

GHS in Japan

- Implementation activity, classification of chemicals and their information provision -

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- GHS classification projects
- Role of National Institute of Technology and Evaluation (NITE) for information provision

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Activity to GHS implementation in Japan (1)

Pre GHS publication (before 2003)

- 2001: Establishment of the GHS inter-ministerial committee (IMC, Consisted of seven government offices* and experts from national laboratories and industries)
 - Information sharing among ministries with respect to the relevant domestic laws
 - Deliberation on the agenda items/documents of the UNSCE GHS meetings
 - Decision making about the Japanese position

*: Ministry of Health, Labour and Welfare (**MHLW**), Ministry of Economy, Trade and Industry (**METI**), Ministry of the Environment (**MOE**), Ministry of Internal Affairs and Communications (**MIC**) [as Fire and Disaster Management Agency (**FDMA**)], Ministry of Agriculture, Forestry and Fisheries (**MAFF**), Ministries of Land Infrastructure and Transport (**MLIT**) and Ministry of Foreign Affairs (**MOFA**)

Activity to GHS implementation in Japan (2)

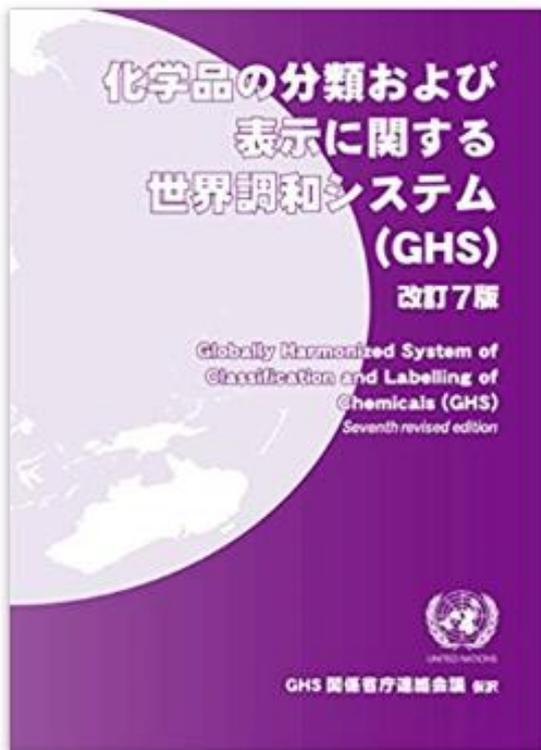
- 2001-2003: Gap analysis between the GHS and the Japanese laws by GHS IMC
 - Identification of the absence of laws for transferring hazard information to users
 - The laws/regulations for risk management without hazard communication
 - Inclusion of specific labelling system only for limited chemicals without pictograms
 - Different signal words from the GHS

Activity to GHS implementation in Japan (3)

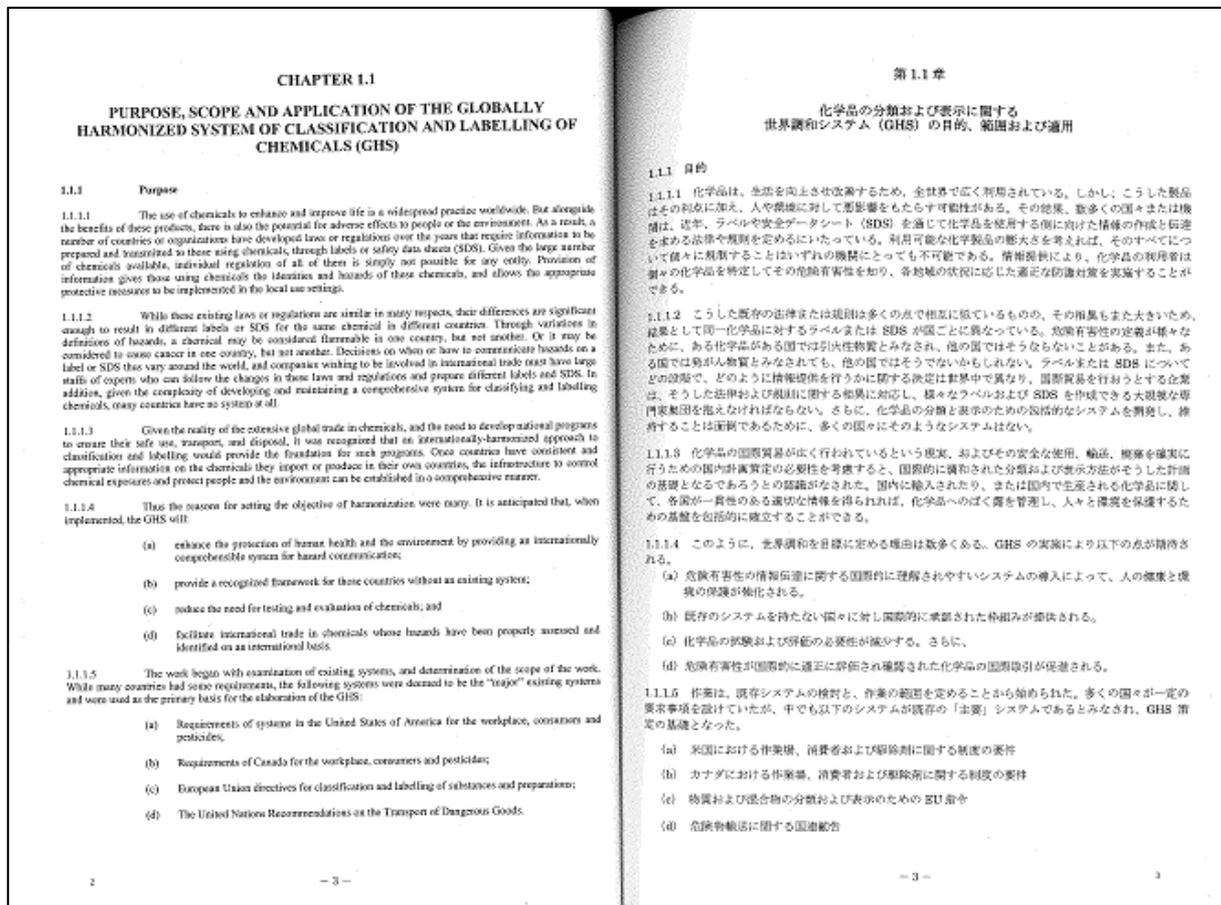
After GHS publication in 2003

- Translation of the GHS text by GHS IMC
 - 2002: Start of translation for GHS draft document
 - 2004: Issue of translation version of the 1st GHS doc
 - 2006: Issue of the 1st revision in Japanese
 - 2008: Issue of the 2nd revision
 - 2010: Issue of the 3rd revision
 - 2011: Issue of the 4th revision
 - 2013: Issue of the 5th revision
 - 2015: Issue of the 6th revision
 - 2018: Issue of the 7th revision
 - 2019: Issue of the 8th revision (Scheduled for October)

GHS text book (Japanese translation version)



7th Revised Edition
(2018/1/18)



Left pages in English / Right pages in Japanese

Activity to GHS implementation in Japan (4)

- Implementation of GHS to the laws
 - 2005: Amended the Industrial Safety and Health Law (ISHL)
 - Assignment of 99 chemicals for GHS label and 640 chemicals for SDS (overlapped)
 - 2017 Amendment: Assignment of 673 chemicals for GHS label and SDS, Duty of efforts of label and SDS for other chemicals
 - 2005: Recommendation to industries by the Poisonous and Deleterious Substances Control Law (PDSCL)
 - Preferable additional application of GHS label and SDS to the legal compliance for ca. 400 chemical or chemical groups (as of 2014)
 - 2012: Law concerning Pollutant Release and Transfer Register (PRTR)
 - Assignment of 673 chemicals (Obligation of SDS and duty of efforts for GHS label)

Activity to GHS implementation in Japan (5)

- GHS classification project
 - 2005-2006: Classification of ca. 1400 chemicals which were regulated under the 3 laws (ISHL, PDSCCL, PRTR: SDS required)
 - Two-year project to help industries issuing SDS and to develop infrastructure for GHS implementation
 - Classification by experts from laboratories/industries
 - Results checked by GHS IMC if deemed necessary
 - First experience of GHS classification in Japan
 - 2007-current: Classification of ca. 200 chemicals/year
 - Ca. 4000 chemicals so far (with amendment if necessary)

Outline of Chemical Regulation in Japan

Exposure		Human		Via Environment	Release, stock pollution	Disposal
		Work Place	Consumer			
Effect on human health	Acute	Poisonous and Deleterious Substances Control Law		Agricultural Chemicals Control Act Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (CSCL) Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof. (PRTR Law)	Air Pollution Control Act Water Pollution Control Act Soil Contamination Countermeasures Act	Wastes Management and Public Cleansing Law, etc.
	Chronic	Industrial Safety and Health Act Agricultural Chemicals Control Act	Agricultural Chemicals Control Act Food Sanitation Act *Pharmaceutical and Medical Device Act Household Goods Quality Labeling Act Act on Control of Household Products Containing Harmful Substances Building Standards Act			
Effect on environment	Effect on living environment (incl. animals and plants)	Application of GHS, due to require SDS		Act on Rational Use and Proper Management of Fluorocarbons Ozone Layer Protection Act	Act on Preventing Environmental Pollution on Mercury	
	Ozone depletion					
	War, terrorism	Act on the Prohibition of Chemical Weapons and the Regulation of Specific Chemicals				

*Before April 2015, the act was called "the Pharmaceutical Affairs Act".

