Risk Assessment/Management Results and Experience Sharing

7th March, 2019

Risk Assessment Division

Chemical Management Center

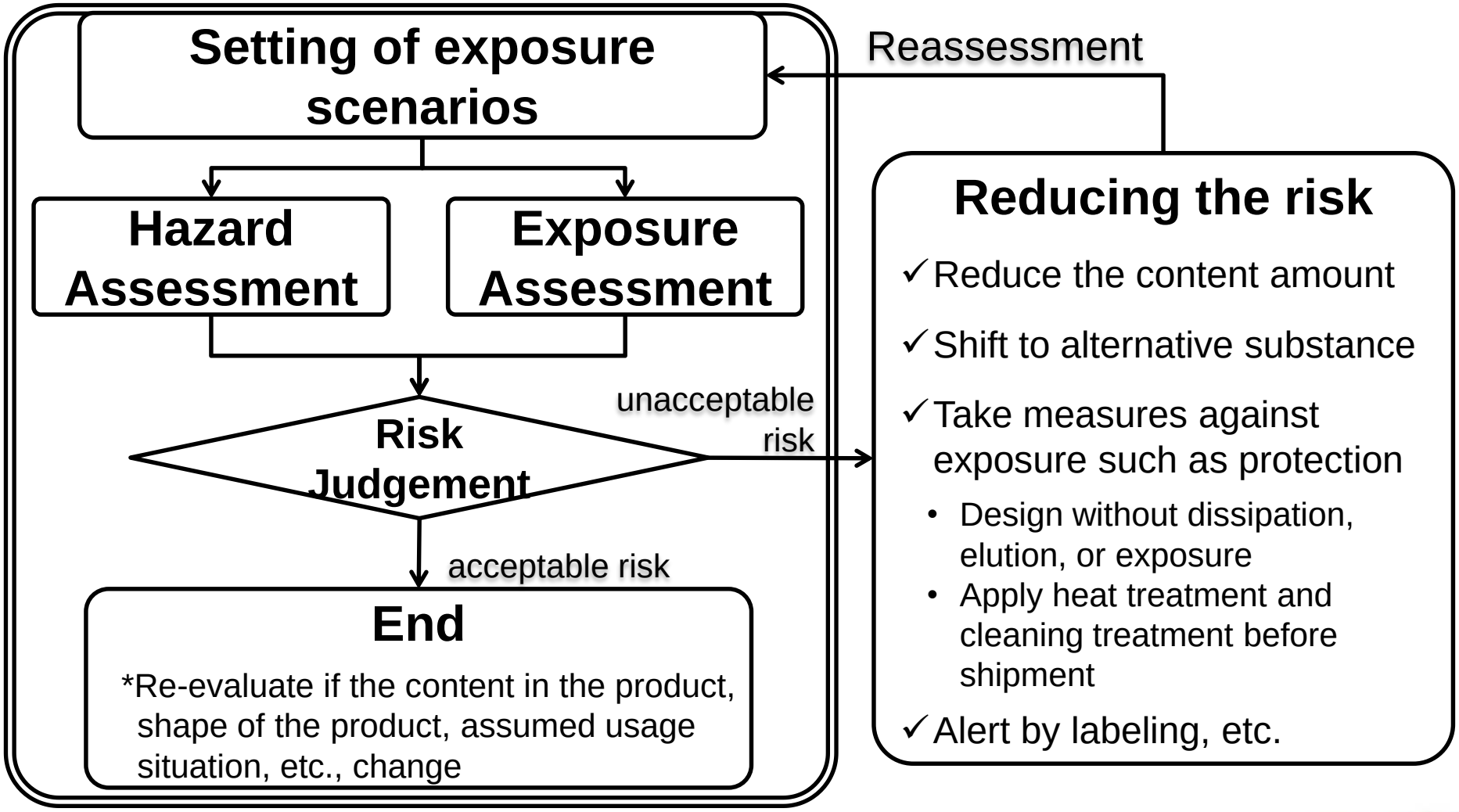
1. Introduction of Risk Assessment and Management of Products containing Class I Chemicals under CSCL (Decabromodiphenyl Ether)

