

# Main Points for Amended CSCL in 2017

21<sup>st</sup> and 22<sup>nd</sup> November, 2018

Safety Assessment Division  
Chemical Management Center

**1. Outline of CSCL**

**2. Introduction of Specific new  
(Specific general) chemical substances  
(Enforced on April 1, 2018)**

**3. Rationalization of new special  
exemption system  
(Enforced on January 1, 2019)**

# Outline of CSCL

## Purpose

- To prevent environmental pollution caused by chemical substances that pose a risk of impairing human health and interfere with the inhabitation and growth of flora and fauna.

## Outline

- Preliminary examination of new chemical substances
  - Notification to and evaluation by the government are required before manufacture/import.
- Continuous management measures for chemical substances after launch
  - Risk assessment based on grasping manufacturing / import quantity (post notification),  
reporting hazard information
- Regulations and measures according to the properties etc. of chemical substances (degradability, accumulation, toxicity, residual situation in the environment)
  - Designated as "Class I Specified Chemical Substance" according to properties
  - Understand manufacturing / import quantity, hazard investigation instruction, manufacturing / import permission, use restrictions, etc.

# Outline of CSCL

Placing on the market

Premarketing  
Notification and  
Evaluation

New  
Chemicals

Advance check

Low Volume  
(Below 10 tons /year)

Small Volume  
( Below 1 tons /year )

Intermediates etc.  
(Used in the Official  
Gazette)

Polymers of Low Concern

**Class I Specified  
Chemicals (33  
substances)**  
(persistent,  
bioaccumulative, toxic)

Into the  
environment  
Avoid  
release

- Manufacturing · Import permission system (Prohibited except essential applications)
- Prohibition of importation of ordinance-designated products
- Instructions for collection etc.

**Monitoring Chemicals  
(38 substances )**  
(persistent and bioaccumulative)

Detailed grasp  
of usage  
situation etc.

- Manufacturing · Import record obligation to report quantity, detailed use etc.

**Class II Specified  
Chemicals (23  
substances )**  
(toxic and high risk)

Into the  
environment  
Suppress  
emission

- Manufacturing · Import (Scheduled and actual) Notification of quantity, use etc.
- Order to change the planned quantity as necessary
- Technical guidelines on handling
- Display of ordinance-designated products

**Priority Assessment  
Chemicals  
(208 substances )**

Detailed grasp  
of  
hazardousness,  
use situation,  
etc.

- Manufacture · Import results · Quantity Notification of shipment quantity etc. by detailed use
- Hazard Investigation Instruction
- Commitment to information transmission effort

