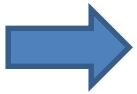
Current trends of CSCL

7th March,2019

International and Planning Office,
Chemical Management Center,
National Institute of Technology and Evaluation (NITE)

Recent trends and future direction of CSCL

1. Enforcement (January, 2019) of revised CSCL in 2017, revision of relative cabinet orders and ministerial ordinances



Explained in 4-1(1)

2. Implementation of risk assessment towards the achievements of the WSSD2020 goal(※).
   - Proceeding with acceleration and rationalization of risk assessment

※**<The WSSD2020 goal>:** ” a goal aiming to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment” (Johannesburg Summit in 2002)

<The National goal based on the WSSD 2020 goal>

✓ Aiming to minimize significant adverse effects of about 28,000 General Chemicals (≒Existing Chemicals) .

✓ Specifically, conducting risk assessments in order to specify Priority Assessment Chemicals(PACs) which are found to be likely to pose a certain level of risks on human and environments, and then designating chemical substances clarified a risk of long-term toxicity for humans and environment as Class II specified chemical substances.

CSCL（Towards achieving the WSSD2020 Goal）

- 96%(About 27,000) of General Chemicals(≒Existing Chemicals) has already being found out enough small on their significant adverse effects through screening and risk assessment.
- In order for proceeding to risk assessment on the rest of General Chemicals, three targets and thirteen methods for their achievements were set out.

Three targets for achieving the WSSD 2020 goal
※Joint Council of three ministries(METI, MHLW and MOE), Oct 2016

Thirteen methods for achieving the three targets
※Joint Council of three ministries, Jan 2017

Checking the achievement status and plans for WSSD 2020 goal
※Joint Council of three ministries, Nov 2018

By the end of 2020,
- Chemical substances being obtained scientifically reliable hazard data sets

【Target 1】
Finishing the screening assessments on those substances in general

【Target 2】
Designating some substances which should be designated as the Class II specified chemical substances