Various Risks from Chemical Substances

Chemical risk	Risk to workers	Risk of having adverse effects on the health of workers due to inhalation of or contact with chemical substances during workplace operations
	Risk to consumers	Risk of having adverse effects on human (consumer) health due to chemical substances contained in products
	Risk to general population or other organisms via environment	Risk of having adverse effects on human health or other organisms due to chemical substances released into the environment
Physical risk	Risk associated with accidents	Risk of damaging materials such as equipment and buildings (assets), human health (lives), or other organisms due to accidents such as explosions or fires

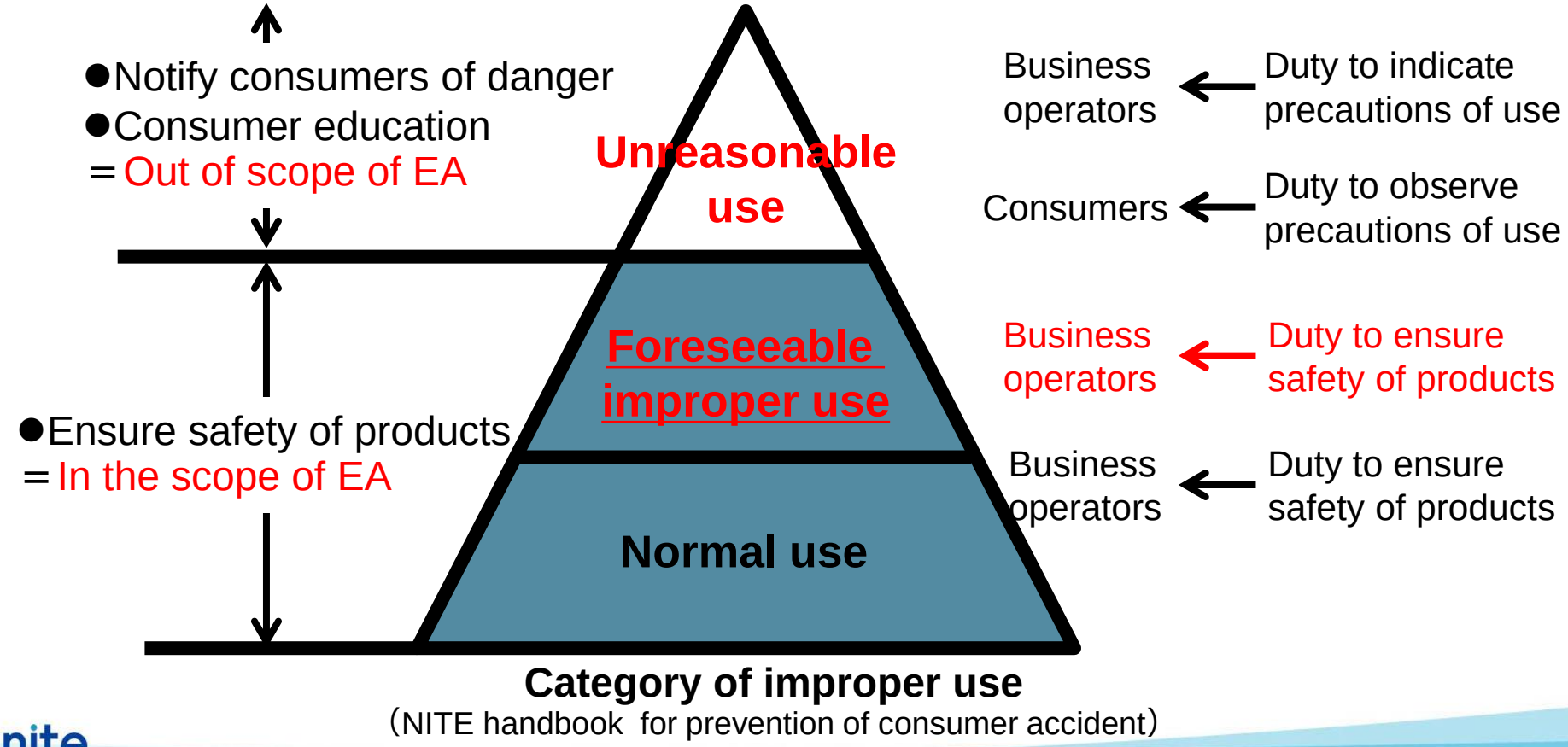
Scope of the CSCL

Flowchart of Risk Assessment of Chemicals Contained in Consumer Products

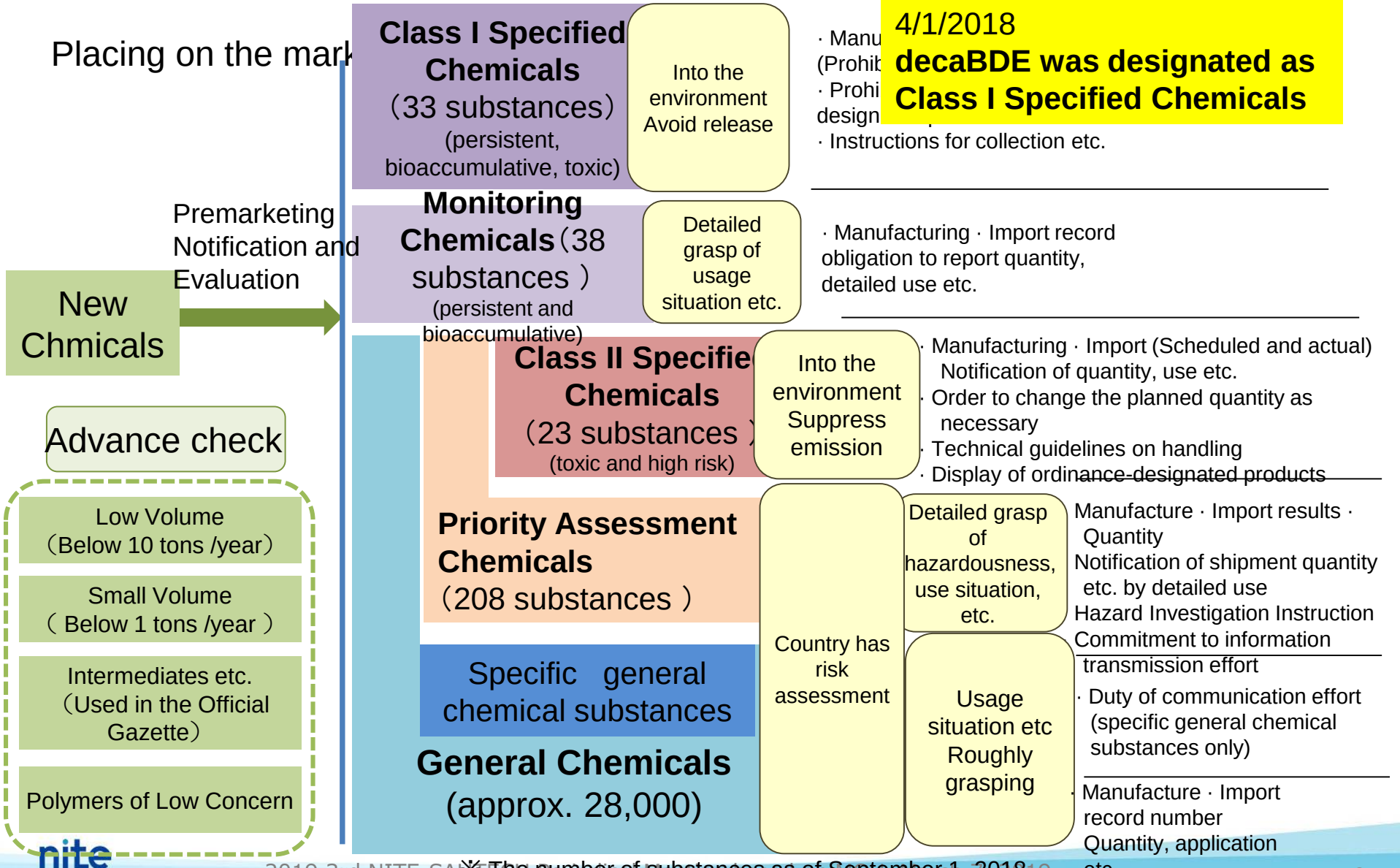


Scope of Risk Assessment of Chemicals in Consumer Products

- ”Foreseeable improper use” occurs due to the knowledge/information gap between business operator and consumer, and/or lack of sufficient understanding /prediction of consumer behavior.



