

Case study analysis on avoiding duplication of effort in chemical risk assessment in Japan

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Abstract

In Japan, there are several standard values on chemicals in each regulation (e.g. in food, in tap water, Environmental Quality Standards(EQS), etc.).

Food Safety Commission of Japan (FSCJ) as a risk assessment organization has conducted approximately 1,400 risk assessments for ten years and has contributed to set some standard values.

Recently, there are some cases that the results of chemical risk assessments (e.g. derivation of ADI) by FSCJ has been shared by the other regulatory authority in non-food field which sets EQSs etc.

So we analyzed several case studies of such good practices that avoid duplication of effort in Japan.

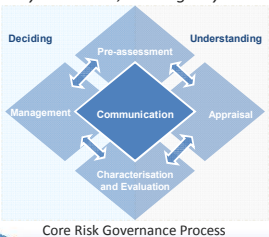
Key words: Chemical, risk assessment, risk management, hazard assessment

Background in EU

- The system which the identification and assessment of risks are slow has hampered research and innovation (EC, 2007; REACH in brief)
- Some regulatory authorities have been interested in potential hazardous chemicals (e.g. Phthalates, Bisphenol A, Parabens, Triclosan, Nanomaterials, Endocrine Disrupters, etc.)
- Network among EU Agencies for optimizing risk assessment(RA) / management(RM) to against for such chemicals
 - Avoiding duplication of effort is needed because the resources are limited



- International Risk Governance Council(IRGC) Framework for trans-boundary, emerging and systemic risk, each agency has been related with each core risk governance process



Appraisal process includes Risk Assessment

Appraisal

- Risk Assessment**
 - Hazard Identification & Estimation
 - Exposure & Vulnerability Assessment
 - Risk Estimation

Concern Assessment

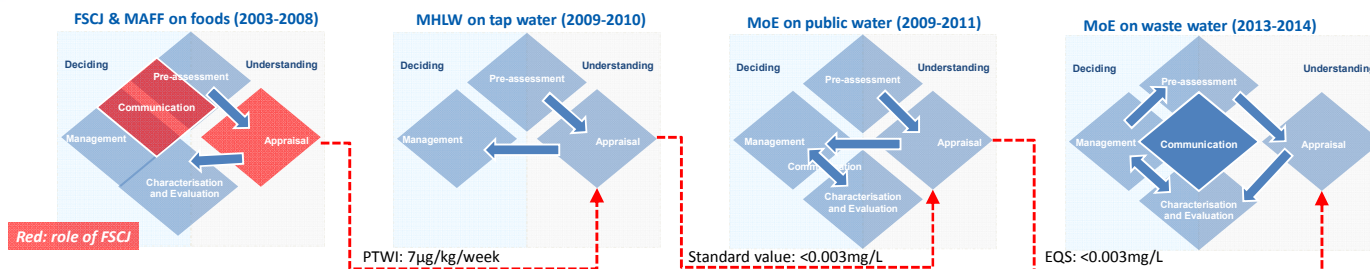
- Risk Perceptions
- Social Concerns
- Socio-Economic Impacts

Objective

- To suggest the solution of the "position of RA" which optimizes the chemical risk management system in Japan by using both normative and descriptive approach.
- To find the gaps of "positions of RA" between practical chemical management systems and normative management systems/frameworks (e.g. IRGC Framework, ISO 31000)
- To find the duplication of efforts among several practical cases and analyze the factors which depend on disturbing from optimizing chemical risk management system
- To develop the indicators which illustrate the performance whether the "position of RA" optimizes the chemical risk management system or not after filling the gaps and/or avoiding the duplications

Result & Discussion

- The result of RA by FSCJ was utilized for setting standard values among four chemical risk management systems in order to avoid duplication of effort
- It took approximately 11 years from request for RA on cadmium to enforcement of standard value for waste water



- The factors depend on influence to duration of RA as a result of interview with cabinet office of FSCJ

- Gathering data for RA by risk management authority
- Reliability assessment of the data by both FSCJ and risk management authority
- Taking account of the dialogue with risk managers
- No influence of drafting RA report by cabinet office
- Deliberation in the expert committee in some cases
- No influence of deliberation in Food Safety Commission
- Variety of difficulties of RA for each chemical

- Further analysis on effectiveness of existing...

- Data set / format for RA
- Criteria of reliability assessment
- Guidance for RA
- Deadline for RA
- Timeline and roadmap for RA

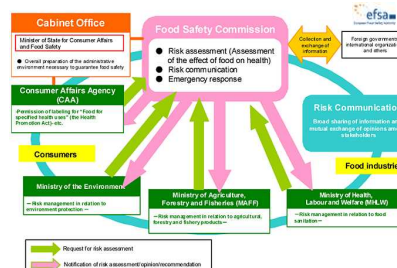
Challenges

- Generalizing the normative approach to analyze gaps
- Development the indicators without "duration of RA"

Background in Japan

- Role of Food Safety Commission of Japan (FSCJ)

- One agency and three ministries can request for risk assessment to FSCJ
- Network between FSCJ and EFSA has been established



- Items for risk assessment on human health (oral intake) by FSCJ

- Food additives*
- Pesticides *
- Veterinary medicinal products *
- Chemicals and contaminants
- Apparatus and containers / packages
- Prions
- Natural toxins / mycotoxins
- Microorganisms and viruses
- Novel foods *
- General modified foods (GMO) *
- Feeds, fertilizers, etc. *
- Others (Trans fatty acids in foods, Konjac gel candy)

* Standard processing period for RA is 1 year (obligation)

- Publication of FSCJ activities: RA reports & Time from request date to notification date for RA

- Chemicals and contaminants (Number of RA reports : Total 58 , by May 2015)
 - Beverage (N=45) ; Time : av. 6 years, min. 60 days, max. 10 years, std. 2 years
 - Tap water (N=9) ; Time : av. 70 days, min 6 days, max. 200 days, std. 50 days
 - Foods (N=1, Cadmium) ; 5 years
 - Rice (N=1, Cadmium) ; 0.5 years
 - Soil for agriculture (N=1, Cadmium) ; 8 days
 - Fishes (N=1, Methyl mercury) ; 1 year
- Apparatus and containers / packages (N=3, Phthalates) ; Time : av. 4 years, min. 3 years, max. 5 years, std. 1 year

- Experimental steps of setting standard values for water when FSCJ was not established

- Drinking water criteria : World Health Organization
- Standard value for tap water under the water supply law in Japan : Ministry of Health, Labor and Welfare (MHLW)
- EQS for public water body and ground water under the basic environmental law in Japan : Ministry of Environment (MoE)
- Standard value for waste water from facility under the water pollution control law in Japan : MoE

value i. = value ii. = value iii. = 1/10 of value iv.

Material & Method

- Definition of terms in this study

- Position of RA : consist of both "Quality of RA" and "Duration of RA"
- Assessment value : Acceptable Daily Intake (ADI), Provisional Tolerable Weekly Intake(PTWI), etc.
- Standard value : Risk management authority sets based on assessment value
- Duration of RA : Time from request date by risk managers to notification date by risk assessors

- Descriptive approach : Case study analysis

- Target chemical : Cadmium (Beverage, Tap water, Foods, Rice, Soil for agriculture, public water body and waste water)
- Textual Analysis: Calculation of duration of RA based on information at website, identification of actors(FSCJ, MAFF, MHLW and MoE) and extraction of assessment values from RA reports
- Interview Analysis (interview with staffs for the Cabinet office of FSCJ)

- Normative approach

- Comparison between this case study and IRGC core risk governance process