

Introduction of Risk Assessment Examples of Chemicals Contained in Consumer Products (Perfluorooctanoic acid: PFOA)

7th November, 2019

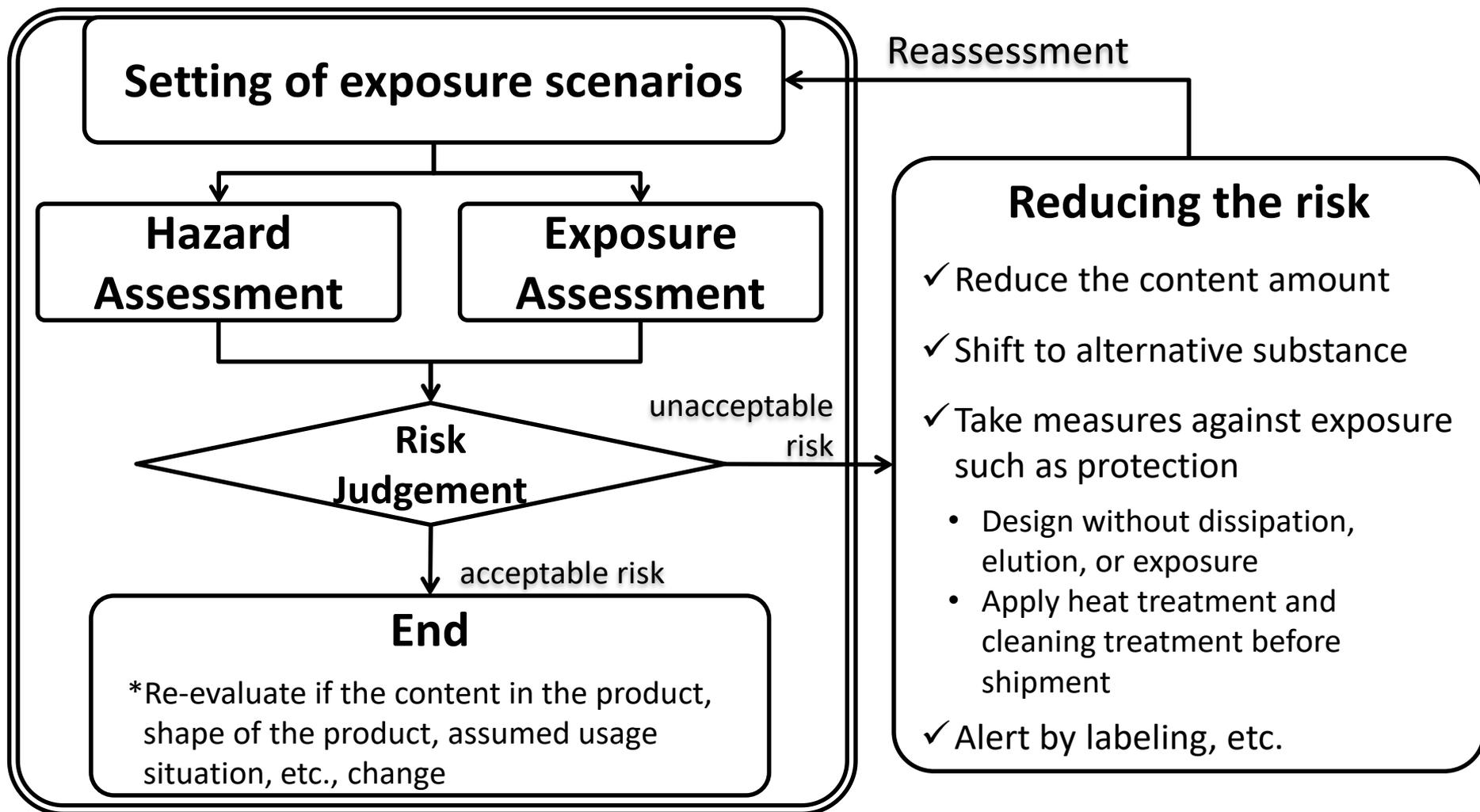
Risk Assessment Division

Chemical Management Center

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

Flowchart of Risk Assessment of Chemicals Contained in Consumer Products



Risk assessment of PFOA derived from consumer products

Why Perfluorooctanoic acid (hereinafter PFOA)?