Outline of CSCL



※The number of substances as of September 1, 2018

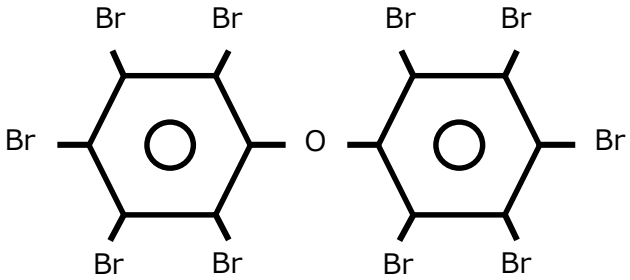
Risk assessment of decaBDE in consumer products

Why Decabromodiphenyl ether (hereinafter decaBDE)?

- Already designated as Type II Monitoring Chemical Substance under CSCL.
- The Stockholm Convention (POPs convention) decided to list decaBDE in Annex A of the convention.
- In June 2013, the Chemical Council judged that decaBDE fulfills conditions to be designated as a **class I specified chemical**.
- decaBDE is widely used in consumer products such as curtain and insulation material as flame retardant for resin products and car fabrics.

so…

- Risk assessment of decaBDE in consumer products is required for policy making.



- Full version (only Japanese)
  https://www.nite.go.jp/chem/risk/products_risk-decabde.pdf
- Summary (English)
  https://www.nite.go.jp/chem/risk/products_risk-decabde_en_summary.pdf

Precondition of conducting the risk assessment

[Target groups of people in the assessment]

A human lifetime of 70 years is adopted.

◆**Children**: Estimated childhood as 0 to 6 years old

(takes into consideration mouthing behaviors such as holding objects in mouth and licking objects especially observed in early childhood)

◆**Adults**: Assumed the time period other than childhood is as an adult within a full lifetime (70 years)

＊Upon assessment of chronic effects, the above two periods are averaged over 70 years of life.

[Dwell time = Time exposed]

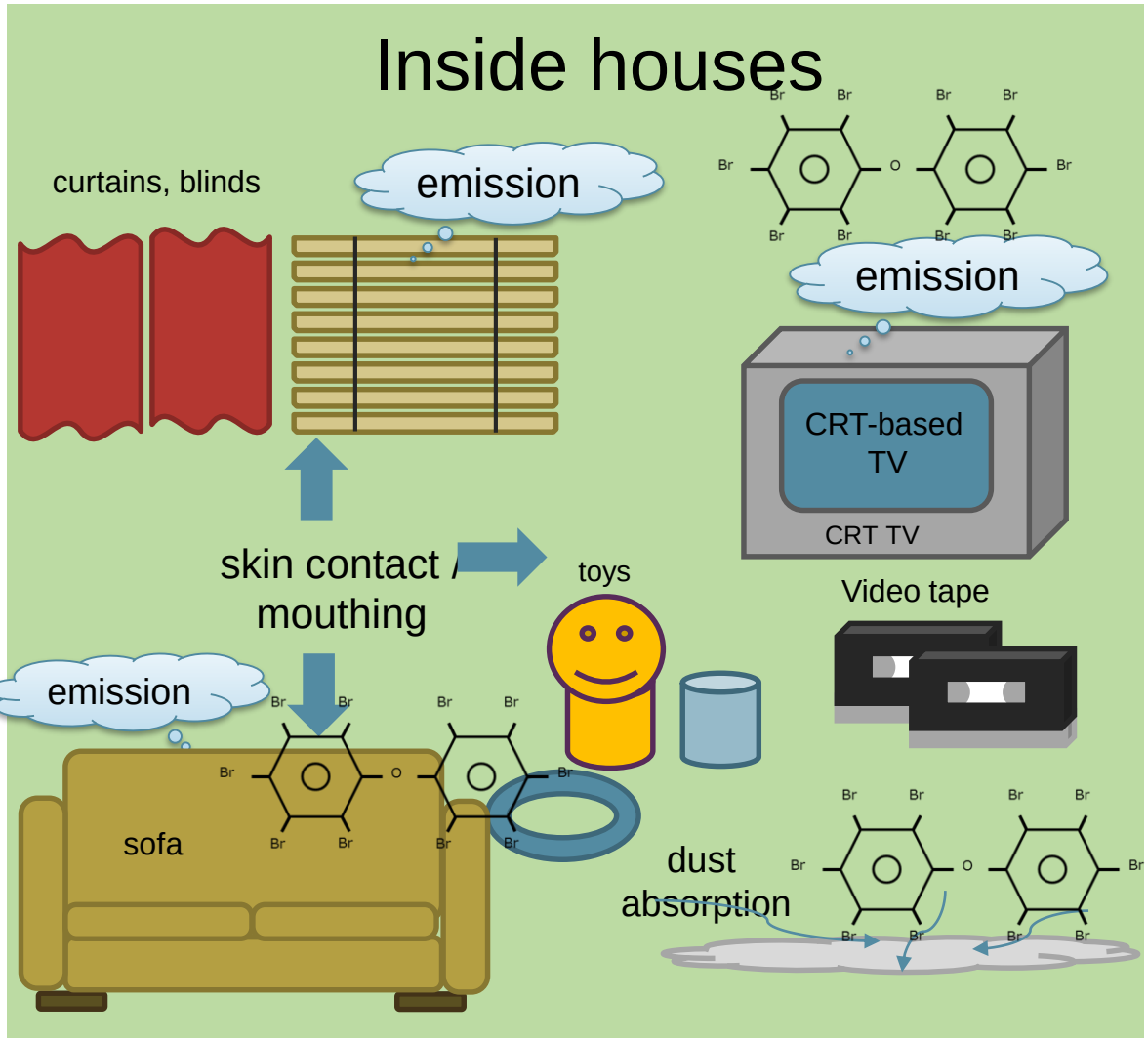
◆**Inside cars**: 2.4 h/day (Dwell time ratio: 0.1)