- Chemical substances not being obtained data sets for assessment

【Target 3】
Having prospects for conducting risk assessments

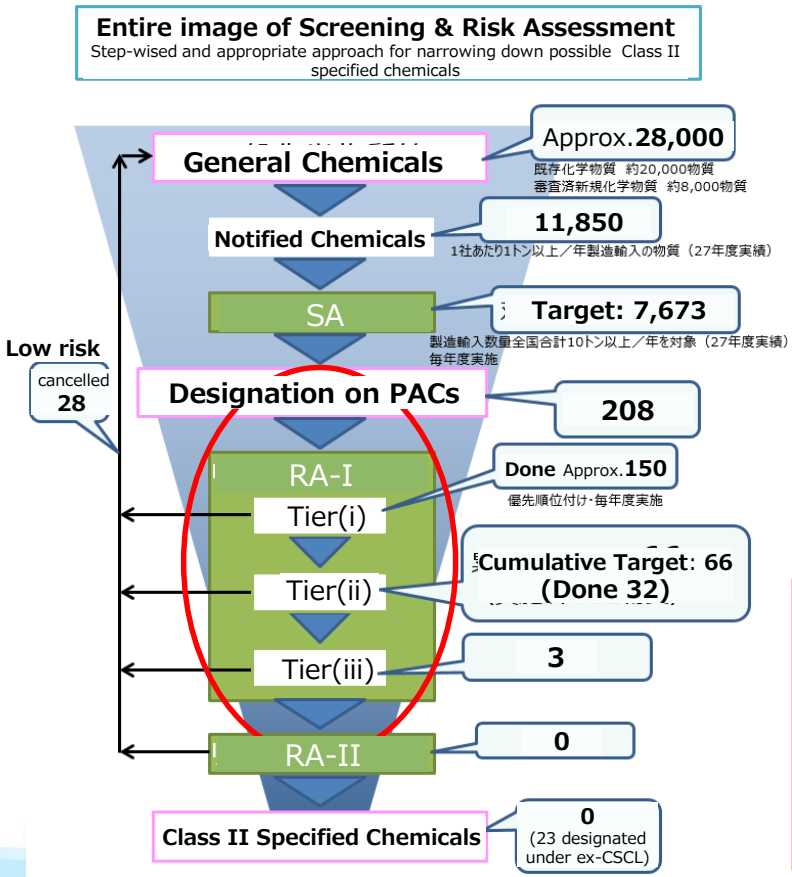
	Points of amendments		Contents of amendments or improvements
Screening Assessment	Basic concept on Screening Assessment/ Screening Assessment under CSCL/Detail of Screening Assessment method	1	Clarification and rationalization of the handling of polymer compounds
		2	Exploring a way of setting hazard classes of chemical substances having a shortage of data for the assessment (Utilization of nationally or internationally established knowledge/ Consideration and accerelation of utilizing hazard predictive methods, such as QSAR, etc.)
	(Improving implementation)	3	Focusing on substances classified in highr ranks of both hazards and exposures until 2020
	Reliability assessment of hazard data, etc. on human health effects under CSCL	4	【Completed】 Clarification of assessment procedures, (ex. establishment of criteria being not necessary for expert judgements) 【Completed】 Efficiency by ranking of data reliability (ex. Regarding highest prioritized literature, preferentially adopting the reasons considered as having particularly high reliability) 【Completed】 Clarification of handling on safety studies owned by METI, NITE, etc. 【Completed】 Clarifying a way of setting mutagenic classes
Risk Assessment	Basic concept on risk assessment of PACs under CSCL/ Process flow on step-wise risk assessment/ Risk assessment method of PACs/ Technical guidance on PACs' risk assessment under CSCL	5	Review on a selection method of an appropriate substance subject to assessment on designating a Class II specified chemical substance(ex. Utilization on PRTR data, Quantitative assessments on carcinogenicity, etc., Sort by utilizing a peer review on impacts of human health, Review on a method of prioritization subject to substances of RA II)
		6	Acceleration for a pace of risk assessment by considering and introducing additional assessment methods (ex. Handling on disassortive substances)
		7	Considering measures including a criteria for requiring additional tests, to address problems on risk assessment methods on substances with positive mutagenicity but no data on carcinogenicity.
	(Improvingimplementation)	8	Regarding substances with no available data, setting a contact point on proividing information including QSAR or category approach for thier accelaration, and directing investigation of toxicity based on clause 1 of Article 10 under CSCL.
		9	Review on RAII schedule
		10	Moving forword to utilize nationally and internationally established knowledge, ex. existing chemicals assessment report or guidelines, etc.
		11	Ratinalization of RAII assessment report on human health in Process
System improvement for gathering necessary information/ data of assessment	Form 11 (for General chemicals) and Form 12 (for PACs) of Ordinance for Enforcement of CSCL relating to METI	12	Revision of the ministerial ordinance for grasping actual structures on manufactured/imported chemicals and easily submitting detail information on structures and composition, in order for setting assessment units of UVCBs and categorizing in hazard classes, etc.
	Article 3 of ministerial ordinance on reporting hazard imformation	13	Modifying "Items such as composition, the property reporting" in order for gathering information on PACs' composition.

Achievement status and plans for the WSSD 2020 goal

<Target 1> Screening Assessment (SA) : proceeding firmly and being expected to be almost completed

<Target 2> Risk Assessment (RA) : proceeding generally and firmly on schedule, however being required more acceleration and rationalization

<Target 3> On chemicals having no available data for assessment : Developing a policy aiming to make the assessment feasible is proceeding firmly. Expected to be almost completed.