Activity to GHS implementation in Japan (6)

- GHS implementation to Japan Industrial Standards (JIS)
 - 2005: JIS Z 7250 (SDS format in accordance with GHS)
 - 2006: JIS Z 7251 (Standard labelling system in accordance with GHS)
 - 2009: JIS Z 7252 (Classification of chemical based on GHS)
 - 2010: Amended JIS Z 7250 and 7251
 - 2012: JIS Z 7253 (Integration of Z 7250 and 7251: Hazard communication of chemicals based on GHS, (based on the GHS 4th revision))
 - 2014: Amended JIS Z 7252 (based on the GHS 4th revision)
 - 2019: Amended JIS Z 7252 and 7253 (based on the GHS 6th revision)
 - Laws/regulations can cite JIS (cannot cite GHS)
 - Easier amendment than laws/regulations
 - More familiar than GHS text (hopefully)

JIS Z 7252 (classification) and JIS Z 7253 (label/SDS)

JAPANESE INDUSTRIAL STANDARD

**Classification of chemicals based on
“Globally Harmonized System of
Classification and Labelling of
Chemicals (GHS)”**

JIS Z 7252 : 2019

(JCIA/JSA)

Revised 2019-05-25

Investigated by
Japanese Industrial Standards Committee

Published by
Japanese Standards Association

Price Code 21

ICS 71.100.01
Reference number : JIS Z 7252:2019(J)

JAPANESE INDUSTRIAL STANDARD

**Hazard communication of chemicals
based on GHS—Labelling and Safety
Data Sheet (SDS)**

JIS Z 7253 : 2019

(JCIA/JSA)

Revised 2019-05-25

Investigated by
Japanese Industrial Standards Committee

Published by
Japanese Standards Association

Price Code 16

ICS 13.300;71.100.01
Reference number : JIS Z 7253:2019(J)

Activity to GHS implementation in Japan (7)

- Other activities

- Software for classification of mixtures in the METI website (ENG)

https://www.meti.go.jp/policy/chemical_management/int/ghs_auto_classification_tool_ver4_EG.html

- Guidance for risk-based labelling of consumer products by NITE (ENG)

https://www.nite.go.jp/en/chem/risk/ghs_risk_consumer_guidance_e.pdf

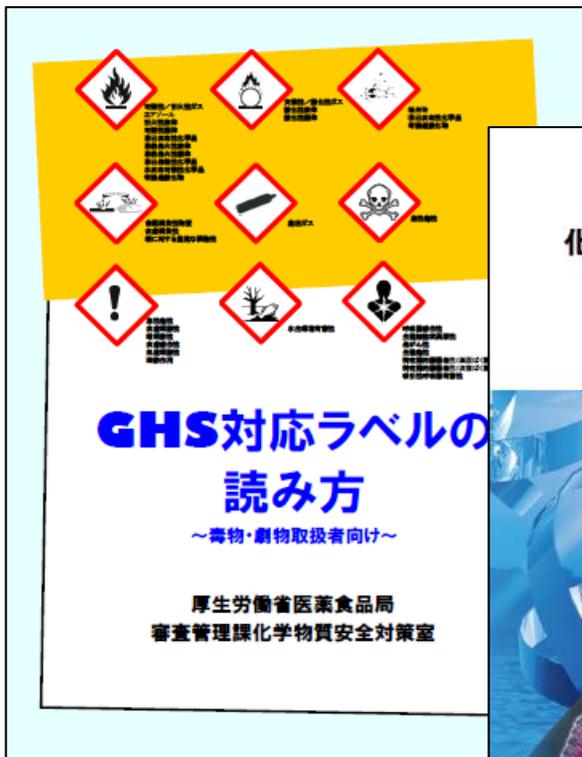
- Brochures, books, scientific papers, workshops, seminars, trainings

Recent activities

Education/Enlightenment/Information tools for GHS

- Explanation on Web site
- Q and A
- Software for classification or labelling
- Leaflet/Broacher
- Guidance/Guidebook
- Book
- Seminar/Training/Workshop

Brochures issued by the government



How to read GHS compatible labels, for poisonous and deleterious substances



Label and SDS provision system in the PRTR, ISHL, and PDSCL Laws in compliance GHS, For chemical business enterprises

Industrial Safety and Health Act

The Global Harmonized System of Classification and Labeling of Chemicals **GHS**

Labelling and Document (SDS) Delivery System under the Industrial Safety and Health Act (1)

Objective of the Labelling and Document (SDS) Delivery System under the Industrial Safety and Health Act

- The Industrial Safety and Health Act was enacted in 1972 with the aim of securing the safety and health of workers in workplaces and facilitating the establishment of comfortable working environments.
- There have been reports of industrial accidents such as explosions or poisoning in workplaces caused by workers' lack of knowledge on hazards or proper handling methods of substances.
- In order to prevent such industrial accidents, it is important to surely provide employers with information on hazards of substances and have them conduct risk assessments based on the relevant information and reasonably manage substances depending on assessed risks.
- The Industrial Safety and Health Act provides for the labelling and information provision using a Safety Data Sheet (SDS) for substances that are liable to cause danger or inflict health impairment upon workers.

Amendment of the Industrial Safety and Health Act (amended in 2014 and enforced on June 1, 2016)

- The Industrial Safety and Health Act and related laws and regulations were amended in order to have employers and workers understand any known hazards of substances and encourage employers to individually create a mechanism to consider and take required measures based on risks, thereby preventing possible industrial accidents due to substances for which certain hazards against people have been clarified.
- With regard to the substances and their preparations (mixtures) as set forth in Appended Table 9 and item (i) of Appended Table 3 of the Order for Enforcement of the Industrial Safety and Health Act, the Amended Act mainly requires the following three measures.
 - (i) Labelling of the container or package used for transfer or provision (supply) (*the coverage expanded through the amendment)
 - (ii) Delivery of a Safety Data Sheet (SDS) (*no change)
 - (iii) Implementation of risk assessments when handling substances, etc. (*made obligatory through the amendment)

Substances Subject to the Labelling and Document (SDS) Delivery System under the Industrial Safety and Health Act

[Substances for which the labelling and document (SDS) delivery is obligatory] (* as of July 1, 2018)

Substances for which the labelling and SDS delivery is obligatory (673 types of substances and mixtures containing any of them, see p.40 to p.46)

- (1) Substances for which the manufacturing permission is required as provided for in item (i) of Appended Table 3 of the Order for Enforcement of the Industrial Safety and Health Act (7 types)
- (2) Substances for which the labelling and notification is obligatory as provided for in Appended Table 9 of the Order for Enforcement of the Industrial Safety and Health Act (666 types)
- (3) Mixtures containing any of the above (The cut-off value*1 is defined for each substance.)

*1 Any substance classified at an amount less than the relevant defined level is not subject to the obligation of labelling or SDS delivery.

[Substances for which efforts for the labelling and SDS delivery should be made]

Based on Article 24-14 and Article 24-15 of the Regulation on Industrial Safety and Health, it is required to make efforts for the labelling and SDS delivery also for all substances that pose hazards*2 other than those for which the labelling and SDS delivery is obligatory and mixtures containing any of the former.

*2 Substances that pose physical hazards or health hazards for which hazard classes, hazard categories and label elements are specified in IHS 2.7.152

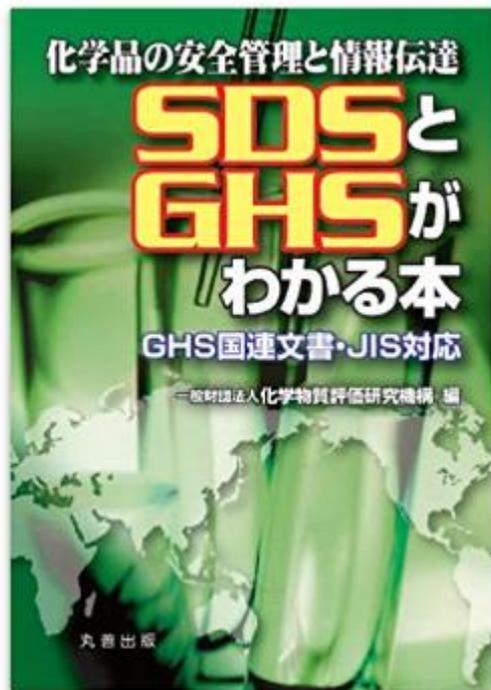
[Products that are intended primarily for ordinary use by general consumers*3 are excluded.]

- *3 Such products include the following.
 - (i) Pharmaceuticals, quasi-drugs and cosmetics specified in the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices
 - (ii) Agricultural chemicals specified in the Agricultural Chemicals Control Act
 - (iii) Products that do not take any form other than solid and that are not made into a powdery or granular state while being handled
 - (iv) Products handled in a state wherein subject substances are completely sealed
 - (v) Foods at the stage of being provided to general consumers; Excluding those for which any work is scheduled during which workers are likely to be exposed to subject substances

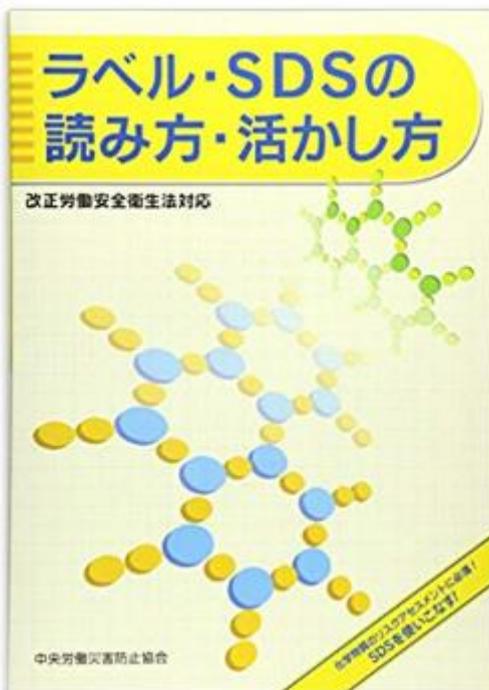
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English version of the left (for ISHL)
<https://www.mhlw.go.jp/new-info/kobetu/roudou/gyousei/enzen/dl/180815-01.pdf>

GHS-related books



Understanding SDS
and GHS
(2014/4/22)



How to read and use
labels and SDS
(2016/8/1)



GHS classification exercise
To develop human resources
for GHS classification
(2019/1/24)

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GHS classification projects (1)

- First, 2-year project in 2005-2006 (ca. 1400 chemicals)
- On going projects (2007-, ca. 200 chemicals/year, ca. 4000 chemicals so far)
- Ministries involved (MHLW, MOE and METI)
- To support industries issuing GHS label/SDS and to develop infrastructure for hazard communication
- Classification by contract institute and review by experts
- Results are not compulsory and allow industries to classify chemicals based on own judgment
- Publication of the results on the NITE website (ENG)
https://www.nite.go.jp/chem/english/ghs/all_fy_e.html

GHS classification projects (2)

- Preparation of “GHS Classification Manual” and “Technical Guidance Document on the GHS Classification” for the first 2-year project by GHS IMC (2005, 2006)
 - To facilitate classification of ca. 1400 chemicals within the limited time schedule
 - To eliminate any conflicting results of classification among experts
 - To provide main rules and reliable data sources by the manual
 - To provide precise rules on health hazards by the technical guidance

GHS classification projects (3)

- Preparation of “GHS Classification Guidance for the Japanese Government” (for pure chemicals, 2009, 2010, 2013, 2015) by GHS IMC
 - Integration of the manual and the technical guidance
 - To help the ministries which conduct GHS classification of applicable chemicals efficiently and consistently
 - To provide information sources to be used and practical classification rules
 - To be revised based on the revision of GHS/JIS
 - On going preparation of 2019 revised edition
 - Available 2013 revised edition (ENG)
https://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25jgov_en.pdf

GHS classification projects (4)

- Preparation of “GHS Classification Guidance for Enterprises” (for pure chemicals and mixtures, 2013, 2015)
 - To allow GHS classification to be carried out correctly and effectively by enterprises
 - To provide classification procedures and information sources to conduct GHS classification on enterprises own
 - To be responsible by the enterprise for classification results
 - Available 2013 revised edition (ENG)
https://www.meti.go.jp/policy/chemical_management/int/files/ghs/h25jenter_en.pdf

GHS classification projects (5)

- Characteristic issues identified in the early GHS classification project

Issues	Examples
Inadequate understanding GHS	<ul style="list-style-type: none">• Inconsistency with classification criteria• Not risk assessment in humans
Insufficient information collection	<ul style="list-style-type: none">• Lack of critical information by using limited sources
Insufficient evaluation of collected information	<ul style="list-style-type: none">• Extraction omission of important information• Not conducted confirmation by original papers or other documents
Lack of expertise/experience	<ul style="list-style-type: none">• First experience of classification work• Not taken into consideration of data quality, importance of effects, weight of evidence (WOE), mode of action (MOA), etc.

