

Development of “Key points for CSA in REACH”

Kazumi KAWAHRA

Chemicals Evaluation and Research Institute (CERI)

財団法人 化学物質評価研究機構

Chemicals Evaluation and Research Institute, Japan

Outline of the Presentation

- ◆ *Objectives of the document*
- ◆ *Background*
- ◆ *Target readers*
- ◆ *Technical committee*
- ◆ *Structure of the document*
- ◆ *Contents of the document*
- ◆ *Topics*
- ◆ *Features of the document*

Objectives of the Document

- **To give additional guidance / information on CSA procedures**
- **To facilitate better implementation of CSA**
- **To provide a user friendly document (less contents not too much technical)**
- **To guide users how to get further / detailed information**
- **Not to be used as a standalone document but together with ECHA's GDs and others for actual RA under REACH.**

CSA: Chemicals Safety Assessment

RA: Risk Assessment

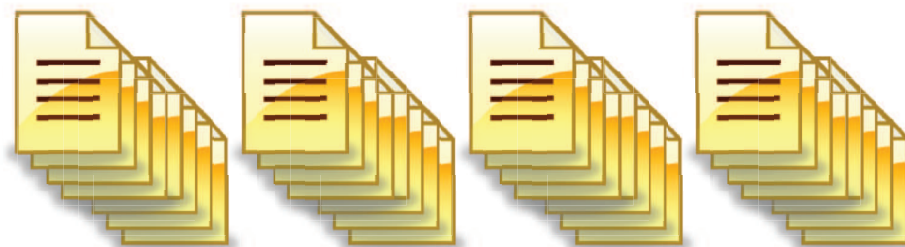
GDs: Guidance Documents

Background

- **Less experience of risk assessment (especially for SMEs in Japan)**
- **Hard to understand how to implement risk assessment and to fulfill the REACH requirements**
- **ECHA gives very exhaustive guidance but difficult to read and understand (only a part of Japanese translation available)**



Concise GDs, Part A – G
376 pages



In-depth GDs, R.2 – R.20
1,900 pages

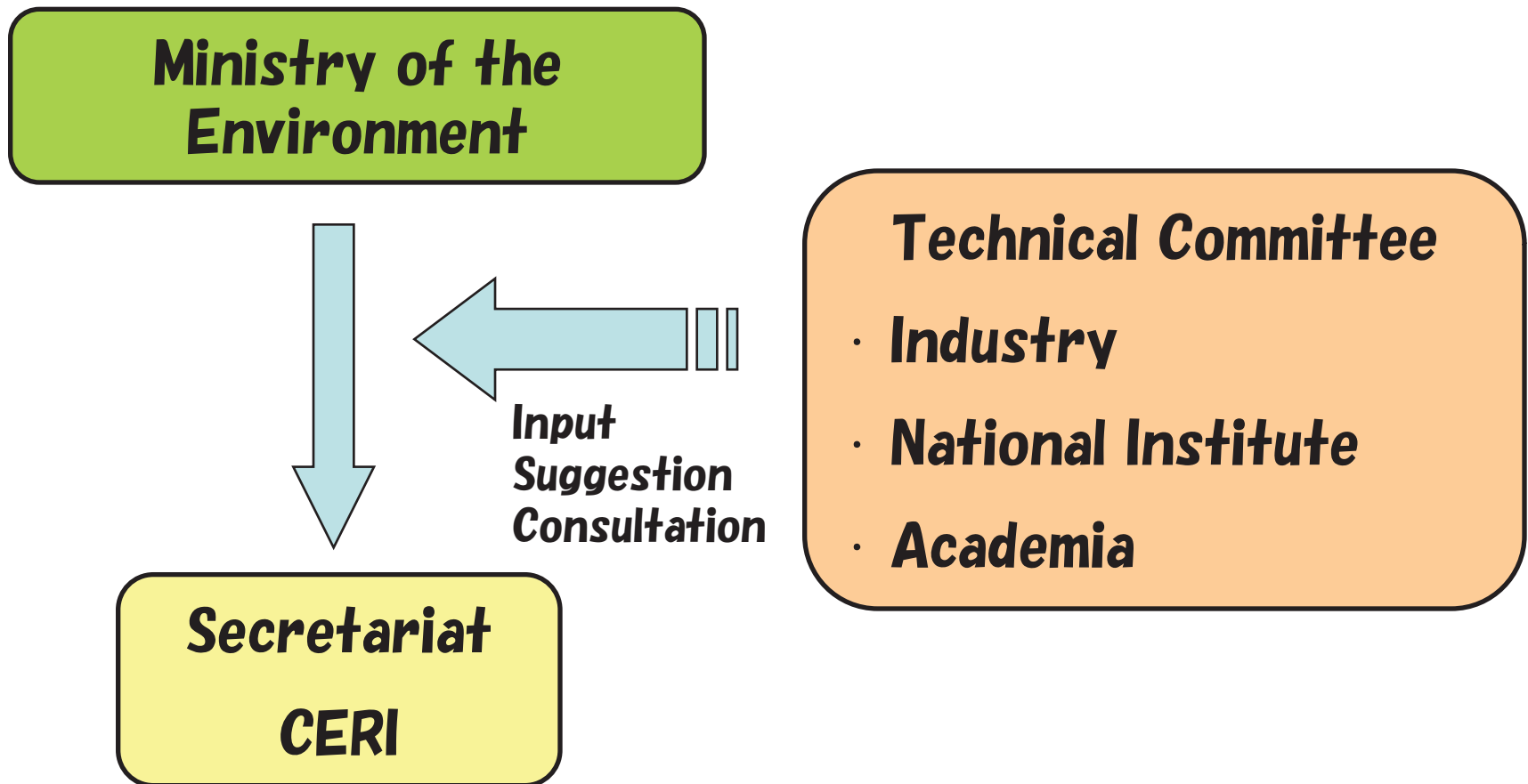
Target readers

Main target readers are persons who are in charge of the implementation of risk assessment under REACH