(Weighted average value for time of weekdays and weekends (90%ile))

＊For details see Life / Behavior Pattern Information on Indoor Exposure by NITE

◆**Inside houses**: 21.6 h/day (Dwell time ratio: 0.9)

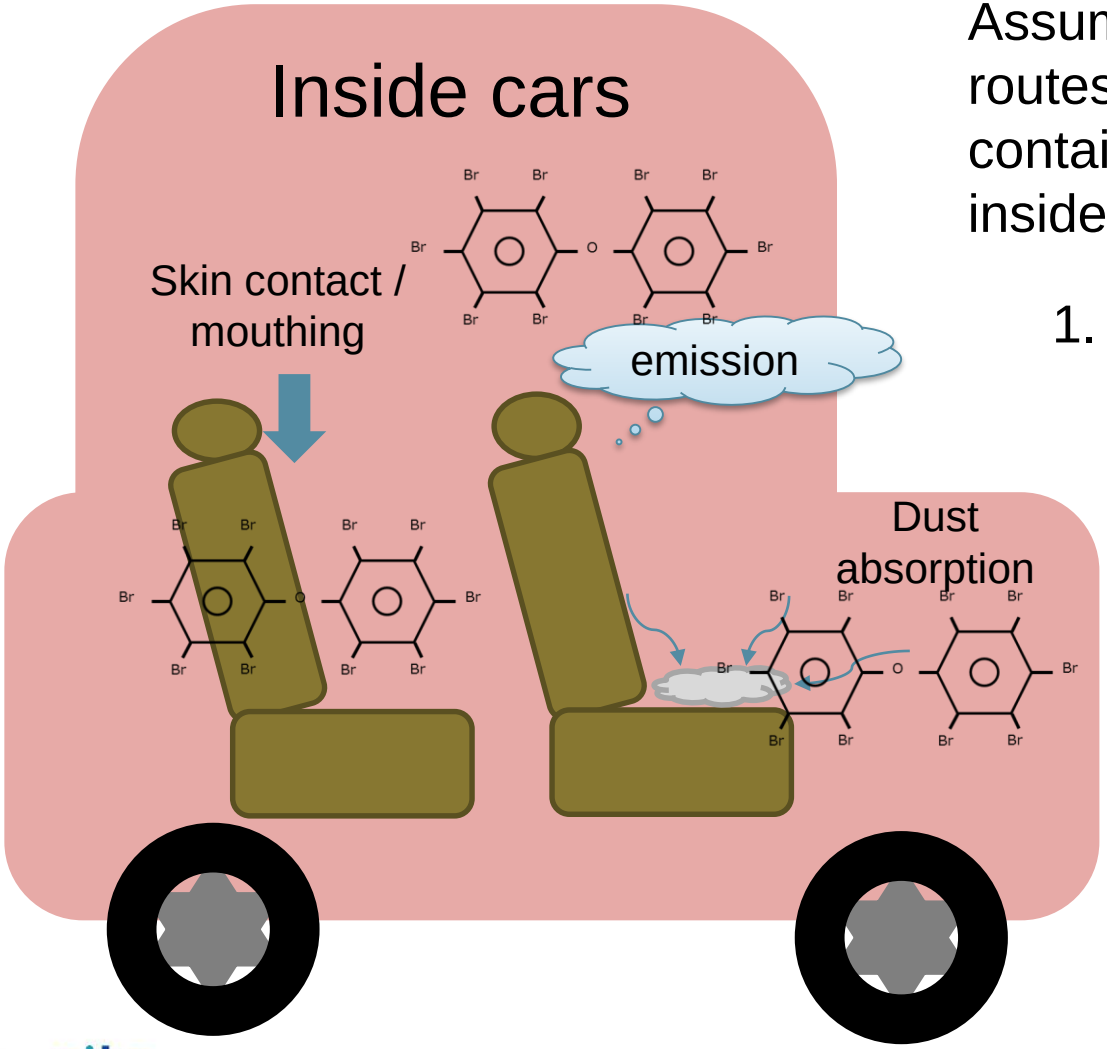
DecaBDE-containing products and assumed exposure sources inside houses