GHS classification projects (6)

- Resolutions of the issues
 - Sources of information
 - All available information should be collected and used in a complementary fashion.
 - Expertise of classifiers
 - The people who have the scientific knowledge, experimental skill and expertise in toxicology should become classifiers.
 - Expert judgment on data quality and weight of evidence
 - Expert judgment plays an important role in making weight of evidence (WOE) determinations in interpreting data for hazard classification of substances. When multiple data for one endpoint exist, the so-called “total WOE approach” must be applied.

GHS classification projects (7)

Issues of expert judgment

- Transparency
 - Objectivity
 - Evidence based toxicology
- Consistency
 - Intra-expert (hopefully inter-experts)
 - Chronologically (if no new data available)
- Standpoint
 - Practical or precautionary



Issues of WOE

- The term WOE does **neither** constitute a scientifically **well-defined** term nor an agreed formalized concept characterized by defined tools and procedures.
- It is **not clear** which methods were used, how they were applied to the scientific evidence, what the results were and how these were used to make decisions in a specific risk assessment.

WOE



Black box?

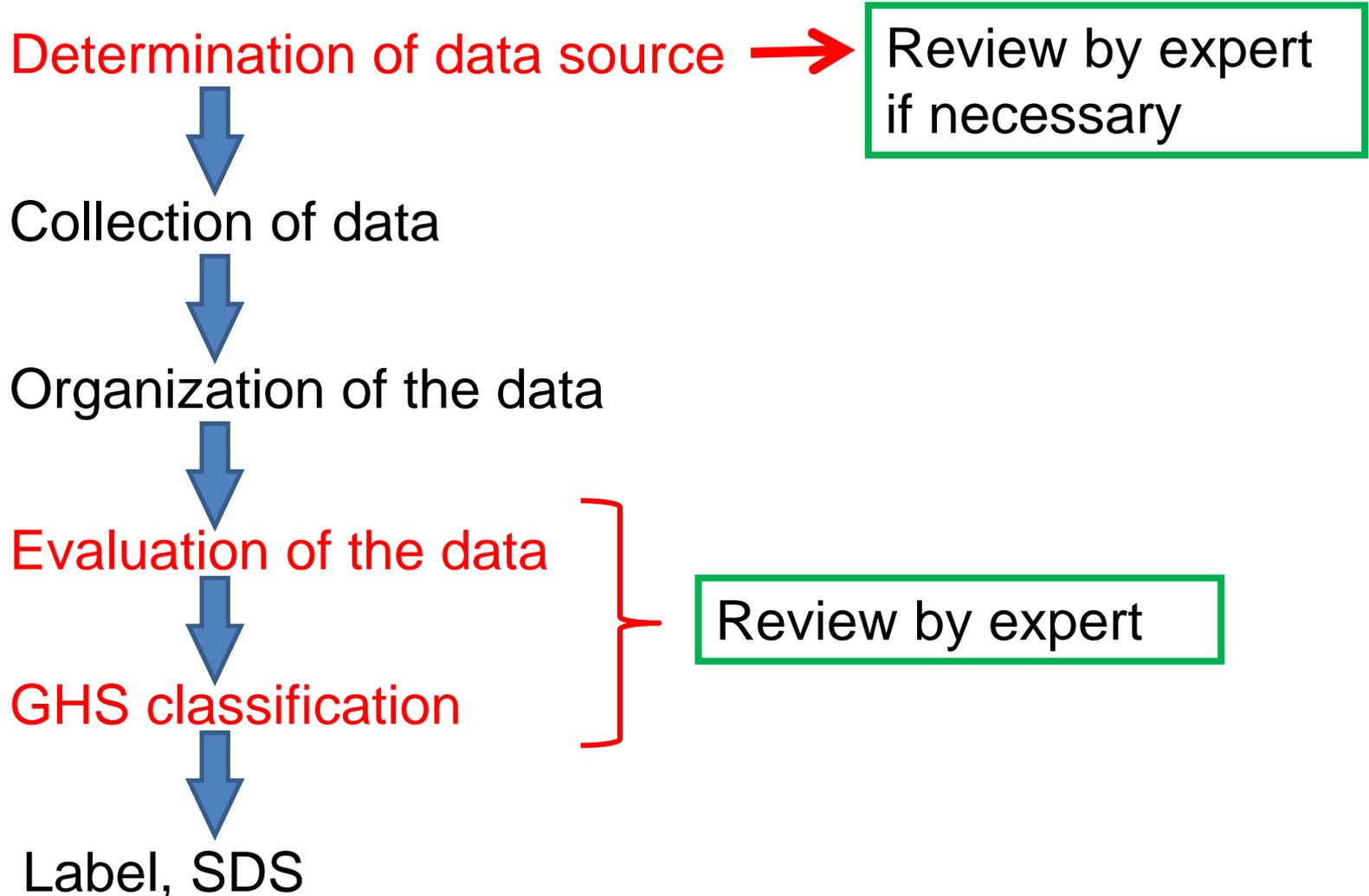
Reliability of toxicological data (Klimisch score)

Reliability of data/Score #	Explanation
Reliable without restrictions/Score 1	Data generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline or in which all parameters described are closely related/comparable to a guideline method.
Reliable with restrictions /Score 2	Data (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable .
Not reliable/Score 3	Data in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. unphysiological pathways of application) or which were carried out or generated according to a method which is not acceptable , the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.
Not assignable/Score 4	Data which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).

Evaluation of data quality by experts

Element	Explanation
Reliability	Evaluating the inherent quality of a test report or publication relating to preferably standardized methodology (e.g., OECD TG) and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings (e.g., GLP).
Relevance	Covering the extent to which data and tests are appropriate for a particular hazard identification or risk characterization.
Adequacy	Defining the usefulness of data for hazard/risk assessment purposes. Where there is more than one study for each endpoint, the greatest weight is attached to the studies that are the most relevant and reliable (e.g., validated method).

Timing of Expert Judgment



GHS classification projects (8)

- Further issues
 - Explanation of non-assignment to each category
 - Not applicable: Different target chemical (e.g., liquid or solid)
 - Not classified: Considered as “safety” in some cases
 - Classification not possible: Assigned even if many data (e.g., conflict, not covered all items)
 - Reason of assignment to the category
 - Long explanations: Reader friendly or too much?
 - Application of target tissues on STOT
 - Suitable (maximum) numbers
 - Extent of consideration of primary or secondary effects
 - Route of exposure
 - Different classification results from EU CLP
 - May need to be justified scientifically

Example of the classification

<https://www.nite.go.jp/chem/english/ghs/17-mhlw-2052e.html>

https://www.nite.go.jp/chem/english/ghs/ghs_download.html

Acetonitrile (75-05-8)

PHYSICAL HAZARDS

	Hazard class	Classification	Pictogram Signal word	Hazard statement (code)	Precautionary statement (code)	Rationale for the classification
1	Explosives	Not applicable	-	-	-	There are no chemical groups associated with explosive properties present in the molecule.
2	Flammable gases (including chemically unstable gases)	Not applicable	-	-	-	Liquid (GHS definition)
3	Aerosols	Not applicable	-	-	-	Not aerosol products.
4	Oxidizing gases	Not applicable	-	-	-	Liquid (GHS definition)
5	Gases under pressure	Not applicable	-	-	-	Liquid (GHS definition)
6	Flammable liquids	Category 2		H225	P303+P361+P353 P370+P378 P403+P235 P210 P233 P240 P241 P242 P243 P280 P501	Based on a flash point of 2 deg C and a boiling point 82 deg C (GESTIS (Access on June 2017)), it was classified in Category 2. Besides, it is classified in Class 3, PGII in UNRTDG (UN 1648).
7	Flammable solids	Not applicable	-	-	-	Liquid (GHS definition)
8	Self-reactive substances and mixtures	Not applicable	-	-	-	There are no chemical groups present in the molecule associated with explosive or self-reactive properties.
9	Pyrophoric liquids	Not classified	-	-	-	It is estimated that it does not ignite at normal temperatures from an autoignition temperature of 524 deg C (HSDB (Access on June 2017)).
10	Pyrophoric solids	Not applicable	-	-	-	Liquid (GHS definition)
11	Self-heating substances and mixtures	Classification not possible	-	-	-	Test methods applicable to liquid substances are not available.
12	Substances and mixtures which, in contact with water, emit flammable gases	Not applicable	-	-	-	The chemical structure of the substance does not contain metals or metalloids (B, Si, P, Ge, As, Se, Sn, Sb, Te, Bi, Po, At).
13	Oxidizing liquids	Not applicable	-	-	-	Organic compounds containing no oxygen, fluorine or chlorine
14	Oxidizing solids	Not applicable	-	-	-	Liquid (GHS definition)
15	Organic peroxides	Not applicable	-	-	-	Organic compounds containing no bivalent -O-O- structure in the molecule
16	Corrosive to metals	Classification not possible	-	-	-	No data available.