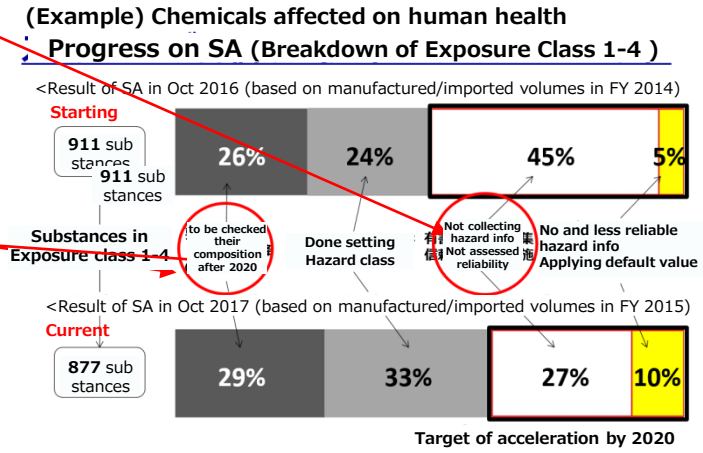
【Target 1】

・**Ratio of chemicals** having **no available hazard data** etc. are **firmly declined.**

【Target 3】

・**Done the revision of** Ministerial ordinance regarding **application form on General Chemicals , etc. in Sep 2018.** (Enforcement in Apr 2019)

・**Available** on **setting an appropriate unit** for assessment and **collecting hazard information** through notified information of structures and properties **on difficult chemicals.**



【Target 2】

To be tackled on the following actions needed for further acceleration and rationalization, which are clarified problems through a progress of 13 methods for 3 targets in practice and a check of evaluation method

- ✓ Confirming thorough notified information under CSCL, ex; usage, etc.
- ✓ Review of RA I –(ii) methods for assessment (Utilization of PRTR data, implementation on quantitative assessment of carcinogens, etc.)
- ✓ Review of the schedule on RA II (ex. Consideration of status of chemical management under other Acts)

(Ref) . Screening Assessment using priority matrix

Regarding General Chemicals,

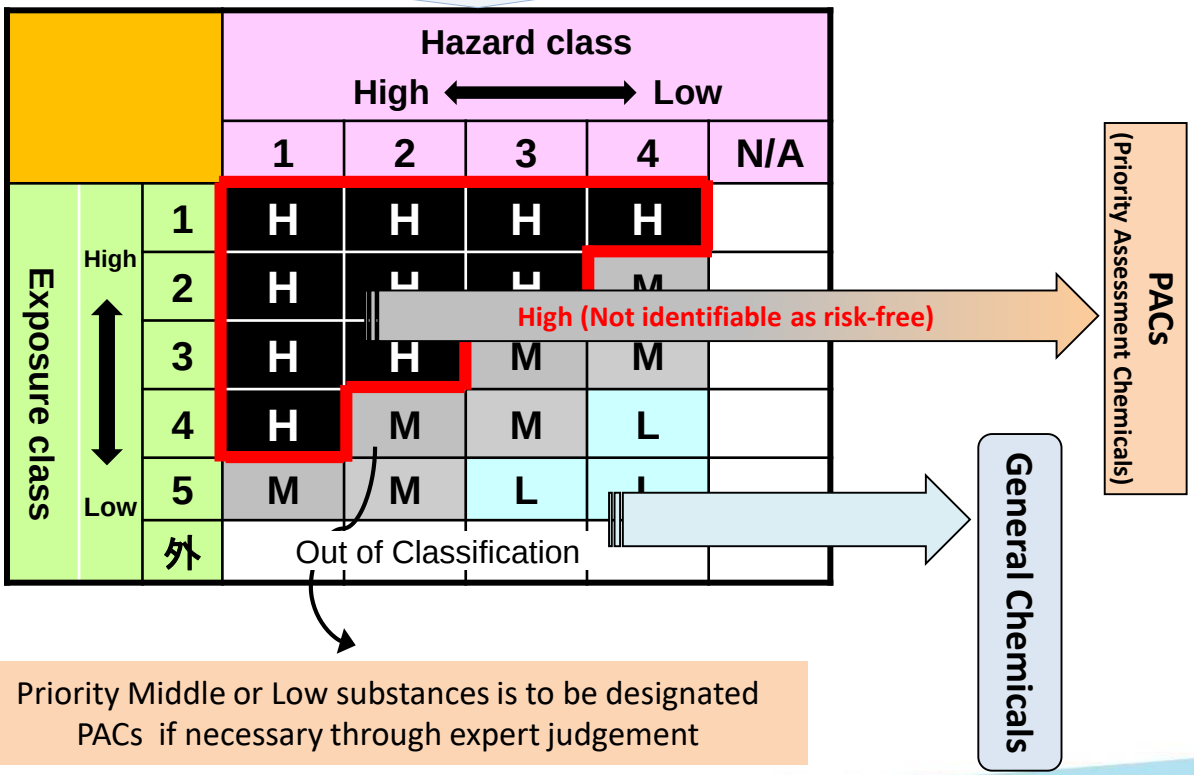
- ✓ Setting exposure class(size of estimated emission amount) and hazard class (strength of Hazard)
- ✓ Conducting Screening Assessment using the following priority matrix