Assume exposure via the following routes, based on various decaBDE-containing products as emission sources.

1. ① Mouthing of the product
   ② Oral intake of dust
   absorption
2. Inhalation of dissipated gas form
3. Skin contact with the product

DecaBDE-containing products and assumed exposure sources inside cars



Assume exposure via the following routes, based on various decaBDE-containing products (fabrics used inside cars) as emission sources.

1. ① Mouthing of the product

   ② Oral intake of dust absorption

2. Inhalation of dissipated gas form

3. Skin contact with the product

Risk assessment of decaBDE in consumer products

- Exposure route and target population

Product category	Exposure route		Target population		
			lifetime	adult	infant
Inside houses	Inhalation		○	○	○
	Oral	Ingestion of dust	○	○	○
		Mouthing	○	–	○
	Dermal		○	○	○
Inside cars	Inhalation		○	○	○
	Oral	Ingestion of dust	○	○	○
		Mouthing	○	–	○
	Dermal		○	○	○

Assumed exposure via oral route

①**Mouthing behaviors** (specific to children)

Ingest decaBDE migrated into saliva
from indoor sofas and car seats

※It is considered that people contact sofas at high frequency and in a large area inside houses.

EHE via oral by mouthing (ng/kg/day)

$$= \frac{\textit{Elution rate}\ (\mathrm{ng/cm^2/min}) \times \textit{Mouthing area}\ (\mathrm{cm^2}) \times \textit{Mouthing time}\ (\mathrm{min/day}) \times \textit{Dwell time ratio}}{\textit{Body weight}\ (\mathrm{kg})}$$

②**Indoor dust** (the intake amount of dust: children＞adults)

Intake of dust adsorbed by decaBDE inside houses and cars

EHE via oral (ng/kg/day)