HEALTH HAZARDS

	Hazard class	Classification	Pictogram Signal word	Hazard statement (code)	Precautionary statement (code)	Rationale for the classification
1	Acute toxicity (Oral)	Not classified	-	-	-	There are ten reports of LD50 values for rats of 1,315 mg/kg (male), 1,730 mg/kg (female), 2,230 mg/kg (female), 2,460 mg/kg (male), 3,053 mg/kg (male), 3,200 mg/kg, 3,445 mg/kg (male), 3,800 mg/kg, 4,050 mg/kg (female), and 6,702 mg/kg (female) (EHC 154 (1993)). Two cases correspond to Category 4, and eight cases correspond to "Not classified" (seven cases of these correspond to Category 5 in UN GHS classification). It was classified as "Not classified" by adopting the category with the larger number of cases. The category was changed from the previous classification according to the GHS classification guidance for the Japanese government.
1	Acute toxicity (Dermal)	Category 3	 Danger	H311	P302+P352 P361+P364 P280 P312 P321 P405 P501	There are three reports of LD50 values for rabbits of 395 mg/kg (male) (75% aqueous solution), 978.8 mg/kg (male) (undiluted solution) (EHC 154 (1993), EU-RAR (2002), Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007)), and 3,915 mg/kg (undiluted solution) (EHC 154 (1993), EU-RAR (2002), PATTY (6th, 2012)). Two cases correspond to Category 3, and one case corresponds to "Not classified" (Category 5 in UN GHS classification). It was classified in Category 3 by adopting the category with the larger number of cases.
1	Acute toxicity (Inhalation: Gases)	Not applicable	-	-	-	Liquid (GHS definition)
1	Acute toxicity (Inhalation: Vapours)	Category 4	 Warning	H332	P304+P340 P261 P271 P312	Based on an LC50 value for rats of 16,000 ppm (female and male) in a 4-hour inhalation exposure test (EHC 154 (1993), EU-RAR (2002), Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007), PATTY (6th, 2012)) and LC50 values for rats of 7,551 ppm (male) (converted 4-hour equivalent value: 10,679 ppm) and 12,435 ppm (female) (converted 4-hour equivalent value: 17,586 ppm) (EHC 154 (1993), EU-RAR (2002), Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007)) in an 8-hour inhalation exposure test, it was classified in Category 4. The category was changed from the previous classification. Besides, since the LC50 values were lower than 90% of the saturated vapor pressure concentration (98,020 ppm), a reference value in the unit of ppm was applied as vapour with little mist.
1	Acute toxicity (Inhalation: Dusts and mists)	Classification not possible	-	-	-	Classification not possible due to lack of data.
2	Skin corrosion/irritation	Not classified	-	-	-	Based on reports that this substance was not irritating or showed slight irritation in multiple skin irritation tests with rabbits (Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007), EU-RAR (2002)), it was classified as "Not classified" (Category 3 in UN GHS classification).
3	Serious eye damage/eye irritation	Category 2	 Warning	H319	P305+P351+P338 P337+P313 P264 P280	Based on reports that eye irritation of this substance was moderate or severe in eye irritation tests with rabbits (Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007), EU-RAR (2002)), it was classified in Category 2. Besides, this substance was classified as "Eye Irrit. 2" in EU CLP classification (ECHA CL Inventory (Access on June 2017)).
4	Respiratory sensitization	Classification not possible	-	-	-	Classification not possible due to lack of data.
4	Skin sensitization	Classification not possible	-	-	-	There is a description that it was negative in a skin sensitization test with guinea pigs (EU-RAR (2002)). However, since this was the result from only one test, it was classified as "Classification not possible."
5	Germ cell mutagenicity	Classification not possible	-	-	-	As for in vivo, a micronucleus test with peripheral blood of mice exposed by inhalation was positive, micronucleus tests with bone marrow cells and peripheral blood of mice given intraperitoneal administration were negative, and an unscheduled DNA synthesis test with hepatocytes of rats was negative (Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007), ACGIH (7th, 2002), DFGOT Vol.19 (1993), EU-RAR (2002), IRIS Tox. Review (1999), EHC 154 (1993), NTP TR447 (1996), Environmental Risk Assessment for Chemical Substances Vol.3 (Ministry of the Environment, 2004)). As for in vitro, bacterial reverse mutation tests were negative, a gene mutation test, a mouse lymphoma test and a chromosomal aberration test with mammalian cultured cells were negative, and a sister chromatid exchange test was weakly positive (Initial Risk Assessment Report (NITE, CERJ, NEDO, 2007), ACGIH (7th, 2002), DFGOT Vol.19 (1993), EU-RAR (2002), IRIS Tox. Review (1999), EHC 154 (1993), NTP TR447 (1996), Environmental Risk Assessment for Chemical Substances Vol.3 (Ministry of the Environment, 2004)). From the above, since on top of the fact that there are defects and an unclear dose response in both of the two micronucleus tests reported as positive in the in vivo tests (the test with bone marrow cells of mice given intraperitoneal administration, the test with erythrocytes of mice exposed by inhalation), the micronucleus tests performed according to OECD TG (tests with bone marrow cells and peripheral blood of mice given intraperitoneal administration) were negative, it is described in the EU-RAR that it is not possible to clearly judge the presence or absence of genotoxicity as a comprehensive genotoxicity evaluation. Therefore, it was classified as "Classification not possible" since there is no clear positive finding in micronucleus tests. Since the positive result in the micronucleus test described in the previous

6	Carcinogenicity	Classification not possible	-	-	-	In carcinogenicity studies with rats and mice exposed by inhalation for two years, a marginal increase in the incidence of hepatocellular adenomas and carcinomas (combined) was observed at the high dose in male rats, but no increase in the incidence of neoplastic lesions was observed in female rats and female and male mice (NTP TR447 (1996)). It is concluded in NTP that there was equivocal evidence of carcinogenicity in male rats, and there was no evidence of carcinogenicity in female rats and female and male mice (NTP TR447 (1996)). As for classifications by other organizations, ACGIH classified it in A4 (ACGIH (7th, 2002)) and EPA as CBD (cannot be determined) (IRIS (1999)). From the above, it was classified as "Classification not possible."
7	Reproductive toxicity	Classification not possible	-	-	-	In developmental toxicity tests with pregnant rats or pregnant rabbits orally dosed, no severe developmental effect was observed in fetuses even at the highest dose (275 mg/kg/day in rats, 30 mg/kg/day in rabbits) where deaths, suppressed body weight gain, and increased resorptions were observed in maternal animals (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007), ACGIH (7th, 2002), Environmental Risk Assessment for Chemical Substances Vol.3 (Ministry of the Environment, 2004)). In addition, even in two developmental toxicity tests with pregnant rats exposed by inhalation, no effect was observed in fetuses at doses where deaths were observed in maternal animals (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007), ACGIH (7th, 2002)). Besides, in a single inhalation test with pregnant hamsters exposed on gestational day 8, teratogenesis such as exencephaly, encephalocele, and fusion of the ribs were reported at or above the concentration twice as high as the concentrations where deaths occurred in maternal animals (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007), ACGIH (7th, 2002), Environmental Risk Assessment for Chemical Substances Vol.3 (Ministry of the Environment, 2004)). From the above, it is considered that from the results of experimental animals, it is unlikely that the substance shows developmental effects in experimental animals by the oral and inhalation route, but there is no information on fertility and sexual function, therefore, classification was not possible due to lack of data.
8	Specific target organ toxicity - Single exposure	Category 1 (central nervous system, respiratory organs)		H370	P308+P311 P260 P264 P270 P321 P405 P501	As for humans, multiple cases are reported including cases of ingestion of this substance by accident or in a suicide attempt and acute inhalation exposure cases due to accidents in plants. There is a description that acute effects were fatigue, nausea, vomiting, confusion, convulsions, coma, etc., resulting in death in the severe cases (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)). In addition, there is a report of irritation of the nose and throat by inhalation exposure (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)). As for experimental animals, there is a report that in a single oral dose test with mice, hypoactivity, tremors, weakness, decreased righting reflex, labored breathing, convulsions, gasping, and salivation were observed at 300-2,000 mg/kg/day within the range of Category 2 (EU-RAR (2002), Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)). In addition, there are reports that hypoactivity, abnormal gait, loss of righting reflex, bradypnea, labored breathing, rapid respiration, gasping, hypothermia, hindlimb extension, lateral position, and yellowing of coat were observed at 3,039-5,000 ppm within the range of Category 2 in a 4-hour single inhalation exposure test with mice (EU-RAR (2002), Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)), and that severe dyspnea, gasping, tremors and convulsions were observed at 500-5,000 ppm (converted 4-hour equivalent value: 250-2,500 ppm, corresponding to within the range of Category 2) in a one-hour single inhalation exposure test with mice (EHC 154 (1993), EU-RAR (2002), Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)). Moreover, there is a report that pulmonary hemorrhage and congestion were observed in both surviving cases and death cases in an 8-hour single inhalation exposure test with rats (EU-RAR (2002), Initial Risk Assessment Report (NITE, CERI, NEDO, 2007)). Although there was no detailed description of doses in this study, LC50 values (converted 4-hour equivalent value) were reported to be 10,678 ppm (male) and 17,585 ppm (female), and it is considered that effects were observed at doses within the range of Category 2. From the above information, it is considered that this substance affects the central nervous system and respiratory organs. Therefore, it was classified in Category 1 (central nervous system, respiratory organs).
9	Specific target organ toxicity - Repeated exposure	Category 2 (haemal system, central nervous system, respiratory organs, ...)		H373	P260 P314 P501	No information on humans is available. As for experimental animals, in a 13-week inhalation toxicity test (6 hours/day, 5 days/week) with rats exposed to the vapour, at or above 800 ppm (1,340 mg/m3 (converted guidance value: 0.97 mg/L)) within the guidance value range for Category 2, deaths, hypoactivity, rough fur, decreased thymus weight, anemia symptoms (decreases in erythrocyte count, hemoglobin concentration and hematocrit value) were found, and in death cases, pulmonary congestion and edema, hemorrhage in the pulmonary alveoli and brain, decreased bone marrow cells, thymic atrophy, decreased lymphocytes in the spleen, and decreased corpora lutea in the ovary were observed (Initial Risk Assessment Report (NITE, CERI, NEDO 2007), Environmental Risk Assessment for Chemical Substances Vol.3 (Ministry of the Environment, 2004), NTP TR447 (1996)), and in a 90-day inhalation toxicity test (7 hours/day, 5 days/week) with rats exposed to the vapour, atelectasis and histiocyte clumps in the alveoli at or above 166 ppm (279 mg/m3 (converted guidance value: 0.33 mg/L)) within the guidance value range for Category 2, and bronchitis and pneumonia at or above 330 ppm (554 mg/m3 (converted guidance value: 0.65 mg/L)) were observed (Initial Risk Assessment Report (NITE, CERI, NEDO, 2007), EU-RAR (2002)). In addition, in a 13-week inhalation toxicity test (6 hours/day, 5 days/week) with mice exposed to the vapour, increased liver weight at or above 100 ppm (168 mg/m3) (converted guidance value: 0.12 mg/L) within the guidance value range for Category 1, focal ulceration with epithelial hyperplasia of the forestomach at or above 200 ppm (335 mg/m3) (converted guidance value: 0.24 mg/L) within the guidance value range for Category 2, deaths and hepatocellular vacuolation at 400 ppm (670 mg/m3) (converted guidance value: 0.48 mg/L), and hypoactivity, hunched position, and muscle stiffness at 800 ppm (1,340 mg/m3) (converted guidance value:

ENVIRONMENTAL HAZARDS

	Hazard class	Classification	Pictogram Signal word	Hazard statement (code)	Precautionary statement (code)	Rationale for the classification
11	Hazardous to the aquatic environment (Acute)	Not classified	- -	-	-	From 72-hour EC50 (rate method) >700 mg/L for algae (<i>Pseudokirchneriella subcapitata</i>), 96-hour LC50 >100 mg/L for fish (<i>Oryzias latipes</i>) (both Results of Aquatic Toxicity Tests of Chemicals conducted by Ministry of the Environment in Japan (Ministry of the Environment, 2017)), and 96-hour LC50 >100 mg/L for crustacea (<i>Daphnia magna</i>) (Environmental Risk Assessment for Chemical Substances vol. 3 (Ministry of the Environment, 2004)), it was classified as "Not classified."
11	Hazardous to the aquatic environment (Long-term)	Not classified	- -	-	-	Due to being rapidly degradable (readily biodegradable, average degradation rate by BOD: 65% (J-CHECK, 1998)), no bioaccumulation (LogPow: -0.34 (PHYSPROP Database: 2017)), 21-day NOEC (reproduction inhibition) = 960 mg/L for crustacea (<i>Daphnia magna</i>) (Environmental Risk Assessment for Chemical Substances vol. 3 (Ministry of the Environment, 2004)), and 72-hour NOEC (rate method) = 700 mg/L for algae (<i>Pseudokirchneriella subcapitata</i>) (Results of Aquatic Toxicity Tests of Chemicals conducted by Ministry of the Environment in Japan (Ministry of the Environment, 2017)), it was classified as "Not classified."
12	Hazardous to the ozone layer	Classification not possible	- -	-	-	No data available.

EU CLP: Acetonitrile

Updated on March 2019

Index No	Chemical name	EC No	CAS No	Classification	Labelling	Specific Conc. Limits, factors and ATEs	Notes	ATP inserted/ATP Updated	
				Hazard Class and Category Code(s)	Hazard Statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)	
608-001-00-3	acetonitrile; cyanomethane	200-835-2	75-05-8	Flam. Liq. 2 Acute Tox. 4 * Acute Tox. 4 * Acute Tox. 4 * Eye Irrit. 2	H225 H332 H312 H302 H319	GHS02 GHS07 Dgr	H225 H332 H312 H302 H319		CLP00
608-007-00-0	triethylacetonitrile	308-885-7	515-06-7	Acute Tox. 3 *	H231	GHS06	H231		CLP00

Different classification between JPN and EU CLP (1)

Acetonitrile (75-05-8)

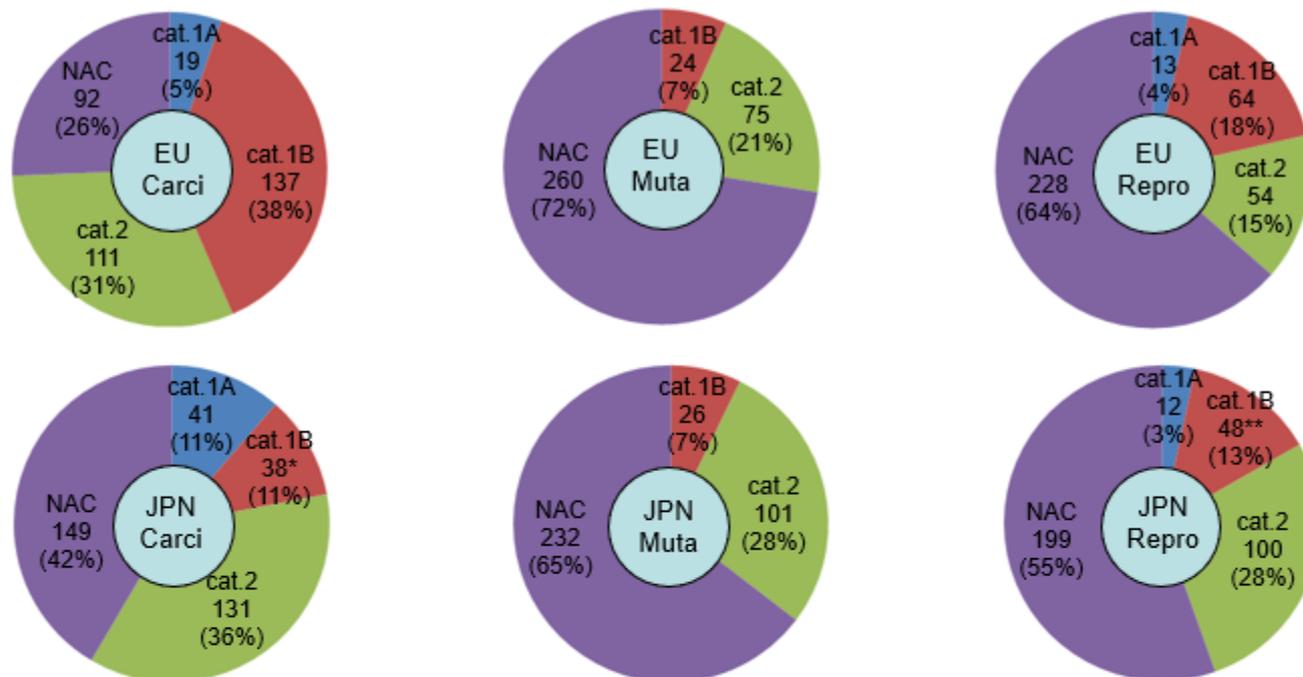
Hazard	JPN GHS	EU CLP	ICSC	NIOSH PG
Flam liquid	Cat. 2	Cat. 2	Cat. 2	Class IB
Acute tox (oral)	Not classified	Cat. 4*	Cat. 4	-
Acute tox (dermal)	Cat. 3	Cat. 4*	Cat. 3	-
Acute tox (inhalation)	Cat. 4	Cat. 4*	Cat. 3	-
Eye irritation	Cat. 2	-	Cat. 2A	-
STOT (single)	Cat. 1 (CNS, respiratory organs)	-	-	irritation nose/throat, respiratory system, cardiovascular system, CNS, liver, kidneys
STOT (repeat)	Cat. 2 (Blood, CNS, respiratory organs, liver, kidney)	-	Cat. 2 (Blood)	
Aspiration hazard	Classification not possible	-	Cat. 2	-

Different classification between JPN and EU CLP (2)

CMR substances (Presented in 2014 EuroTox)

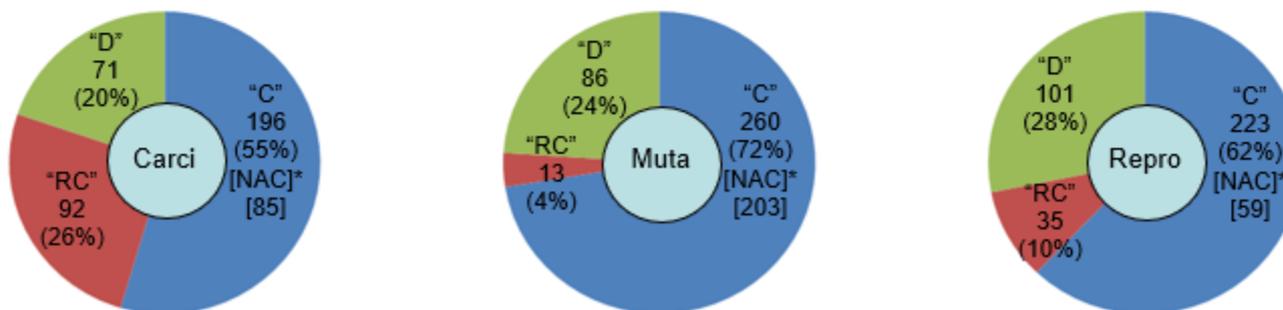
- Databases used: EU CLP and J-GHS (as of 2014)
- Chemicals analyzed: 359 CMR substances (Fig. 1)
 - Chemicals were divided into 3 groups (Fig. 2)
 - Consistent (C): same hazard class and category
 - Roughly Consistent (RC): same hazard class but different category
 - Different (D): different hazard class and category
Large D: 1A/1B against “not assigned any categories (NAC)” including “not classified (NC)” or “classification not possible (CNP)”
 - Number and name of the “D” chemicals in CMR (Tables 1-4)

Fig. 1 GHS classification on CMR substances in EU or Japan (n=359)



*: including 1 chemical without subcategory (not specified 1A or 1B)
 **: including 2 chemicals without subcategory (not specified 1A or 1B)

Fig. 2 Comparison of the classification between EU and Japan (n=359)



*: Number of NAC chemicals within "C" chemicals

Table 1 Number of the “D” chemicals in each of CMR

EU	Japan	Number of chemicals		
		Carci	Muta	Repro
cat. 1A/1B	NAC	21	2	15
cat. 2	NAC	43	27	21
NAC	cat. 1A/1B	4	7	12
NAC	cat. 2	3	50	53
Total		71	86	101
“Large D” chemicals (1A/1B vs NAC, n=61)		25	9	27

NAC includes NC and CNP.

Table 2 The “Large D” chemical list between EU and Japan in carcinogens (n=25)

#	Chemical	CAS	CMR	EU	Japan
1	(6-(4-Hydroxy-3-(2-methoxyphenylazo)-2-sulfonato-7-naphthylamino)-1,3,5-triazin-2,4-diyl)bis[(amino-1-ethylethyl) ammonium] formate	108225-03-2	C	1B	CNP
2	2,3-Dinitrotoluene	602-01-7	C	1B	CNP
3	2,4,5-Trimethylaniline hydrochloride	21436-97-5	C	1B	CNP
4	2,5-Dinitrotoluene	619-15-8	C	1B	CNP
5	2-Nitronaphthalene	581-89-5	C	1B	NC
6	3,4-Dinitrotoluene	610-39-9	C	1B	CNP
7	3,5-Dinitrotoluene	618-85-9	C	1B	NC
8	4-Amino-3-fluorophenol	399-95-1	C	1B	CNP
9	6-Hydroxy-1-(3-isopropoxypropyl)-4-methyl-2-oxo-5-[4-(phenylazo)phenylazo]-1,2-dihydro-3-pyridinecarbonitrile	85136-74-9	C	1B	CNP
10	Benzo[e]pyrene	192-97-2	C	1B	NC
11	Carbadox	6804-07-5	C	1B	CNP
12	Diazomethane	334-88-3	C	1B	NC
13	Dimethylsulfamoylchloride	13360-57-1	C	1B	CNP
14	C.I Direct Red 28	573-58-0	C	1B	CNP
15	C.I Direct Black 38	1937-37-7	C	1B	CNP
16	(2S)-(+)-Glycidyl tosylate	70987-78-9	C	1B	CNP
17	Phenyldiazinium chloride	59-88-1	C	1B	CNP
18	Phenyldiazinium sulphate (2:1)	52033-74-6	C	1B	CNP
19	R-1-Chloro-2,3-epoxypropane	51594-55-9	C	1B	CNP
20	Trisodium [4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)-biphenyl-1,3',3'',1''-tetraolato-O,O',O'',O'']copper(II)	164058-22-4	C	1B	CNP
21	α,α,α -4-Tetrachlorotoluene	5216-25-1	C	1B	CNP
22	Lead 2,4,6-trinitro-m-phenylene dioxide	15245-44-0	C	-*	1B
23	Lead diazide	13424-46-9	C	-	1B
24	Lead hexafluorosilicate	25808-74-6	C	-	1B
25	N,N-Dimethylformamide	68-12-2	C	-	1B