Setting hazard class through hazard data notified or reported, etc. under CSCL on,
【Human health】 general toxicity, Repeated Dose Toxicity, Reproductive Toxicity, Mutagenicity, Carcinogenicity
【Ecosystem】Eco-toxicity (Algae, Daphnia, fish)

【Total estimated emission amount to environment】
Setting exposure class by calculating total estimated emission amount to environment from (updated every year)

- ✓ notified information on manufactured /imported amount
- ✓ result of Judgment result on non-/readily-degradable

Exposure Class	Total estimated emission amount to environment
Class1	over 10,000 t
Class2	1,000 – 10,000 t
Class3	100 – 1000 t
Class4	10 – 100 t
Class5	1–10 t
Out of class	Less than 1t



Priority Middle or Low substances is to be designated PACs if necessary through expert judgement

Future direction of CSCL

- **Further discussion towards adoption of comprehensive assessment, such as Weight of Evidence※ approach, on biodegradability and bioaccumulation by using a variety of data**

■ **Background** : Within chemical properties, especially biodegradation and bioaccumulation, etc. in the environment are evaluated under CSCL

■ **Current situation** :

・<New chemicals evaluation on biodegradation and bioaccumulation, etc. under CSCL>
  ✓Using data acquired by CSCL test methods, which are submitted by businesses

・<Risk assessment on General Chemicals (≒Existing Chemicals)>
  ✓ Using available test data. It may conflict to data acquired by CSCL test methods, if both test data are available.

■ **Problems** :

・Using only data acquired by CSCL test methods is impossible to cover whole behavior in real environment

・Less progress to use data acquired by internationally admitted many test methods

※An approach on assessment how to validate an assumption that a substance causes an specific effect, not by using only single data, but by using combination of plural available data.

・Analysis the relation between the results of various test and estimated methods, and that acquired by CSCL test methods, etc.

・Expanding acceptable test methods
・Further utilization of QSAR or Read Across
・Utilizing data in the real environment

Regarding biodegradation and bioaccumulation,
・Clarify the various test and estimated methods
・Clarify the criteria

Future direction

- Adoption of comprehensive assessment methods by utilizing various data on biodegradation and bioaccumulation
- Linkage in handling between New Chemicals evaluation and risk assessment on General Chemicals

<Ref> Development of Chemicals Management Platform for realization of one-stop service