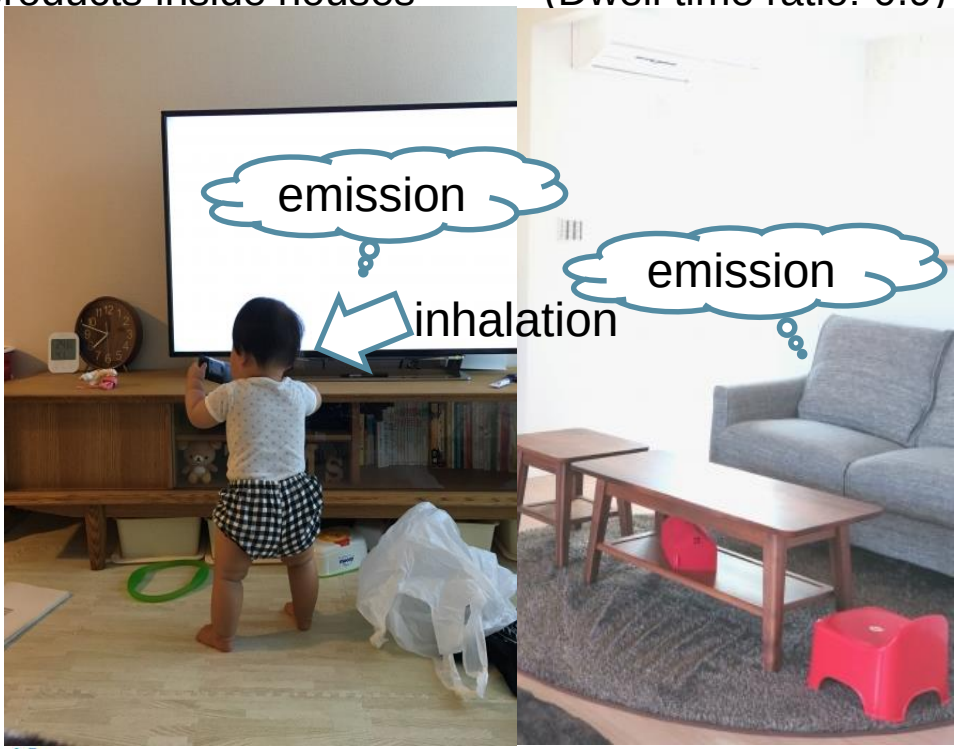
$$= \frac{\textit{Exposure concentration in the indoor dust of houses/cars}\ (\mathrm{ng/g}) \times \textit{Dust intake per day}\ (\mathrm{g/day}) \times \textit{Dwell time ratio}}{\textit{Body weight}\ (\mathrm{kg})}$$

Assumed exposure via inhalation route

Assuming that decaBDE (gas state) existing in the air of houses/cars is inhaled during the time of staying at houses/cars, the exposure amount is estimated.

$$\textit{EHE via inhalation}\ (\text{ng/kg/day}) = \frac{\textit{Exposure concentration in the air inside cars}\ (\text{ng/m}^3) \times \textit{Dwell time ratio} \times \textit{Respiration volume}\ (\text{m}^3/\text{day})}{\textit{Body weight}\ (\text{kg})}$$

Inhalation of gases released from decaBDE-containing products inside houses (Dwell time ratio: 0.9)



Inhalation of gases released from decaBDE-containing car fabrics inside cars (Dwell time ratio: 0.1)

Assumed exposure via dermal route

Bare skin comes into direct contact with indoor sofas and car seats, and absorbs decaBDE through sweat.

EHE via oral by dermal (ng/kg/day)

$$= \frac{\text{Surface area of skin contact (cm}^2\text{/day)} \times \text{Thickness of the aqueous phase (sweat) (cm)} \times \text{Concentration of decaBDE in aqueous phase (sweat) (mg/cm}^3\text{)} \times \textit{Dwell time ratio} \times \text{Absorption rate}}{\textit{Body weight} \text{ (kg)}}$$

Skin contact with the sofa (Dwell time ratio: 0.9)

Skin contact with the car fabric
(Dwell time ratio: 0.1)

Risk assessment of decaBDE in consumer products

Product category	Exposure route		Estimated exposure: ng/kg/day <lifetime = (adult×64 years+infant×6 years)÷70 years>		
			lifetime	adult	infant
Inside houses (21.6 h/day)	Inhalation		0.35	0.34	0.49
	Oral	Ingestion of dust	8.69	5.9	38.5
		Mouthing	0.07	–	0.81
	Dermal		0.07	0.07	0.1
Total Inside houses			**9.19**	**6.24**	**39.9**
Inside cars (2.4 h/day)	Inhalation		0.17	0.16	0.23
	Oral	Ingestion of dust	20.11	13.6	89.5
		Mouthing	0.01	–	0.09
	Dermal		0.01	7.4×10^{-3}	0.011
Total Inside cars			**20.29**	**13.76**	**89.82**
Exposure in total			**29.5**	**20.0**	**129.7**
Target toxicity			**Increase in serum glucose, Changes in some of liver gene transcripts**		
NOAEL (ng/kg/day)			**50**		**200**
RESULT: Hazard Quotient			**0.6**		**0.6**
			No risk concern		