Specific general  
chemical substances

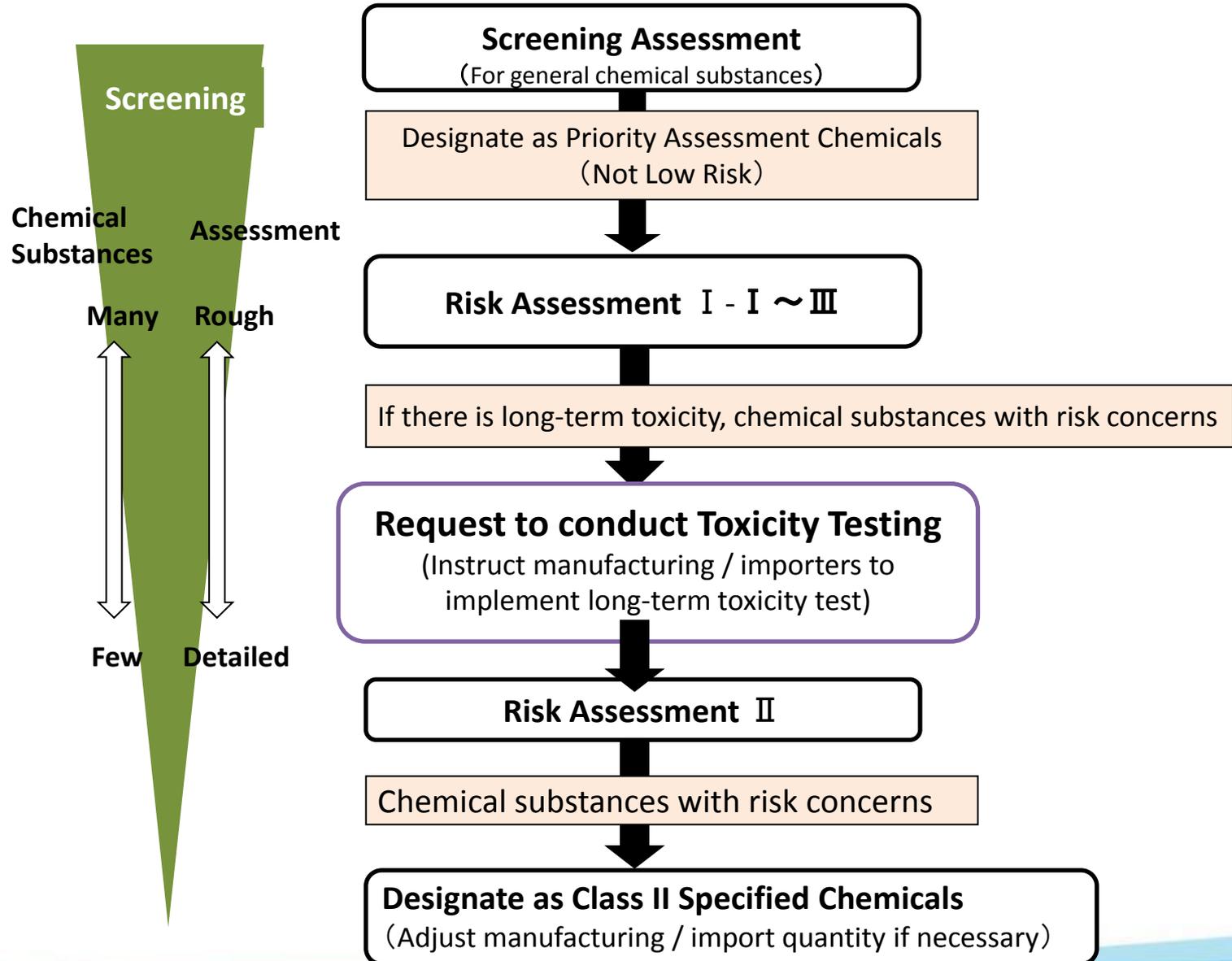
**General Chemicals  
( ≒ Existing Chemical Substances )  
(approx. 28,000)**

Government  
has risk  
assessment

Usage  
situation etc  
Roughly  
grasping

- Duty of communication effort (specific general chemical substances only)
- Manufacture · Import record number Quantity, application etc

# Outline of CSCL



# Introduction of Specific new (specific general) of chemical substances

- In recent years, chemical substances with high functionality are highly toxic due to their reactivity. Since these chemical substances are often low in environmental emissions, they do not fall under the priority evaluation chemical substances.
- Designated as a specific new chemical substance for those newly noticed toxic by new chemical substance screening. (Specified general chemical substance after public notice)

	persistent, bioaccumul ative	toxic	Remarks
Class I Specified Chemicals	○	○	
Class II Specified Chemicals		○	Substantial residual in a considerably wide area
Priority Assessment Chemicals		There is no thing Not clear	Substantial residual
specific general chemical substances (※Prior to public notice, specific new chemical substances)		○	Less environmental emissions
General Chemicals			Less environmental emissions

Large



Comprehensive risk



Small

New definition

# Introduction of Specific new (specific general) chemical substances

## < Human health >

- Regarding repeated dose toxicity test, when the hazard assessment value (Note 1) is 0.0005 mg / L or less
- For AMES test and chromosomal aberration test, if one is strongly positive and the other is positive or more

## < environment >

- When the PNEC (Note 2) calculated from the chronic toxicity test result is  $3 \times 10^{-4}$
- When the PNEC calculated from the test result including the acute toxicity test is  $3 \times 10^{-5}$

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Note 1) Numerical values obtained by dividing NOAEL etc. of repeated dose toxicity test by uncertainty coefficient product