- After the revision of CSCL in 2009, PFOA was designated as General Chemical Substance based on screening assessment.
- The Stockholm Convention decided to list PFOA, its salts and PFOA-related compounds in Annex A (Elimination) in May 2019.
- July, 2019: The Chemical Council judged that PFOA, its salts and PFOA-related compounds fulfill conditions to be designated as a **class I specified chemical**.

PFOA, its salts and PFOA-related compounds are widely used in consumer products such as **carpets and outdoor jackets** as **textile and leather treatment**.

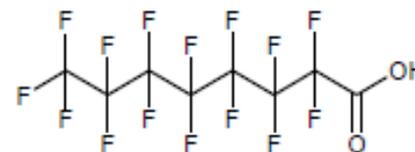
⇒ **Risk assessment of PFOA in consumer products** is required for policy making.

- Risk assessment for chemical substances contained in products (only Japanese)
https://www.nite.go.jp/chem/risk/products_risk-PFOA_jp_full.pdf

Target compounds in the Stockholm Convention

According to the report of the risk management evaluation (UNEP/POPRC, 2017), PFOA, PFOA salts and PFOA-related compounds cover:

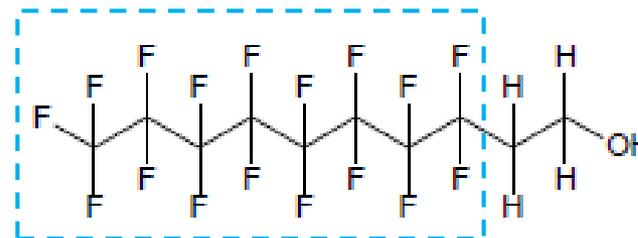
- (a) PFOA (including its isomers)
- (b) Its salts; and



PFOA

- (c) PFOA-related compounds which are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C₇F₁₅)C as one of the structural elements, for example:

- (i) Polymers with C₈ to C₁₆ based fluorinated side chains
- (ii) 8:2 fluorotelomer compounds
- (iii) 10:2 fluorotelomer compounds



8:2FTOH

Target compounds in exposure assessment from consumer products

◆ Focusing on PFOA itself in risk assessment of direct exposure from consumer products.

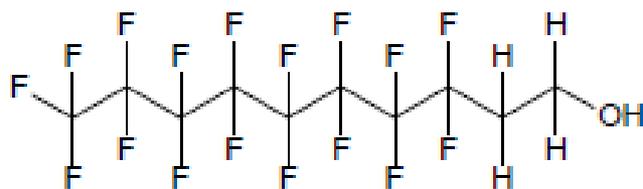
◆ PFOA-related compounds

Degradation of PFOA-related compounds in the environment is excluded because the purpose is to evaluate the effects of direct exposure from consumer products.

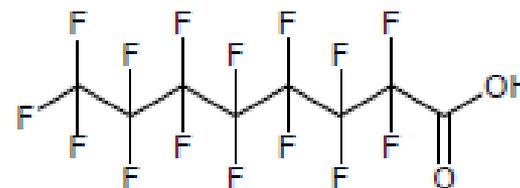
※ However, PFOA-related compounds which information about biotransformation to PFOA has been obtained, are considered.

- 0.3% of 8:2 FTOH is biotransformed to PFOA by metabolism (Gomis *et al.*, 2016) .

⇒ Estimating the risk of 8:2 FTOH being metabolized to PFOA in the human body.



8:2FTOH



PFOA

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.

◆ **Body weight:**

Adults: 50 kg (General setting in the risk assessment under the CSCL)