Junior	Person in charge of REACH registration	Experienced person (risk assessor)	Expert
×	◎	○	△

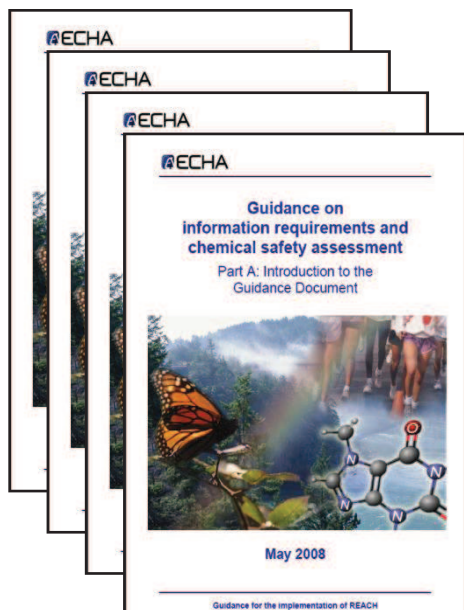
The document can also be used as a navigation tool for ECHA's GDs.

Technical Committee for the development of the document



Face-to-face meetings twice, and e-mail consultations

Structure of the document



CSA Concise GDs



RIP3.2 Final Report

Extracted key issues mainly from CSA Concise GDs, amended some wordings appropriately

+

Additional explanation from in-depth GDs and others

Some figures from RIP3.2

+

Introduction, original topics, abbreviations, useful links, note on translation into JPN terms

Contents of the document-1

Contents

Related ECHA's GD

Introduction ----->	Original
CSA, CSR and SDS in REACH ----->	Original
Overview of ECHA's GDs on CSA ----->	Part A: Introduction
Hazard Assessment ----->	Part B: Hazard Assessment
PBT Assessment ----->	Part C: PBT Assessment
Exposure Assessment ----->	Part D: Exposure Assessment
Risk Characterisation ----->	Part E: Risk Characterisation
CSR ----->	Part F: CSR
SDS ----->	Part G: eSDS
Topic 1 – 7 ----->	Original
Abbreviations ----->	Original
Useful Links ----->	Original

CSR: Chemical Safety Report

(e)SDS: (extended) Safety Data Sheet

ECHA: European Chemical Agency

PBT: Persistent Bioaccumulative and Toxic

Contents of the document-2

Introduction

- ✓ **Objective**
- ✓ **Background**
- ✓ **Target reader**
- ✓ **Technical committee**

CSA, CSR and SDS in REACH

- ✓ **Function of CSA, CSR and SDS in REACH**
- ✓ **Outline of CSA (std, steps)**
- ✓ **Contents of Technical Dossier and CSR**
- ✓ **Output of CSA**

Overview of ECHA's GDs on CSA

- ✓ **Structure of Concise and in-depth GDs**
- ✓ **Summary contents of Concise GDs**

Hazard Assessment

- ✓ **Basic methodology of Hazard Assessment (HA)**
- ✓ **Adaptation of information requirements**
- ✓ **Human Health HA**
- ✓ **Environmental HA**
- ✓ **Physico-chemical HA**
- ✓ **Reliability of Data**

PBT Assessment

- ✓ **Overview of PBT Assessment**
- ✓ **Aim and Procedure of PBT Assessment**
- ✓ **Screening of PBT Assessment**
- ✓ **PBT, vPvB Criteria**
- ✓ **Further measures for PBT substances**

Exposure Assessment

- ✓ **Overview of Exposure Assessment (EA)**
- ✓ **Actors in supply chain in REACH**
- ✓ **Determinants for Exposure Scenario (ES) Development**
- ✓ **Development of ES (standard workflow)**
- ✓ **Risk Management Measures (RMMs)**
- ✓ **Outline of Exposure Estimation**
- ✓ **Use of Measured Data**
- ✓ **Occupational EA**
- ✓ **Consumer EA**
- ✓ **Environmental EA**
- ✓ **Use of final ES in Supply Chain**
- ✓ **Exposure Estimation Models (Tier 1)**

Risk Characterisation

- ✓ **Overview of Risk Characterisation (RC)**
- ✓ **Procedures of RC**
- ✓ **RC for Physico-chem**
- ✓ **RC for Human Health**
- ✓ **RC for Environment**

Contents of the document-5

CSR

- ✓ **Standard format of CSR**
- ✓ **CSR Template**

Abbreviations

- ✓ **55 terms in JPN version**
(including notes on translation)

SDS

- ✓ **Objective of SDS in REACH**
- ✓ **Requirements for extended SDS**

Useful Links

- ✓ **9 major websites**

Topic-1: Viewpoints of Risk Assessment in REACH

Topic-2: What is Weight of Evidence?

Topic-3: DNEL and PNEC in REACH

Topic-4: Category Approach

Topic-5: What is Klimisch Code?

Topic-6: Uncertainty Analysis

Topic-7: CSR Format Using IUCLID 5

Features of the document

- Concise (**40 pages**: 1 / 10 of volume of the original concise GDs) and easy to read
- Main **target readers** are non-experts but **risk assessors** in REACH and/or general
- Focus on mainly **technical guidance** on CSA
- Contains **original topics** which should give additional information for the implementation of CSA
- Contains **notes on JPN translation**
- Can also be used as **a guided material for ECHA's extensive GDs**
- To be **open to the public** via internet



Thank you for your attention!!

財団法人 化学物質評価研究機構

Chemicals Evaluation and Research Institute, Japan