*: Not assigned to any categories

Table 3 The “Large D” chemical list between EU and Japan in germ cell mutagens (n=9)

#	Chemical	CAS	CMR	EU	Japan
1	2-Nitrotoluene	88-72-2	M	1B	CNP
2	4,4-Oxydianiline	101-80-4	M	1B	CNP
3	3-Propanolide	57-57-8	M	-	1B
4	o-Aminoazotoluene	97-56-3	M	-	1B
5	Captafol	2425-06-1	M	-	1B
6	DDT	50-29-3	M	-	1B
7	Dimethylnitrosamine	62-75-9	M	-	1B
8	Tris(2-chloroethyl) phosphate	115-96-8	M	-	1B
9	Cyclohexylamine	108-91-8	M	-	1B

Table 4 The “Large D” chemical list between EU and Japan in reproductive toxins (n=27)

#	Chemical	CAS	CMR	EU	Japan
1	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	R	1B	CNP
2	4,4-Isobutylethylidene diphenol	6807-17-6	R	1B	CNP
3	Ammonium dichromate	7789/9/5	R	1B	CNP
4	Binapacryl	485-31-4	R	1B	CNP
5	Cobalt sulphate	10124-43-3	R	1B	CNP
6	Formamide	1975/12/7	R	1B	NC
7	Linuron	330-55-2	R	1B	NC
8	Nickel dihydroxide	12054-48-7	R	1B	CNP
9	Sodium chromate	7775/11/3	R	1B	CNP
10	Sodium dichromate anhydrate	10588-01-9	R	1B	NC
11	Diboron trioxide	1303-86-2	R	1B	CNP
12	Disodium tetraborate	1330-43-4	R	1B	CNP
13	Diisobutyl phthalate	84-69-5	R	1B	CNP
14	Triethyl phosphate	25155-23-1	R	1B	CNP
15	Ammoniumpentadecafluorooctanoate	3825-26-1	R	1B	NC
16	1,4-Dichlorobenzene	106-46-7	R	-	1B
17	Cadmium cyanide	542-83-6	R	-	1B
18	Chloromethan	74-87-3	R	-	1B
19	Diarsenic trioxide	1327-53-3	R	-	1A
20	Dieldrin	60-57-1	R	-	1B
21	Ethylene oxide	75-21-8	R	-	1B
22	Heptachlor	76-44-8	R	-	1B
23	Heptachlor epoxide	1024-57-3	R	-	1B
24	Hexachlorobenzene	118-74-1	R	-	1A
25	Pentachlorophenol	87-86-5	R	-	1B
26	Phenol	108-95-2	R	-	1B
27	Trichloroethylene	79-01-6	R	-	1B

Results and conclusions

- The analysis suggests that about 20 – 30% chemicals are assigned different classification, i.e., “D”, CMR or not, between EU and Japan.
- Some of them (17.0%, 61/359) were “Large D”, i.e., GHS cat. 1A/1B against NAC.
- They should be justified scientifically.
 - Several chemicals have been assigned to different categories through the re-evaluation process.

Current situation of GHS (1)

- Expansion of GHS inter-ministerial committee (GHS IMC)
 - 8 government offices by participation of **Consumer Affairs Agency** (CAA, MHLW, METI, MOE, MIC, MAFF, MLIT and MOFA)
 - Japan Chemical Industry Association (JCIA)
 - UN committee members of UNSCEGHS and UNSCETDG
 - Experts of physical and health hazards
 - Secretariat (NITE)

Current situation of GHS (2)

- Recognition of GHS in the target audiences
 - Consumers: Low
 - Workers: Middle (high in Industry)
 - Transport workers: Maybe low
 - Emergency responders: Maybe low
- Application of GHS label to household consumer products
 - Depend on the industrial associations, each company and chemicals regulated
 - Detergent, paint, bleach, deodorant, fragrance, adhesive, etc.
- Not implemented to pesticides
 - Regulated by the Agricultural Chemicals Regulation Law

Examples of GHS label for consumer products



まぜるな危険

塩素系

- 酸性タイプの製品と一緒に使う(まぜる)と有害な塩素ガスが出て**危険**。
- 液が目に入ったら、すぐ水で洗う。
- 子供の手にふれないようにする。
- 必ず換気をよくして使用する。

体調のすぐれない方は使用しないでください。






酸性タイプと併用不可



危険 重篤な眼の損傷 皮膚刺激 (JSDA-GHS)

Japan Soap Detergent Association
<https://jsda.org/w/index.html>

Example of GHS label for industrial chemical (reagent)

Reagent 試薬
137-01823

Lot. _____

Guaranteed Reagent
試薬特級

Wako

Methanol
(Methyl Alcohol)
メタノール
(メチルアルコール)

DANGER 危険
UN1230
医薬用外劇物
メタノール含量：99.8%

危険物第四類
アルコール類 危険等級Ⅱ
火気厳禁 水溶性

3L

CH₃OH=32.04
Store in the dark.

JIS
JGA
JQ0506018
T
JIS K 8891

成分：メタノール

Assay (CH₃OH) (GC)..... min. 99.8% (mass/mass)

FUJIFILM
FUJIFILM Wako Pure Chemical Corporation
1-2 Doshomachi 3-Chome, Chuo-Ku, Osaka 540-8605, Japan
富士フイルム 和光純薬株式会社
大阪市中央区道修町三丁目1番2号 Tel: 06-6203-3741

See SDS
For Laboratory Use Only
試験研究用

■ Wear protective gloves, protective goggles or face shield, etc. ■ Use respirator if necessary. ■ In case of contact, consult a physician.
■ Keep away from source of fire and combustibles. ■ In case of contact with eyes, skin and clothes etc., wash with plenty of water. ■ Give instructions about taking precautionary measures against static discharge.
■ Highly flammable liquid and vapour ■ Causes serious eye irritation ■ Harmful if swallowed ■ May damage fertility or the unborn child
■ Causes damage to organs ■ May cause drowsiness or dizziness ■ Causes damage to organs through prolonged or repeated exposure

成分：メタノール

■ 保護手袋および保護眼鏡・保護面等、必要に応じて呼吸用保護具を着用して下さい。■ 暴露または暴露の懸念のある場合、医師の診断/手当てを受けること。■ 着火源および可燃物から遠ざけて下さい。■ 眼、皮膚、衣類等についた場合、多量の水で洗い流して下さい。■ 静電気放電に対する予防措置を講じて下さい。

■ 引火性の高い液体及び蒸気
■ 強い眼刺激 ■ 飲み込むと有害
■ 生殖能または胎児への悪影響のおそれ ■ 臓器の障害 ■ 眠気又はめまいのおそれ ■ 長期又は反復暴露による臓器の障害

Fujifilm Wako Pure Chemical Co.
<https://labchem-wako.fujifilm.com/jp/product/detail/W01W0113-0182.html>

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Contents

- Activity to GHS implementation in Japan
- GHS classification projects
- **Role of National Institute of Technology and Evaluation (NITE) for information provision**

What is NITE ?

- The mission

NITE continually contributes to the safety of society and supports challenges of the future by proven technologies and reliability information.

- The history

NITE was originally founded in 1928 as an organization in the Ministry of International Trade and Industry (MITI, Now the Ministry of Economy, Trade and Industry(METI)) and became independent administrative institution in 2001.

- The current NITE

NITE is the incorporated Administrative Agency under the METI.
Approximately 620 (420 permanent) staff work in NITE.

- The location

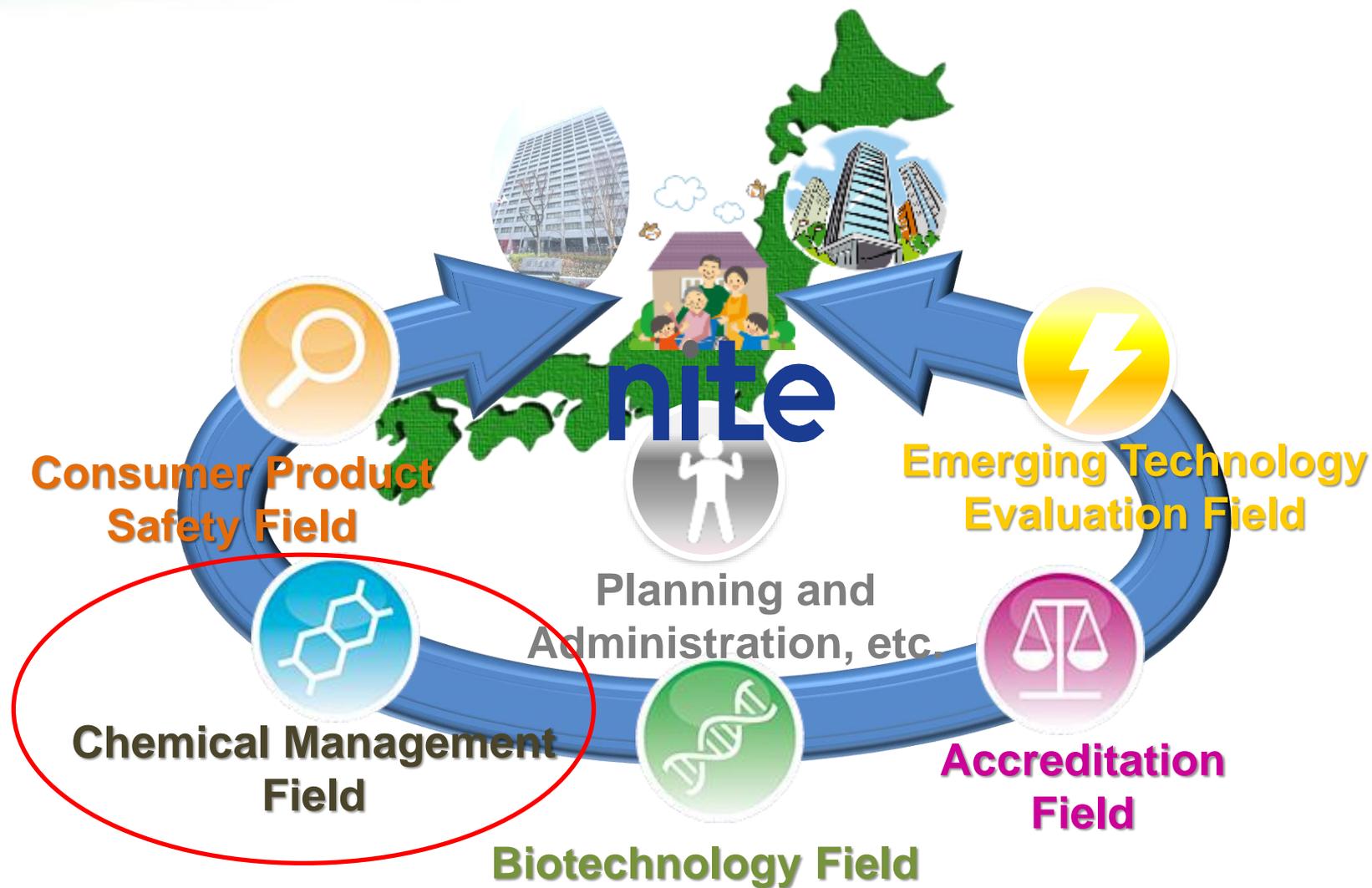
Head Office is located at Tokyo.