Note 2) Numerical values obtained by dividing NOEC etc. of aquatic toxicity test by uncertainty coefficient product

# Introduction of Specific new (specific general) of chemical substances

- In order to ensure careful prevention of environmental emissions, the following matters already practiced are prescribed by the law

## 1. notification

Notified to the business operator from the three ministers that it is a highly toxic chemical substance among general chemical substances

## 2. Information transmission obligation

When an entrepreneur assigns and provides the chemical substance, it obliges to strive to communicate information to the effect that toxicity is strong among general chemical substances

## 3. Instruction and advice

Provide necessary guidance and advice from the competent minister to business operators (for example, instruct and advise to provide information such as measures to improve management methods along the supply chain to prevent environmental pollution.)

## 4. Report on handling situation

The competent minister can request report from the business operator on the status of handling (Thus, for example, it is necessary for businesses handling highly toxic chemical substances to report to the relevant chemistry. It will be possible to keep records on substance delivery and inventory status in documents for a certain period of time.)

# Rationalization of new special exemption system

- Regarding the upper limit of the national quantity of the special case system, review current " manufacturing / import quantity" on the premise of ensuring safety to human health and ecosystems.
- By changing the nationwide quantity upper limit to "environmental emissions" taking into account "application information" so that the load on the environment will not increase as in the past, the number of cases receiving quantity adjustment decreases, Contributing to raising the foreseeability of the business plan.
- When converting manufacturing / import quantity to environmental emissions, we set the emissions factor for each use (already used for screening evaluation · risk assessment) on the safety side, and apply these factors.

Change before

After change

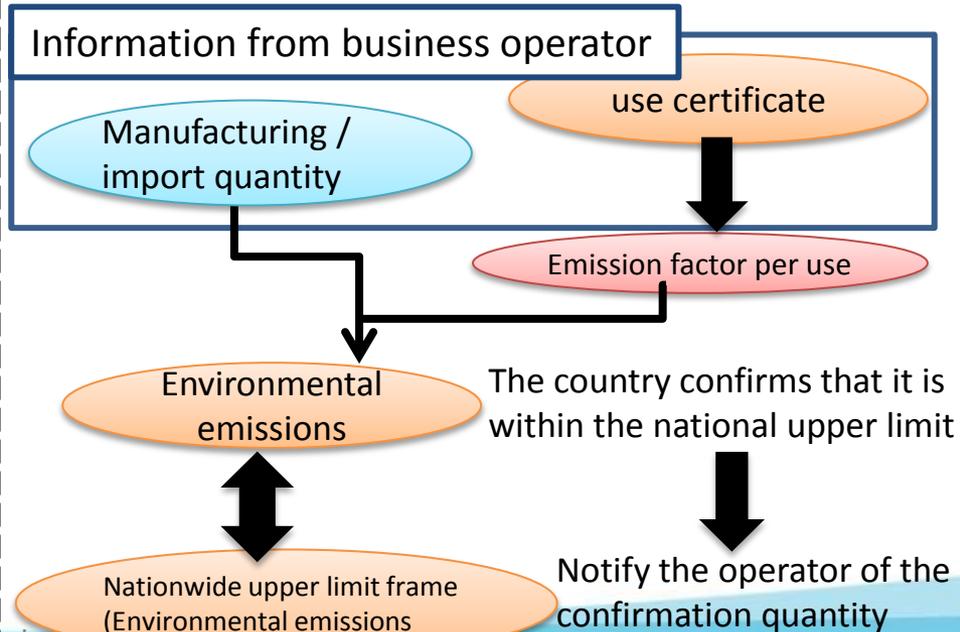
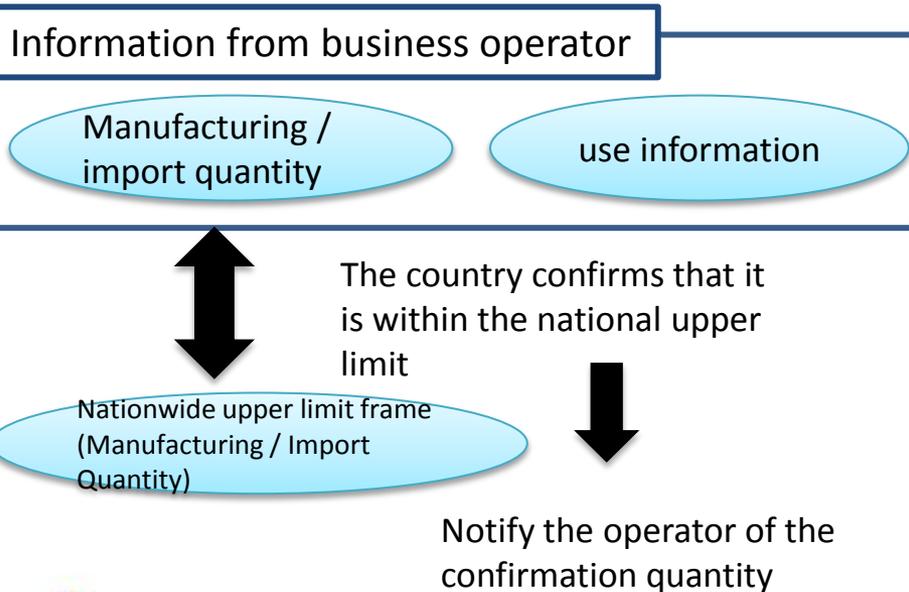
	Unit Capacity Ceiling	National Capacity Ceiling		Unit Capacity Ceiling	National Capacity Ceiling
Small Volume	1 ton (Manufacturing / Import Quantity)	1 ton (Manufacturing / Import Quantity)	→	1 ton (Manufacturing / Import Quantity)	1 ton (Environmental emissions)
Low Volume	10 ton (Manufacturing / Import Quantity)	10 ton (Manufacturing / Import Quantity)		10 ton (Manufacturing / Import Quantity)	10 ton (Environmental emissions)