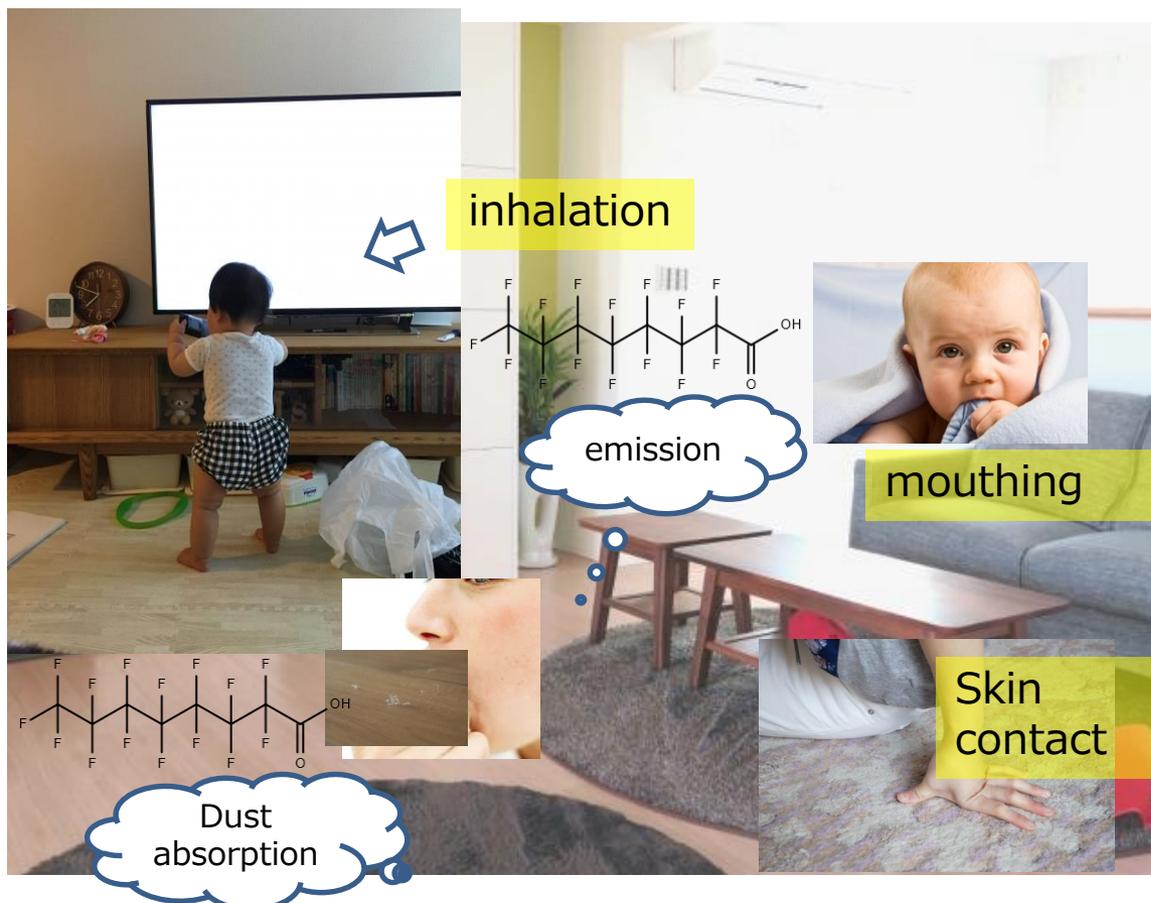
Children: 15.2 kg (Average weight of children ages 1 to 6, National Health and Nutrition Survey, 2015.)

PFOA and its related compounds-containing products and assumed exposure sources inside houses

Inside houses

Assuming exposure via following routes, based on various products which contain PFOA and its related compounds as emission sources.