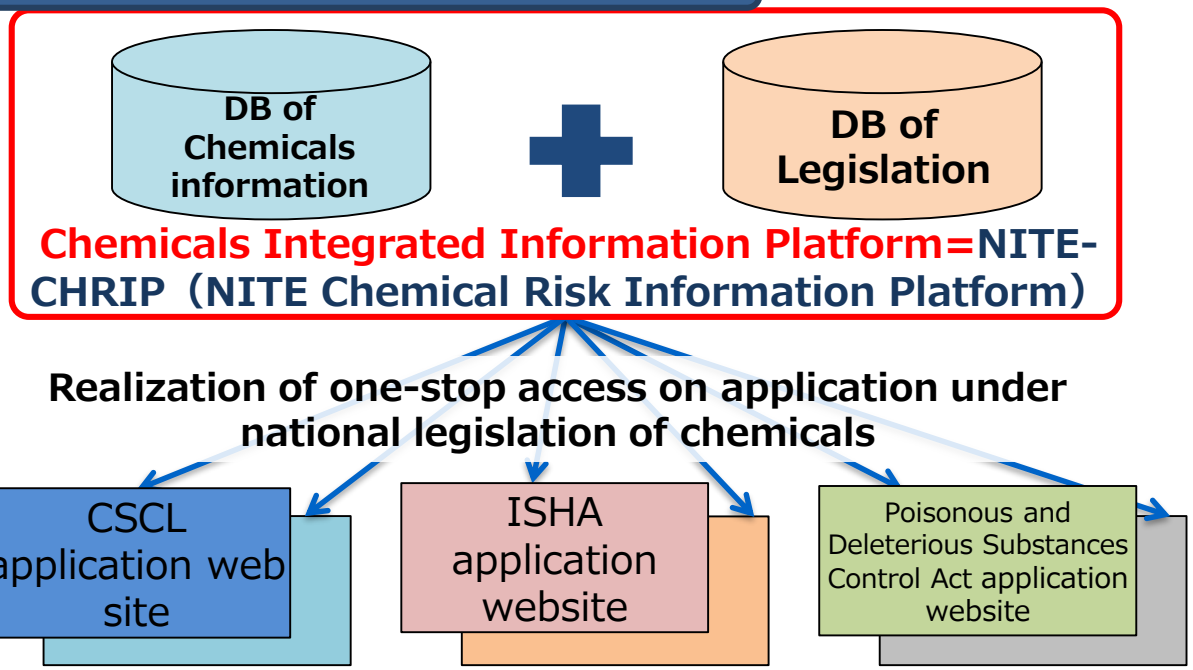
- ✓ **Requiring a mechanism for reducing a burden on businesses.**

(Background) The businesses are required to comply corresponding laws at their each business stage, such as products development, manufactures and sales, etc.

- ✓ **Developing a platform of easy-access to the legal application websites required to each substance in FY 2018,** in order for encouraging businesses to improve their convenience and comply corresponding regulations.

➡ **Businesses can make a one-stop collection of information on regulatory compliance.**

Chemicals Management Platform



<Remarks>

- ✓ Developed by, for example, integrating a new “legislation DB” ※2 into “NITE-CHRIP” ※1

※1 : NITE-CHRIP is searched 3 million times a year.

※2 : To be stored 12 of national laws and regulations on chemical management information, which are administrated by METI, MHLW, MOE or MIC.

■Update on NITE-CHIRP

Afte

After Update on March 2019, there will be showing Outline of the Regulations and hyperlink to the informative webpage

Laws and Regulations in Japan	Affiliated ministries
Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (Chemical Substances Control Law ; CSCL)	METI, MHLW, MOE

Outline of the Regulation

To prevent environmental pollution caused by persistent chemical substances that pose a risk of impairing human health or interfering with the inhabitation and/or growth of flora and fauna, a preliminary evaluation of new chemical substances and notification of the quantity of manufacture or import of chemical substances after marketing are required. Regulations with respect to the manufacture, import permission, usage restrictions, etc., are carried out with due consideration to the properties of the chemical substance.

Related Material

Act Outline Application for low volume new chemical substances (in Japanese) Application for new chemical substances (in Japanese) Procedure for New Chemicals Import Clearance Procedures Notification of the Manufacturing Amount, etc Operation

Chemical List

Japan C... I Specified Chemical Substances — Data Description

Japan C... Specified Chemical Substances

Japan CSCL: Existing Chemical Substances

Click here, you can get more information to comply with laws and regulations.

You can easily confirm the Outline of Regulations (Scope of the law, Obligatory submission, etc.).

Thank you for your cooperation

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