# Rationalization of new special exemption system

- In order to promote this rationalization, since the importance of the application information increases, in order to ensure the accuracy of the use information, additional information is sought from the business operator.
- In collecting additional information from business operators, we established a system that enables the government to properly check the usage information while preventing excessive burden on business operators.

## Before rationalization: National upper limit (manufacturing / import quantity)

## After rationalization: nationwide upper limit (environmental emissions)



# Rationalization of new special exemption system

- Since it is important to determine the purpose for calculating the amount of environmental emissions, in principle, it is necessary to attach a use certificate
- Example of use certificate
  - ① Sale contracts, quality assurance forms, invoices etc. that have been concluded between companies
  - ② Documents signed and imprinted by the user of the requested substance to SDS with limited special application
  - ③ Confirmation of use (form prescribed by the government)
- Descriptions necessary for the purpose certificate
  - ① Destination of use certificate (company name, name of responsible person)
  - ② Name of the new chemical substance (or product), application number and use classification
  - ③ User (department, name of person in charge, address, telephone number, e- mail address)

# Rationalization of new special exemption system

## Emission factor related to confirmation of New Chemicals (Small Volume and Low Volume)

Use number	Use classification	Factor	Use number	Use classification	Factor
101	Intermediates	0.004	125	Textile products	0.2
102	Solvents for paints, varnishes, coatings, inks, toners and biocidal products	0.9	126	Paper and pulp products	0.1
103	Solvents for adhesives, pressure sensitive adhesives and sealants	0.9	127	Plastic products	0.03
104	Solvents for cleaning and degreasing metals	0.8	128	Rubber products	0.06
105	Solvents for cleaning fabrics	0.8	129	Leather products	0.02
106	Solvents for cleaning others (excl. #104,105)	0.8	130	Glass, enamel and cement products	0.03
107	Solvents for chemical manufacture and processing(excl. #102-106)	0.4	131	Ceramics and porcelain, refractory and fine ceramics products	0.1
108	Solvents for aerosol and physical foaming agents	1	132	Grinding wheel, abrasive compound, friction material and solid lubricant products	0.1
109	Other solvents (excl. #102-108)	1	133	Metal products	0.1
110	Chemical process regulators	0.02	134	Surface treatment chemicals	0.1
111	Colorants	0.01	135	Welding, soldering and fusion cutting products	0.03
112	Washing and cleaning products (industrial use)	0.07	136	Hydraulic fluids, insulating oils, lubricating oils	0.02
113	Washing and cleaning products (household use, institutional use)	1	137	Metalworking fluids, rust preventive oils	0.03
114	Polishes and wax blends(e.g. for floors, cars, leathers)	1	138	Electrical and electronic products	0.01
115	Paints and coatings	0.01	139	Electrical batteries	0.03
116	Ink and toners	0.1	140	Water treatment chemicals	0.05
117	Antifoulants for ship bottom paints, antifoulants for fish nets	0.9	141	Desiccants and absorbents	0.09
118	Biocidal products (on to/in to articles)	0.04	142	Heat transfer fluids	0.08
119	Biocidal products (industrial use and not onto/in to articles)	0.2	143	Anti-freeze and de-icing products	0.08
