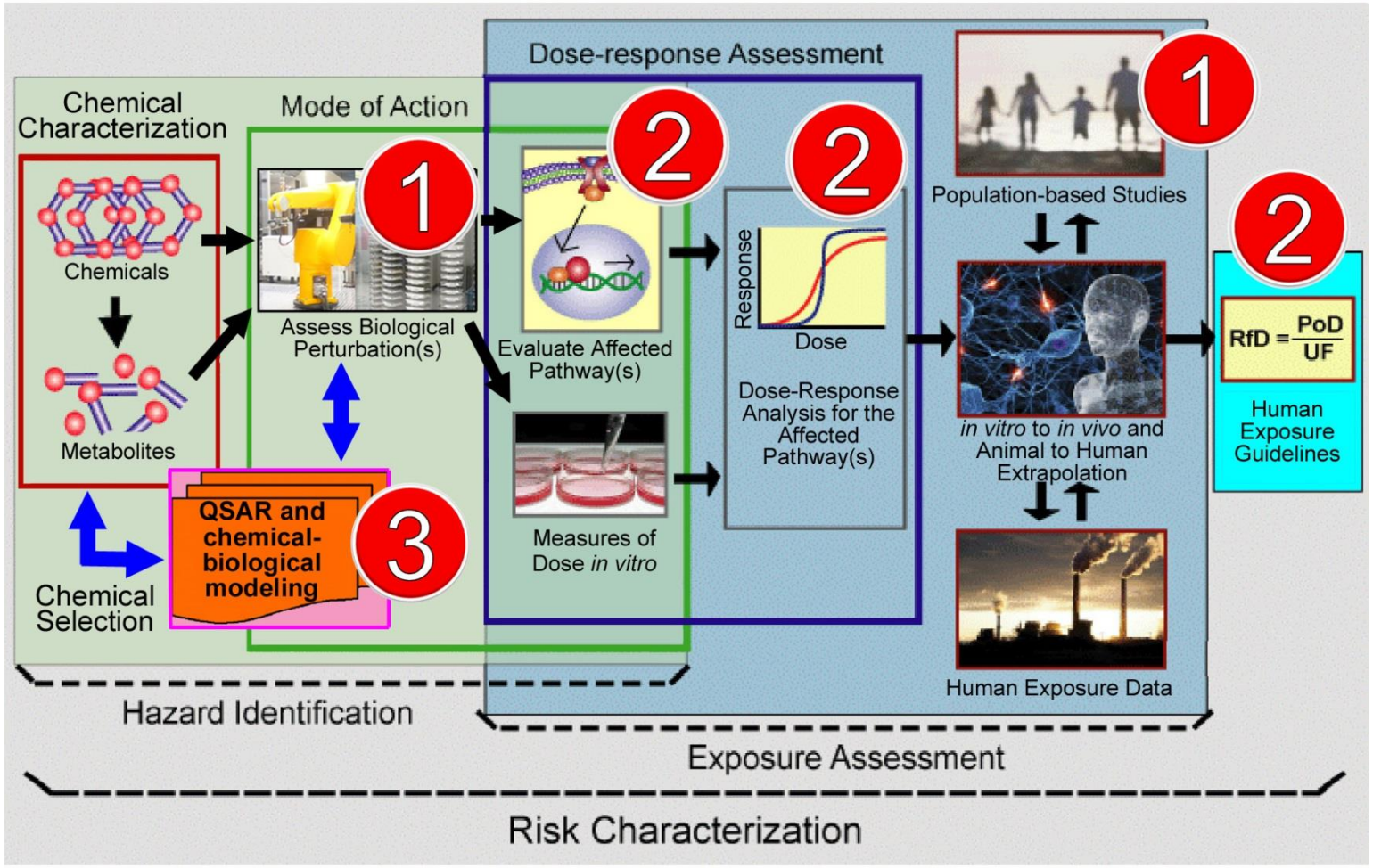
Understanding Risk Management



Basic Understanding on Chemical Risk Assessment

Summary in Brief Risk Characterization Process



Source: http://comptox.us/

Basic Understanding on Chemical Risk Assessment

Final Summary Risk Assessment vs Characterization

Risk Assessment

$$Risk = Hazard \times Exposure$$

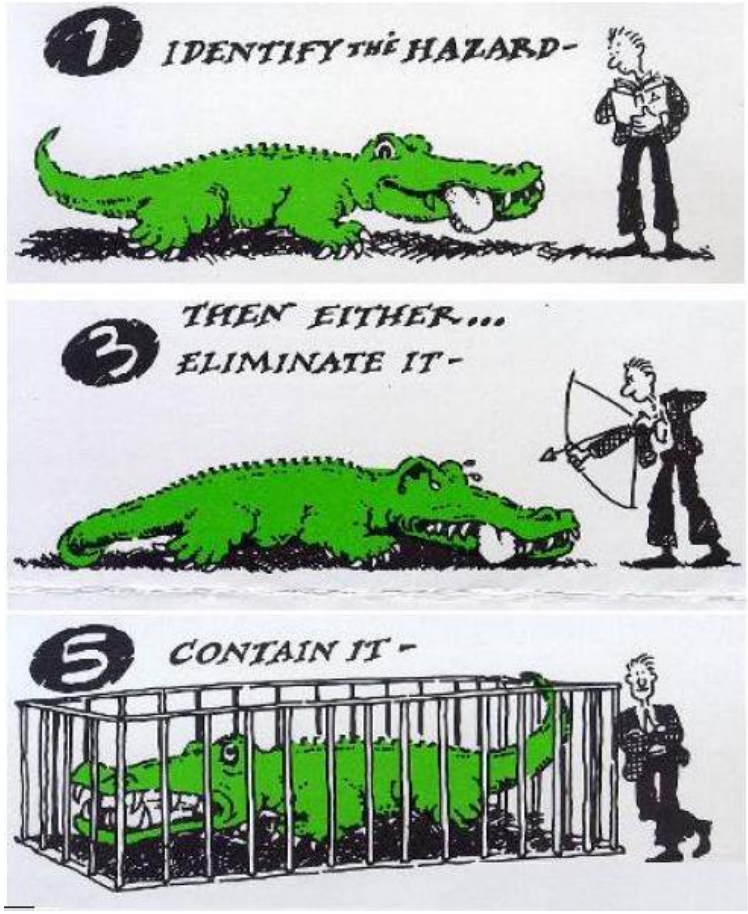
Risk Characterization

$$(Real)\ Risk = \frac{(Actual)\ Exposure}{(Maximum\ No\ Effect)\ Hazard}$$

Health and Environment

Basic Understanding on Chemical Risk Assessment

Summary: Risk Assessment and Management



Summary: Risk Assessment and Management

กรมโรงงานอุตสาหกรรม
DEPARTMENT OF INDUSTRIAL WORKS

Questions and Answers

RESPONSIBLE CARE ดูแลด้วยความรับผิดชอบ

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