Results of risk assessment of decaBDE in consumer products

◆Hazard assessment value

The Minimal Risk Level (MRL) for intermediate-duration oral exposure estimated by the ATSDR is the smallest and most recent hazard assessment value. (200 ng/kg/day by dividing the 0.05 mg/kg/day LOAEL by an UF of 300)

Therefore, the hazard assessment value for chronic-duration oral exposure used in this risk assessment is derived by extrapolating the value used as intermediate-duration oral MRL when considering the uncertainty factors※1, .

the hazard assessment value for chronic-duration oral exposure: 50 ng/kg/day

※1 UF: 10 (Species difference) × 10 (Individual difference) × 10 (LOAEL+Test period) = 1000

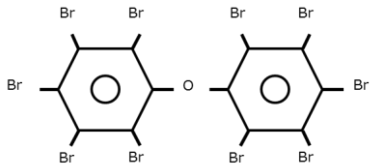
◆ Estimated exposure amount (EHE) over a lifetime (average/total)

Considering 8 exposure scenarios in total for each environment and exposure coefficients which are set slightly on the safe side, estimate the exposure amount inside houses and cars.

***EHE averaged over a lifetime* (ng/kg/day): 30 ng/kg/day**

◆The Results of Risk Assessment

$$HQ^{*2} = \frac{\text{EHE averaged over a lifetime (ng/kg/day)}}{\text{Hazard assessment value (ng/kg/day)}} = 0.6$$



※2 HQ ≧ 1: Risk Concern; HQ < 1: No Risk Concern

No Risk Concern

Summary

Summarize the points for risk assessment, especially exposure assessment.

- Assume an appropriate exposure scenario, judging from various factors of the domestic status.
  - Understand how to use and install the product (amount, number of times, etc.); A large difference may be caused by differences of individuals and use environments
  - Assume “Foreseeable improper use”
- Select algorithm (model formula) according to exposure scenario
- Set appropriate exposure factors
- Estimate the exposure amount for each environmental route
- Determine the total *EHE*, to compare with the *hazard assessment value*.

The exposure amount varies greatly depending on the exposure scenario and selection of exposure factors. Therefore, we need to pay attention in order not to underestimate as well as not unrealistically overestimate when considering foreseeable improper use.

✓ The management of risk tradeoff is also a future issue

2. Introduction of Risk Assessment Tools

Risk Assessment Tool

	PRAS-NITE (PACSs Risk Assessment System)	Chem-NITE (Consumer Human Exposure Model -NITE)	METI-LIS (Ministry of Economy , Trade and Industry-Low rise Industrial Source dispersion)	AIST-ADMER (National Institute of Advanced Industrial Science and Technology-Atmospheric Dispersion Model for Exposure and Risk Assessment)
Summary	This tool can estimate the concentration of chemical substances in air or water emitted from factory or company. This is composed of Excel spreadsheet.	It is a software to estimate the consumer exposure from various products. This is composed of Excel spreadsheet.	It is a model for the estimation of concentration distribution of chemical substances around the factory released from its chimney.	This software can estimate the concentration of chemicals in air or human exposure. It is used for calculation of concentration map for PRTR.
Range	-Emission source – 10km, through out Japan -River	Indoor air	-emission source – 10km,	Throughout Japan (5km×5km, or 100m×100m as maximum)
Feature	The concentration of chemical substances in air or water can be estimated. Also, exposure of human or eco is calculated by the estimation of concentration in crops, livestock, or seafood.	The consumer exposure from products can be estimated using physical chemical property, use, shape of products etc.	It can estimate the average concentration for every duration(year, month, day, hour). Also, the effect of the buildings for diffusion of chemicals, tall chimney, and short chimney etc. are considered in this model.	The concentration of chemical substances in air can be estimated using emission of chemicals or the weather data. The average concentration for every duration(year, month, or 4 hours) can be calculated.
URL	https://www.nite.go.jp/chem/risk/pras-nite.html	https://www.nite.go.jp/chem/risk/chem_nite.html	http://www.jemai.or.jp/tech/meti-lis/download.html	https://admer.aist-riss.jp/