120	Biocidal products (household use, institutional use)	0.4	144	Building materials and constructional articles, and additives for them	0.3
121	Explosive products, chemical foaming agents, solid fuel	0.02	145	Sprinkler chemicals, chemicals for treatment of bottom ashes and fly ashes	1
122	Air fresheners, deodorizers	1	146	Flotation reagents, collectors	0.1
123	Adhesives and sealants	0.02	147	Fuels and fuel additives	0.004
124	Resist materials, photographic materials and printing plate materials	0.05	199	For export	0.001

# Rationalization of new special exemption system

- Small Volume will increase the electronic application from the previous 4 times a year to acceptance 10 times a year. In addition, we will be able to offer by optical disc and accept it 4 times a year.
- Low Volume will begin accepting applications by electronic and optical discs.

Small Volume (1 t/year)	Application period			Receptionist
	Part 1	After 2nd	Times	
Electronic	January 20th - 30th	April - December (1st - 10th)	10 times	Electronic application
Optical disk	January 20th - 30th	June, September, December (1st - 10th)	4 times	Contact, Mail
Written	January 20th - 30th	June, September, December (1st - 10th)	4 times	Contact
Low Volume (10 t/year)	Application period			Receptionist
	Part 1	After 2nd	Times	
Electronic	March 1st – 10th	April - March	13 times	Electronic application
Optical disk	March 1st – 10th	April - March	13 times	Contact
Written	March 1st - 10th	April - March	13 times	Contact

# Rationalization of new special exemption system

- Instead of the conventional structural code (described by the submitting company itself), the structure information of the submitted substance is requested to be submitted in the MOL format structural information file (prepared by appropriate software).

## **What is MOL format structure information file (MOL file) ...**

- File format developed to be installed in commercial chemical structure database at MDL (currently BIOVIA) after 1979
- Since it is possible to save 3D coordinates for each atom in a file, it is possible to cope with almost all the compound's stereo notation
- The type and number of elements of the target substance, the bond relation / style, stereochemistry and chain / ring, charge state etc. are expressed in a table (matrix) form called a Connection table (Ctab)

# Rationalization of new special exemption system

- When actually drawing the structural formula, use one of the following software. **Software other than the below can not be used for submitting a small amount of new chemical substances because confirmation of conversion to another notation (SMILES or InChI) has not been confirmed.**

Type	Software name	Supported OS	supported language	manual	Developer
Paid software	ChemDraw	Windows, Mac OS	English	There (Japanese)	PerkinElmer (CambridgeSoft)
free software	Marvin JS	Windows, Mac OS	English	There (Japanese)	Chemaxon
	BIOVIA Draw	Windows	English	There (Japanese)	Dassault Systems Biovia

When importing to Japan from overseas, It is necessary to provide structural information from overseas manufacturers (exporters) to importers

# Rationalization of new special exemption system

Published by NITE's HP so that you can use MOL file creation software "Marvin JS" for free

nite National Institute of Technology and Evaluation  
独立行政法人 製品評価技術基盤機構

化学物質管理

少量申請 > MOLファイル作成システム

少量新規化学物質の申請に必要なMOLファイルの作成

クリア

構造式整形

MOLファイル保存

高さ変更

Valid license cannot be found

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