NITE has 7 branches and 3 offices nationwide.

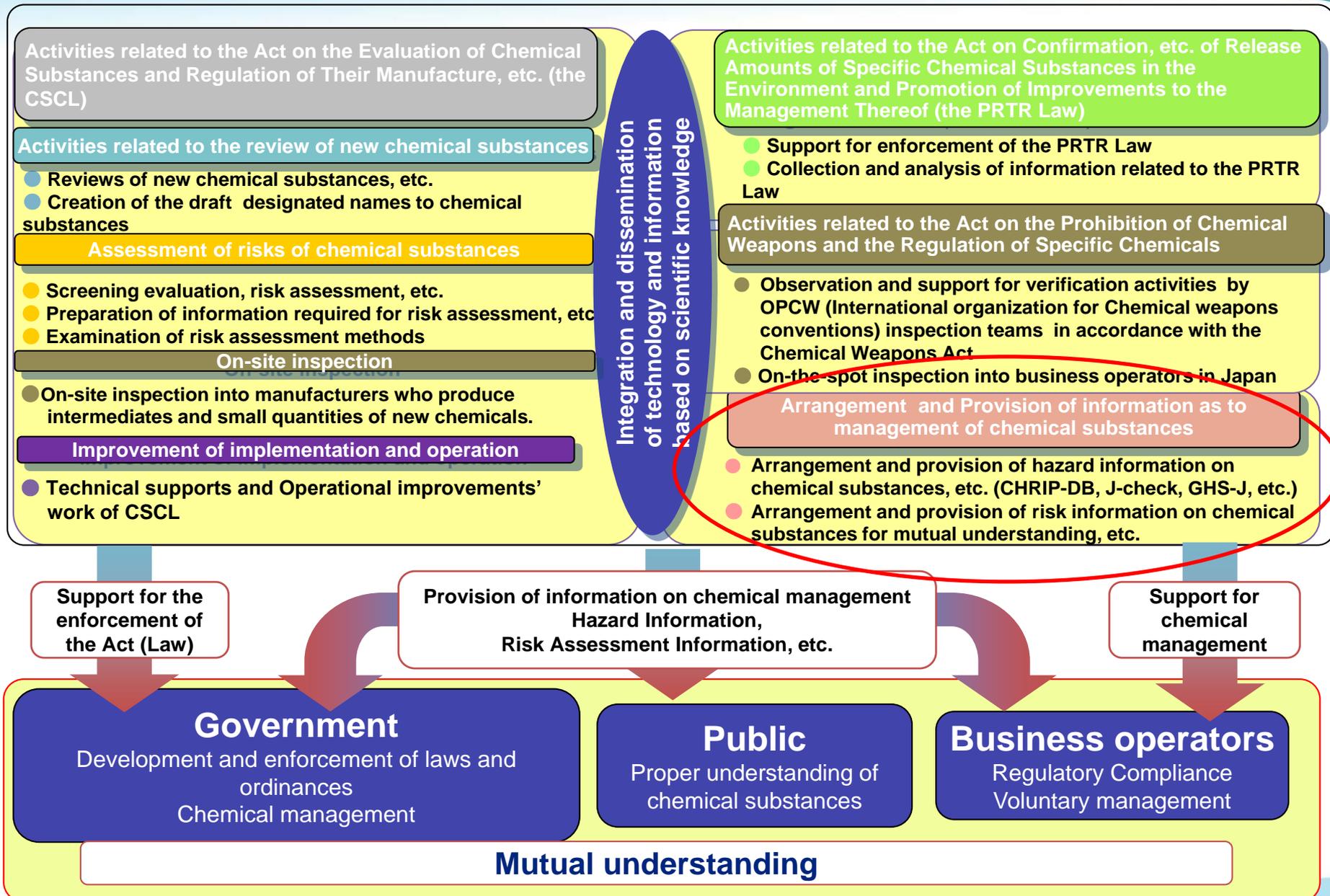


Head Office (Tokyo)

NITE's activities in five fields



Role of Chemical Management Center



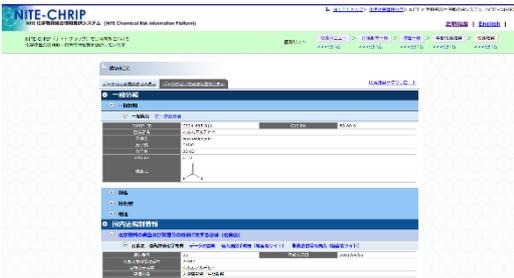
Chemical Management Center Data Analysis Division

- Arrangement and provision of technical information as to safety and risks on chemical substances
- Research and study as to development of information infrastructure

Arrangement and Provision of Chemical Substance Management Information

Role of NITE

NITE-CHRIP (Chemical Risk Information Platform)



- Japan and other countries' laws and regulations, and toxicity information
- 250,000 chemical substances can be searched for with CAS number, MITI number, etc.

J-CHECK (Japan Chemicals Collaborative Knowledge Database)



- information regarding CSCL
- Developed by 3 authorities of the law, MHLW, MOE, METI.
- 9,500 test reports
- link to OECD eChemPortal

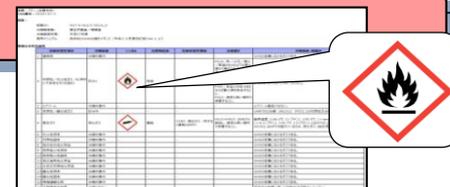
AJCS (ASEAN-Japan Chemical Safety Database)



- Regulatory information provided directly by the governments of ASEAN countries, hazardous information, GHS Classification results, sample SDS, etc.

GHS information

- GHS Classification Results by the Japanese Government for about 4,000 substances
- Links to Guidance for GHS classification, OECD eChemPortal, etc.



Arrangement and provision of information for mutual understanding concerning risks, etc., of chemical substances

- Provides the information on chemical substances to the public
- Implements the provision of the examples of risk communications, etc. to business operators



Provision of information and arrangement of technology

- NITE collects, arranges, and provides information of hazards, etc. on the risks of chemical substances in order to improve the understanding and voluntary management of business operators, municipalities, and people on the safety of chemical substances and the mutual understanding among the interested parties.
- NITE also arranges the technology infrastructures for risk assessments and provides the information.

Provision of information on chemical management (1)

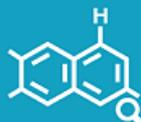
- Chemical Risk Information Platform (NITE-CHRIP)
https://www.nite.go.jp/en/chem/chrip/chrip_search/systemTop
 - A portal site available free of charge for searching information on Japan and other countries' laws and regulations, and toxicity information on chemical substances
 - Highly reliable regulatory information on chemical substances published by national/international authorities
 - Collection of ca. 80 information sources
 - Information on about 250,000 substances
 - Link to GHS classification results
 - Updated every two months
 - Changeable language between Japanese and English on the search result page or list page
 - Free of charge

NITE-CHRIP Top Page

https://www.nite.go.jp/en/chem/chrip/chrip_search/systemTop

Total Search System for Chemical Substances

The current 25 users have been using this site.



Search by chemical ▶

You can search the comprehensive information on a target chemical substance by entering its number, name, molecular formula or structure. Information is hazardous property/ hazard assessments or regulations, etc.

Search keywords are as follows

- Chemical Substance Name
- CAS Registry Number
- MITI number
- ISHA number



Search within laws/regulations, etc. ▶

You can search chemical substances regulated by laws and assessed by organizations, etc. Besides, outlines of individual laws and regulations will be displayed with related materials (ex. application website, supplementary information etc.) .