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



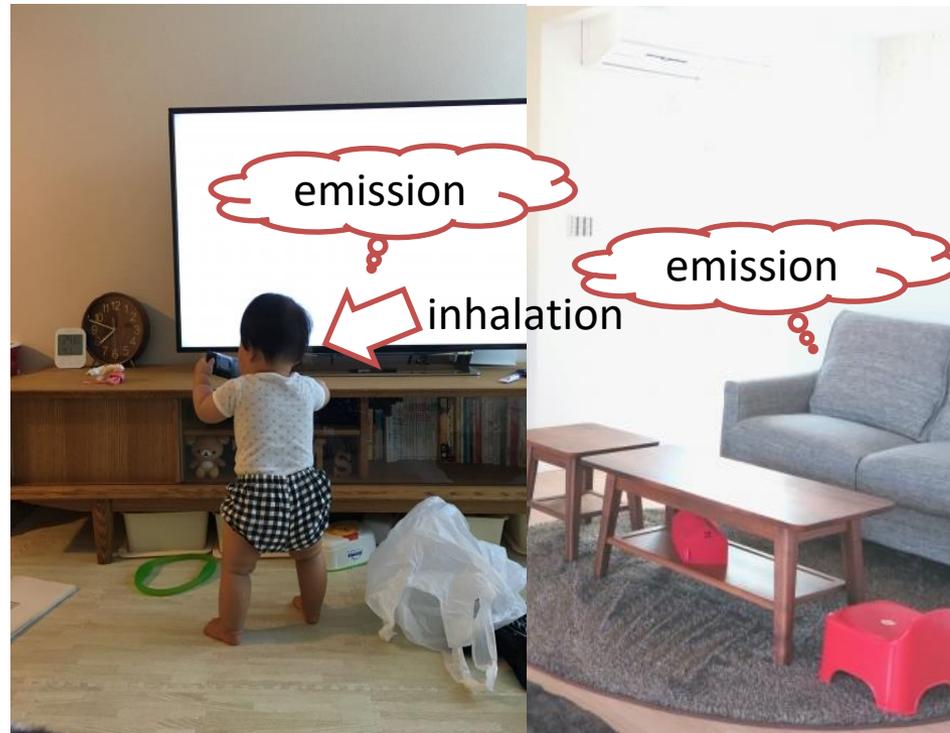
Assumed exposure via inhalation route

Assuming that PFOA and 8:2 FTOH (gas state) existing in the air of houses, the exposure amount is estimated.

EHE via inhalation (ng/kg/day)

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

Inhalation of gases released from PFOA and 8:2 FTOH-containing products inside houses



Assumed exposure via oral route

① Moutching behaviors (specific to children)

Ingest PFOA migrated into saliva from baby's bibs

※It is considered that baby's bibs account for large contribution to exposure amount among treated textiles.



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

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

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

Intake of dust adsorbed by PFOA and 8:2 FTOH inside houses

EHE via oral (ng/kg/day)

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



Assumed exposure via dermal route

Bare skin comes into direct contact with indoor carpets and absorbs PFOA and 8:2 FTOH through sweat.

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

$$= \frac{\text{Surface area of skin contact (cm}^2\text{/day)} \times \text{Thickness of the aqueous phase (sweat) (cm)} \times \text{Concentration of PFOA and 8:2 FTOH in aqueous phase (sweat) (mg/cm}^3\text{)} \times \text{Dwell time ratio} \times \text{Surface area of skin contact (cm}^2\text{/day)}}{\text{Body weight (kg)}}$$

Skin contact with the carpets



Skin contact

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

Risk assessment of PFOA derived from consumer products

Exposure route	Exposure scenario	Infant	Adult	Lifetime
Inhalation	Inhalation of indoor air	1.4	0.96	1.0
Oral	Ingestion of dust	2.1	0.38	0.53
	Mouthing	0.17	–	0.014
Dermal	Skin contact with carpets	1.4×10^{-3}	9.6×10^{-4}	9.9×10^{-4}
Exposure in total		3.6	1.3	1.5

Results of risk assessment of PFOA derived from consumer products

◆ Hazard assessment value

The reference dose of a lifetime drinking water Health Advisory for PFOA of 0.07 µg/L by the U.S.EPA. (20 ng/kg/day by dividing the 0.0053 mg/kg/day LOAEL by an UF ※¹ of 300)

the hazard assessment value for chronic-duration oral exposure: 20 ng/kg/day

※¹ UF: 3 (Species difference) × 10 (Individual difference) × 10 (LOAEL+Test period) = 300

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

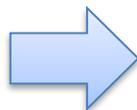
Considering 4 exposure scenarios in total for each environment and exposure coefficients which are set slightly on the safe side, estimate the exposure amount inside houses.

EHE averaged over a lifetime (ng/kg/day): 1.5 ng/kg/day

◆ The Results of Risk Assessment

$$HQ^{*2} = \frac{\text{EHE averaged over a lifetime (ng/kg/day)}}{\text{Hazard assessment value (ng/kg/day)}} = \mathbf{0.077}$$

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



Not at the level of 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
 - 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.

- ✓ The management of risk tradeoff is also a future issue

Thank you for your cooperation.