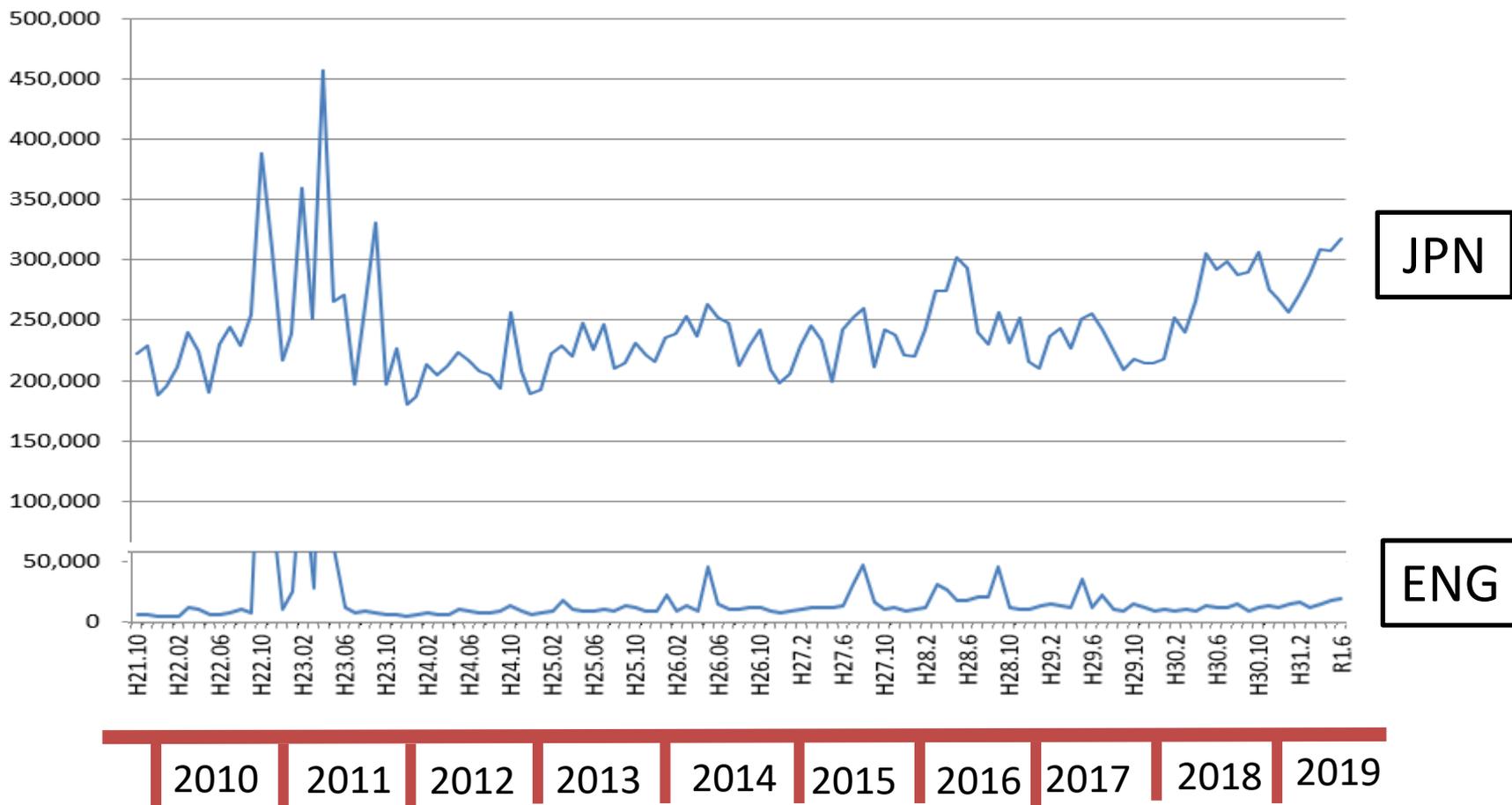
Search lists are as follows

- Laws and Regulations in Japan
- Laws and Regulations in Other countries
- Chemical Hazard and Risk Information
- Test Data and Reports

[Contact us](#) | [FAQ](#) | [Manual](#) | [Operating environment](#) | [Notes for the NITE-CHRIP](#)

Access number of NITE CHRIP Search (per month)

- Ca. 250,000 per month (ca. 3,000,000 per year)
- Slightly increasing recent years



Provision of information on chemical management (2)

- Japan Chemicals Collaborative Knowledge Database (J-CHECK)

https://www.nite.go.jp/chem/jcheck/top.action?request_locale=en

- Database developed to provide the information regarding Chemical Substances Control Law (CSCL) by the authorities of the law, MHLW, METI and MOE
- Provides the list of CSCL, safety data of chemical substances for risk assessment, etc.
- Transmits Japanese safety data globally
- Cooperation with eChemPortal by OECD (link to the portal)

J-CHECK Search Page

https://www.nite.go.jp/chem/jcheck/search.action?request_locale=en

nite Incorporated Administrative Agency
National Institute of Technology and Evaluation

Japanese



化審法データベース
Japan CHEMicals Collaborative Knowledge database

Term

Information

About J-CHECK

Update history

Search

Chemical Substances Search

Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc. (after amendment in FY 2009)

Class I Specified Chemical Substances

Class II Specified Chemical Substances

Monitoring Chemical Substances

Priority Assessment Chemical Substances (PACs)

Newly Announced Chemical Substances (notified on and after April 1, 2011)

Newly Announced Chemical Substances

Newly Announced

Search

Search

Please enter or select search items and Click Search button.

Search

Reset

CAS Registry Number

MITI Number

Chemical Substance Name

Substructure Match ▾

Use structure selection search

Use No Use

Regulatory Classification

- All
- Class I specified chemical substance
- Class II specified chemical substance
- Monitoring Chemical Substances
- Priority Assessment Chemical Substances (PACs)
- Newly Announced Chemical Substances (notified on and after April 1, 2011)
- Newly Announced Chemical Substances (notified by March 31, 2011)
- Existing chemical substances
- Type II Monitoring Chemical Substances (before amendment in FY 2009)
- Type III Monitoring Chemical Substances (before amendment in FY 2009)
- Not regarded as a new chemical substance
- The Japan HPV Challenge Program
- Canceled - Priority Assessment Chemical Substances

Clear

#1: Appearance/physical state/colour

#2: Molecular structure



eChemPortal

eChemPortal by OECD (external link) for searching on chemical properties

eChemPortal

Provision of information on chemical management (3)

- GHS information

https://www.nite.go.jp/chem/english/ghs/ghs_index.html

- GHS Classification Results (Excel, HTML)
 - Ca. 4000 chemicals?
- GHS Classification Guidance
- Support Tools
- List of Classification Results (link to NITE CHRIP)
- Substance Search (link to NITE CHRIP)
- Guidance on a Consumer Product Risk Assessment

GHS Classification Results (Excel, HTML) Page

https://www.nite.go.jp/chem/english/ghs/ghs_download.html

GHS Classification Results (Excel, HTML)

[日本語で表示](#)

The GHS classification results with Hazard statement codes and Precautionary statements and codes are available in Excel and HTML format at "Substances List".

[NOTE]

* GHS Classification Result by the Japanese Government is intended to provide a reference for preparing a GHS label or SDS for users. To include the same classification result in a label or SDS for Japan is NOT mandatory.

* Users can cite or copy this classification result when preparing a GHS label or SDS. Please be aware, however, that the responsibility for a label or SDS prepared by citing or copying this classification result lies with users.

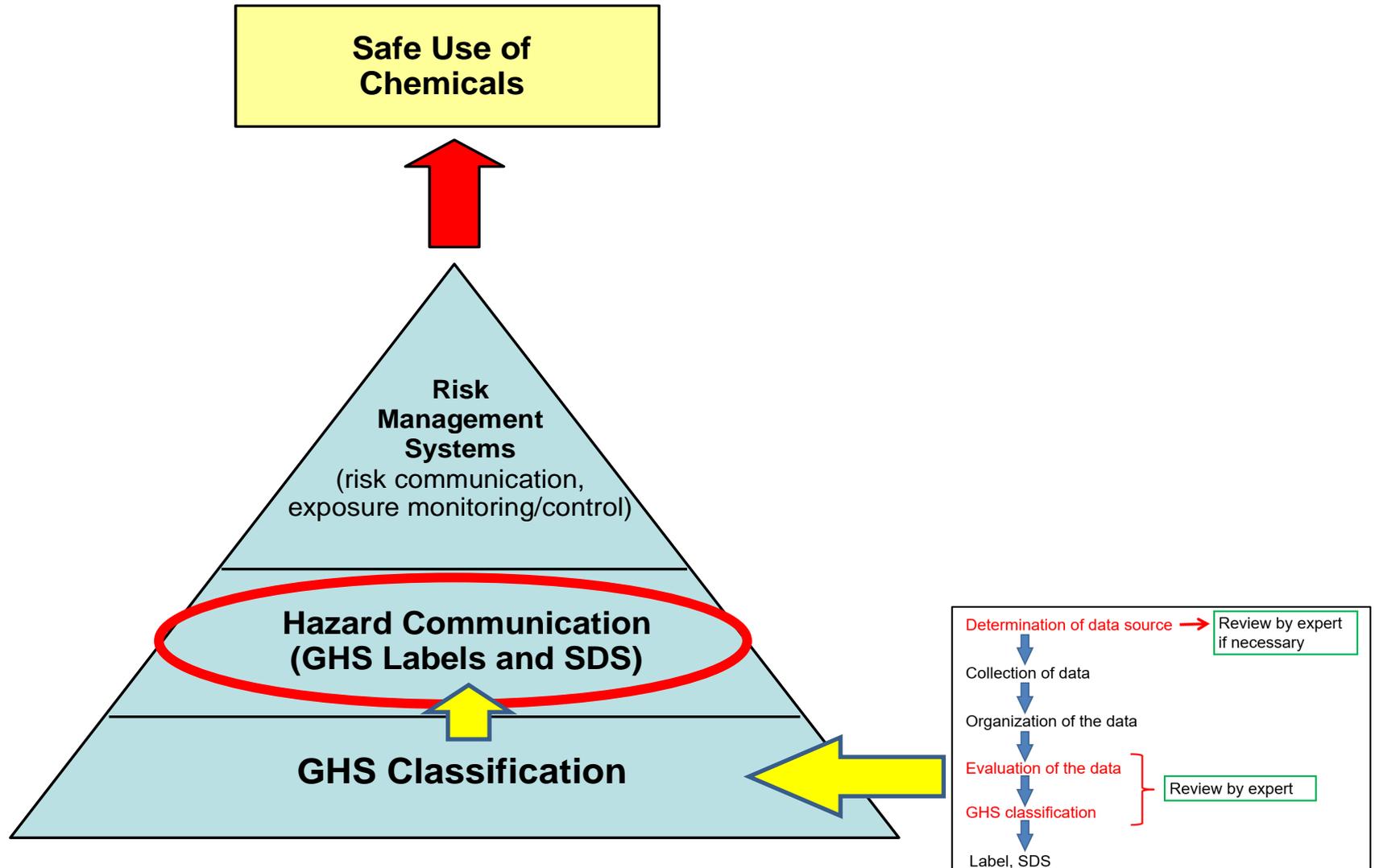
* This GHS classification was conducted based on the information sources and the guidance for classification and judgement which are described in the GHS Classification Guidance for the Japanese Government etc. Using other literature, test results etc. as evidence and including different content from this classification result in a label or SDS are allowed.

Year	Ministry (Classifier)	Substances List List [New format]	Files for download* [Previous format: Excel]	Note
All FY		List August, 2019 To display the list may take some time.	List (884KB) July, 2019	
FY 2018	MHLW*, METI*, MOE**	List		
FY 2017	MHLW*, MOE**	List		 The list of errata  (December, 2018)
FY	MHI W* MFTI** MOF**	List		 The list of errata 

Arrangement of Technology Infrastructures on Chemical Management

- Risk assessments of chemical substances contained in products
 - Promotes risk assessments of chemical substances contained in consumer products around us
 - Use for administration, etc.
- Guidance on a consumer product risk assessment for GHS labelling
 - To assess chronic health risks of consumer products
 - Together with the estimated human exposure dose estimation software compatible with the guidance
 - Available:
https://www.nite.go.jp/en/chem/risk/ghs_consumer_product.html

Suitable classification for good communication



Thank you for your cooperation



Society for Chemical Hazard Communication